Effect of Cervical Length to The Efficacy of Nifedipine and Bed Rest for Inhibiting Threatened Preterm Labor

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Objective: *To compare the success rates and gestational ages at delivery of nifedipine administration as a tocolytic agent to pregnant women with threatened preterm labor based on cervical length.*

Material and Method: *One hundred eighty eight pregnant women with threatened preterm labor between 26 and 35 weeks were enrolled in the present study. Cervical measurement was performed in all patients and divided in two groups. The first group, 60 cases, was patients with cervical length less than 30 mm. The second group, 128 cases, was patients with cervical length 30 mm or greater. All women in each group were randomly inhibited uterine contraction with nifedipine and were bed rest.*

Results: *If the cervical length was 30 mm or greater, nifedipine and bed rest succeeded to inhibit uterine contraction without statistical significance. Nifedipine was appropriate for contraction inhibition when the cervical length was less than 30 mm with statistical significance.*

Conclusion: *Nifedipine and bed rest can be used successfully to inhibit contractions in threatened preterm labor. However, nifedipine should be used if the cervical length is less than 30 mm. If cervical length is 30 mm or greater, bed rest should be advised to avoid unnecessary medical intervention.*

Keywords: *Cervical length, Nifedipine, Bed rest, Threatened preterm labor*

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Perinatal morbidity and mortality among preterm labor is still high. Siriraj Hospital, one of the tertiary centers in Bangkok, had the prevalence of preterm labor about 12.89%[1]. In order to decrease the perinatal morbidity and mortality from preterm birth, many trials were initiated to inhibit or prevent preterm birth.

From the previous author's study[2], nifedipine and bed rest interventions can be used to inhibit uterine contraction in threatened preterm labor. However, nifedipine took a shorter time than bed rest to inhibit uterine contraction. The present study suspected that the cervical length might influence the efficacy of both interventions.

Cervical effacement is one of the first steps in the parturition process, preceding labor by four to eight weeks. When cervical length decreases, the risk of spontaneous preterm birth increases[3,4]. Gestational age is also a factor; the risk of spontaneous preterm birth is higher with early gestational age at diagnosis of short cervix[5]. Therefore, the effect of cervical length to nifedipine and bed rest intervention for inhibiting contraction in threatened preterm labor was interesting to study.

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Material and Method

The present study was approved by Siriraj Ethics Committee of the Faculty of Medicine Siriraj Hospital, COA No. Si 619/2009. The sample size, using a power and precision analysis formula was calculated by the incidence of threatened preterm labor at Siriraj Hospital, which was about 1.3%/year[1]. One hundred and eighty-eight pregnant women with threatened preterm labor between May 1, 2009 and December 31, 2010, were enrolled in the present study. All women with singleton pregnancies presenting to the labor ward with painful and regular uterine contractions at 26 to 35 weeks of gestation were diagnosed as threatened

preterm labor. In all cases, gestation was calculated from the menstrual history and by a transvaginal ultrasound[6-8] scan in early pregnancy.

Threatened preterm labor was defined as regular uterine contractions occurring at the frequency of at least one time in 10 minutes with no effacement and the dilatation of cervix, between 20 and 37 weeks[2]. Transvaginal ultrasound was performed to measure the cervical length. The examination of uterine contraction was taken at least 30 minutes[2].

Women in active labor, defined by the presence of cervical dilatation $\geq$ 3 cm, those with cervical insufficiency, and those with ruptured membranes were excluded. Classic cervical insufficiency is a diagnosis, based on an obstetric history of recurrent second- or early third-trimester fetal loss, following painless cervical dilatation, prolapse or rupture of the membranes and expulsion of a live fetus despite minimal uterine activity[9].

If causes of threatened preterm labor including bacterial vaginosis, cervicitis from any causes and urinary tract infection were found, they were treated according to their causes and excluded from the present study. The patients with threatened preterm labor that occurred spontaneously were included in the present study. The cervix was measured in all patients and classified into two groups. The first group was the patients with cervical length lesser than 30 mm and the second group was those with the cervical length 30 mm or greater. The patients in each group were randomly inhibited uterine contraction with nifedipine administered or bed rest. The patients were randomly allocated to each group. The first group of patients with cervical length less than 30 mm consisted of 60 persons. Nifedipine administered and bed rest were randomly allocated in 31 and 29 persons, respectively in the first group (Fig. 1). The second group of those with cervical length 30 mm or greater consisted of 128 persons (Fig. 1). Nifedipine administered and bed rest were randomly allocated in 76 and 52 persons, respectively in this group. The number of pregnant patients with nifedipine administered is larger than the bed rest group because eighteen cases of known causes of threatened preterm labor were later excluded.

A loading dose of nifedipine 20 mg orally every 30 minutes for three times, then maintained with nifedipine SR 20 mg every 12 hours was used[10-12]. Contractions were recorded every hour until 12 hours.

Successful cessation of uterine contractions was defined as no contractions after inhibition for 12 hours by nifedipine or bed rest.

Unsuccessful cessation of uterine contraction was defined as continuing contractions during and after inhibition for 12 hours.

If the inhibition succeeded, the same intervention in each group was continued until 34 weeks. If the inhibition failed and there was no contraindication to use bricanyl intravenously, then bricanyl was used[11]. When any complication or contraindication of nifedipine was found, the contraction inhibition was changed to be bricanyl intravenous and the patient was excluded from the present study. Maternal vital signs and fetal heart rate monitoring were recorded during the intervention.

Measurement of the cervical length

The vaginal transducer is gently placed in the anterior fornix until the cervix is visualized. The image is enlarged to fill at least one-half of the ultrasound screen. Fetal membranes in the cervical canal or beyond the cervix should be identified. The appropriate sagittal view for measuring cervical length includes the V-shaped notch at the internal os, the triangular area of echodensity at the external os and the endocervical canal, which appears as a faint line of echodensity or echolucency between the two (Fig. 2). Three measurements were obtained and the shortest of these was chosen.

Statistical analysis

SPSS version 13 (for windows) was used to analyze data. Fisher's exact, Chi-square, one-way ANOVA and time-to-event test were used to compare the data. Results were reported as means, standard

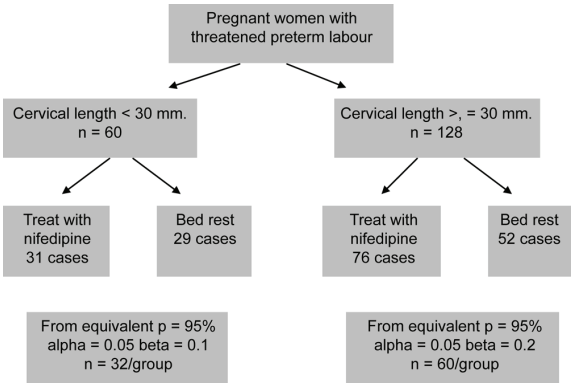

Fig. 1 Numbers of pregnant patients with different cervical length were randomly allocated into 2 groups for treating with nifedipine and bed rest, respectively

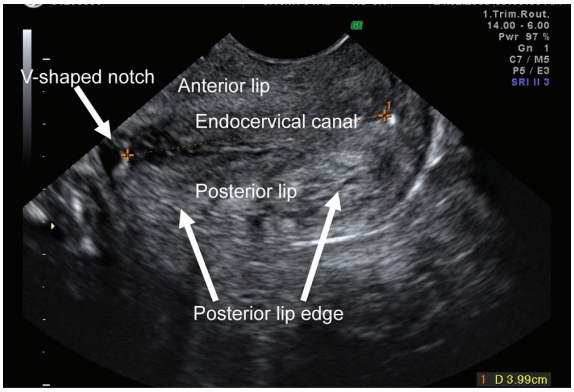

Fig. 2 Cervical length was measured as presented

deviations (SD) and 95% confidence interval or percentages. The level of statistical significance was $p < 0.05$.

Results

Between May 1, 2009 and December 31, 2010, 188 pregnant women with the diagnosis of threatened preterm labor were admitted at the labor room, Siriraj Hospital. The first group with cervical length less than 30 mm and the second group with cervical length 30 mm or greater consisted of 60 and 128 pregnant women, respectively.

Thirty-one and 29 pregnant patients in the first group were inhibited uterine contraction with nifedipine administered and bed rest, respectively. Seventy-six and 52 pregnant patients in the second group were inhibited uterine contraction with nifedipine administered and bed rest, respectively.

There was no statistical significance in maternal age, educational level, income, mean gestational age of admission, mean gravida, parity, and abortion between the patients in the two groups (Table 1). Nifedipine and bed rest were used to inhibit contraction with the patients in both groups. The success rates of nifedipine inhibition and bed rest of the patients in the first group were 83.9% (26 cases) and 55.2% (16 cases), respectively (Table 2). The success rates of nifedipine inhibition and bed rest of the patients in the second group were 98.7% (75 cases) and 100% (52 cases), respectively (Table 2).

By the time to event test, nifedipine took the shorter time than bed rest for contraction inhibition in threatened preterm labor of the patients in the first group (cervical length less than 3 cm) with statistical significance (nifedipine; 2.7.00 $\pm$ 0.12 hours with

Table 1. Demographic data before delivery of the patients with uterine contraction inhibition by nifedipine and bed rest in different cervical length group

Demographic data before delivery	Cervical length	Type of inhibition (number of patients)	Mean $\pm$ SD (range)	p-value
Age	< 3 cm	Nifedipine (31)	25.3 $\pm$ 5.4	
		Bed rest (29)	27.4 $\pm$ 4.4	
	$\geq$ 3 cm	Nifedipine (76)	28.1 $\pm$ 5.3	
		Bed rest (52)	26.0 $\pm$ 5.2	0.06
Gravida	< 3 cm	Nifedipine (31)	2.3 $\pm$ 1.7 (1-7)	
		Bed rest (29)	2.1 $\pm$ 1.2 (1-6)	
	$\geq$ 3 cm	Nifedipine (76)	2.0 $\pm$ 1.2 (1-5)	
		Bed rest (52)	1.9 $\pm$ 1.3 (1-5)	0.07
Parity	< 3 cm	Nifedipine (31)	0.7 $\pm$ 0.7 (0-3)	
		Bed rest (29)	0.8 $\pm$ 0.9 (0-2)	
	$\geq$ 3 cm	Nifedipine (76)	0.7 $\pm$ 0.6 (0-3)	
		Bed rest (52)	0.8 $\pm$ 0.9 (0-3)	0.07
Abortion	< 3 cm	Nifedipine (31)	0.7 $\pm$ 1.4 (0-5)	
		Bed rest (29)	0.2 $\pm$ 0.7 (0-3)	
	$\geq$ 3 cm	Nifedipine (76)	0.4 $\pm$ 0.6 (0-2)	
		Bed rest (52)	0.3 $\pm$ 0.6 (0-2)	0.06
Gestational age of admission	< 3 cm	Nifedipine (31)	32.8 $\pm$ 1.5	
		Bed rest (29)	33.4 $\pm$ 1.2	
	$\geq$ 3 cm	Nifedipine (76)	30.3 $\pm$ 1.4	
		Bed rest (52)	31.4 $\pm$ 1.6	0.06

Table 2. Type of inhibition and outcome of treatment in pregnant women with different cervical length

Cervical length	Outcome	Type of inhibition		Total (cases)	p-value
		Nifedipine (cases) (%)	Bed rest (cases) (%)		
< 3 cm	Success	26 (83.9)	16 (55.2)	42	0.016
	Failure	5 (16.1)	13 (44.8)	18	
Total		31 (100)	29 (100)	60	
≥ 3 cm	Success	75 (98.7)	52 (100)	127	0.594
	Failure	1 (1.3)	0	1	
Total		76 (100)	52 (100)	128	

By Fisher's exact test was significant in < 3 cm group

Table 3. Mean ± SD and median time and 95% CI of succession after inhibition with nifedipine and bed rest in different cervical length group

Cervical length	Type of inhibition	Mean time (hour)	95% CI	p-value
< 3 cm	Nifedipine	2.7 ± 0.12	2.4-2.9	
	Bed rest	3.4 ± 0.26	2.9-3.9	
	Total	3.1 ± 0.16	2.8-3.4	0.027
≥ 3 cm	Nifedipine	2.5 ± 0.16	2.2-2.8	
	Bed rest	2.6 ± 0.1	2.4-2.8	
	Total	2.5 ± 0.1	2.3-2.7	0.887

By time to event test

95% CI of 2.4-2.9, bed rest; 3.4 ± 0.26 hours with 95% CI of 2.9-3.9) (Fig. 3, Table 3).

Mode and gestational age of delivery, mean neonatal body weight and mean APGAR score between the patients in the two groups were not significant in statistical analysis (Table 4). Income and educational level of the patients were not significant between the two groups. The patients who failed from nifedipine and bed rest inhibition were later inhibited with bricanyl. The patients with cervical length < 30 mm and inhibited with nifedipine and bed rest had normal vaginal delivery 31 and 29 cases, respectively. No caesarean section was performed in this group. The patients with cervical length ≥ 30 mm and inhibited with nifedipine and bed rest had caesarean section performed in 16 and 17 cases, respectively. The indication of caesarean section were previous caesarean section (31 cases) and CPD (2 cases in bed rest group). The patients with cervical length ≥ 30 mm and inhibited with nifedipine and bed rest had normal vaginal delivery 59 and 36 cases, respectively.

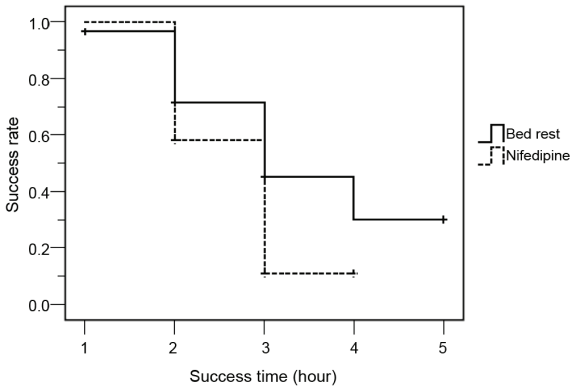

Fig. 3 Mean time of succession between nifedipine and bed rest for inhibiting uterine contraction in threatened preterm labour by time to event test (in the group of cervical length < 3 cm)

Discussion

Threatened preterm labor, which is classified as regular uterine contractions, can progress to preterm birth in about 30% of cases[10,12]. If this process can be stopped the chances of both preterm birth and perinatal morbidity and mortality could be reduced. The cervix should stay closed throughout pregnancy

Table 4. Demographic data after delivery of the patients with uterine contraction inhibition by nifedipine and bed rest in different cervical length group

Demographic data after delivery	Cervical length	Type of inhibition (number of patients)	Mean ± SD	p-value
Gestational age of delivery	< 3 cm	Nifedipine (31)	34.9 ± 1.2	
		Bed rest (29)	34.1 ± 1.8	
	≥ 3 cm	Nifedipine (76)	38.3 ± 1.5	
		Bed rest (52)	38.4 ± 1.1	0.07
Body weight	< 3 cm	Nifedipine (31)	2,365.3 ± 635.9	
		Bed rest (29)	1,931.5 ± 545.0	
	≥ 3 cm	Nifedipine (76)	3,041.6 ± 252.6	
		Bed rest (52)	3,109.6 ± 340.9	0.06
APGAR at 1 minute	< 3 cm	Nifedipine (31)	8.6 ± 0.8	
		Bed rest (29)	7.9 ± 0.8	
	≥ 3 cm	Nifedipine (76)	8.9 ± 0.1	
		Bed rest (52)	8.9 ± 0.3	0.06
APGAR at 5 minute	< 3 cm	Nifedipine (31)	9.6 ± 0.7	
		Bed rest (29)	8.9 ± 0.8	
	≥ 3 cm	Nifedipine (76)	9.9 ± 0.1	
		Bed rest (52)	9.7 ± 0.6	0.08

By one-way ANOVA test was not significant between two groups

until just before the birth. If the cervix starts to open too soon, there is a chance of preterm delivery.

The normal cervix is between 30 and 50 mm in length. Transvaginal ultrasound is the best method to measure the cervix because it can be seen much more clearly. Cervical length measurements before 15 weeks of gestation have no clinical value[13]. Cervical length normally decreases slightly between 20 and 32 weeks, and more substantially after 32 weeks. Before 22 weeks, at 22 to 32 weeks and after 32 weeks, the median cervical length is 40 mm, 35 mm (50th centile), and 30 mm, respectively[14].

When the labor starts, the internal os begins to open first and this will look like a V shape on the scan. As the os opens further it becomes U shaped. This is called funneling. If the closed part of the cervix is measured less than 25 mm (10th centile), the risk of preterm labor increases[15]. Therefore, many interventions combined with cervical length have long been used to prevent preterm labor.

Cervical effacement mostly precedes preterm birth by several weeks. A short cervix without dilatation predicts a preterm birth risk and when combined with uterine contraction, the risk is significantly increased. The present study used the cervical length of 30 mm as a cut-off point in order to avoid problem in ethical issue.

The first line drug to inhibit uterine contraction is terbutaline (bricanyl), which has been used intravenously or subcutaneously for over 20 years[16,17]. However, the oral form of salbutamol has evidence supported of failure to inhibit contraction[16,17]. Magnesium sulfate has not been approved by the FDA for inhibition contraction due to a higher risk of maternal and fetal morbidity[18]. Nifedipine was studied and was strongly recommended for administration to inhibit contractions[19-21]. The side effects and complications of nifedipine to mother and fetus are fewer than for beta-agonist and magnesium sulfate[17-19].

From the previous study[2], nifedipine and bed rest interventions were successful inhibiting contraction in threatened preterm labor at about 80% and 64%, respectively. Cervical length may influence the efficacy of bed rest for the treatment of threatened preterm. If the cervix is not short, bed rest intervention should be appropriate to stop uterine contraction. However, there was neither a study nor strong evidence that supported the use of bed rest to inhibit uterine contraction in threatened preterm labor. Therefore, nifedipine to inhibit threatened preterm labor is studied here and compared to bed rest intervention with different cervical length.

From the present study, nifedipine and bed rest interventions were successful for inhibiting contraction in threatened preterm labor with cervical length 3 cm or greater. There was no statistically significant difference among those interventions.

Therefore, bed rest intervention firstly used in those cases can reduce unnecessary medication, which may relate with side effects and complications.

When time to event test was used, nifedipine took the shorter time (2.7 ± 0.12 hours) to inhibit contraction in threatened preterm labor than bed rest intervention (3.4 ± 0.26 hours) in the group of cervical length less than 3 cm. Nifedipine 20 mg loading dose was given orally every 30 minutes (for 3 times) then maintained with nifedipine SR (20 mg) every 12 hours. There was statistically significant difference among those interventions. Therefore, if the cervical length is less than 3 cm, nifedipine should be used instead of bed rest intervention in order to prevent true labor. However, the present study had only a limited sample size. Further study should be considered for precise interpretation.

Mean gestational age at delivery, neonatal body weight and mean APGAR score between the patients in the two groups were not significant. Complication of nifedipine was not detected. Pregnant patients in the group of cervical length less than 3 cm mostly delivered at gestational age of 34 weeks while the other group was mostly delivered at gestational age of 38 weeks.

No significant or definite risk was detected in the failure group of patients with cervical length less than 3 cm and had an intervention of bed rest. There was about 30% found. This incidence was similar to the previous study which found about 30%[10]. Even though the incidence was low, if the contraction could be stopped, the preterm birth could be minimized.

Many trials concluded that all of the tocolytic agents were more effective than placebo or no therapy for delaying delivery 48 hours or seven days. However, those interventions were not associated with significant reduction in overall rates of respiratory distress syndrome or neonatal death[22]. The result of the present study could not show validity of these interventions to minimize the risk of preterm labor and to improve neonatal outcome, but proper intervention to stop uterine contraction was associated with the minimal risks of medical intervention in cases of cervical length 3 cm or more.

In conclusion, nifedipine should be used to inhibit uterine contraction in threatened preterm labor with cervical length less than 3 cm. Those patients with cervical length 3 cm or more should be firstly advised to have bed rest. Therefore, unnecessary medical intervention and complication from tocolytic drugs can be reduced.

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Potential conflicts of interest

None.

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ผลของความยาวของปากมดลูกต่อประสิทธิภาพของยา nifedipine และการนอนพักในการยับยั้งภาวะเจ็บครรภ์คลอดก่อนกำหนดคุกคาม

สายฝน ชวาลไพบูลย์, อนุวัฒน์ สุตัณฑวิบูลย์

วัตถุประสงค์: เพื่อศึกษาอัตราความสำเร็จและอายุครรภ์ที่คลอดเปรียบเทียบระหว่างการใช้ยา nifedipine เพื่อยับยั้งการหดรัดตัวของมดลูกและการนอนพักในกลุ่มสตรีตั้งครรภ์ที่มีภาวะเจ็บครรภ์คลอดก่อนกำหนดคุกคาม และมีความยาวของปากมดลูกที่แตกต่างกัน

วัสดุและวิธีการ: ทำการศึกษาในสตรีตั้งครรภ์ที่มีภาวะเจ็บครรภ์คลอดก่อนกำหนดคุกคามที่มีอายุครรภ์ระหว่าง 26-35 สัปดาห์ จำนวน 188 ราย ทำการตรวจวัดความยาวของปากมดลูกในสตรีตั้งครรภ์กลุ่มนี้ และแบ่งเป็น 2 กลุ่ม กลุ่มแรกมีจำนวนสตรีตั้งครรภ์ 60 ราย มีความยาวของปากมดลูกน้อยกว่า 30 มิลลิเมตร กลุ่มที่ 2 มีจำนวนสตรีตั้งครรภ์ 128 ราย มีความยาวของปากมดลูกตั้งแต่ 30 มิลลิเมตร ขึ้นไป สตรีตั้งครรภ์ทั้ง 2 กลุ่ม จะได้รับการสุ่มเพื่อให้การยับยั้งการหดรัดตัวของมดลูกด้วยการให้ยา nifedipine หรือการนอนพัก

ผลการศึกษา: สตรีตั้งครรภ์ที่มีความยาวของปากมดลูกตั้งแต่ 30 มิลลิเมตร ขึ้นไปจะประสบความสำเร็จในการยับยั้งการหดรัดตัวของมดลูกด้วยยา nifedipine และการนอนพักโดยไม่มีนัยสำคัญทางสถิติ การใช้ยา nifedipine มีความเหมาะสมในการยับยั้งการหดรัดตัวของมดลูกในกรณีที่ปากมดลูกมีความยาวน้อยกว่า 30 มิลลิเมตรอย่างมีนัยสำคัญ ทางสถิติ

สรุป: ทั้งยา nifedipine และการนอนพักมีประโยชน์ในการยับยั้งการหดรัดตัวของมดลูกในภาวะเจ็บครรภ์คลอดก่อนกำหนดคุกคาม อย่างไรก็ตาม ควรใช้ยา nifedipine ถ้าความยาวของปากมดลูกน้อยกว่า 30 มิลลิเมตร แต่ถ้าปากมดลูกมีความยาวตั้งแต่ 30 มิลลิเมตรขึ้นไป ควรใช้การนอนพักแทน เพื่อหลีกเลี่ยงการใช้ยาโดยไม่จำเป็น