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https://doi.org/10.15017/1931807

出版情報：九州大学, 2017, 博士（看護学）, 課程博士
バージョン：
権利関係：

Original Article

Development of a New Cervical Dilatation Curve for Spontaneous Vaginal Delivery in Japanese Primigravid Women

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Abstract

Aim : To develop a cervical dilatation curve for spontaneous vaginal delivery in Japanese primiparas.

Material and methods : This is an observational study. Data were retrospectively collected from delivery records. The subject sample included 483 Japanese primiparas who delivered by spontaneous vaginal delivery at the study institution between January 2012 and June 2015. For statistical analysis, a cervical dilatation curve was created using a smoothing spline function, which was compared with the Friedman's labor curve. In addition, a prediction model for delivery progress of Japanese women was developed using nonlinear regression.

Results : (1) A new cervical dilatation curve for Japanese primiparas was created. The active labor period was longer in the cervical dilatation curve for Japanese women compared with that in the Friedman's labor curve. (2) As a new indicator for the management of labor and delivery in Japanese women, we developed a four-parameter logistic approximation curve model formula.

Conclusions : The cervical dilatation curve for Japanese primiparas showed a sigmoid pattern with respect to the Friedman's labor curve and resembled the four-parameter logistic model.

Key words : japanese primigravid women, spontaneous vaginal delivery, cervical dilatation, Friedman's labor curve, delivery prediction model

Introduction

In Japan, the labor curve developed by Friedman[1)] who belonged to the United States is widely used as an index for the management of labor and delivery[2)~4)]. Friedman's curve displays the standard relationship between the time course after the start of labor and the degree of cervical dilatation and is used to determine whether labor progression is normal. However, because more than 60 years have passed since the Friedman's labor curve was created in 1950s, there is a need to re-evaluate the curve.

Laughton et al. conducted a cohort study to compare the duration of labor from 1959 to 1965 with that from 2002 to 2008 and reported that the duration was longer in the latter period compared with that in the former[5)]. Similarly, Albers reported that the duration of labor was longer in healthy women[6)]. On the contrary, it has been reported that since the 1960s in Japan, the duration of labor has reduced over time[7)]. Kawada et al. confirmed that the duration of labor in Japanese women was shorter than that reported by Friedman[8)].

Furthermore, Hendricks, Brenner, and Kraus voiced a different opinion with respect to the progress of normal delivery claimed by Friedman, where in the S-curve drawn presented the active period for cervical dilatation and did not corres-

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pond to the latent phase[9]. Zhang et al. noted that the active phase lacks a deceleration period and argued that the progress of labor in recent years significantly differs with respect to that shown in the Friedman's labor curve[10]. To date, attempts to predict labor have been undertaken based on the degree of cervical dilatation in Japanese women ; however, most of these efforts have used old survey data, and the explanation of the statistical analysis methods have been inadequate[11)~15)].

In Japan, with recent issues such as the declining birth rate, advancing maternal age, and declining birth weight, the circumstances surrounding the labor and delivery of Japanese women have changed greatly[16)17)]. Thus, the Friedman's labor curve might not be applicable to modern Japanese women. Therefore, re-evaluation of the curve, particularly the creation of a new curve unique to Japanese primiparas, is an urgent task that needs to be addressed for the clinical management of labor and delivery in this country.

Aim

The present study aimed to develop a cervical dilatation curve for spontaneous vaginal delivery in Japanese primiparas.

Materials and Methods

The present study was an observational study with two stages. In study Ⅰ, a new cervical dilatation curve of Japanese primiparas was created. In study Ⅱ, a model was developed to predict labor in Japanese primiparas based on the cervical dilatation curve created in study I. The study institution includes the maternity ward of a secondary emergency medical care center located in a Japanese metropolitan area. Only one institution was studied to minimize the influence on management policies by local social and economic factors as well as by the medical institution. Data were retrospectively collected from delivery charts and partograms. The policy for the management of labor and delivery at the study institution was that the midwife in-charge conducted pelvic examinations as needed at the discretion of the doctor. Therefore, the interval between measurements of cervical dilatation varied. In the present study, to adjust these points, measurements were processed using statistical methods.

The selection criteria for subjects included in the analyses are as follows.

1. Study subjects

1) Inclusion criteria : Japanese women who gave birth at the study institution from January 2012 to June 2015.
2) Exclusion criteria : Women who underwent cesarean section or had miscarriage, premature delivery, post-term delivery, multiple births, and breech presentation and who used medication to induce and accelerate labor and received cervical treatment were excluded. Women whose partogram could not be obtained and multiparas were also excluded.

2. Study items

The study items were obstetric history, age, number of pregnancy weeks and days at delivery, number of fetuses, mode of delivery, delivery method (presence or absence of labor induction and cervical treatment), fetal presentation, degree of cervical dilatation, maternal physique (height, non-pregnant weight, and weight at delivery), neonate physique (weight and height), overall blood loss, and duration of labor.

3. Study design

Study Ⅰ : Creation of a cervical dilatation curve for Japanese primiparas

1) Subjects who met the inclusion criteria were selected from the study candidates and defined as subjects for analysis.
2) For measured values, to adjust variations in the interval between measurements, the spline predicted value was calculated for

each subject every 30 min from the start of labor until full cervical dilatation using the smoothing spline function. Then, we created a cervical dilatation curve starting from hospital admission until full dilatation using the 50 percentile of the spline predicted value[18].

3) With regard to the active phase (from 4-cm cervical dilatation until full dilatation), we created and compared two curves, i.e., a curve for all subjects and a curve for subjects who presented cervical dilatation of 3 cm or less on admission, to explain shifts in cervical dilatation using objective data. The curves were screened to determine which would be suitable as new cervical dilatation curves for Japanese women and compared with the Friedman's labor curve[19].

Study Ⅱ : Development of a delivery prediction model for Japanese primiparas

The most appropriate model for the cervical dilatation curve was estimated using nonlinear regression. The five types of sigmoid function, showing parameters a, b, c, d, e, and f are as follows :

Logistic (1) : 3 parameters (a,b, and c), 4 parameters (a,b,c, and d), 5 parameters (a,b,d,c,d, and f)

Gompertz (2) : 3 parameters (a, b, and c), 4 parameters (a,b,c, and d)

The corrected Akaikeinformation criterion (AICc) was used as the selection criteria for the most suitable model.

Logistic equation

$$c+\frac{[d-c]}{[1+\mathrm{Exp}[-a*[\mathrm{time}(h)-b]]]^{f}} \quad (1)$$

The prediction mode is 1, a = increasing rate, b = inflection point, c = asymptote 1, d = asymptote 2, and f = exponent.

Gompertz equation

$$a+[b-a]*\mathrm{Exp}[-\mathrm{Exp}[-c*[\mathrm{time}(h)-d]]] \quad (2)$$

The prediction mode is 2, a = lower asymptote, b = upper asymptote, c = increasing rate, and d = inflection point.

Data were statistically analyzed using JMP® 11.2 (SAS Institute Inc., Cary, NC, USA). The present study was performed with the approval of Kyushu University Institutional Ethical Review Board for Clinical Research [approval number : 27-155 (27-338)]. There are no conflicts of interest to declare.

Results

1. Study I results

1) Subject attributes

Fig. 1 presents the selection of each study subject. The study subject sample included 2,443 women (1,420 primiparas and 1,023 multiparas). A total of 483 primiparas met the inclusion criteria, among whom 216 women had cervical dilatation of 3 cm or less upon admission.

Table 1 presents the attributes of the study subjects.

2) Creation of the cervical dilatation curve

Fig. 2 presents the distribution of the number of pelvic examinations and the findings in primiparas. The maximum number of pelvic examinations during the course of labor was five times. The smallest pelvic examination finding was 2cm and the largest was 10 cm.

Fig. 3 shows an example of a spline predicted value calculation from the measured value. The spline predicted value was calculated from the measured values of each subject. In the figure, the "○" mark and the "×" mark represent the measured and spline predicted values, respectively.

Fig. 4 shows the progress of cervical dilatation during labor. Curves A and B represent the curve of 481 primiparas (two cases without spline prediction values were excluded from 483 cases.) and the curve of the 216 women selected from all primiparas (those with cervical dilatation < 3 cm upon admission), respectively. The degree of cervical dilatation at admission was 3.6 cm

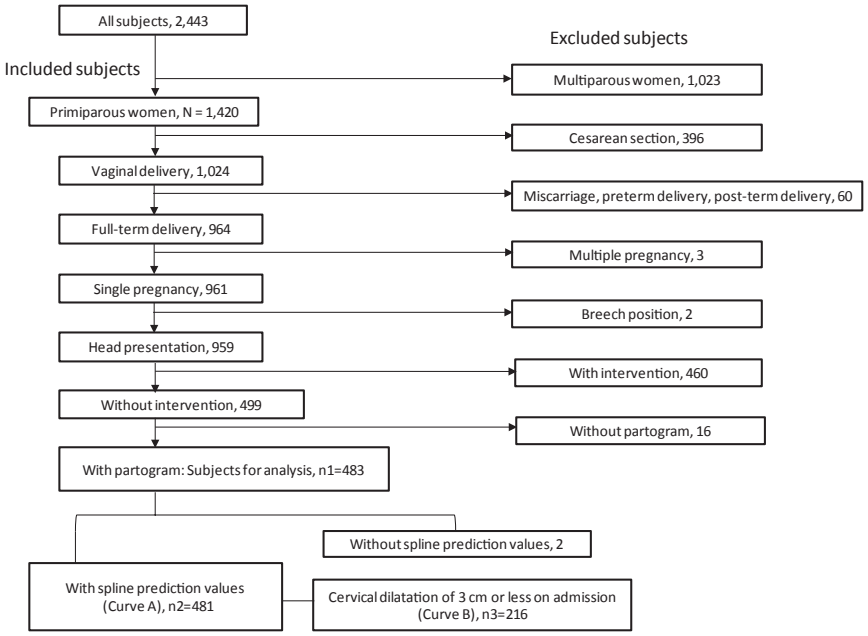

Fig. 1 Analyzed subjects' selection criteria algorithm

Table 1 Attributes : Analyzed subjects with spline prediction values

	Analyzed subjects with spline prediction values : Curve A (n2=481)		Selected subjects with spline prediction values : Curve B (n3=216)	
	n	Mean ± standard deviation	n	Mean ± standard deviation
Age	481	30 ± 4.8	216	30 ± 5.0
Gestational age (weeks)	481	39 ± 0.9	216	39 ± 1.0
Gravidity*	463	0 (0-4)	209	0 (0-3)
Height (cm)	439	159 ± 5.1	198	160 ± 5.2
Non-pregnant weight (kg)	318	51 ± 6.8	143	51 ± 6.7
Labor body weight (kg)	343	61 ± 7.1	164	61 ± 7.1
Total amount of bleeding (g)	481	391 ± 267	216	369 ± 246
Newborn weight (kg)	481	2,962 ± 318	216	2,960 ± 306
Newborn height (cm)	481	48 ± 1.7	216	48 ± 1.7
Apgar score (1 min)*	481	8 (4-10)	216	8 (4-9)
Apgar score (5 min)*	481	9 (7-10)	216	9 (7-10)
Labor duration (min)*	481	595 (87-2,338)	216	628 (111-1,827)

for curve A and 2.8 cm for curve B. In curve B, an objective evaluation was possible from the point of time when cervical dilatation was 3 cm or less, but in curve A, the evaluation was not possible. Therefore, curve B was selected as the cervical dilatation curve for Japanese women in the present study.

3) Comparison of the cervical dilatation curve for Japanese women with the Friedman's labor curve

Fig. 5 presents the division of the cervical dilatation curve for Japanese primiparas. The cervical dilatation curve for Japanese women was sigmoid with respect to the Friedman's labor curve. Upon examining the type of the cervical dilatation curve for Japanese women according to the presentation method reported by Friedman, the active phase from 4

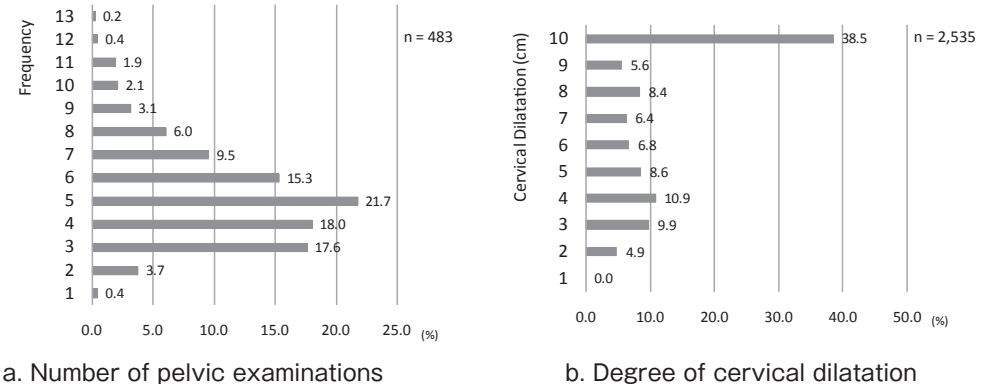

Fig. 2 Distribution of the number of pelvic examinations and degree of cervical dilatation

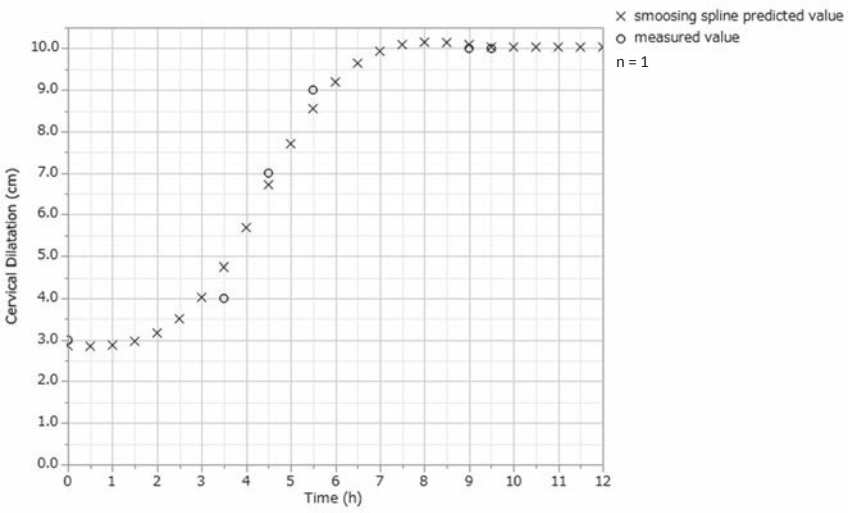

Fig. 3 Plot of cervical dilatation value according to smoothing spline predicted value This figure shows the results for one arbitrary primipara case.

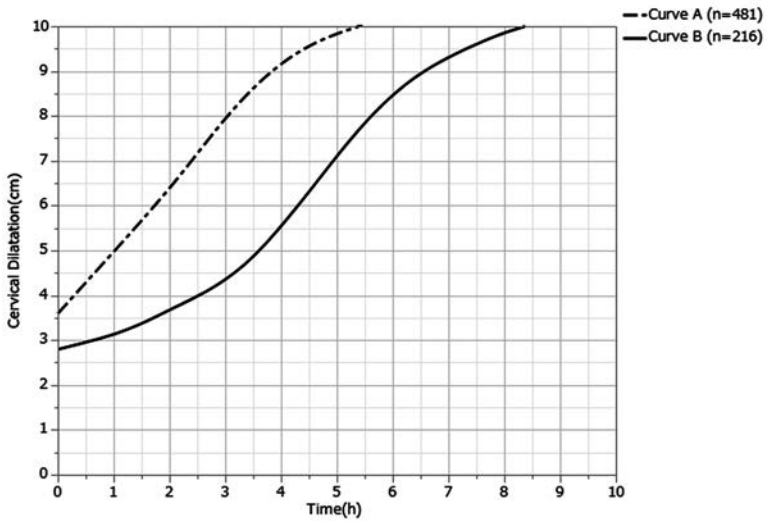

Fig. 4 Labor curve of Japanese primiparas Curves A and B present the curves for all subjects and the selected subject group, respectively.

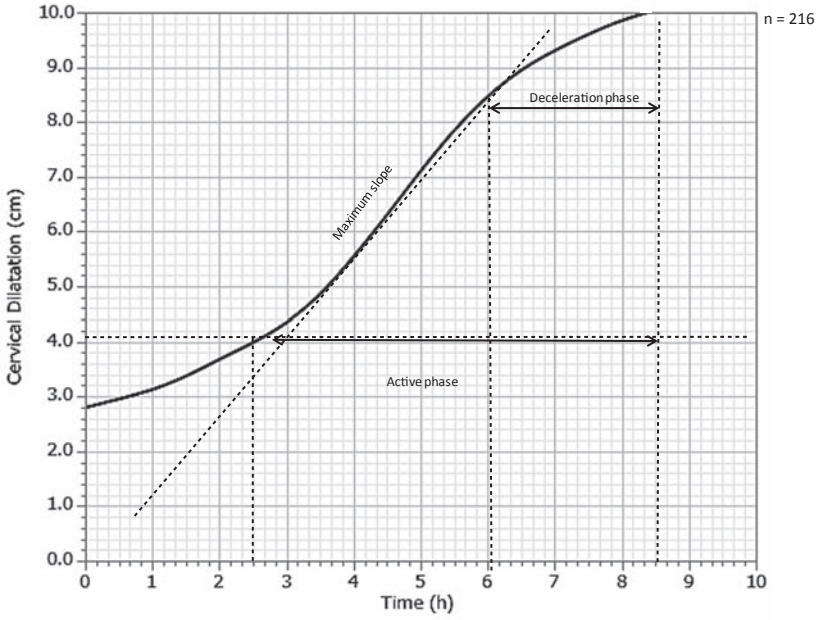

Fig. 5 Division of the labor curve for Japanese primiparas

Table 2 Comparison of the labor curve of Japanese women and Friedman's curve The "ideal" series includes 200 primiparas with normal delivery (citation)

Primiparas		N	Active phase (h)	Maximum slope (cm/h)	Deceleration phase (h)
Sekiya-Kaku's Curve		216	6	1.3	2.5
Friedman's	Total series	500	4.9	3.0	0.9
	Ideal series	200	3.4	3.5	0.7

cm to 10 cm was divided into the maximum slope and deceleration phases.

Table 2 presents a comparison of each division of the cervical dilatation curve for Japanese women with the Friedman's labor curve. The active (h) and deceleration phases (h) were prolonged in the cervical dilatation curve for Japanese women (6 and 2.5, respectively) compared with those in the Friedman's labor curve (4.9 and 0.9, respectively). On the contrary, the maximum slope phase (cm/h) was 1.3 in the cervical dilatation curve for Japanese women and 3.0 in the Friedman's labor curve, indicating that it was shorter in Japanese women. Furthermore, compared with the "ideal" series created by Friedman, which included 200 primiparas with a normal delivery, the cervical dilatation curve for Japanese women showed longer active and deceleration phases and a shorter maximum slope phase (cm/h).

2. Study Ⅱ results

Fig. 6 presents five types of approximation curve models for the cervical dilatation curves of Japanese women. The AICc for each model were as follows : 3-parameter logistic model, AICc = 20.8 ; 4-parameter logistic model, AICc = − 23.0 ; 5-parameter logistic model, AICc = − 21.5 ; 3-parameter Gompertz model, AICc = 25.8 ; and 4-parameter Gompertz model, AICc = − 4.5.

Accordingly, the best fitting approximation curve model was the 4-parameter logistic model

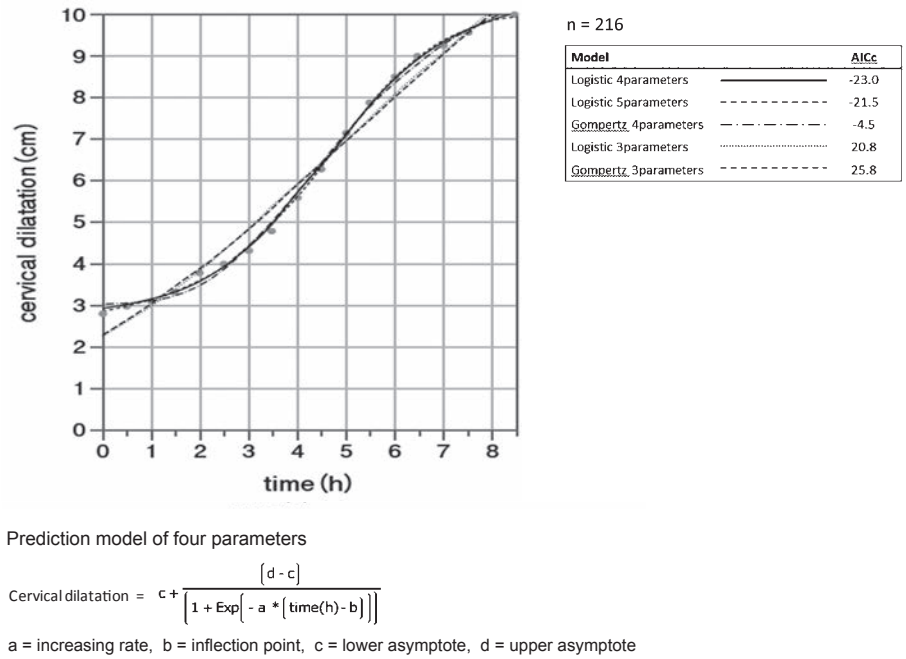

Fig. 6 Labor prediction model for Japanese women Five types of sigmoid functions were compared to obtain curves. The best fitting model was the 4-parameter logistic model.

shown below (3).

$$\text{Cervical dilatation} = 2.7 + \frac{7.6}{[1 + EXP[-0.8 * [time(h) - 4.6]]]} \quad (3)$$

Discussion

Reasons for the delay in the first stage of labor include weak contractions, narrow pelvis, rigidity of the soft birth canal, cephalopelvic disproportion, and malpresentation. Therefore, it is important to examine the interrelationship between the three elements of labor, namely, expulsive force, the birth canal, and the expelled fetus. Furthermore, given the differences underlying the time when the studies were conducted and the subject's attributes, we believe that the study should include differences in race and ethnicity as well as sociocultural background.

1. Factors that prolonged the active phase

In Table 2, compared with American women, modern Japanese women required more time to progress from cervical dilatation of 4 cm to full dilatation, which is considered to be the active phase. The active phase was longer in Japanese women than American women because of the following factors : (1) differences in maternal expulsive force, (2) differences in the maternal bony birth canal, and (3) differences in lifestyle.

Underlying the first factor is a difference in physical strength between Japanese and American women. Compared with the Mongoloid people, Caucasians tend to be taller and heavier and are thought to have a higher proportion of muscle mass to body weight. Comparison with the results of earlier studies indicated that Japanese women have less muscle mass than American women[20)21)]. Cheung et al. reported that comparison between Caucasian and Asian women showed that Caucasian women have a higher body mass index and their pelvic organs descend more upon holding one's breath and when abdominal pressure is applied[22)]. On the contrary, the standard maximum oxygen uptake value needed for endurance was relatively low in Japanese women

than American women in their 20s[23)24)]. Physical strength differs according to the individual and region ; hence, we believe that because Japanese women have less muscle mass and lower endurance than American women, they have less physical strength. The fact that Japanese women have less physical strength than American women implies that they tend to experience fatigue during labor and that cervical effacement and dilatation promotion by the gestational sac associated with contractions is inefficient. These factors contributed to the slow rate of cervical dilatation.

Underlying the second factor is the difference in maternal pelvic aperture angle. Ethnic differences might have attributed to the pelvic aperture angle, which is thought to be smaller in Japanese women than in western women[3)]. It was reported that a narrow pelvic aperture angle is a risk factor for cesarean section[25)]. Therefore, compared with western women, engagement of the fetal head might not proceed smoothly because of the pelvic shape in Japanese women.

Lifestyle habits related to periodontal diseases, such as eating and smoking, can be considered as the background of the third factor. Goepfert et al[26)]. investigated the association between periodontitis and premature births and found reported that women with spontaneous abortion are more susceptible to severe periodontal disease than those with scheduled or late labors. The periodontal disease incidence rate [Community Periodontal Index (CPI) 3–4)] was higher among Japanese in the 1980s than in the recent years compared to the recent Japanese[27)28)]. Periodontal disease prevalence may also be related to the smoking[29)].

In the progression of labor, cervical ripening is important ; although the cervix is firmly closed with abundant collagen fibers, collagen degradation increases and the cervix softens in the third trimester. This enables cervical dilatation during labor[3)]. Cervical ripening involves abundant dehydroepiandrosterone secretion by the fetal adrenal gland in the third trimester as well as highly increased collagenolytic enzyme activity by estrogen, progesterone, and relaxin[3)]. It is thought that both smoking and periodontal disease have mechanisms associated with cervical ripening caused by stress and inflammatory substances[30)31)].

It is thought that the current daily habits of expectant mothers differ greatly from those in the 1950s when the Friedman's labor curve was created. This may be because, for instance, health guidance for expectant mothers might not have been adequate and appropriate at that time. Differences in lifestyle habits between Japanese and American people associated with cultural and social background may influence cervical dilatation to some extent.

However, each individual's labor progression is affected by both maternal and fetal factors in a complex manner. It has been pointed out that in addition to the three elements of labor, other factors that determine the difficulty in the progression of labor include mental anxiety of the parturient woman and failure of cervical ripening[32)]. Therefore, when determining labor progression, it is probably important to conduct a comprehensive evaluation, including that of data such as fetal weight and health status as well as the mother's mental state.

2. Examination of the new labor prediction model for Japanese women

In Fig. 5, the cervical dilatation curve for Japanese women was sigmoid with respect to the curve created by Friedman in the 1950s. In the 1970s, Hendricks et al. pointed out, using statistical analysis, that in the active phase, cervical dilatation progresses in a straight line, without deceleration, and does not form a sigmoid pattern with respect to the Friedman's labor curve[9)]. However, Friedman re-evaluated his labor curve around 1980 and stressed that the labor curve was sigmoid[33)34)].

On the contrary, Zhang et al. statistically

examined the cervical dilatation curve model, and as per Hendricks et al., they found no deceleration phase in the active phase in the cervical dilatation curve and reported that as the cervical canal dilates at once, the curve cannot be sigmoid[35]. These reports re-evaluating Friedman's data were adopted by many Japanese researchers in the 1980s, who reported various attempts to create a predictive model for labor progression by utilizing cervical dilatation data and using polynomial regression, exponential curve, and Markov model[11)~15)]. Among these, Sato et al.[11)]. and Ariyasu et al[14)]. used a logistic model. Thus, the trajectory followed by the labor curve is controversial, which is probably caused by the reference points of the curve. In several earlier studies in which the start of labor was defined as the time of hospital admission rather than the start of regular contractions, the labor curves of primiparas were clearly similar even when labor was defined as per Friedman's curve[36)]. Therefore, the labor prediction model with the sigmoid function developed in the present study could potentially be used as a new index for the management of labor and delivery.

Furthermore, for statistical analyses in the present study, we calculated the predictive value for cervical dilatation using the smoothing spline function. This enabled us to eliminate the variation between data measurement intervals. However, because actual measurements were not used, we cannot conclude that the actual extent of cervical dilatation is shown. Given this, in actual clinical practice, it is unrealistic and lacking in ethical consideration to perform pelvic examinations every 30 min on women giving birth. Therefore, the present method is considered to be highly valid. Estimating the progress of cervical dilatation for each parturient woman using the newly developed labor prediction model provides a promising resource to predict labor abnormalities such as prolonged and obstructed labor. Accordingly, it is expected to help achieve safe and comfortable labor and delivery for the mother and child. In contrast, for multiparas, investigations on this topic should take factors such as the number of previous childbirths into account. In future, we aim to conduct a large-scale empirical study involving coordinating social and financial factors as well as apply the delivery progress prediction model developed in this study for clinical cases.

Limitations

The present study was conducted at a single institution considering the characteristics of the study institution. Thus, there could have been a bias according to the region and institution. Furthermore, to clarify the progression of spontaneous delivery, subjects who required medical intervention during labor and delivery because of diagnosis such as of slow and obstructed labor were excluded. Therefore, the time taken for delivery was biased, and many women who required a long time for delivery were excluded. Thus, we were unable to perform a simple comparison of the time required for delivery in the present study against the Friedman's labor curve.

Conclusions

(1) We created a new cervical dilatation curve for Japanese primiparas. The active phase in the cervical dilatation curve of Japanese primiparas was longer than that in the Friedman's labor curve.

(2) We developed an approximation curve model formula for a 4-parameter logistic curve as a new indicator for the management of labor and delivery in Japanese women.

There were no conflicts of interest associated with this study.

Acknowledgments

We would like to express our deepest gratitude to all of the subjects who participated in the creation of the present report and to all of the staff at the study institution.

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(Received for publication July 14, 2017)

（和文抄録）

日本人初産婦の自然経腟分娩における新たな子宮頸管開大曲線の開発

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目的：本研究の目的は，初産婦の日本人女性の自然経腟分娩における子宮頸管開大曲線の開発である．
方法：研究デザインは観察研究とした．データは分娩記録から後方視的に収集した．分析対象は 2012 年 1 月から 2015 年 6 月までに調査施設において自然経腟分娩をした初産婦の日本人女性 483 例であった．統計的分析方法として平滑化スプライン関数を用いて子宮頸管開大曲線を作成し，フリードマン分娩曲線と比較した．さらに，非線形回帰を用いて日本人女性の分娩経過予測モデルを開発した．
結果：⑴新たに日本人女性の初産婦の子宮頸管開大曲線を作成した．日本人女性の子宮頸管開大曲線はフリードマン分娩曲線と比較して活動期が延長した．
⑵日本人女性の初産婦の新たな分娩管理指標として，4 parameters ロジスティック曲線の近似曲線モデル式を開発した．
結論：日本人女性の初産婦の子宮頸管開大曲線は，フリードマン分娩曲線と同様にシグモイドを呈し，4 parameters ロジスティックと近似した．

キーワード：日本人初産婦，自然経腟分娩，子宮頸管開大曲線，フリードマン分娩曲線，分娩予測モデル