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硬膜外減痛分娩效果不佳之相關因素

Factors Associated with Ineffectiveness of Epidural Analgesia for Labor Pain

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本論文係葉昱伶君（學號 P95846001）在國立臺灣大學預防醫學研究所完成之碩士學位論文，於民國 97 年 7 月 15 日承下列考試委員審查通過及口試及格，特此證明

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中文摘要

研究目的: 產痛可能是女性一生中需經歷最痛的疼痛，嚴重的產痛可能產生許多潛在有害的生理反應，而目前用來解除產痛最有效且最沒有副作用的方式是硬膜上腔止痛。有很多研究探討產婦施行硬膜上腔止痛的安全性及優越性，但是非常少人討論與硬膜上腔止痛效果不佳有關的因素，在台灣也無人發表過相關的文章，而這跟改善產婦照護及產婦滿意度有相當大的關聯。因此，我們的研究希望了解目前臺北地區產婦施行硬膜上腔止痛的盛行率及硬膜上腔止痛的失敗率，並分析與硬膜上腔止痛效果不佳相關的因素。

過程與方法: 這是一個回溯性研究。我們蒐集了台北市新光吳火獅紀念醫院從 2005 年 1 月到 2006 年 12 月所有做硬膜上腔止痛的產婦的資料。我們從病歷、產科日誌及麻醉科紀錄中蒐集了產婦的基本資料、產程跟生產資料及疼痛處理的資料，所有產婦資料被分為兩組，訓練組(training group) 與確認組(validating group)。我們定義硬膜上腔止痛效果不佳為疼痛分數大於 3，在給予硬膜上腔止痛藥物三十分鐘後。使用卡方檢定跟 t 檢定分析所有的變項，找出跟硬膜上腔止痛效果不佳相關的因素。有差異的變項再放入邏輯式回歸分析，試著建立預測模式。確認組的資料則用來確定此模型的準確度。

結果: 台北市新光吳火獅紀念醫院從 2005 年 1 月到 2006 年 12 月間共有 5809 位產婦生產，其中 1015 位接受了硬膜上腔減痛分娩，盛行率為 17.47%。兩年中每個月的人數穩定。止痛效果不佳的比例為 26%，此失敗組有較短時間的第一產程(310.7 比 264.43 分鐘),給藥三十分鐘後子宮頸擴張程度較大(3.25 比 2.9 公分)，子宮頸擴張速度較快(1.52 比 0.67 公分/小時)，較少使用產箝或真空吸引接生(11.25%比 21.69%)，對減痛分娩較不滿意(21.77%比 51.49% 表示非常滿意)。硬膜上腔止痛使用的藥物種類也有顯著差異，在失敗組較多產婦使用 Lidocaine 及 Bupivacaine 一次給藥，較多使用 Bupivacaine 持續給藥。邏輯式回歸分析建立的預測模型，選擇出有意義的變項為子宮頸擴張速度與使用的藥物種類，此預測模型的操作特性

曲線下的面積(AUC, area under ROU curve)為 0.6712。當可能性的切點為 0.5 時，確認組的準確度為 0.6873。

結論: 這是台灣第一個分析產婦施行硬膜上腔減痛分娩效果不佳因素的研究。結果顯示跟硬膜上腔減痛分娩效果不佳相關的因素包括子宮頸擴張速度較快，使用 Lidocaine 或 Bupivacaine 一次給藥，使用 Bupivacaine 持續給藥。未來的研究可以加入更多的因子來分析。

關鍵字: 產痛，硬膜上腔止痛，硬膜外止痛，減痛分娩，危險因子

Abstract

Objectives: Labor pain is probably the most painful event in the life of a woman. There are many potential adverse physiological effects of severe labor pain. In recent years, epidural analgesia technique is the most effective and least depressant treatments for labor pain. Previous studies mostly focused on the safety and superiority of epidural analgesia than other techniques. Only very few discussed the factors related to the ineffectiveness of epidural painless labor. To improve patient care and the satisfaction of women in their labor and delivery experience continues to be one of the primary goals and challenges in obstetric analgesia services. In this study we expect to determine the prevalence of epidural analgesia for labor pain and failure rate in Taipei City. Then try to evaluate the factors associated with inadequate pain relief.

Materials and Methods: We perform a retrospective chart review in parturients who underwent epidural analgesia for labor pain in Shin-Kong hospital in Taipei City, from January 2005 to December 2006. We retrieved each patient's demographic characteristics, the course of labor and delivery, and the management of epidural analgesia from medical chart. All participants were divided into training group or validating group. Ineffectiveness of epidural analgesia of labor pain was defined as NRS > 3 at 30 minutes after epidural drug administration. We analyzed the data of the training group. Potential univariate correlated of ineffectiveness epidural analgesia were

identified. Then forward stepwise logistic regression analysis was used to select significant ones that might predict the ineffectiveness of epidural painless labor. The ROC (receiver operating characteristic) curve by different cut-off points of this model was done. Then validating group was used to confirm the accuracy of this model.

Results: A total of 1015 parturients received the epidural painless labor among the 5809 parturients who gave births during January 2005 to December 2006 in Shin-Kong hospital. The prevalence was 17.47%. The monthly utilization rates were stable in these two years. The failure rate of training group was 26%. The failure group has shorter duration of phase I (310.7 versus 264.43 minutes), more cervical dilatation in 30 minutes (3.25 versus 2.91 cm), faster progression of cervical dilatation (1.52 versus 0.67 cm/per hour), less instrumentation delivery (11.25% versus 21.69%), and less satisfied (21.77% versus 51.49% pronounced very satisfied) about epidural painless labor. Epidural drugs resulted in significant different between two groups. The failure group used more Lidocaine and Bupivacaine then Ropivacaine as loading drug, and more Bupivacaine then Ropivacaine as continue drug. The predictive model of ineffectiveness epidural painless labor was established. Selective factors were cervical dilatation velocity, loading drugs, and continue drugs. The AUC (area under ROC curve) is calculated as 0.6712. When the cut point of probability is 0.5, the accuracy of validating group was 0.6873.

Conclusions: This is the first study about the determinants of ineffectiveness epidural analgesia of labor pain in Taiwan. Our results revealed that factors associated with ineffectiveness of epidural analgesia of labor pain are faster cervical dilatation velocity, loading with Lidocaine or Bupivacaine and continue infusion with Bupivacaine. More factors to be concluded in analyses are suggested in further investigation.

Key Words: labor pain, epidural analgesia, painless labor, effectiveness, risk factors

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Abbreviations

AUC: area under ROC curve

NRS: numeric rating scale

OP presentation: occipital posterior presentation

ROC curve: receiver operating characteristic curve

VAS: visual analog scale

Chapter 1 Introduction

Labor pain is probably the most painful event in the life of a woman. Melzackn et al.[1] evaluated several kinds of pain syndrome with McGill Questionnaire pain score. He concluded that labor pain was painful than toothache, fracture, postherpetic neuralgia, phantom limb pain, low back pain and even nonterminal cancer pain, only causalgia and pain of digit amputation are greater than labor pain (Figure 1-1). Brown et al.[2] reported that before five centimeter of cervical dilatation, 24.4% parturients described their pain as horrible or excruciating, whereas after five centimeter of cervical dilatation, 46.2% did so.

There are many potential adverse physiological effects of severe labor pain. As reviewed by Brownridge[3], pain itself can increase oxygen consumption and basal metabolic rate, induce hyperventilation with hypocarbia (PaCO2 decreases 10 to 20 mmHg) and respiratory alkalosis. Autonomic stimulation and catecholamine release (epinephrine increases 3 to 6 times, norepinephrine increases 2 to 4 times, and cortisol increased 2 to 3 times) resulting in maternal tachycardia, high blood pressure, high cardiac output, and increased left ventricle loading. At the extreme end of the spectrum, these responses may produce decreased placental perfusion, uncoordinated uterine activity, and fetal acidosis. On the other hand, the fear of pain or suffered from pain for several hours may push parturients choosing cesarean section. That might increase the

inappropriate cesarean sections.

Therefore the American College of Obstetricians and Gynecologists published jointly with the American Society of Anesthesiologists the following statement: “Labor causes severe pain for many women. There is no other circumcision where it is considered acceptable for an individual to experience untreated severe pain, amenable to safe intervention, while under a physician’s care. In the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labor.”[4, 5]

Due to the concept of “labor pain” may just warning women the labor is beginning and to get a place for safety to birth the baby. Lasting pain is meaninglessness and could have negative effects on mothers and infants. “Painless labor” is gradually acceptable by parturients and obstetricians. In the past one hundred years, several kinds of inhalation agents (ethylene, nitrous oxide, cyclopropane), injectable agents (barbiturate, many forms of opioids), and nerve blocks (para-cervical, sacral, para-vertebral, epidural) were introduced[6].

By the present consensus, neuraxial analgesia techniques (epidural, spinal, and combined spinal-epidural) are the most effective and least depressant treatments for labor pain[5]. Previous studies mostly focused on the safety and superiority of epidural analgesia than other techniques. Only very few discussed the factors related to the

ineffectiveness of epidural painless labor. To improve patient care and the satisfaction of women in their labor and delivery experience continues to be one of the primary goals and challenges in obstetric analgesia services.

Chapter 2 Literature Review

2.1 Prevalence of epidural painless labor

The prevalence rates of epidural analgesia during labor (epidural painless labor) varied in different countries. In the United States, more then 50% parturients use epidural analgesia intrapartum[7, 8], even up to 78% use rate in some institutes[9]. The epidural rate for labor pain was 23.6% in an annual statistic of United kingdom in 1997 to 1998. There had been neither increase nor decrease then before[10]. In French, The overall epidural rate for labor pain ware 37.2% in 1991 but increased to 61.6% in an epidemiological study in 2006[11, 12]. In Germany, there were fewer parturients receive epidural painless, about 17.5% in a survey in 2008[13].

Compare with these developed counties, the prevalence of epidural painless labor is much lower in Asia. In a large survey covering 30% of deliveries in Malaysia, only 1.5% used epidural analgesia[14]. In Hong Kong, about 10% of parturients received epidural painless labor in 1995 and increased to 15% in 2001[15]. In China, less then 1% utilization rate was reported in 2007[16]. Chan and Ng found that the availability of regional analgesia for labor paralleled the economic status of the country[17].

In Taiwan, only one survey in a teaching hospital was published and found that the utilization rate of epidural painless was 13.7% in 2000 and increased to 25.6% in 2004%[18].

2.2 Risk factors of pain during labor

The intensity of labor pain increase with greater cervical dilatation, and positively associated with the intensity, duration, and frequency of uterine contractions[6]. Many events have an influence on the pain experience during labor. Both psychosocial factors, like women's own expectation to labor pain and culture or ethnicity, and physical factors play important roles[19]. Although few studies focus on physical factors associated with the severity of pain during labor, parity, age, mother height, mother weight before pregnancy, weight height ratio, and fetus weight had been mentioned[20-22]. Kate M. et al. analyzed oxytocin as a covariant showed that women treated with oxytocin reported 48% more pain at the start of labor[23]. Sizer et al. reported that epidural analgesia was strongly associated with delivery in the occipital posterior position[24]. This may be due to the more severe pain in the occipital posterior position pushed women to request analgesia.

2.3 Risk factors of ineffectiveness epidural painless labor

There are only very few studies about the determinants of ineffectiveness epidural painless labor.

A prospective study in one university teaching hospital in France included 596

painless labors concluded that risk factors of inadequate pain relief during labor and delivery were: radicular pain during epidural placement, fetus posterior presentation, inadequate analgesia efficacy of the first dose, duration of epidural analgesia more than six hours, and epidural analgesia less than one hour[25]. The definition of “inadequate pain relief” was VAS >= 30 mm or the need for >= 3 top-ups in addition to epidural infusion. The defect of this survey was that 23.5% parturients data were missing.

Another prospective observational study in one tertiary care academic medical center in the United States found factors associated with recurrence breakthrough pain (>= three times) were null parity, heaver fetal weight, and epidural catheter placement at an earlier cervical dilation[9]. No studies were conducted in Asian countries.

A prospective study enrolled 1753 surgical patients (not limited to labor) who used epidural analgesia postoperatively identified operation site, procedure involving malignancy, weight (positive), and age (negative) as determinants of epidural analgesia requirements. The authors established a linear regression model for drug consumption out of these predictors, $R^2 = 0.472$. Height and sex have no impact on epidural analgesia demand[26].

According to these previous studies, possible factors associated to ineffectiveness of epidural analgesia for labor pain including null parity, heavier fetal weight, epidural in early cervical dilatation, fetus occipital presentation, radicular pain when catheter

placement, and analgesia duration longer than 6 hours or shorter than 1 hour. But there were no study performed on Taiwanese or Asia women.

2.4 Reliability and validity of VAS and NRS

Pain is a subjective feeling and therefore, is difficult to measure. There is no "gold standard" method exists for pain measurement. There are three commonly used pain rating scales: visual analog scale (VAS), verbal rating scales (VRS), and the numeric rating scales (NRS). The reliability and validity of the VAS and NRS for measurement of acute pain is well-established[27-29], and could be applied well on Chinese patients[30]. The ratio properties of both VAS and NRS were established in previous studies[31, 32]. A linear relationship between VAS and NRS are noted in laboring patients (Figure 2-1)[32]. Compare to VAS, NRS can be easily administered without any devices or writing material.

Chapter 3 Materials and Methods

3.1 Study purpose

We expect to determine the prevalence of epidural analgesia for labor pain and failure rate in Taipei City. Then try to evaluate the factors associated with inadequate pain relief.

3.2 Study design

We perform a retrospective chart review in parturients who underwent epidural analgesia for labor pain in Shin-Kong hospital, from January 2005 to December 2006.

Shin-Kong hospital is a medium-size teaching hospital in Taipei City. The service of epidural painless labor is available twenty-four hours a day. Whenever parturients in labor request epidural painless labor, the anesthesiologist in duty comes to evaluate her condition. If there is no contraindication such as infection at the site of injection, coagulopathy or anticoagulant medication, preexisting neurological deficits, hypovolemic shock, and severe heart disease, the anesthesiologist explains the whole procedure and possible side effects to the parturient and performs the procedure after the patient has signed the consent.

Usually the parturient lying down on a left decubitus position, draws the knees up to the chin as possible as she can. After the skin is infiltrated with 1% xylocaine, epidural

catheter (Portex® Epidural Minipack, as Figure 3-1 show) is inserted via L3-4 or L4-5 intervertabral space through a 16 or 18 Gauge Touphy needle. A “loss of resistance technique” is used to identify the epidural space. The catheter is threaded through the needle and toward the cephalad for 4 to 7 centimeter, test with 1% Xylocaine to ensure the function and ruled out intrathecal or intravascular catheter. The catheter is fixed with adhesive tape on the back (Figure 3-2).

A bolus dose of 1% Xylocaine, 0.2% Bupivacaine (Marcaine) or 0.17% Ropivacaine (Naropine) is given, with or without Fentanyl 50 microgram. Then 0.12% Bupivacaine (Marcaine) or 0.1% Ropivacaine (Naropine) with Fentanyl 2 microg/ml is prescribed by continues infusion with velocity 8-15 mg/hour.

A nurse anesthetic takes care of parturients. The verbal numeric rating scale (NRS) of pain is used to evaluation the labor pain. Parturients are asked to rate their pain on a scale of 0 to 10, where 0 represents “no pain” and 10 presents “the worst pain imaginable”, using whole numbers (11 integers including zero). NRS before epidural was administrated, thirty minutes after epidural drug has been applied, and any time she complains pain are recorded by a nurse anesthetic immediately. Maternal satisfaction of painless labor is also evaluated on the first postpartum day.

All the procedures of analgesia and evaluation are standardized and recorded on the medical chart of each parturient.

3.3 Patients selection criteria and ethics review

This study was approved by Ethic Committee/Institutional Review Board of Shin-Kong hospital on Dec 18, 2006. (No. 95E-061)

All parturients who received epidural analgesia during January 2005 to December 2006 in Shin-Kong hospital were included. Parturients who had abortion or intrauterine death, unintentional intrathecal catheter when perform procedure, or epidural catheter replaced at any time during labor were excluded.

3.4 Variables

We retrieved each patient's demographic characteristics, the course of labor and delivery, and the management of epidural analgesia from medical chart.

The demographic data include mother's age, height, weight, education status, marital status, whether accompanied by family when in labor, newborn's sex, height, weight, gestation weeks, birth order, the presentation of occipital, Apgar score at one and five minutes after being born.

The course of labor and delivery data include the use of oxytocin, the use of demerol before epidural analgesia, time of he first stage of labor (defined as time from begging of epidural analgesia to cervical full dilatation), time of he second stage of labor

(defined as time from cervical full dilatation to delivery), the mode of delivery (vaginal or cesarean section), the use of instrumental delivery (forceps or vacuum).

The management of epidural analgesia data includes the status of cervical dilation at initiation of epidural analgesia and at thirty minutes after the epidural drugs given, type of loading drugs (Xylocaine or Bupivacaine or Ropivacaine), loading volume, with or without Fentanyl, type of continuing drugs (Bupivacaine or Ropivacaine), the performer of epidural analgesia (resident or visiting physician), the satisfaction about the current and previous epidural painless labor experience measured by a Likert multipoint order scale (zero as very unsatisfied, 1 as unsatisfied, 2 as fair, 3 as satisfied, 4 as very satisfied).

The major outcome variable is the NRS of pain thirty minutes after epidural analgesia was administration. The numeric rating score (NRS, 0 to 10) of pain before epidural catheter insertion and the maximum NRS of pain during labor after epidural analgesia was administration were also measured.

3.5 Statistical analysis

We firstly describe the prevalence of the utilization of epidural painless labor in the study hospital and the NRS pain score before and 30 minutes after treatment. To establish and test our predictive model, eligible parturients then were randomly split

into two groups, the training group and the validating group.

Among 1015 parturients received the epidural painless labor, three patients' chart records couldn't be found, two had intrauterine death and nine had epidural catheter replaced, after excluding these 14 patients, a total of 1001 parturients remained eligible. These 1001 parturients were randomized divided into two groups the training group (500 parturients) and the validating group (501 parturients) (Figure 3-3).

Ineffectiveness of epidural analgesia of labor pain was defined as NRS > 3 at 30 minutes after epidural drug administration. First we analyzed the data of the training group. Potential univariate correlated of ineffectiveness epidural analgesia were identified using t-test for continuous variables and chi-square test or Fisher's exact test for categorical variables. All variables whose *p* values were less than 0.1 were included into a forward stepwise logistic regression analysis to select significant ones that might predict the ineffectiveness of epidural painless labor. The validating group was used to confirm the accuracy of this model by estimating the ROC (receiver operating characteristic) curve by different cut-off points, and calculating the area under curve (AUC), and the accuracy rate (the rate of correct prediction, the percentage of true positive and true negative in all cases) with the cut-off point of probability over 0.5 as positive. All statistical analyses were conducted with SAS 9.1.

Chapter 4 Result

4.1 Data characteristics

A total of 1015 parturients received the epidural painless labor among the 5809 parturients who gave births during January 2005 to December 2006 in Shin-Kong hospital. The prevalence was 17.47%. The monthly utilization rates were stable in these two years (Figure 4-1).

Compare with the training and validating group, the demographic data were no difference as Table 4-1 shows. In the training group parturients, the mean age of mothers was 30.04 (±3.80) years old, mean height was 160.08 (±4.99) cm, and mean weight when delivery was 67.83 (±9.21) kg. The data of mother education level was 35.2% missing. 76.54% of recorded data were above college, and 23.15% were high school. Almost all of them are married and accompanied by husband or relatives when in labor room.

There were 500 newborns in the training group because there was no twin pregnancy which had tried vaginal delivery. A total of 53.6% newborns were male. 86.2% were the first baby and 11.6% were the second one. The mean gestation age of newborns was 38.97 (±1.29) weeks, the mean birth weight was 3174.71 (±381.66) gm, and the mean birth height was 50.11 (±1.98) cm. The mean Apgar score was 8.63 (±0.80) at 1 minute, and 8.95 (±0.25) at 5 minute.

During the labor course, only 9 (1.8%) parturients didn't use Oxytocin. A total of 77(15.4%) parturients request for Mepedipine before epidural painless was performed. The median time of phase I labor, defined as the duration from epidural drugs administration to cervical full dilatation, was 230 minutes (range from 10 to 1390 mins). The median time of phase II labor, defined as the duration from cervical full dilatation to baby delivery, was 60 minutes (range from 5 to 865 mins). The cesarean section rate of these parturients was 18.8% (94 parturients). Among the 406 vaginal deliveries, 76(18.72%) of them needed instrumentation-assisted delivery such as forceps or vacuum. There were thirteen (2.6%) newborns whose presentations were occipital posterior (OP).

A total of 287(57.4%) epidural catheter placements were performed by visiting staffs and the rest by residents of anesthesiology. The mean cervical dilatation when epidural catheter insertion was 2.53 (±1.05) cm, and 3.00 (±1.62) cm at 30 minutes after epidural drug administration. The mean velocity in the 30 minutes was 0.89 cm per hour. The loading drugs were 1 % Xylocaine (227 parturients, 45.4%), 0.2% Bupivacaine (21 parturients, 4.2%), or 0.17% Ropivacaine (251 parturients, 50.2%). Four hundred and nineteen (80.3%) loadings contained Fentanyl 50 μg in it. The mean loading volume was 11.10 (±0.16) ml. The continuing drugs were Ropivacaine (489 parturients, 97.8%) or Bupivacaine (11 parturients, 2.2%).

Over 90% of the parturients described their experiences of epidural painless labor as very satisfied or satisfied. Only 2.2% described very unsatisfied or unsatisfied. The mean NRS before epidural analgesia was 8.43 (±2.10) and decreased to 2.32 (±2.44) at thirty minutes after epidural drug was administrated. There were 26% (130 parturients) parturients who had NRS > 3 at 30 minutes after epidural drug administration (Figure 4-2).

4.2 Univariate analysis

As Table 4-1 shows, variables such as mother age, weight, height, newborn gestation age, sex, weight, height, the rank of child, and Apgar score seems no different in two groups. Mothers' education level above college in failure group seems higher then in successful group, 83% and 74% respectively, but statistical no significant different. The incidence of occipital posterior presentation were 2.98% and 1.51%, it seem higher in successful group but not significant. There were no different between two groups in duration of phase I labor, cesarean section rate, length of cervical dilatation when epidural catheter insertion, and loading drug volume. The use rate of Demerol before epidural analgesia is higher in failure group (19.53% versus 14.57%), and the visiting staff anesthesiologist perform more epidural in successful group (59.51% versus 52.67%). But these two factors have no statistical significant different.

The duration of phase I, cervical dilatation in 30 minutes after epidural catheter placement, cervical dilatation velocity, loading drugs, loading with Fentanyl, continues drugs, instrumentation delivery, and satisfaction were associated with the ineffectiveness of epidural painless labor. The failure group has shorter duration of phase I (310.7 versus 264.43 minutes), more cervical dilatation in 30 minutes (3.25 versus 2.91 cm), faster progression of cervical dilatation (1.52 versus 0.67 cm/per hour), less instrumentation delivery (11.25% versus 21.69%), and less satisfied (21.77% versus 51.49% pronounced very satisfied) about epidural painless labor. Epidural drugs resulted in significant different between two groups. The failure group used more Xylocaine and Bupivacaine then Ropivacaine as loading drug, and more Bupivacaine then Ropivacaine as continue drug. There were less loading with Fentanyl in failure group (75.57% versus 86.96%). The mean and standard deviation were show in Table 4-1.

4.3 Multivariate analysis

Logistic regression analyses was used to identified potential factors including loading with Fentanyl, phase one, cervical dilatation when epidural catheter placement, cervical dilatation velocity, loading drugs, and continue drugs. We found factors including cervical dilatation velocity, loading drugs, and continue drugs as the most

significant predictors of ineffectiveness of painless labor, with odds ratios of 2.33 (1.40-3.89), 1.83 (1.15-2.90), and 5.55 (1.39-22.20) respectively. The results are described in Table 4-2.

All significant factors were put into a stepwise logistic regression to select a best predictive model. The result as Table 4-3 shows. The predictive model of ineffectiveness epidural painless labor in our study is as follows: Z= -1.6458+0.8404 (cervical dilatation velocity) + 0.6710 (loading drug) + 1.8274 (continue drug). Where the probability= $1/(1+e^{-Z})$. And the variables are coded as follows: cervical dilatation velocity (less then 1cm/hour=0, more then 1cm/hour=1), loading drugs (Ropivacaine=0, non or Bupivacaine or Xylocaine=1), continue drugs (Ropivacaine=0, Bupivacaine=1).

4.4 Validation of the model

The ROC (receiver operating characteristic) curve of this model is presented in Figure 4-3. And AUC (area under ROC curve) is calculated as 0.6712.

Data of validating group were used to detect the validity of this predictive model. The validity (or accuracy) is the percentage of true positive and true negative in all cases. When the cut point of probability is 0.5, the validity is 0.6873.

Chapter 5 Discussion

5.1 Prevalence of epidural painless labor

The prevalence of epidural painless labor in this study was 17.5%, which is much lower than many developed countries like the United States and the European Union[7, 8, 10-12]. This study was conducted in a medium-size teaching hospital in Taipei City and the service of epidural painless labor is available twenty-four hours a day. The result can't represent the prevalence in whole Taiwan. But we believe the prevalence in the rural areas in Taiwan is lower than our result due to the insufficient anesthesiologists.

Factors influencing parturients' decision of using epidural painless labor or not are discussed in some studies. Chang et al. found nulliparity and high education level are positive predictors of epidural painless labor. The fear of side effects, fear of severe complications, and fear of needle are the major reasons of refuse epidural analgesia[18]. The attitude of obstetricians and midwifes toward epidural analgesia may influence parturients' decision making[33]. In general, the older generation tends to refuse spinal and epidural analgesia or anesthesia. The attitude of relatives such as mother or mother-in-law may change parturients decision. In additionally the insurance payment may be a key factor[34, 35]. In Taiwan, epidural painless labor is paid by out-of pocket money and charges for NT 6000 to 8000. The price may decrease the parturients' will. The availability of epidural painless is a problem, too. Lack of anesthesiologists or

anesthetic nurses makes it difficult to provide the service of epidural painless labor for twenty-four hours in local hospitals.

5.2 Labor pain and satisfaction

In our study, we took satisfaction as an independent variable. We found a positive correlation between satisfaction and labor pain. Although in a systematic review about pain and women's satisfaction with the experience of childbirth by Ellen et al., the influences of pain or pain relief on subsequent satisfaction are not obvious then the influences of the attitudes and behaviors of the caregivers[36]. This may be due to the complex components of "satisfaction". It involves both a positive attitude and effective response to an experience. Our simple measurement scale may not really present the "satisfaction" of whole procedure. Besides our parturients pay for epidural painless labor may expect totally "painless". When the difference between expectation and reality appears, they feel dissatisfied.

5.3 Labor pain and the mode of delivery

The epidural analgesia is unlikely to increase the risk of cesarean section but may increase the risk of instrumental vaginal delivery (relative risk 1.38, 95% CI 1.24-1.53) is well documented in Anim-Somuah's systematic review in Cochrane database[37]. And

Hwa et al. had the same conclusion in Taiwan[38]. Epidural analgesia may increase the risk of instrumental delivery by several mechanisms. Reduction of serum Oxytocin levels can result in a weakening of uterine activity. This may be due in part to intravenous fluid infusions being given before epidural analgesia[39]. Maternal efforts at expulsion could also be impaired, causing fetal persisted malposition (occipital posterior or occipital transverse presentation) during descending phase[40]. And the fetal malposition definitely increases the incidence of instrumentation delivery[41].

In our study, the cesarean rate was no different in two groups. But the ineffectiveness of epidural painless labor decreased the instrumentation delivery rate. This result supports previous conclusion of epidural analgesia of labor pain may increase the risk of instrumentation delivery. The decreasing Oxytocin may cause poor uterus activity and therefore less painful sensation. And painless may makes parturients' impaired effort at expulsion.

5.4 Evaluation of risk factors

The overall failure rate (defined as NRS>3) found in this study was 26%. This failure rate is similar to previous data reported by Michael et al. for 23% and Ghislaine et al. for 20%[25, 42]. Using a multivariate analysis, we are able to determine factors which are associated with ineffectiveness of epidural painless labor. Three significant factors

are identified.

1. Cervical dilatation velocity

Labor pain during first stage results from stimuli arising from mechanical distension of the lower uterine and cervical dilatation[43]. The increasing intensity of pain accompany with progression of cervical dilatation[2, 44]. The mechanism may be a lower activation threshold in the mechanoreceptors, and the chemoreceptor stimulation produced by the repeated stimuli of uterine contractions[3]. As expected, the faster cervical dilatation, the more painful sensation was detected. Timing of epidural catheter insertion is no different in two groups. The result advocates that pain is subjective and depends on the person's past experience of pain. Every parturients thought their pain is the "most pain imaginable" when ask for epidural painless.

2. Loading drugs and continuing drugs

In previous study about the risk factors related to ineffectiveness painless labor, the regimen of loading and continue drugs were the same in all cases and were not been analysis[9, 25]. In our study, different regimens with fixed concentration were used.

Ropivacaine is an amino amide local anesthetic that is structurally similar to bupivacaine. In comparison with Bupivacaine, Ropivacaine is equally effective for epidural block for surgery, obstetric procedures and postoperative analgesia[45]. There are no significant differences in pain VAS between 0.1% Ropivacaine, and 0.125%

Bupivacaine given for labor epidural analgesia.[46] Recommended epidural doses of Ropivacaine for postoperative or labor pain are 20-40 mg as bolus with an interval of >or=30 minutes[47]. But there are different results in our study. Our study showed Bupivacaine is associated with ineffectiveness but not Ropivacaine in both loading and continue use. It's difficult to explain. The possible reason is the correlation between drug and volume or performer is not investigated. Interaction between drugs and volume, drugs and performers may exist and not analyzed in our study.

Factors associated with ineffectiveness of epidural painless labor in univariate analysis but not significant in multivariate analyses are described as follows.

1. Loading with Fentanyl

Loading without Fentanyl is associated with ineffectiveness of epidural painless labor in our univariate analysis. The use of epidural administered opioids to control postoperative pain is a well established and widely accepted technique[48]. And so did in labor pain. Lee et al. reported that epidural infusion of 0.1% Ropivacaine alone provided adequate analgesia in the first stage of labor, and that of additionally 2 μg/mL Fentanyl improved analgesia to a quality similar to 0.2% Ropivacaine alone. But the VAS was higher in parturients with 0.1% Ropivacaine[49].

2. Duration of phase I

Our result concluded that parturients experience poor pain relief had shorter duration of phase I. This result is compatible with that faster cervical dilatation velocity is a factor associated with ineffectiveness epidural analgesia. In spite of Le Coq et al. demonstrated that epidural duration shorter than one hour or longer than six hours are both risk factors to inadequate painrelief[25]. Our study showed different results. Although the result was not significant different in multivariate analysis.

Other factors related to inadequate pain relieve found in previous studies but not significant in our study including follows.

1. Nulliparity

Nulliparous women experience greater pain than multiparous women in early labor but the difference is lesser as labor progression[6]. Hess et al. concluded that nulliparity was independently associated with recurrent breakthrough pain during labor epidural analgesia[9]. But Le Coq et al. reported no differences between nulliparities and multiparities in inadequate pain relief using epidural. Our results support the latter one. And this issue needs to be further investigated.

2. Fetal weight

Hess et al. concluded that heavier fetal weight was independently associated with recurrent breakthrough pain during labor epidural analgesia[9]. But others had the

opposite opinion that there was no relation between birth weight and pain scale in natural vaginal delivery[21, 25, 50]. Our results agree with that fetal weight is not related to ineffectiveness of epidural painless labor. The possible explanation is that our study focused on the analgesia effect during the first phase of labor. The pain during first stage of labor mainly arises from uterus contracture and cervical dilatation. And bigger fetus may cause more traction on pelvic structure and perineum which mainly occurs on late first stage and second stage. More evidence is needed to approve it.

3. Fetal occipital posterior presentation

The incidence of fetus occipital posterior (OP) presentation is ranging from 4.6% and 5.5% by Yancey and Sizer, to 6% by Ponkey[51]. OP presentation are definitely associated with a marked increase in the risk of Caesarean section delivery, To W. et al. reported the odds ratio for the OP group was 30.2 (95% CI 25.6-35.5) for Caesarean section then occipital anterior group[41]. Sizer et al. reported a higher incidence of emergency Cesarean deliveries in OP compared with occipital anterior labors (41.7% versus 13.7%, $p<0.001$)[24]. It means many fetuses with OP presentation were delivered by Cesarean section and the presentations didn't be recorded in our study. So the incidence of OP presentation in may be lower estimated. The standard diagnosis tool of fetal presentation is ultrasound. In our study there were no routine examinations of fetal presentation when parturients in labor. The presentation was recorded in the moment of

delivery and may underestimate the incidence of OP presentation too.

The incidence of OP presentation in our study is 2.6% in training group. There were no different between failure group and successful group. Due to the low incidence of OP presentation, we are in doubt on this conclusion and more data should be collected to confirm it.

4. The epidural catheter implantation in early cervical dilatation

Most study concerned about the effects of early epidural analgesia on Cesarean or instrumental delivery in parturients. Massimo et al.'s systematic review concluded that cervical dilatation is not a reliable means of determining when epidural analgesia should be initiated[53]. Few concerned about early epidural analgesia and effectiveness of pain relief. Hess et al. found earlier cervical dilatation was positive related to breakthrough pain during epidural painless labor. But Le Coq et al. had the opposite finding. Our result showed no difference between two groups in timing of epidural initiation. More studies will be needed in this issue.

5.5 Study limitation

This is the first study about the determinants of ineffectiveness epidural analgesia of labor pain in Taiwan.

We acknowledge several limitations in our conclusions. First, the numeric rating

scale is a single quantitative dimension of pain intensity and couldn't reveal the complex multidimensional phenomenon of pain. Acute pain such as labor pain is considered to have at least two dimensions, a sensory and an affective or distress component[3]. For example, anxiety, fear of pain, and psychological factors are commonly associated with pain and can't be distinguished by only NRS. Parturients may confuse these negative emotions with pain sensation and pronounce they are painful. Many methods of measuring pain in a more objective way have been developed such as McGill pain questionnaire, which Chinese translation edit is validated, and currently development Present Behavioral Intensity Scale may be a choice to evaluate labor pain.

Second, an arbitrary definition of ineffectiveness of epidural painless labor was used in our study. In our experience of management acute pain including, the NRS is used to confirm clinical nursing judgment as to the need for further intervention[32]. NRS less than three document that the goal of analgesia has been achieved.

Third, there might be some factors related to ineffectiveness of painless labor didn't include in our analyses. For example, technique factors mentioned in previous studies were not recorded and analysis in our study. The two major causes of inadequate block were found to be transforaminal escape of the catheter tip, and persistent unilateral block associated with an obstructive barrier in the epidural space in Collier et al.'s study

of epidurogram[52]. Thus the incidence of paresthesia during epidural placement, the catheter migration after delivery, the unilateral analgesia may be important factors.

Forth, participates in our study are limited in one medical center in Taipei City. There may be limitations for extrapolating. The characteristics of parturients in other hospital in Taiwan may differ from our hospital. For example the age, education level and income may higher than other rural hospitals and clinics. Second the regimens of epidural painless labor may be different in drugs and concentrations. Although there are limitations exist, to apply our results in a population similar to our participants is appropriate.

5.6 Conclusion

Our results revealed that factors associated with ineffectiveness of epidural analgesia of labor pain are cervical dilatation velocity, type of loading drugs and type of continue drugs. Improvement of effectiveness and of epidural analgesia of painless labor could be aimed at these factors. And more factors to be concluded in analyses are suggested in further investigation.

Figure 1-1 Comparison of the intensity of labor pain with other clinical pain syndromes.

(From Melzack R. Pain 1984;19:321-37)

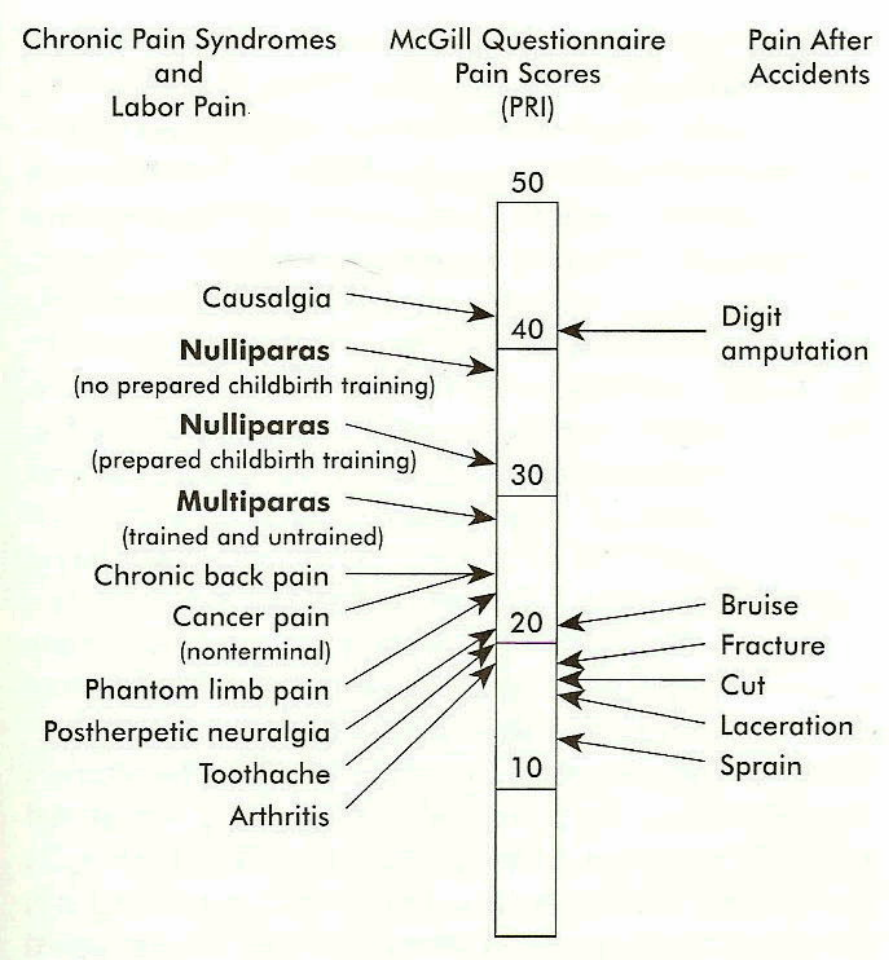

Figure 2-1 The linear relationship between VAS and NRS of obstetrical pain. (From Hartrick CT. Pain Pract 2003;3(4):310-6)

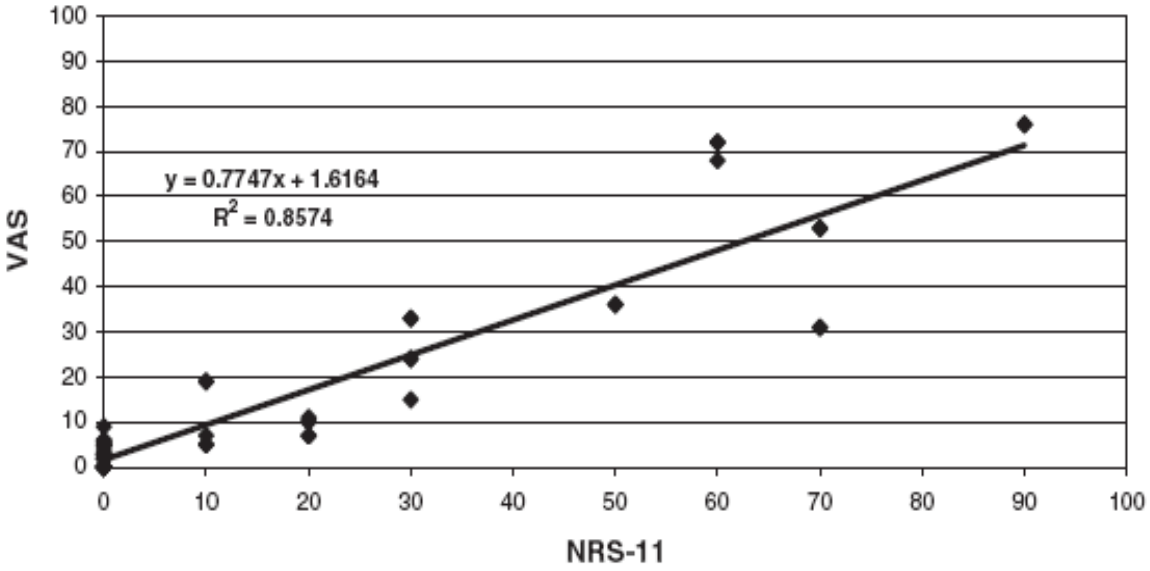

Figure 3-1 The Portex ® epidural minipack (system 1, clear catheter, 3 lateral eyes. Portex Ltd. CT21 6JL, UK) (From website of Smiths medical ASD Inc.)

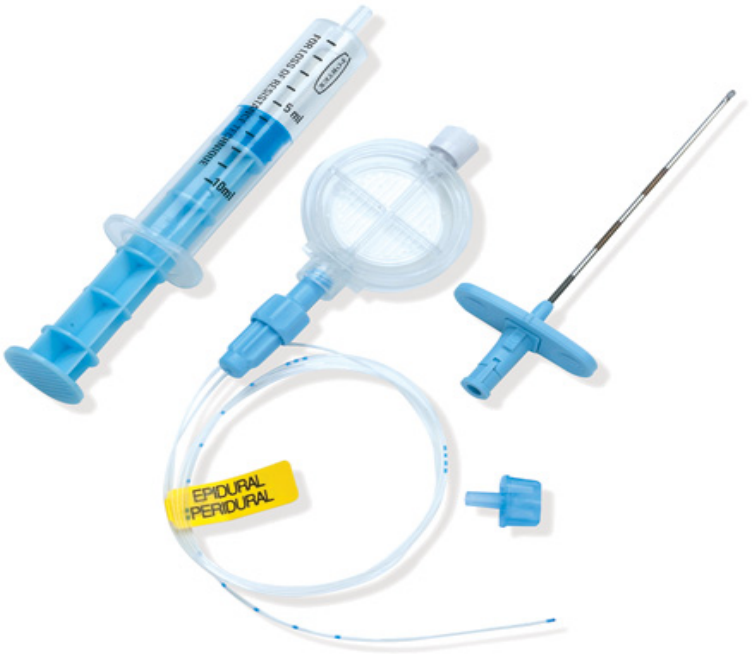

Figure 3-2 The place and position of epidural catheter insertion.

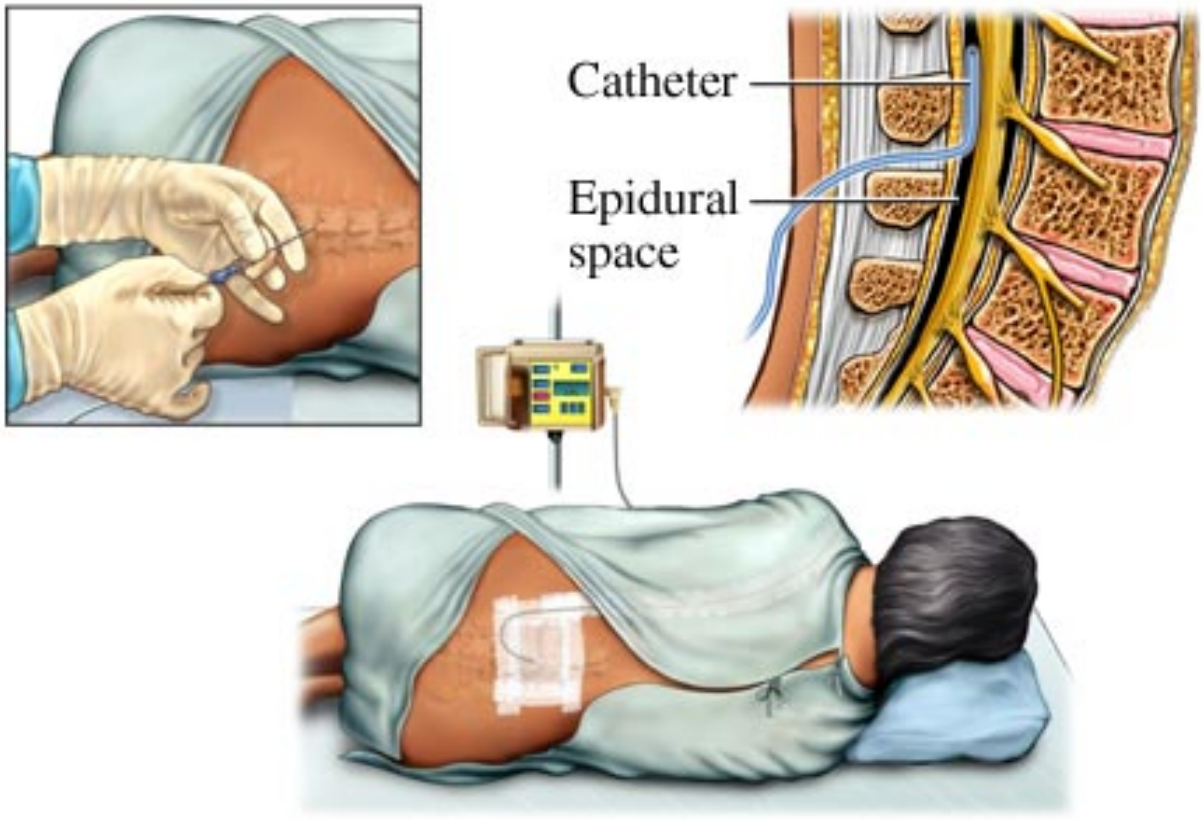

Figure 3-3 Results of data collection.

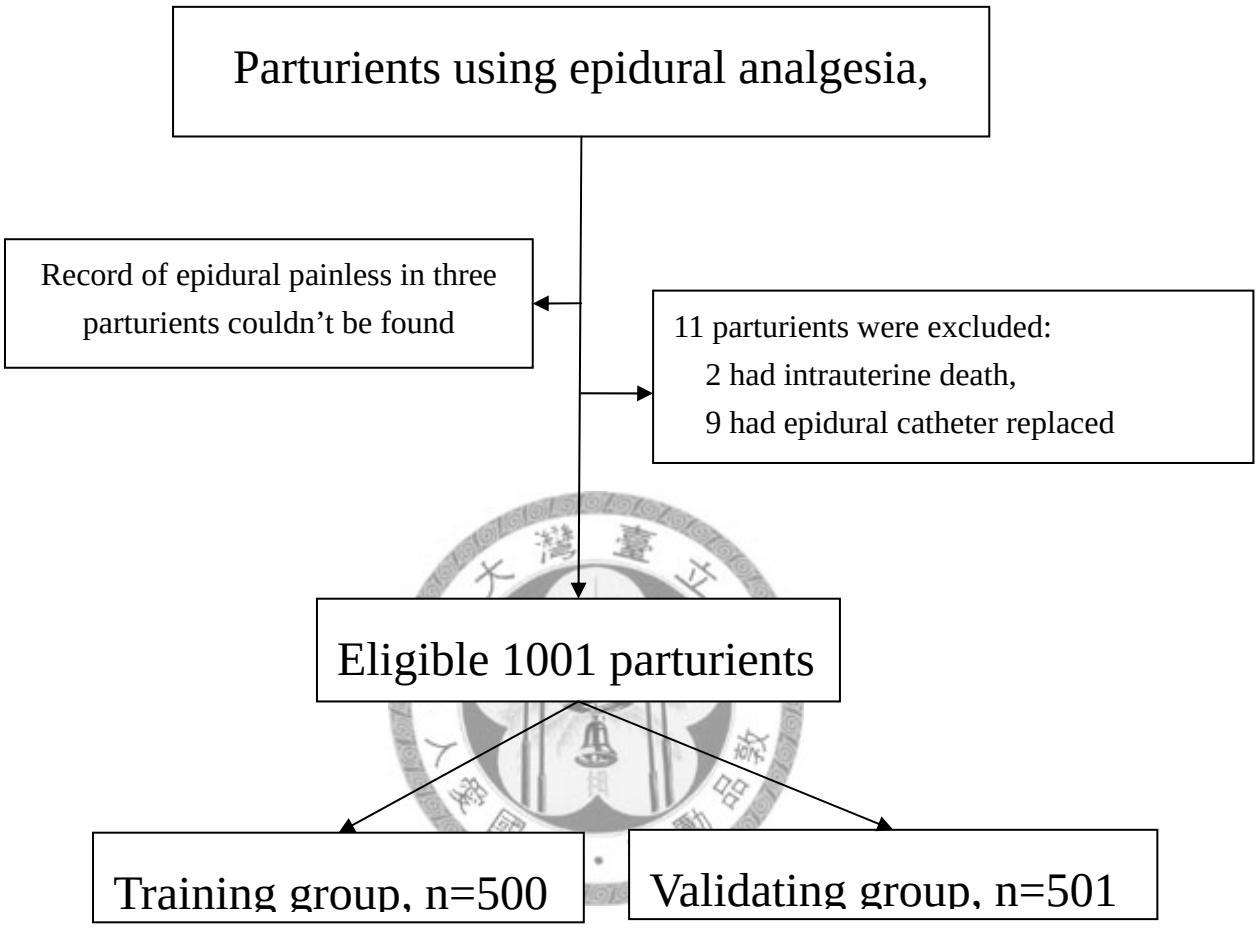

Figure 4-1 Trend of usage rate of epidural painless labor.

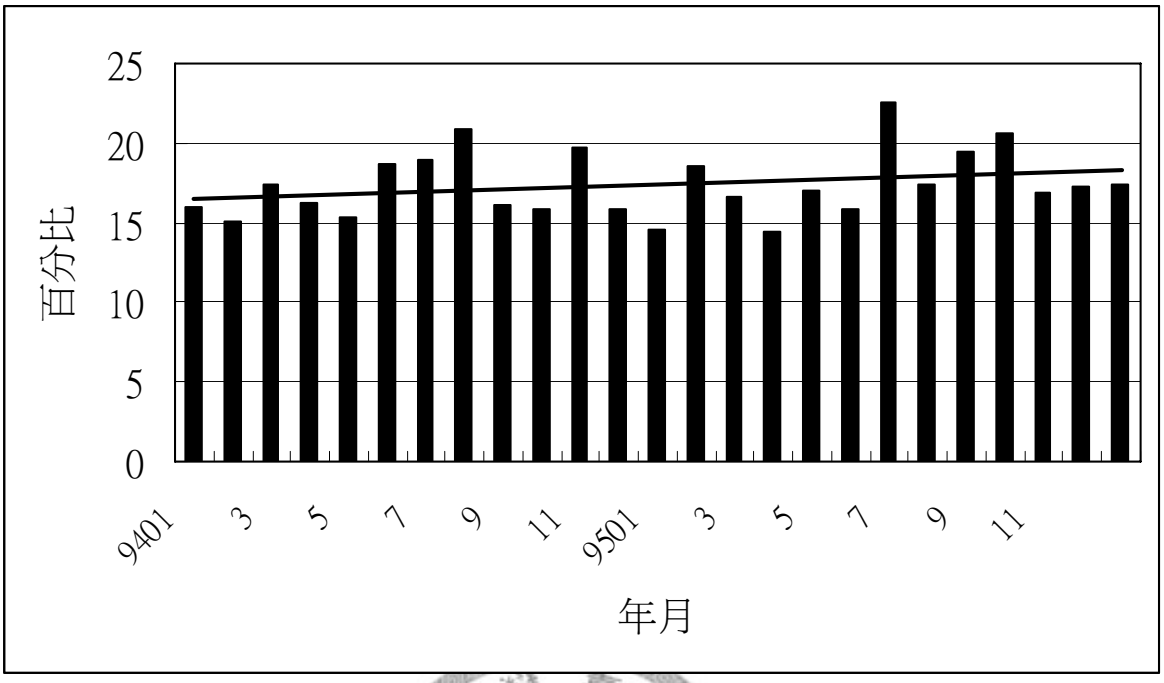

Figure 4-2 The distribution of NRS before the epidural catheter insertion (upper figure), 30 minutes after epidural drugs administration (middle figure), and the maximum NRS of pain during labor after epidural painless labor (lower figure).

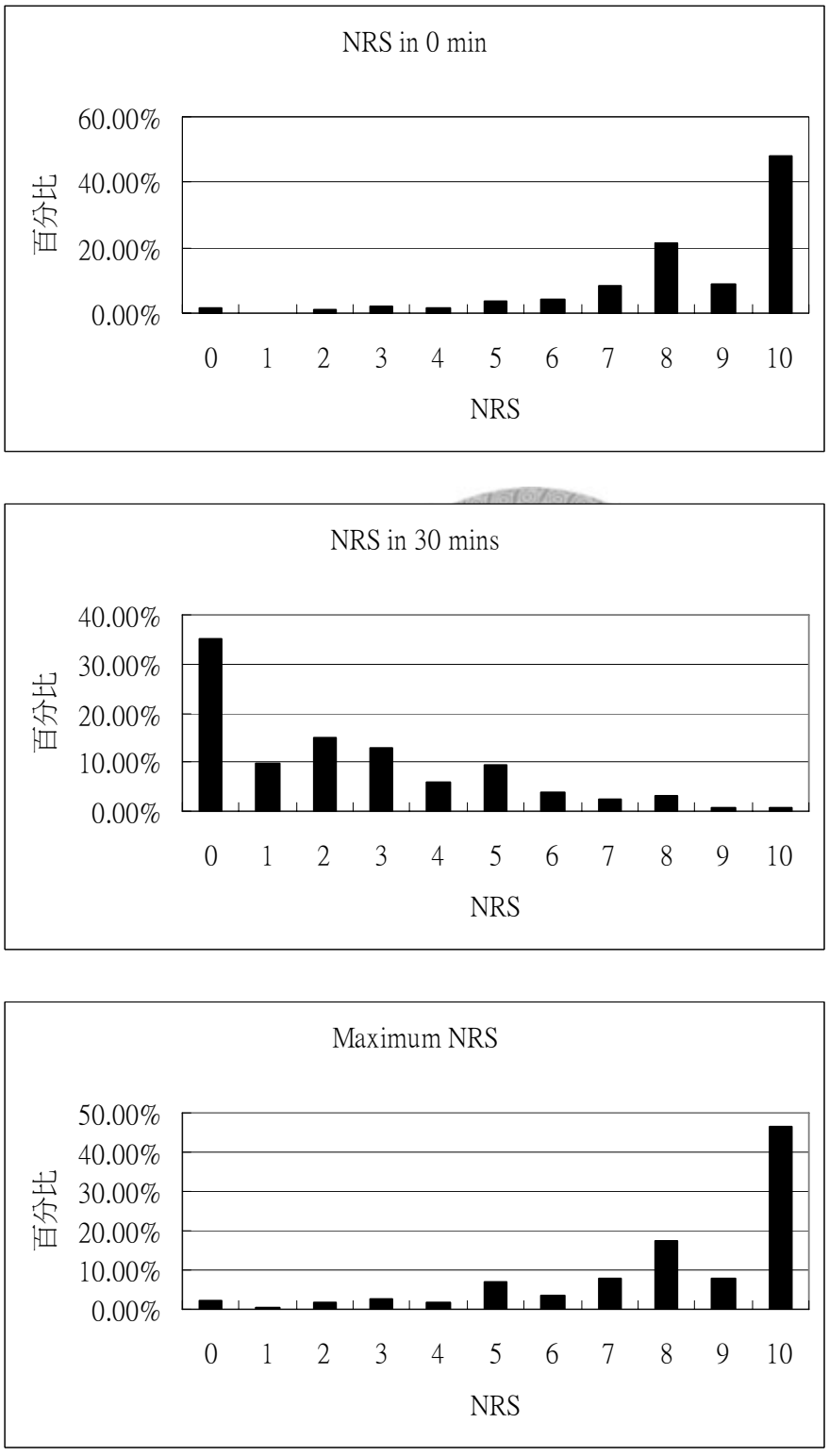

Figure 4-3 ROC (receiver operating characteristic) curve of logistic regression model for predict ineffectiveness epidural painless labor.

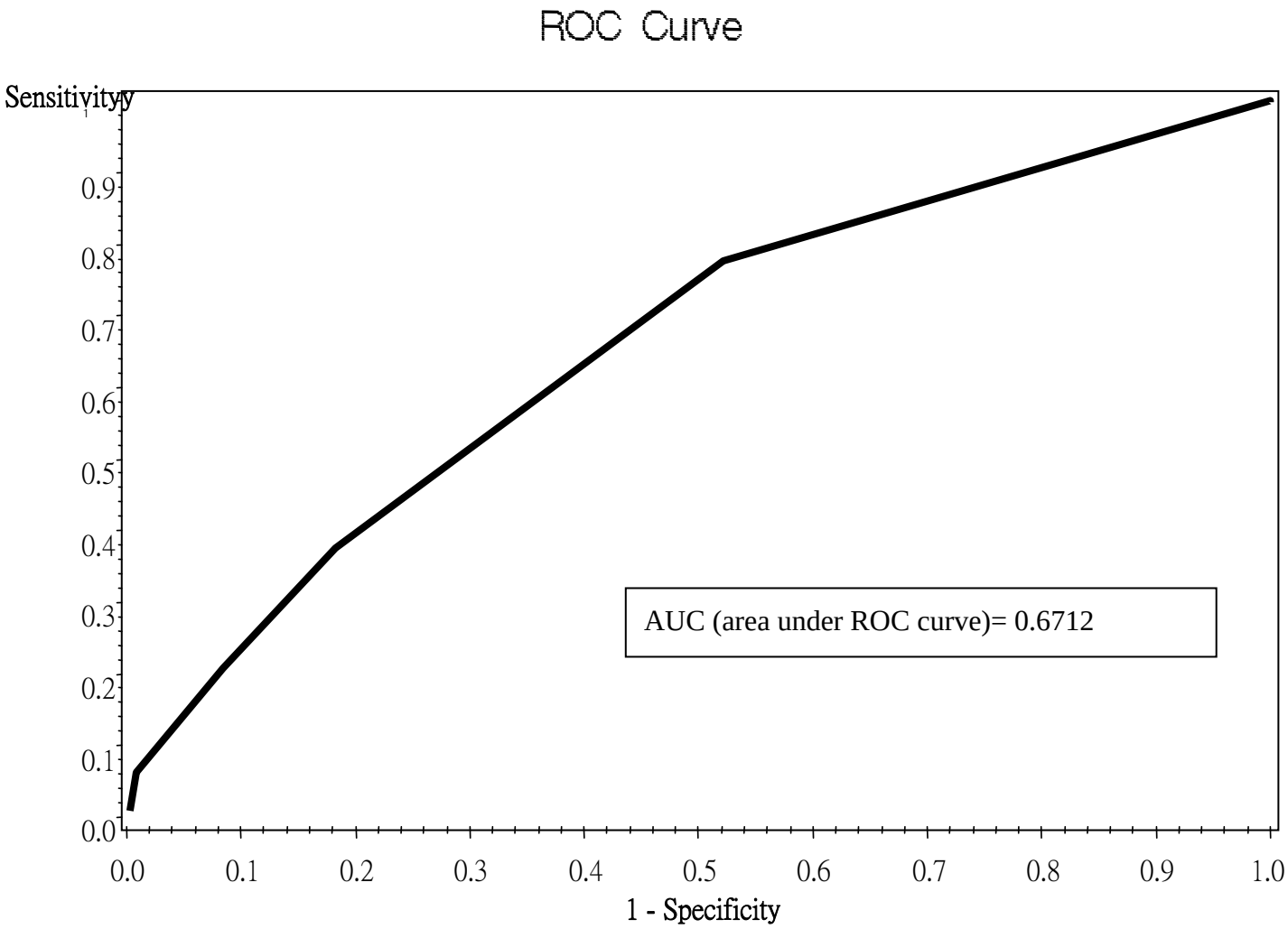

Table 4-1 The demographic data of training and validating group

	Training group	Validating group	*P*-value (two tail)
Mother age	30.04±3.8	30.08±4.06	0.9108
Mother height (cm)	160.08±4.99	160.27±4.71	0.5439
Mother weight (kg)	67.83±9.21	67.94±8.28	0.8506
Gestation weeks	38.97±1.29	39.04±1.29	0.4052
Newborn height (cm)	50.11±3.92	50.18±2.01	0.5818
Newborn weight (kg)	3174.71±	3180.13±363.45	0.8182

Table 4-2 Univariate analysis of two groups (NRS>3 and NRS<=3) using t-test for continuous variables and chi-square test or Fisher's exact test for categorical variables. * p<0.1 # Fisher's exact test

	NRS<=3 (N=370, 74%)	NRS>3 (N=130, 26%)	*p*-value
Mother age	29.989(29.593-30.385)	30.214(29.591-30.837)	0.5615
Mother height	159.96(159.47-160.46)	160.4(159.48-161.32)	0.393
Mother weight	67.77(66.81-68.73)	68.01(66.49-69.53)	0.7999
Education (above college)	74.15%	82.95%	0.227
Gestation age	39.02(38.88-39.15)	38.85(38.65-39.04)	0.199
Newborn weight	3185.4(3145.8-3225.0)	3144.9(3081-3208.8)	0.298
Newborn height	50.16(49.96-50.37)	49.98(49.64-50.31)	0.3553
Newborn sex (male)	54.67%	53.49%	0.8169
Children number (first)	86.18%	86.26%	0.294
OP presentation	2.98%(11)	1.51%(2)	#0.5291
Apgar score at 1 min	8.61(8.53-8.69)	8.67(8.53-8.81)	0.4516
Apgar score at 5 min	8.96(8.93-8.98)	8.95(8.91-9.00)	0.8442
Stage1	310.7(283.74-337.67)	264.43(218.47-310.39)	*0.0847
Stage2	77.40(68.17-86.64)	75.58(64.93-88.23)	0.9234
Cervivle dilatation in 0 min	2.55(2.44-2.66)	2.50(2.32-2.67)	0.6417
Cervicle dilatation in 30 min	2.91(2.76-3.07)	3.25(2.93-3.57)	*0.0407
Cervicle dilatation velocity	0.67(0.46-0.89)	1.52(0.46-2.05)	*0.0006
Use of Mepedipine	14.57%	19.53%	0.1872
Instrumentation delivery	21.69%	11.25%	*0.0256
C/S rate	70(18.97%)	24(18.46%)	0.8701
Loading drug			*#<0.0001
Non	0.82%(3)	0	
Lidocaine	41.58%(153)	54.2%(71)	
Bupivacaine	2.45(9)	9.16%(11)	
Ropivacaine	55.16%(203)	36.64%(48)	
Loading with Fentanyl	86.96%(320)	75.57%(99)	*0.0023
Loading volume	11.25(10.89-11.60)	10.73(10.10-11.35)	0.1194
Continue drug			*#0.0015
Bupivacaine	0.81%(3)	6.11%(8)	
Ropivacaine	99.19%(366)	93.89%(122)	
Satisfaction(very satisfy)	51.49%	21.77%	*<0.0001
Anesthesiologist(VS)	59.51%	52.67%	0.1736

Table 4-3 Multivariate analysis using logistic regression.

	Odds ratio	95% CI	P-value	
Fentanyl (with Fentanyl)	0.729	0.409-1.299		0.2841
Stage 1 (<300 mins)	1.338	0.830-2.157		0.2315
Cervical dilatation at 30 min (>3cm)	0.875	0.553-1.385		0.5696
Cervical dilatation velocity (>1cm/hour)	2.333	1.400-3.889	*0.0012	
Loading drug (non or Lidocaine or Bupivacaine)	1.827	1.150-2.904	*0.0108	
Continue drug (Bupivacaine)	5.546	1.386-22.195	*0.0155	

Table 4-4 Stepwise logistic regression to select model of prediction ineffectiveness of epidural painless labor.

Parameter	**Estimate**	**Standard error**	**Chi-square**	**Pr>Chi-square**
Intercept	-1.6458	0.1765	869384	<0.0001
Cervical dilatation (>1cm/hour)	0.8404	0.2377	12.4985	0.0004
Loading drugs (non or Lidocaine or Bupivacaine)	0.6710	0.2154	9.7081	0.0018
Continue drugs (Bupivacaine)	1.8274	0.6977	6.8611	0.0088

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