Prediction of Early Pain Score in the Postanesthesia Care Unit With Heart Rate Variability and Insomnia Severity Index: A Pilot Study

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Abstract

Background:

Postoperative pain is distressful, and it imposes adverse effects on multi-systems. Early intervention and effective postoperative pain management had always been major concerns of clinical anesthesiologists. For pain is subjective, psychological factors had been taken into considerations to make predictions in several studies. Temporal changes of heart rate variability (HRV) across the perioperative period, which reflects the dynamic activities of the autonomic nervous system (ANS), is another important part we want to incorporate into the prediction model. Our goal was to develop a better prediction model of pain severity based on both the demographic factors and intraoperative indices.

Method:

We enrolled 80 women ≥ 20 years of age scheduled for gynecological surgeries under general anesthesia. All participants were American Society of Anesthesiologists classification of physical status 1 to 3 without using drugs affecting HRV. Questionnaires including Insomnia Severity Index (ISI) and Beck Depression Inventory-II (BDI-II) were used to evaluate participants' sleep qualities and severity of depression, respectively. Physiological signals were recorded perioperatively. After surgery, the numeric rating scale (NRS) for pain was measured as a patient's arrival at the postanesthesia care unit (PACU). The HRV indices of frequency-domain and nonlinear-domain were computed and analyzed offline. The demographic factors and intraoperative indices were included to build a prediction model of postoperative pain severity by using the stepwise linear regression.

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Key Words:

Pain, Postoperative; Sleep; Heart Rate Variability; Anesthesia, General

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Running title: Prediction of early pain score in PACU

Results:

We used the stepwise linear regression to build a model for the initial NRS scale on arrival at the PACU. The formula of the final multivariable model is as follows: NRS = −0.784 × Surgery Type (1 for laparoscopic surgery and 0 for open surgery) + 0.086 × ISIscore − 0.044 × Age + 0.002 × Volume of blood loss + 0.006 × deltaVLF + 0.014 × deltaSD1 − 0.006 × deltaSD2 − 0.003 × deltaEntropy. (delta in the formula denotes the change ratio from the midpoint of the surgery to before the end of surgery) The results showed that this model is a significant predictor of the initial pain score in the PACU ($F_{8,71}$ = 3.798, P = .0009). The adjusted square of R was .22.

Conclusions:

With sleep quality, demographic factors, and changes in measures of intraoperative HRV, we develop a prediction model of initial NRS on arrival at the PACU. Further research is required to validate the results of this pilot study.

Introduction

Pain is an unpleasant sensory and emotional experience associated with tissue damage and is one of the most frequently reported symptoms in the postanesthesia care unit (PACU). It is a critical concern that not only causes discomfort in the patient but also has multisystem adverse effects, such as poor wound healing and cardiopulmonary complications and thromboembolic diseases.[1] Therefore, adopting an effective analgesic strategy in the postoperative period is imperative.[2]

For early intervention and effective management of postoperative pain, establishing a prediction model for pain severity enables clinicians to develop a thorough plan for analgesia before the end of the surgery. Given that pain is subjective and multidimensional, several relevant studies have considered psychological factors.[3-5]However, without dynamic indicators from the intraoperative period, reflecting the subtle differences in surgical stress experienced by patients, even those undergoing the same type of procedure, is difficult.

Heart rate variability (HRV) is an established measure for assessing autonomic nervous system (ANS) activities. Frequency-domain analysis reveals the periodic oscillations of heart rate signals. These signals are decomposed at different frequencies and the power spectrum of each part provides information regarding the different aspects of the ANS.[6] Nonlinear-domain analysis of HRV has revealed the scaling invariance of the ANS[7] and the complex interactive mechanisms that operate in the body across multiple spatial and temporal scales. These HRV indices may provide us with insight regarding how our bodies respond to surgical stresses and anesthesia.

Preoperative psychological factors, surgical types, age and HRV indices are reported factors affecting the severity of acute postoperative pain.[8]In this study, we hypothesized that acute postoperative pain can be predicted through a combination of preoperative psychological surveys, patients' characteristics and monitoring of changes in intraoperative HRV. The purpose of this study was to develop a prediction model of pain severity on arrival at the PACU, referred as early pain score. By identifying the different risks of severe pain, we may be able to plan customized preventive analgesia, thereby optimizing the quality of pain control and minimizing the occurrence of complications related to acute pain.

Materials and Methods

This prospective observational study was conducted at Chi Mei Medical Center in Tainan, Taiwan and was approved by the Institutional Review Board of Chi Mei Medical Center on March 26, 2018 (IRB serial number: 10703-005; Committee address: No. 901, Zhonghua Rd., Yongkang Dist, Tainan City 710, Taiwan).

The eligibility criteria for participation were women ≥ 20 years of age who had an American Society of Anesthesiologist classification of physical status in the range of 1 to 3 and who underwent gynecological surgery under general anesthesia between March 30, 2018, and May 2, 2019. Patients with hypertension, arrhythmia, a pacemaker, or severe peripheral or cardiac neuropathy and those who were on medications that interfere with cardiac rhythm or ANS activity were excluded. Moreover, patients who were on long-term opioid use (oral morphine equivalent > 30 mg for >6 weeks) for any reason were also excluded from this study.

The participants were administered 2 questionnaires: The Insomnia Severity Index (ISI) and Beck Depression Inventory-II (BDI-II). The ISI is a seven-item self-report questionnaire used for evaluating sleep quality and is rated on a 5-point scale from 0 to 4 corresponding to increasing severity. It has reliable internal consistency and validity for identifying patients with insomnia, and the total ISI score is significantly correlated with the measures of fatigue, quality of life, anxiety, and depression [9,10]. The BDI-II is a 21-item self-report multiple-choice inventory, and it is widely used as an indicator of the severity of depression. The validity and reliability of the Chinese version of the BDI-II have been demonstrated to be favorable by studies in various domains.[11] In our study, the total scores of the ISI and BDI-II were regarded as indicators of sleep condition and depression severity.

General anesthesia was induced through intravenous administration of anesthetics (propofol or thiamylal), fentanyl, and a muscle relaxant. Anesthesia was maintained by administering inhalational anesthetics (desflurane or sevoflurane), analgesics (fentanyl or morphine), and muscle relaxants. All patients who received anticholinergics, ketamine, or any other drugs that affect heart rate before the emergence of anesthesia were excluded. Additionally, the numeric rating scale (NRS) for pain perception was recorded after the patient had regained the ability to communicate and been sent to the PACU.

Physiological indicators such as blood pressure, electrocardiograms (ECGs), entropy measure for anesthesia depth, and Surgical Pleth Index (SPI) were collected from the time that the participants entered the operation room until the end of surgery. The raw data were acquired using a personal computer with S/5 iCollect data acquisition software (GE Healthcare Finland Oy, Helsinki, Finland). The sampling rate was 300 Hz, and all analyses were performed offline. The 10-minute ECG data were extracted in the middle and before the end of the surgeries, and the HRV indices were computed using Matlab software (2018a, MathWorks, Inc.) with the open-source mhrv package provided by the PhysioZoo platform.[12] Next, the ratio of changes in HRV was calculated from the middle to before the end of the surgeries.

Frequency-domain measures consist of high-frequency (HF) power (0.15–0.40 Hz), low-frequency (LF) power (0.04–0.15 Hz), very-low-frequency (VLF) power (0.003–0.04 Hz), and the LF/HF ratio. Nonlinear-domain measures incorporate Poincaré plot standard deviation perpendicular to the line of identity (SD1), Poincaré plot standard deviation along the line of identity (SD2), Log–log slope of detrended fluctuation analysis in the low-scale region (Alpha1), Log–log slope of detrended fluctuation analysis in the high-scale region (Alpha2), and sample entropy (SampEn).

The HF power primarily correlates with the vagal modulation of the ANS, whereas an increase in the LF area usually denotes an elevation of sympathetic activity, even though the LF power is modulated by both sympathetic and parasympathetic activities. The LF/HF ratio in the frequency domain usually refers to the global sympathovagal balance, and the VLF power generally reflects physical activity and is modulated by the stress response. In nonlinear analysis, SampEn is a measurement of the complexity of signals. It is multiscaled and generally reflects the ability of the cardiovascular system to adapt to and function in an ever-changing environment. The SD1 measures short-term HRV in millisecond (ms) and correlates with baroreflex sensitivity (BRS), and the SD2 measures both short-term and long-term HRVs, LF power, and BRS.

Since surgical stress was fluctuating during surgery, HRV analysis at certain periods might not reflect the overall intensity of stimuli patients received. Therefore, we adopted the change ratio of HRV across different periods (from the midpoint period of surgery to that before the end of surgery) as dynamic indicators, which revealed the trends of different components of ANS.

Statistical analyses were conducted using R statistical software (version 3.5.2.)[13] The ISI total score, BDI-II total score, five demographic variables and nine HRV indices were included in the initial model of the multiple linear regression as predictors. A stepwise method was chosen for model selection and the iterate stopped while the smallest Akaike information criterion (AIC) was reached. Residual analyses included the residual normality, autocorrelation, non-constant error variance were performed. After the model was built, we used the freeware G*Power (Version 3.1.9.4) to calculate the required sample size of the main study.

Results:

This study commenced on March 27, 2018. Informed consent was obtained from 112 women for participation. Of the total number of participants, 19 were excluded because of preoperative use of anticholinergic agents. During the process of data cleaning, 10 patients were excluded owing to incomplete data, and 3 others were excluded owing to various artificial interferences.

Patients' demographic characteristics are listed in Table 1. Our participants had a mean age of 42.9 years and an average body mass index of 23.0. Overall, 65% of surgeries were laparoscopic, whereas 35% were traditional open surgery. The average scores on the ISI and BDI-II questionnaires were 7.6 ± 5.9 and 7.4 ± 6.5, respectively. The mean volume of blood loss was 139.4 ± 177.3 mL, and the mean intraoperative oral morphine equivalent (OME) was 49.3 ± 12.4 mg.

The results of HRV indices from the midpoint/before the end of the surgery and the ratio of changes in HRV indices are presented in Table 2. As shown in Table 3, all variables were divided into 2 groups: demographic variables and those that denoted the ratio of change in HRV from the midpoint of the surgery to just before the end of the surgery. Standard frequency-domain and nonlinear-domain measures were included in the analysis. Initially, 16 variables were included as independent variables. In the univariate analysis, ISI score, the ratio of changes in SD1 (deltaSD1), and Alpha1 (deltaA1) from the midpoint of surgery to before the end of surgery were found to be significantly correlated with the pain score (NRS) on arrival at the PACU (P = .017, P = .004, and P = .017, respectively). The stepwise method was used to perform multivariable model selection using the AIC. The AIC of the initial model with all variables included was 120.5; after a combined backward and forward stepwise search, the final model comprised only 8 variables (surgery type, ISI score, age, volume of blood loss, deltaSD1, deltaSD2, deltaVLF, and deltaEntropy) with a minimum AIC of 112.06. The results showed that this model is a significant predictor of the early pain score in the PACU ($F_{8,71}$ = 3.798, P = .0009). The adjusted square of R was .22. The formula for our model is as follows:

NRS = −0.784 × Surgery Type (1 for laparoscopic surgery and 0 for open surgery) + 0.086 × ISIscore − 0.044 × Age + 0.002 × Blood loss + 0.006 × deltaVLF + 0.014 × deltaSD1 − 0.006 × deltaSD2 − 0.003 × deltaEntropy

The normality and independence of the residuals and the constancy of the error variance were verified. We used the results of this pilot study to estimate the sample size for the main study with the freeware G*Power (Version 3.1.9.4). With an alpha error of 0.1 and power of 0.95, we calculated the sample size from the 5 main variables (Total score for the ISI questionnaire, deltaSD1, deltaSD2, deltaVLF, and deltaEntropy) that were most relevant to our hypothesis. The surgery type (open surgery vs. laparoscopic surgery), age, and the volume of blood loss were regarded as controlled factors in our study. According to the results of the power analysis, the sample size should be at least 102 patients. Considering the dropout rate, the total number of patients should be at least 145.

Discussion

In this pilot study, we found that sleep quality and changes in certain HRV indices were associated with early pain scores upon arrival at the PACU. Therefore, we developed a formula to predict the first NRS score in PACU by using demographic variables (surgery type, age, and volume of blood loss), ISI scores and changes in HRV indices (VLF, SD1, SD2, and sample entropy). A pragmatic approach was adopted to consider the patients' analgesic needs after emergence from anesthesia.

Sleep disturbance has been reported to be significantly and reciprocally associated with pain. Current evidence suggests that insomnia predisposes individuals to chronic pain or the worsening of painful conditions.[14,15] Not limited to chronic conditions, sleep problems can increase the risk of reduced pain tolerance on a daily basis.[16] Depression also has a mutual link with pain, and research has shown that depression is associated with increased perception of pain severity in acute conditions.[17] Therefore, it was reasonable to speculate that the participants with higher ISI scores or higher BDI-II scores were more likely to have a higher ranking in the NRS assessment. Our results indicated that patients with inadequate sleep rhythms experienced more severe pain; however, a higher depression score seemed to be unrelated to ratings on the initial pain scale upon arrival at the PACU. The lack of findings regarding the lack of association between a higher depression score and a higher score on the initial pain scale can be attributed to the unbalanced distribution of depression severity in our patient group; in this study, few patients were categorized as having severe depression.

HRV is a well-established method for evaluating the ANS. SD1 is a nonlinear measure of the Poincaré plot, and it reflects rapid and HF changes in HRV, whereas SD2 depicts long-term changes in HRV. Those 2 indices have been proposed as markers of acute pain response in newborns.[18] In our study, the change in SD1 was a strong predictor of pain scores, both in the univariate analysis and multivariate regression. Considering that the depth of anesthesia decreases toward the end of surgeries, the rebound in SD1 may be an indicator of the level of surgical stress across surgeries. As for Alpha1 and Alpha2, the fractal analysis of heartbeat control reveals the scaling properties of this nonlinear regulatory system. In related studies, the decrease of these indices has been associated with cardiac risk, aging, and sudden death.[19] In our analysis, the change in Alpha1 was associated with the early pain score in the PACU; however, it was not included in the final multiple regression model. The relationship between Alpha1 and pain requires further investigation.

The surgery type, volume of blood loss, and age of the patient were regarded as corrected variables in our model. According to our formula, the patients who received laparoscopic surgery would have a lower pain score compared with those who received open surgery, and this is compatible with the results of many other studies.[20] The effect of age on pain sensitivity has also been revealed in prior research.[21] Moreover, surgery type and age were included in another pain prediction model developed by Kalkman, et al.[3] The amount of intraoperative hemorrhage was not found to be directly associated with the first NRS in the PACU. It was, however, significantly correlated with the change in VLF power, another relevant predictor in our formula.

Several studies have been conducted to predict acute postoperative pain severity. A study by Kalkman used score on the Amsterdam Preoperative Anxiety and Information Scale, age, sex, level of preoperative pain, incision size, and type of surgery to predict early postoperative severe pain.[3] Rehberg, et al. developed a prediction model for moderate-to-severe postoperative pain by using scores on the pain sensitivity questionnaire and for the Spielberger's State-Trait Anxiety Inventory, age, axillary dissection, and type of surgery.[4] Most of these predictive models use psychological factors, measurable pain threshold before surgery, and demographic data to predict a binary outcome (moderate-to-severe pain or no pain). However, without indicators of the dynamic changes in the body during the intraoperative period, how the body responds to surgical stress cannot be determined. After all, surgery itself is definitely not a "standard stimulus," and everyone who undergoes the same procedure cannot be guaranteed to experience the same amount of stress.

This study had some limitations. First, this pilot study was observational in nature. The dosage of opioids, depth of anesthesia (entropy), and SPI (an indicator of nociceptive/antinociceptive balance under general anesthesia) were not controlled, which may have led to bias while building the prediction model. Second, the distributions of sleep quality and depression severity tended toward the milder side, which may limit the scope of the model's application.

Conclusion

Pain is multifactorial, and both physiological and psychological factors attribute to pain perception. We used a combination of sleep quality, demographic factors, and changes in measures of intraoperative HRV to develop a prediction model of early pain score (NRS) on arrival at the PACU. Further research is required to validate the results of this pilot study, and further evaluation of different patient groups and surgery types is warranted for external validation.

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Table 1 Demographic Characteristics of 80 female participants

Measurement	Mean ± SD
Age (years)	42.9 ± 10.5
Body Mass Index (kg/m^2)	23.0 ± 3.5
Blood loss (ml)	139.4 ± 177.3
ISI score	7.6 ± 5.9
BDI-II score	7.4 ± 6.5
OME (mg)	49.3 ± 12.4
	Number (Percentage)
ASA Classification	
I	12 (15.0)
II	60 (75.0)
III	8 (10.0)
Surgical Type	
Open	28 (35.0)
Laparoscope	52 (65.0)

ISI : Insomnia Severity Index; BDI-II: Beck Depression Inventory II; ASA : American Society of Anesthesiologists; OME: Oral Morphine Equivalent; SD : Standard Deviation

Table 2 Intraoperative HRV indices and the ratio of changes in HRV indices

Variables	Middle Section	End Section	Ratio of Change(%)
	Mean ± SD	Mean ± SD	Mean ± SD
VLF power	1.9 ± 0.4	5.6 ± 1.5	197.6 ± 87.6
LF power	4.1 ± 1.3	3.6 ± 1.2	-7.9 ± 28.9
HF power	3.7 ± 1.2	3.7 ± 1.4	3.7 ± 32.2
LF / HF ratio	2.0 ± 1.6	1.4 ± 1.8	6.9 ± 129.7
SD1	12.3 ± 8.4	12.0 ± 7.5	7.8 ± 48.8
SD2	67.5 ± 40.4	70.2 ± 64.9	22.0 ± 102.6
Alpha 1	1.1 ± 0.3	1.0 ± 0.3	-11.8 ± 22.0
Alpha 2	1.2 ± 0.2	1.2 ± 0.3	3.3 ± 25.3
SampEn	1.0 ± 0.5	1.0 ± 0.6	32.1 ± 121.0

HRV: Heart Rate Variability; VLF: Very Low Frequency; LF: Low Frequency; HF: High Frequency; SD1: Poincaré Plot Standard Deviation Perpendicular the Line of Identity; SD2: Poincaré Plot Standard Deviation along the Line of Identity; Alpha 1: Log-log Slope of Detrended Fluctuation Analysis in the Low-scale Region; Alpha 2: Log-log Slope of Detrended Fluctuation Analysis in the High-scale Region; SampEn: Multi-scale Sample Entropy

Table 3 Linear Correlation Coefficient between NRS and demographic variables/ ratio of changes of HRV for the prediction of early pain scores

	Single risk factor			Multivariate		
	Beta	SE	P-value	Beta	SE	P-value
Demographics						
BMI	-0.120	0.068	0.084			
ISI Score	0.099	0.040	0.017*	0.086	0.040	0.034*
BDI-II Score	0.058	0.037	0.126			
ASA	0.778	0.481	0.110			
Blood loss	0.001	0.001	0.384	0.002	0.001	0.104
Age	-0.022	0.023	0.340	-0.044	0.023	0.054
Laparoscope	-0.451	0.508	0.378	-0.784	0.525	0.140
Ratio of changes of HRV #						
deltaVLF	0.004	0.002	0.067	0.003	0.003	0.028*
deltaLF	-0.005	0.008	0.547			
deltaHF	0.007	0.007	0.326			
deltaLF/HF	-0.003	0.002	0.081			
deltaSD1	0.014	0.005	0.004*	0.014	0.005	0.006*
deltaSD2	0.000	0.002	0.945	-0.006	0.003	0.033*
deltaAlpha1	-0.026	0.011	0.017*			
deltaAlpha2	-0.003	0.009	0.755			
deltaSampEn	-0.002	0.002	0.303	-0.003	0.002	0.147

NRS : Numeric Rating Scale ; HRV : Heart Rate Variability ; BMI : Body Mass Index ; ISI : Insomnia Severity Index ; BDI-II : Beck Depression Inventory II; ASA : American Society of Anesthesiologists ; deltaVLF: Ratio of Change of Very Low Frequency Power; deltaLF: Ratio of Change of Low Frequency Power; deltaHF: Ratio of Change of High Frequency Power; deltaLF/HF : Ratio of Change of Low-frequency / High-frequency Ratio ; deltaSD1: Ratio of Change of Poincaré Plot Standard Deviation Perpendicular the Line of Identity; deltaSD2: Ratio of Change of Poincaré Plot Standard Deviation along the Line of Identity; deltaAlpha 1: Ratio of Change of Log-log Slope of Detrended Fluctuation Analysis in the Low-scale Region; deltaAlpha 2: Ratio of Change of Log-log Slope of Detrended Fluctuation Analysis in the High-scale Region; deltaSampEn: Ratio of Change of Multi-scale Sample Entropy

Ratio of Changes of HRV between the mid-surgery and the end-stage of surgery was calculated as follow for every individual:(HRV(end-stage)-HRV(mid-surgery))/HRV(mid-surgery)*100

透過心率變異度變化和失眠嚴重度預測恢復室疼痛指數：前導性研究

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背景：

術後疼痛不僅造成病人的不適，所帶來的壓力亦會產生不利影響。由於疼痛受多重因子調節，心理與生理層面皆須納入考量。先前的研究曾利用憂鬱或焦慮的問卷來預測術後的疼痛，但術中的動態生理指標的納入，才能反映不同個體面對手術壓力的反應差異。我們的研究目標是融合術前的身心理評估與術中的自主神經系統活性變化，來建立一個預測術後疼痛程度的模型。

方法：

此研究收錄80位年滿20歲，接受婦科手術的女性。我們於術前完成失眠嚴重度量表和貝克憂鬱量表的評估，作為個案睡眠品質和憂鬱程度的指標。手術當中全程收錄生理監測資料並以Matlab來計算心率變異度。之後以病人基本資料、問卷結果以及心率變異度變化來進行多因子線性迴歸。

結果：

我們所建立的術後疼痛(NRS)的模型如下：

術後疼痛分數 = −0.784 × 手術種類 + 0.086 × 睡眠問卷總分 − 0.044 × 年紀 + 0.002 ×出血量 + 0.006 × VLF頻域變化 + 0.014 × SD1變化 − 0.006 × SD2變化 − 0.003 × Entropy變化。

結論：

本前瞻研究建立了有意義的疼痛預測模型。後續的主研究可證實這個模型的可信度。

關鍵字：術後疼痛；睡眠；心率變異度；全身麻醉

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