



US 20190125275A1

(19) **United States**

(12) **Patent Application Publication**
LI et al.

(10) **Pub. No.: US 2019/0125275 A1**
(43) **Pub. Date: May 2, 2019**

(54) **METHOD FOR ANALYZING HEART RATE VARIABILITY, APPARATUS AND USE THEREOF**

Publication Classification

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(51) **Int. Cl.**

A61B 5/00 (2006.01)

A61B 5/024 (2006.01)

A61B 5/0402 (2006.01)

(52) **U.S. Cl.**

CPC *A61B 5/7278* (2013.01); *A61B 5/0402* (2013.01); *A61B 5/02438* (2013.01); *A61B 5/02405* (2013.01)

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(57)

ABSTRACT

A method for analyzing heart rate variability, and an apparatus and use thereof, the method for analyzing heart rate variability including collecting ECG data in vitro; digitizing and denoising the ECG data; forming the processed ECG data into a sinus NN interval sequence; selecting sinus NN interval data of 4 hours in an awake state; performing MSE calculation on the sinus NN interval sequence of 4 hours in an awake state; and extracting parameters representing the complexity of a heart rate by using MSE curves. The present invention may provide accurate and efficient screening for drug-refractory epilepsy patients who are suitable for vagus nerve stimulation surgery, thus avoiding unnecessary expenses, and avoiding missing the most opportune moment for treatment. At the same time, patients suitable for VNS surgery are selected by using MSE complexity feature parameters of ECG, thus improving the overall efficacy of VNS therapy.

(21) Appl. No.: **16/086,436**

(22) PCT Filed: **Aug. 4, 2017**

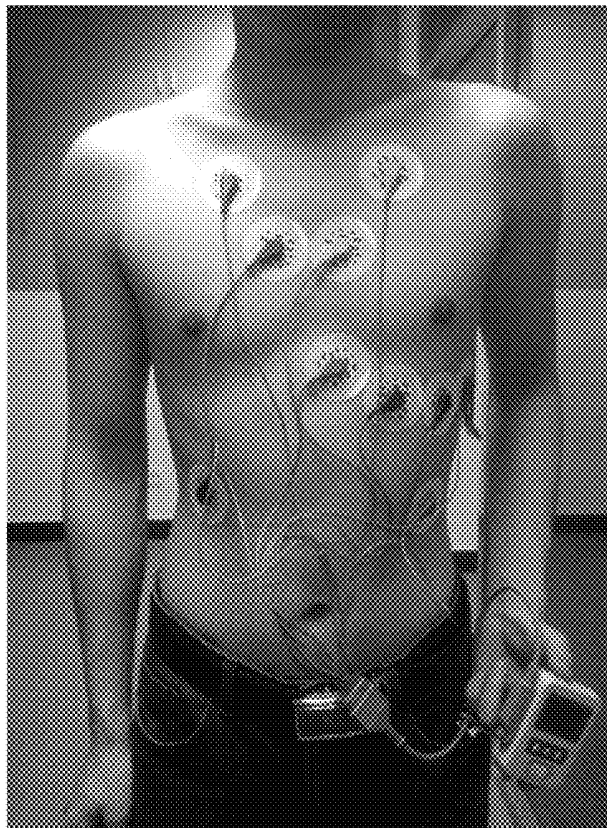
(86) PCT No.: **PCT/CN2017/095952**

§ 371 (c)(1),

(2) Date: **Sep. 19, 2018**

(30) **Foreign Application Priority Data**

Aug. 23, 2016 (CN) 201610709242.7



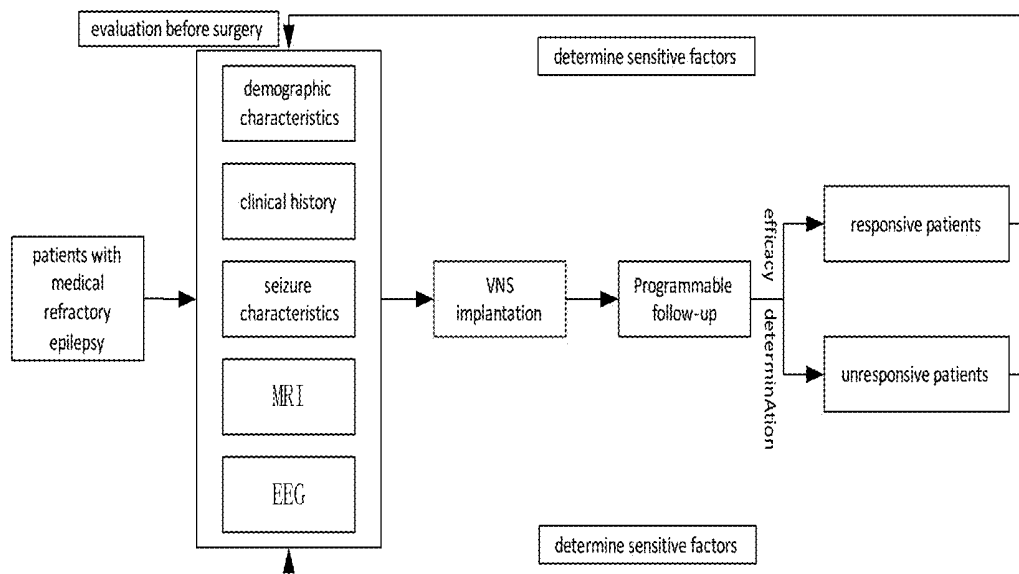


Fig. 1

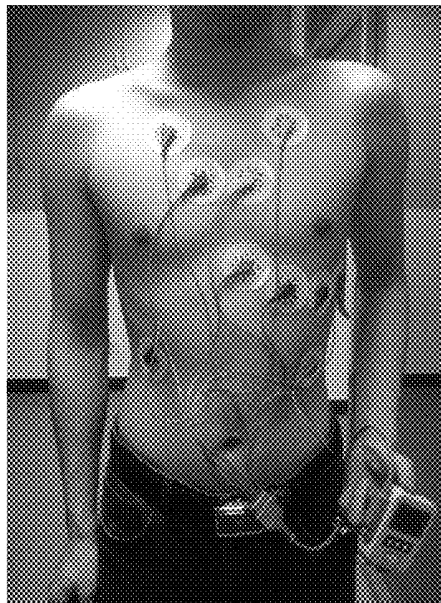


Fig. 2

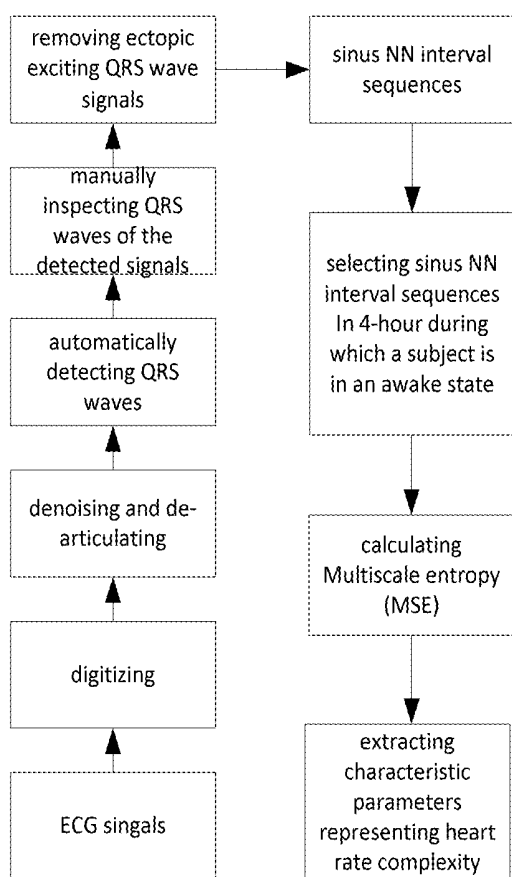


Fig. 3

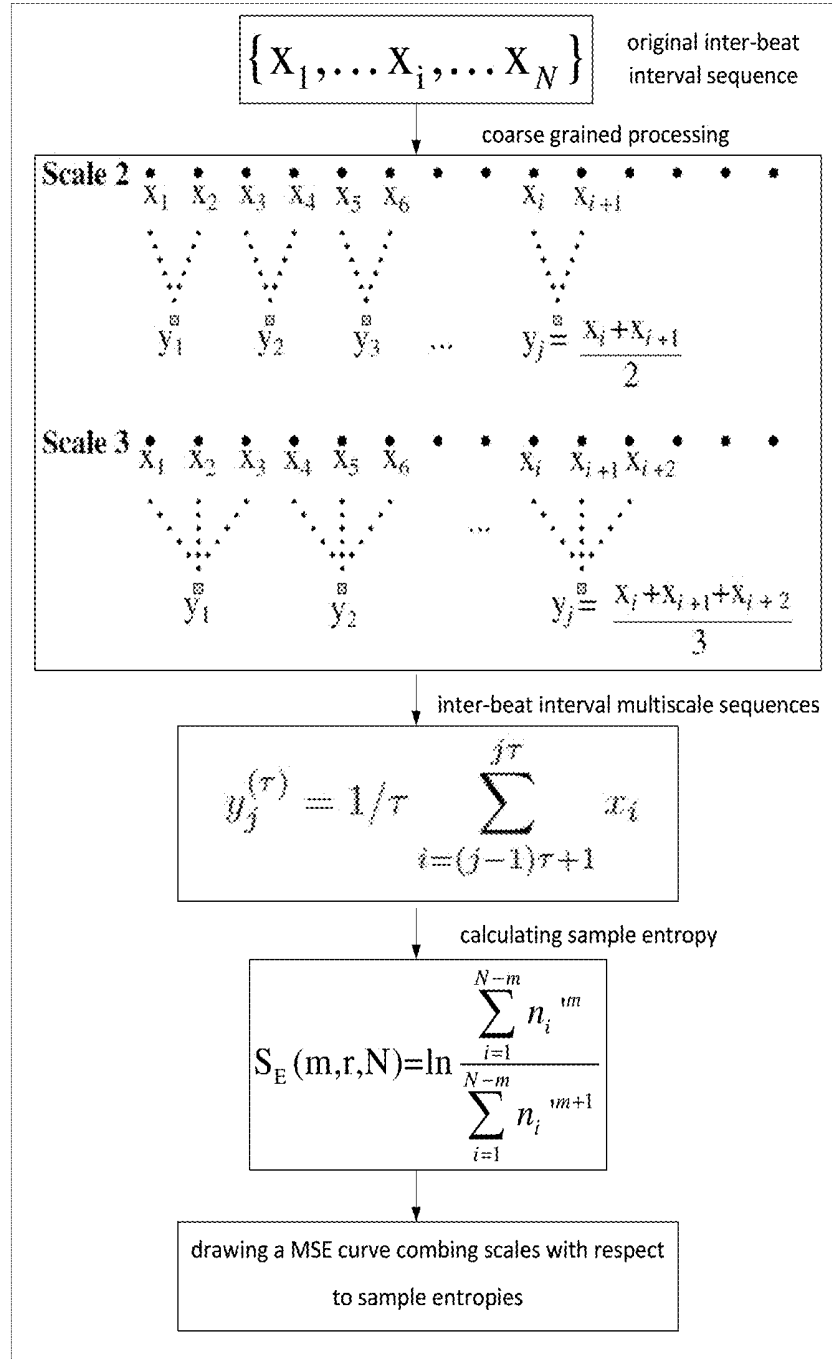


Fig. 4

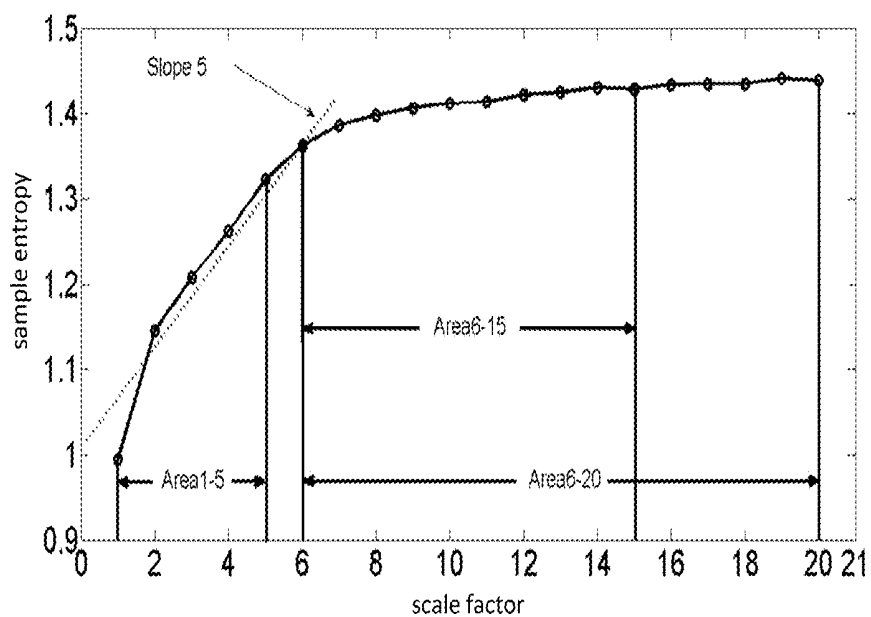


Fig. 5

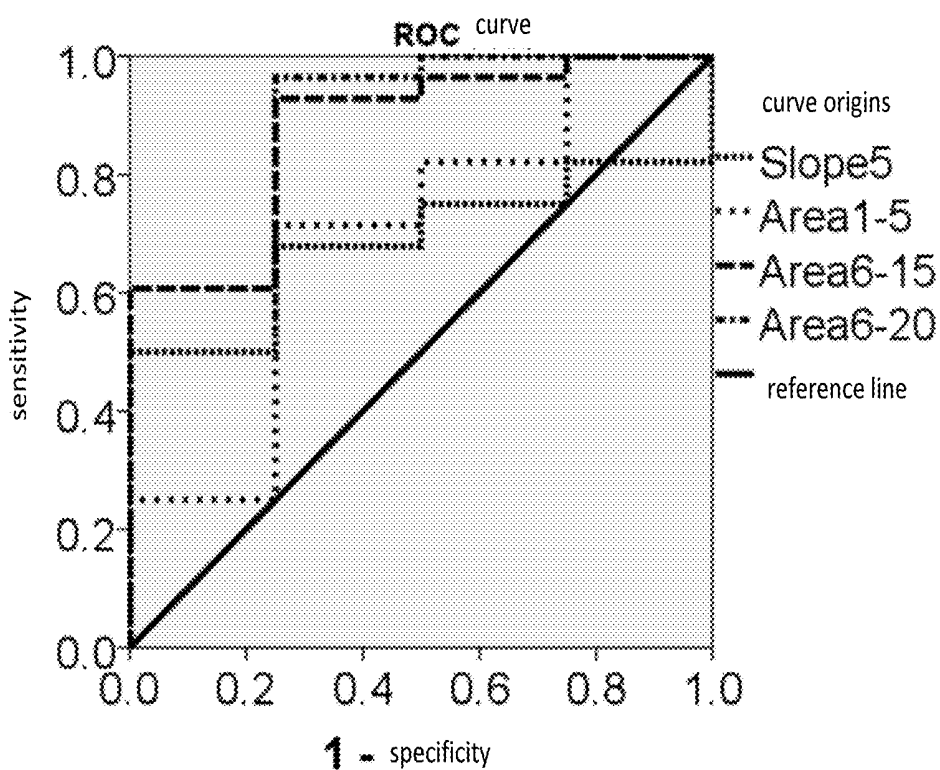


Fig. 6

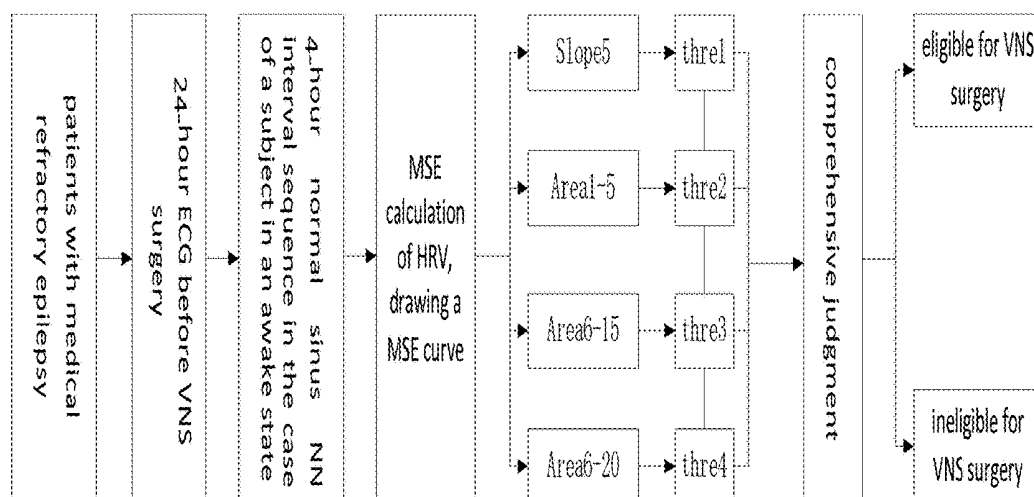


Fig. 7

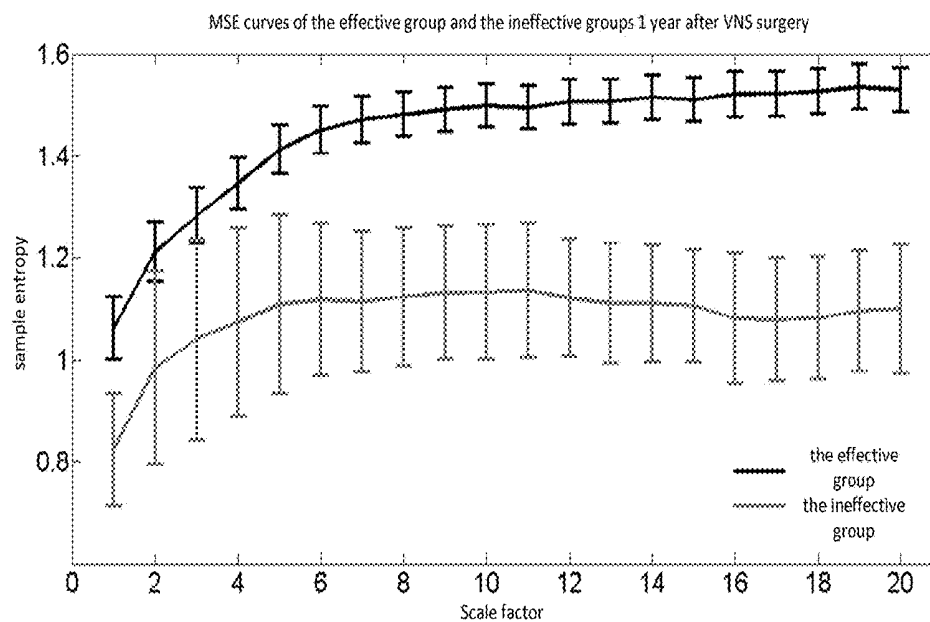


Fig. 8

METHOD FOR ANALYZING HEART RATE VARIABILITY, APPARATUS AND USE THEREOF

TECHNICAL FIELD

[0001] The invention relates to a method and an apparatus for analyzing heart rate variability and use thereof, in particular to a method for analyzing heart rate variability for patients with Vagus Nerve Stimulation (VNS) indications.

BACKGROUND

[0002] Epilepsy as a disease affects the lives of patients. For most patients, epileptic seizures could be controlled by one or more drugs. However, some patients are still not sensitive to drug treatment. These patients are called patients with drug refractory epilepsy. As an adjuvant therapy, Vagus Nerve Stimulation (VNS) can effectively control epileptic seizures in patients with drug refractory epilepsy. However, the individual differences in efficacy thereof are very large and uncertainties are pretty high. Statistical analysis shown that, epileptic seizures were completely relieved in only 5% to 9% of patients with drug refractory epilepsy who were treated with VNS surgery, about 10% of patients were completely ineffective, and the rest shown seizure frequency reduction with varying degrees. Overall, 50% reduction in seizure frequencies could be achieved in 50%-60% of patients with drug refractory epilepsy who were treated with VNS surgery. In view of uncertainties and large individual differences in the efficacy of VNS for treating drug refractory epilepsy, researchers have been trying to screen patients suitable for VNS surgery through preoperative evaluation.

[0003] At present, there has been no definitive screening method for VNS surgical indications clinically applied. Meanwhile, studies on VNS efficacy factors have been performed based on EEG (Electroencephalography, EEG), Magnetic Resonance Imaging data (MRI), patient demographic characteristics (gender, age, etc.), clinical history (disease duration), seizure characteristics (including seizure type, seizure frequency, lesion location, etc.), and the conclusions thereof are not consistent, sometimes even contradictory.

[0004] The solution in the prior art is shown in FIG. 1. Firstly, systematic and comprehensive preoperative evaluations are performed for patients with drug refractory epilepsy (including demographic characteristics, medical history, seizure characteristics, MRI, EEG, etc.) before VNS surgery. Then, VNS implantation surgery is operated. After about 2 weeks, the devices are turned on. According to each patient's specific response to VNS acute stimulation, stimulation parameters are gradually adjusted in accordance with the VNS product performance and technical features, and seizure reduction of all patients are regularly analyzed. After the corresponding follow-up period (usually 1 year), the patients are classified according to reduction of seizures (i.e., efficacy). Finally, the preoperative evaluation data of patients with different efficacies are statistically analyzed, and parameters which are statistically different between patient groups are selected as sensitive factors for screening VNS patients or predicting efficacy.

[0005] The existing EEG and MRI methods have disadvantages of high cost, complicated operations, and high requirements on professional knowledge. Overall, studies based on these methods have not been clinically applied.

The main reason lies in inconsistent or even contradictory conclusions for an identical problem. The method based on 24-hour dynamic ECG signals of the present invention only requires a subject to wear a portable dynamic ECG recording box, and the ECG data is collected without limiting the subject's activities, which is simple. 24-hour dynamic ECG is charged ¥240 yuan in ordinary hospital outpatients, which is relatively low, compared with long-term video electroencephalography and nuclear magnetic resonance imaging which are charged about ¥1,000 yuan. Most of all, compared with EEG and MRI, the 24-hour dynamic electrocardiogram acquisition is not limited by activities, thus is relatively simple and has good consistency.

[0006] Heart Rate Variability (HRV) refers to changes of adjacent cardiac intervals with time in Electrocardiography (ECG) signals. It originates from the autonomic nervous system's modulation of the sinus node's self-discipline, which leads to tens of milliseconds or even greater differences or fluctuations between inter-beat intervals. HRV contains a large amount of information about neurohumoral regulation, which is currently a quantitative, non-invasive and repeatable indicator for assessing activities and regulatory functions of the autonomic nervous system and the cardiovascular system. HRV analysis can indirectly reflect the interaction between sympathetic and parasympathetic nerves.

[0007] To date, there have been no studies and technical solutions for screening VNS patients using electrocardiographic signal HRV analysis technology. Epileptic diseases have a close relationship with cardiac autonomic dysfunction. With the onset and progression of epilepsy, a patient's cardiac autonomic nervous system balance is broken, which is generally manifested as increased sympathetic nerve activities and decreased parasympathetic nerve activities. Based on this conclusion, low-cost, portable and wearable signal acquisition equipment is adapted in the present invention, thus 24-hour ECG signals of an epileptic before surgery could be acquired. A multiscale entropy (MSE) of ECG could be calculated through a programmed HRV analysis, wherein characteristic parameters representing heart rate complexity are extracted on the basis of a MSE curve, thus a drug refractory epileptic suitable for VNS surgery could be accurately and efficiently screened.

SUMMARY OF THE INVENTION

[0008] The applicant found that epileptic diseases have a close relationship with cardiac autonomic dysfunction. With the onset and progression of epilepsy, a patient's cardiac autonomic nervous system balance is broken, which is generally manifested as increased sympathetic nerve activities and decreased vagus nerve activities. Moreover, it is also found that Heart Rate Variability (HRV) is a very important indicator. HRV refers to changes of adjacent cardiac intervals with time in Electrocardiography (ECG) signals. It originates from the autonomic nervous system's modulation of the sinus node's self-discipline, which leads to tens of milliseconds or even greater differences or fluctuations between inter-beat intervals. HRV contains a large amount of information about neurohumoral regulation, which is currently a quantitative, non-invasive and repeatable indicator for assessing activities and regulatory functions of the autonomic nervous system and the cardio-

vascular system. HRV analysis can indirectly reflect the interaction between sympathetic and parasympathetic nerves.

[0009] Based on this finding, low-cost, portable and wearable signal acquisition equipment is adapted in the present invention, thus 24-hour ECG signals of an epileptic before surgery could be acquired. A multiscale entropy (MSE) of ECG could be calculated through a programmed HRV analysis, wherein characteristic parameters representing heart rate complexity are extracted on the basis of an MSE curve, and a drug refractory epileptic suitable for VNS surgery could be accurately and efficiently screened, thus saving unnecessary expenditures and avoiding delaying the optimal timing for treatment. At the same time, a patient suitable for VNS surgery is clearly selected through characteristic parameters of ECG's MSE heart rate complexity, which could generally improve the efficacy of VNS therapy.

[0010] The present invention provides a method for analyzing heart rate variability, comprising the following steps:

[0011] 1) collecting ECG data in vitro;

[0012] 2) digitizing and denoising the ECG data;

[0013] 3) forming the processed ECG data into a sinus NN interval data;

[0014] 4) selecting sinus NN interval data of 4 hours in an awake stake;

[0015] 5) performing MSE calculation on the selected 4-hour sinus NN interval sequence in an awake stake;

[0016] 6) extracting parameters representing heart rate complexity by means of a MSE curve.

[0017] The specific method of steps 5)-6) is as follows:

[0018] i. performing coarse grained processing on the NN interval sequence $\{X_1, \dots, X_j, \dots, X_N\}$ in step 4), to obtain reconstructed sequences

$$y_j^\tau = 1/\tau \sum_{i=(j-1)\tau+1}^{j\tau} x_i, 1 \leq j \leq N/\tau$$

with different scales, τ as a scale factor;

$$y_j^\tau = 1/\tau \sum_{i=(j-1)\tau+1}^{j\tau} x_i.$$

[0019] ii. calculating a sample entropy, for each scale's sequence

[0020] iii. drawing a curve of the sample entropy with respect to the different scale factors, and obtaining characteristic parameters indicative of the heart rate complexity.

[0021] The characteristic parameters indicative of the heart rate complexity are acquired as follows:

[0022] For the curve in step iii, Slope $n1$ is obtained by linearly fitting points with scales of 1- $n1$; scales $n2$ - $n3$ are segmented, and each area encompassed by each segment of the scale curve and the horizontal axis is calculated to obtain parameters Area1.

[0023] Further, $n1 < n2 < n3$, $n3 \leq 40$; the number of parameters Area1 is between 1 and 7.

[0024] Further, $n1=5$, the slope parameter Slope is Slope 5, $n2=6$, $n3=20$. And parameters Area1 are Area1 1-5, Area1 6-15, and Area1 6-20.

[0025] Further, threshold judgment is performed for the parameters Slope and Area1. Further, the threshold of Slope 5 is 0.071 ± 0.002 , the threshold of Area1 1-5 is 4.32 ± 0.04 , the threshold of Area1 6-15 is 10.57 ± 0.2 and the threshold of Area1 6-20 is 15.85 ± 0.3 .

[0026] The present invention further provides a device for analyzing heart rate variability, wherein comprising a heart rate complexity calculation module, which calculates by means of the above-mentioned method.

[0027] The device further comprises one or more of a data acquisition module, a digitization processing module, a denoising module, and a judgment module.

[0028] The present invention further provides a wearable electrocardiographic monitoring apparatus, wherein comprising the above-mentioned device for analyzing heart rate variability.

BRIEF DESCRIPTION OF DRAWINGS:

[0029] FIG. 1 is a flow chart of the prior art for screening patients with VNS indications.

[0030] FIG. 2 is a diagram of 12-lead ECG acquisition.

[0031] FIG. 3 is a flow chart of ECG signal processing.

[0032] FIG. 4 is a flow chart of MSE analysis method.

[0033] FIG. 5 is a diagram of extracting indicators of MSE Complexity.

[0034] FIG. 6 is a threshold selection ROC curve

[0035] FIG. 7 is a flow chart for judgment.

[0036] FIG. 8 shows MSE curves of the effective group and the ineffective group

EMBODIMENTS

EXAMPLE 1

[0037] As shown in FIG. 2, a standard 12-lead ECG acquisition for 24 hours before surgery requires: sampling frequency of the ECG acquisition device is greater than or equal to 500 Hz; during ECG recording, activities such as strenuous exercises and medications that could affect cardiac functions should be avoided; the recording period is 24 hours. Recording environment and conditions of subjects should be basically similar. The data used for HRV analysis should be ensured to be normal sinus NN intervals. During HRV analysis, normal sinus NN intervals of 4 hours are selected for MSE analysis from the 24-hour long-term ECG records during which the subject is in an awake state. The specific processing flow of ECG signals is shown in FIG. 3.

[0038] 1) collecting and digitizing ECG signals;

[0039] 2) denoising and de-articulating digital signals;

[0040] 3) automatically detecting QRS waves thereof;

[0041] 4) manually inspecting QRS waves of the detected signals;

[0042] 5) removing ectopic exciting QRS wave signals;

[0043] 6) forming a sinus NN interval sequence;

[0044] 7) selecting 4-hour sinus NN interval sequences in the case of a subject in an awake state;

[0045] 8) calculating MSE based on the 4-hour sinus NN interval sequences;

[0046] 9) drawing a MSE curving, wherein the scale factor is as the horizontal and the entropy value corresponding to the scale factor is as the ordinate;

[0047] 10) extracting characteristic parameters representing heart rate complexity, according to the MSE curve.

[0048] The MSE calculation method in the HRV analysis adopted in the present invention extracts characteristic parameters of Slope5, Area1-5, Area6-15, and Area6-20 to represent the heart rate complexity.

[0049] The MSE method has the following steps(see FIG. 4):

[0050] (1) performing coarse grained processing on the 4-hour normal sinus NN interval sequence $\{X_1, \dots, X_i, \dots, X_N\}$ to obtain reconstructed sequences

$$y_j^\tau = 1/\tau \sum_{i=(j-1)\tau+1}^{j\tau} x_i, 1 \leq j \leq N/\tau$$

with different scales, τ as a scale factor;

[0051] (2) calculating a sample entropy, for each scale's sequence

$$y_j^\tau = 1/\tau \sum_{i=(j-1)\tau+1}^{j\tau} x_i;$$

[0052] (3) drawing a curve of the sample entropies with respect to the different scale factors, shown in FIG. 5; linearly fitting points of scales 1-5 to obtain slope 5; then calculating Area1-5, Area 6-15, and Area 6-20 encompassed by scale 1-5, scale 6-15, scale 6-20 curve and the horizontal axis, wherein, the above four parameters are characteristic parameters representing the heart rate complexity.

[0053] For patients with drug-resistant epilepsy, 24-hour electrocardiogram acquisition was performed before surgery. The 24-hour electrocardiogram data collected was processed, according to the above-mentioned method, to obtain normal sinus NN interval sequences in 4 hours during which a subject is in an awake state. The MSE analysis was performed on the above-mentioned 4-hour NN interval sequences according to the above-mentioned method. Characteristic parameters such as Slope5, Area1-5, Area6-15, Area6-20, etc., which represent heart rate complexity, were extracted. Then comprehensive judgment selection was performed through corresponding threshold judgment (as shown in FIG. 6). The VNS surgical patients in the training set were classified according to follow-up efficacy after a certain period of time (effective group and ineffective group). The above-mentioned heart rate complexity indicators of the effective group and the ineffective group were statistically analyzed, and Receiver Operating Characteristic (ROC) curves were drawn for Slope5, Area 1-5, Area 6-15, and Area 6-20. The threshold of each indicator (Youden index) is a point in each curve which has the shortest distance to the top left corner (that is, the coordinates (1, 1)). Finally, patients who are eligible for VNS surgery and patients who are not eligible for VNS surgery are distinguished based on the corresponding threshold (as shown in FIG. 7). When the four characteristic parameters Slope5, Area1-5, Area6-15 and Area6-20, representing heart rate complexity, are used to distinguish patients eligible for VNS surgery from patients ineligible for VNS surgery respectively, their corresponding threshold value selection and their corresponding screening accuracy are as follows:

[0054] When Slope5=0.071, patients with a value higher than said value were considered eligible for VNS surgery. The screening accuracy was 67.9%.

[0055] When Area 1-5=4.32, patients with a value higher than said value were considered eligible for VNS surgery. The screening accuracy was 71.4%.

[0056] When Area6-15=10.57, patients with a value higher than said value were considered eligible for VNS surgery. The screening accuracy was 92.9%.

[0057] When Area6-20=15.85, patients with a value higher than said value were considered eligible for VNS surgery. The screening accuracy was 96.4%.

EXAMPLE 2

[0058] The complexity indicator Area 6-n, when the scale factor to n, could also be used for screening VNS patients as described above.

[0059] In the present invention, for patients with drug refractory epilepsy, preoperative electrocardiogram acquisition 24 hours before surgery and the MSE analysis of HRV were performed. In this way, patients with drug refractory epilepsy could be screened before surgery, thereby guiding patients who are not eligible for VNS therapy not to receive the surgery and choose other therapies, which could save unnecessary expenditures and avoiding delaying the optimal timing for treatment. Meanwhile, patients with VNS surgical indications were clearly selected by extracting characteristic parameters representing heart rate complexity through ECG's MSE curve, which could improve overall VNS therapeutic efficacy.

EXAMPLE 3

[0060] In accordance with the above screening method, 32 patients with medical refractory epilepsy, who had undergone VNS surgery at Beijing Tiantan Hospital from Aug. 13, 2014 to Dec. 31, 2014, were selected for test. Before VNS surgery, these 32 patients with medical refractory epilepsy were comprehensively evaluated (including demographic characteristics, clinical history, history of antiepileptic medication, 24-hours video-EEG, MRI, and 24-hour dynamic electrocardiogram etc.).

[0061] According to the above ECG signal processing method, the MSE analysis was performed, based on 24-hour dynamic electrocardiographic data. The corresponding characteristic parameters Slope5, Area1-5, Area6-15, and Area6-20 were extracted based on each patient's MSE curve. At the end of 1-year follow-up, among 32 patients with drug refractory epilepsy who had undergone VNS treatment, 28 patients' seizure frequencies had been reduced to various degrees (seizures had been completely controlled in 6 patients), who were considered as the effective group, and the remaining 4 patients' seizure frequencies after VNS surgery hadn't changed compared with those before VNS surgery, who were considered as the ineffective group. The MSE curves of the effective group and the ineffective group differ greatly, which suggested that the MSE method could be adapted to screen patients with VNS indications. Furthermore, each patient's characteristic parameters Slope5, Area1-5, Area6-15, and Area6-20 before surgery could be adapted to predict efficacy. The results shown that, among the above four parameters, Area6-20 was the most accurate parameter: when its threshold was set to 15.85, only one

patient's Area6-20 was 15.09 among the 28 effective patients, as shown in Table 1, and the rest patients' Area6-20 were greater than 15.85. The screening accuracy-rate exceeded 96%, which confirmed that the MSE method of the above HRV analysis could accurately and effectively screen patients with VNS indications.

TABLE 1

		Slope5	Area1-5	Area6-15	Area6-20
Effective group	patient1	0.141	5.651	14.074	21.871
	patient2	0.098	2.925	9.587	15.093
	patient3	0.012	7.596	16.155	24.702
	patient4	0.069	5.341	14.477	23.084
	patient5	0.081	4.531	10.915	17.081
	patient6	0.045	6.766	16.296	25.248
	patient7	0.092	4.150	11.503	18.059
	patient8	0.101	3.685	11.804	18.769
	patient9	0.091	6.962	17.257	27.045
	patient10	0.177	3.983	14.009	22.139
	patient11	0.169	5.571	14.666	23.090
	patient12	0.116	5.529	15.255	23.922
	patient13	0.112	4.124	11.135	17.381
	patient14	0.144	4.189	12.097	19.044
	patient15	0.099	4.953	12.932	20.050
	patient16	0.070	5.904	13.657	21.414
	patient17	0.172	4.599	11.162	16.557
	patient18	-0.024	5.839	13.736	21.497
	patient19	0.098	6.115	15.443	23.849
	patient20	-0.066	5.197	11.964	19.043
	patient21	0.072	3.875	10.273	16.025
	patient22	0.087	5.132	14.689	23.120
	patient23	0.101	6.058	15.677	24.371
	patient24	0.053	4.871	14.701	23.563
	patient25	0.128	5.580	15.252	23.891
	patient26	-0.041	5.299	13.201	20.832
	patient27	0.107	4.417	13.854	21.959
	patient28	0.030	3.322	10.847	17.468
Ineffective group	patient29	0.070	4.226	9.647	14.219
	patient30	0.093	5.740	12.949	20.118
	patient31	0.033	2.257	7.488	12.139
	patient32	0.068	4.043	10.298	15.680

[0062] The above description is only preferred embodiments of the present invention. It should be noted that, those skilled in the art can make improvements and modifications, without departing from the principle of the present invention. These improvements and modifications should be regarded in the scope of the present invention. In addition, although specific terms are used in this description, these terms are merely for convenience of illustration and do not constitute any limitation to the present invention.

1-10. (canceled)

11. A method for analyzing heart rate variability, comprising the following steps:

- 1) collecting ECG data in vitro;
 - 2) digitizing and denoising the ECG data;
 - 3) forming the processed ECG data into a sinus NN interval data;
 - 4) selecting sinus NN interval data of 4 hours in an awake stake;
 - 5) performing MSE calculation on the selected 4-hour sinus NN interval sequence in an awake stake;
- extracting parameters representing heart rate complexity by means of an MSE curve.

12. The method for analyzing heart rate variability of claim 11, wherein the specific method of step 5)-6) is as follows:

- i. performing coarse grained processing on the NN interval sequence $\{X_1, \dots, X_i, \dots, X_N\}$ acquired in step 4), to obtain reconstructed sequences with different scales

$$y_j^\tau = 1/\tau \sum_{i=(j-1)\tau+1}^{j\tau} x_i, 1 \leq j \leq N/\tau,$$

τ as a scale factor;

- ii. calculating a sample entropy for each scale's sequence

$$y_j^\tau = 1/\tau \sum_{i=(j-1)\tau+1}^{j\tau} x_i.$$

- iii. drawing a curve of the sample entropy with respect to the different scale factors, and obtaining characteristic parameters indicative of the heart rate complexity.

13. The method for analyzing heart rate variability of claim 12, wherein the method of acquiring characteristic parameters indicative of the heart rate complexity further comprises:

for the curve in step iii, Slope n1 is obtained by linearly fitting points with scales of 1-n1; scales n2-n3 are segmented, and each area encompassed by each segment of the scale curve and the horizontal axis is calculated to obtain the parameter Area1.

14. The method for analyzing heart rate variability of claim 13, wherein $n1 < n2 < n3$, $n3 < 40$; and the number of Area1 parameters is between 1 and 7.

15. The method for analyzing heart rate variability of claim 13, wherein $n1=5$, the slope parameter Slope is Slope5, $n2=6$, $n3=20$, and parameters Area1 are Area1 1-5, Area16-15, and Area16-20.

16. The method for analyzing heart rate variability of claim 13, wherein threshold judgment is performed for the parameters Slope and Area1.

17. The method for analyzing heart rate variability of claim 16, wherein the threshold of Slope 5 is 0.071 ± 0.002 , the threshold of Area1 1-5 is 4.32 ± 0.04 , the threshold of Area1 6-15 is 10.57 ± 0.2 and the threshold of Area1 6-20 is 15.85 ± 0.3 .

18. A device for analyzing heart rate variability, comprising:

a heart rate complexity calculation module, which calculates according to the method of claim 11.

19. The device for analyzing heart rate variability of claim 18, wherein further comprising one or more of a data acquisition module, a digitization processing module, a denoising module, and a judgment module.

20. A wearable electrocardiographic monitoring apparatus, wherein comprising the device for analyzing heart rate variability of claim 18.

* * * * *

专利名称(译)	用于分析心率变异性的方法，装置和用途		
公开(公告)号	US20190125275A1	公开(公告)日	2019-05-02
申请号	US16/086436	申请日	2017-08-04
[标]申请(专利权)人(译)	北京品驰医疗设备有限公司 清华大学		
申请(专利权)人(译)	清华大学		
当前申请(专利权)人(译)	清华大学		
[标]发明人	LI LUMING LIU HONGYUN YANG ZHAO		
发明人	LI, LUMING LIU, HONGYUN YANG, ZHAO		
IPC分类号	A61B5/00 A61B5/024 A61B5/0402		
CPC分类号	A61B5/7278 A61B5/02405 A61B5/02438 A61B5/0402 A61B5/0245 A61B5/0468 A61B5/7235 A61B5/04085 A61B5/0456 A61B5/4064 A61B5/4094 A61B5/6823 A61B5/7275 G16H50/30		
优先权	201610709242.7 2016-08-23 CN		
外部链接	Espacenet USPTO		

摘要(译)

一种分析心率变异性的方法及其装置和用途，所述心率变异性分析方法包括体外采集ECG数据；对ECG数据进行数字化和去噪；将处理后的ECG数据形成为窦NN区间序列；在清醒状态下选择4小时的窦性NN间期数据；在清醒状态下对4小时的窦性NN间期序列进行MSE计算；并通过使用MSE曲线提取表示心率复杂度的参数。本发明可以为适合迷走神经刺激手术的药物难治性癫痫患者提供准确有效的筛查，从而避免不必要的费用，并避免错过治疗的最佳时机。同时，采用心电图的MSE复杂度特征参数选择适合VNS手术的患者，从而提高VNS治疗的整体疗效。

