US 20190090803A1

(19) United States

(12) Patent Application Publication

(10) Pub. No.: US 2019/0090803 A1

LI et al.

(43) Pub. Date: Mar. 28, 2019

(54) MODELING METHOD FOR SCREENING SURGICAL PATIENTS

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(21) Appl. No.: 16/086,428

(22) PCT Filed: Aug. 4, 2017

(86) PCT No.: PCT/CN2017/095951

§ 371 (c)(1),
(2) Date: Sep. 19, 2018

(30) Foreign Application Priority Data

Aug. 23, 2016 (CN) 201610708479.3

Publication Classification

(51) Int. Cl.

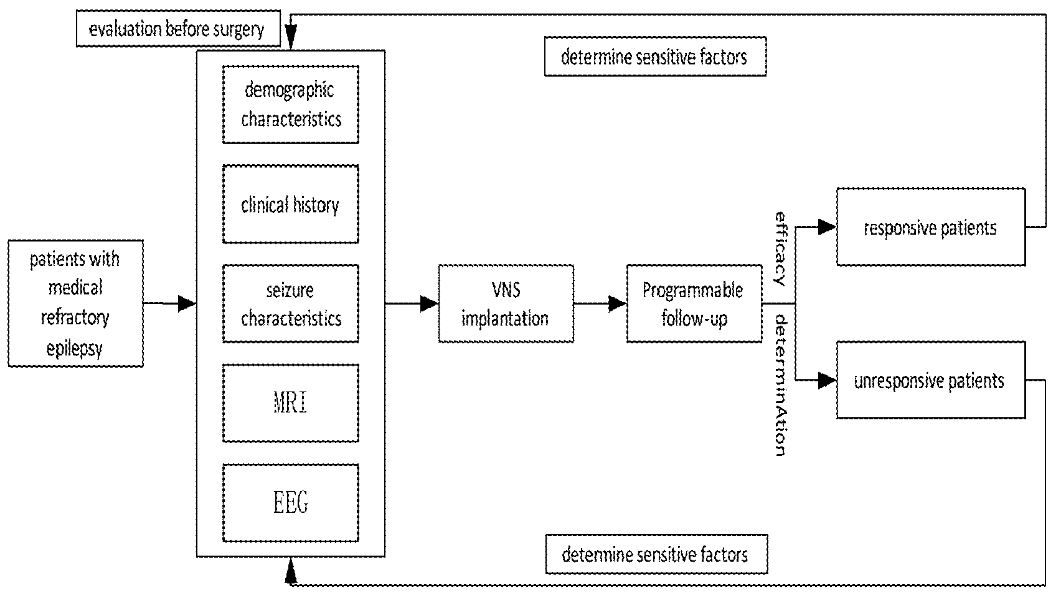
A61B 5/00 (2006.01)
A61B 5/024 (2006.01)
A61B 5/0245 (2006.01)

(52) U.S. Cl.

CPC *A61B 5/4094* (2013.01); *A61B 5/04011* (2013.01); *A61B 5/0245* (2013.01); *A61B 5/02405* (2013.01)

(57) ABSTRACT

A modeling method for screening surgical patients, used in analysis modeling for heart rate variability (HRV). Low-cost, portable and wearable signal acquisition equipment is utilized to acquire an electrocardiography (ECG) signal of an epileptic 24 hours before surgery; a multiscale entropy (MSE) of the ECG is calculated by means of a programmed HRV analysis method, wherein characteristic parameters representing heart rate complexity are extracted on the basis of an MSE curve, and a medical refractory epileptic suitable for vagus nerve stimulation (VNS) surgery is accurately and efficiently screened, thus avoiding unnecessary expenditures and avoiding delaying an optimal opportunity for treatment. Meanwhile, the curative effects of the VNS treatment may be wholly improved by means of clearly selecting VNS surgical indication patients according to the characteristic parameters of the MSE complexity of the ECG.



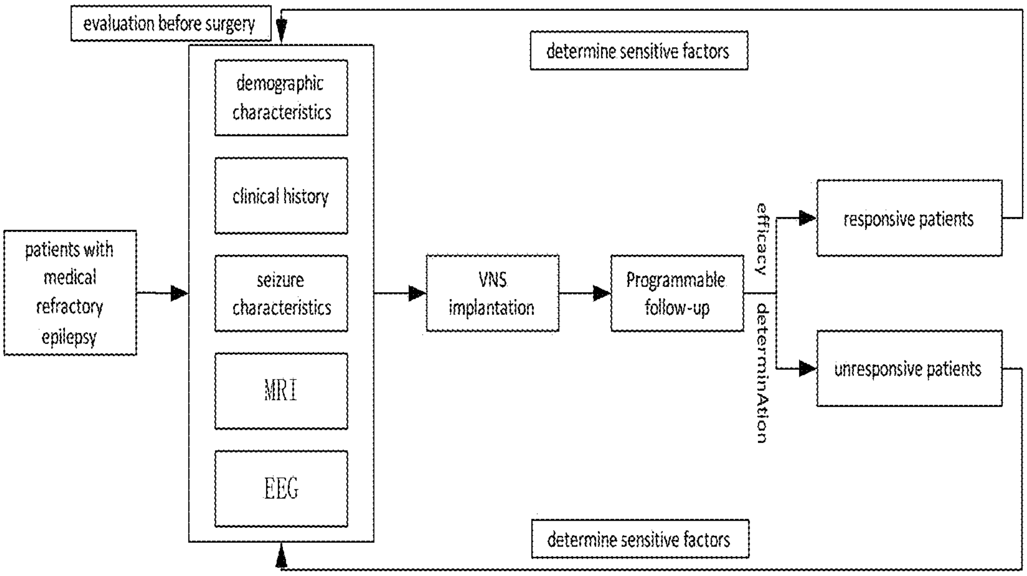

evaluation before surgery
determine sensitive factors
demographic characteristics
clinical history
seizure characteristics
MRI
EEG
patients with medical refractory epilepsy
VNS implantation
Programmable follow-up
efficacy determinAtion
responsive patients
unresponsive patients
determine sensitive factors

Fig. 1

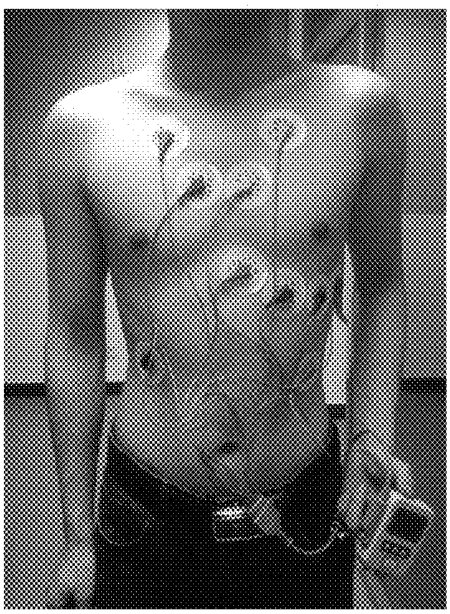


Fig. 2

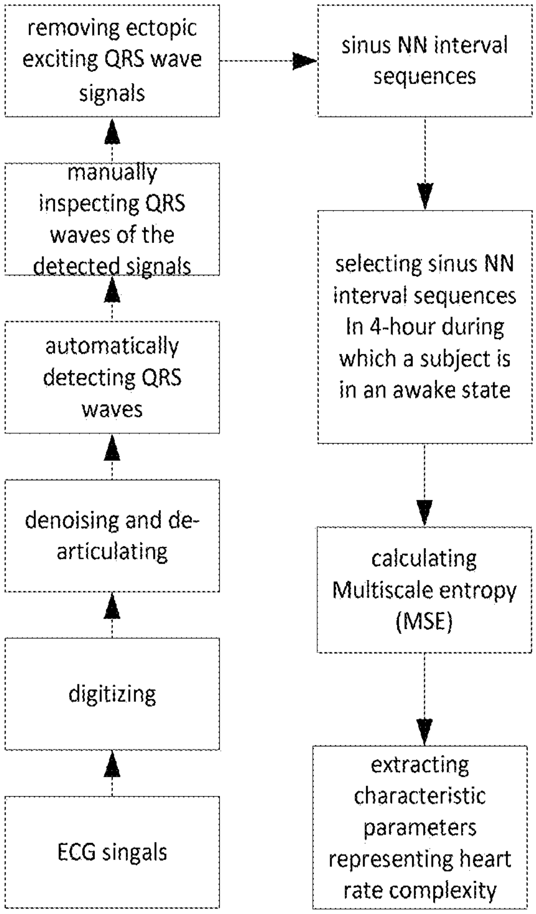

removing ectopic exciting QRS wave signals
manually inspecting QRS waves of the detected signals
automatically detecting QRS waves
denoising and de-articulating
digitizing
ECG singals
sinus NN interval sequences
selecting sinus NN interval sequences In 4-hour during which a subject is in an awake state
calculating Multiscale entropy (MSE)
extracting characteristic parameters representing heart rate complexity

Fig. 3

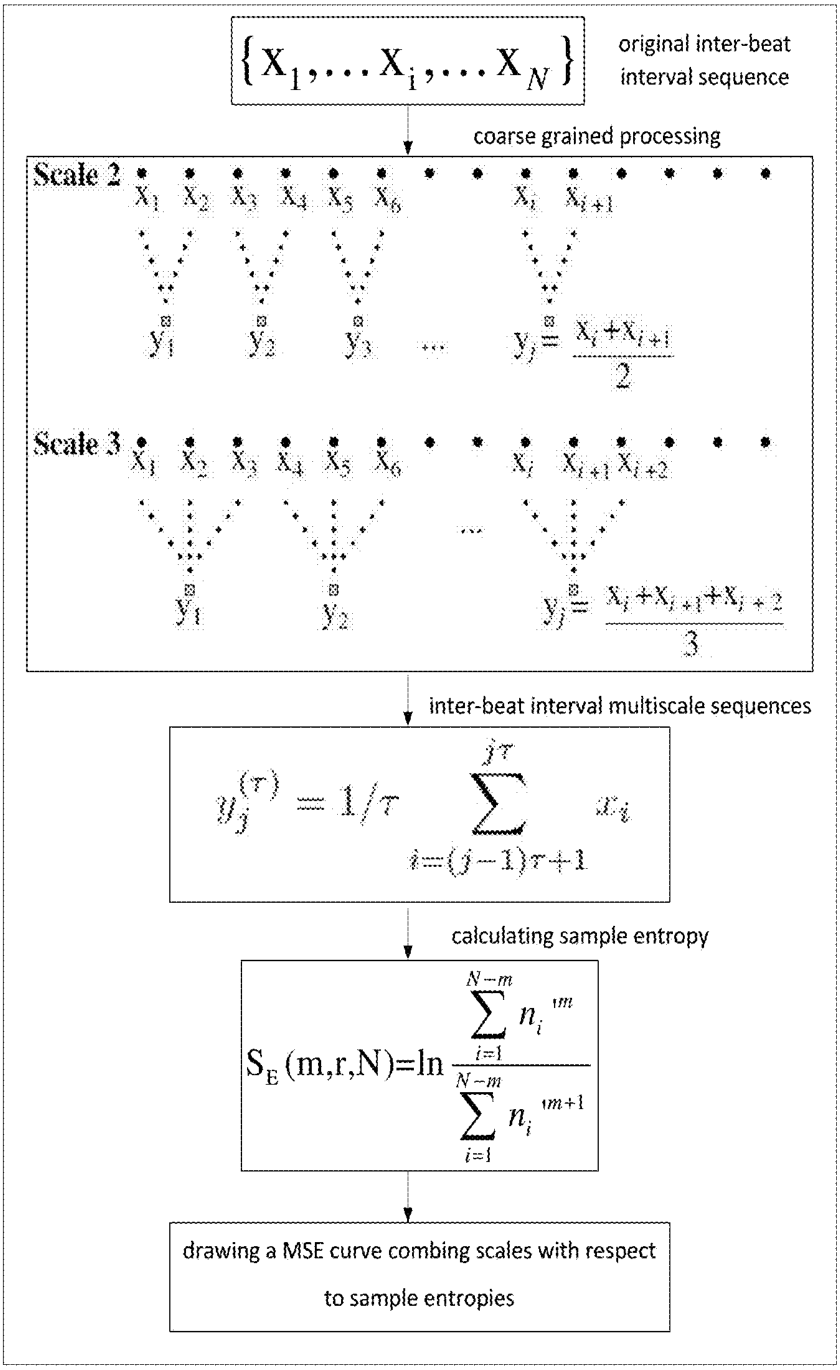
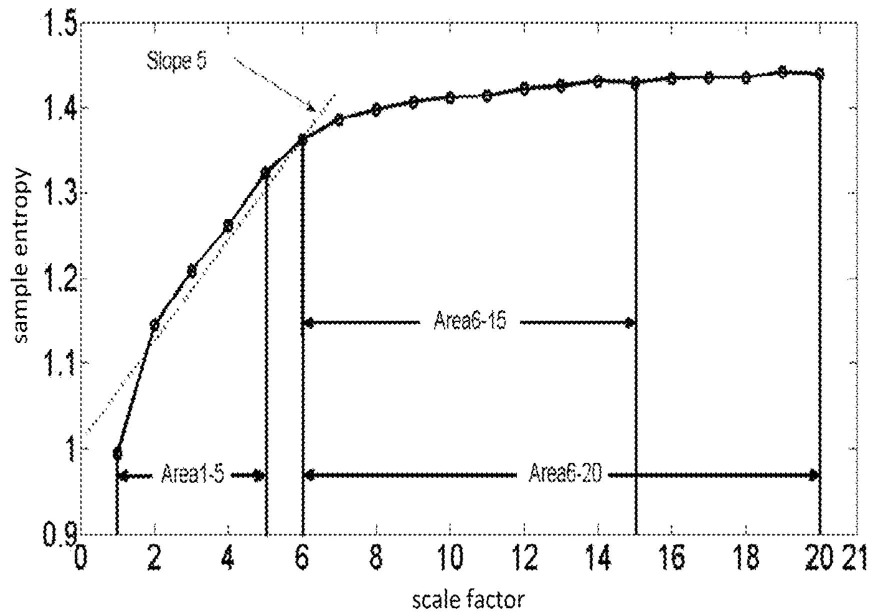
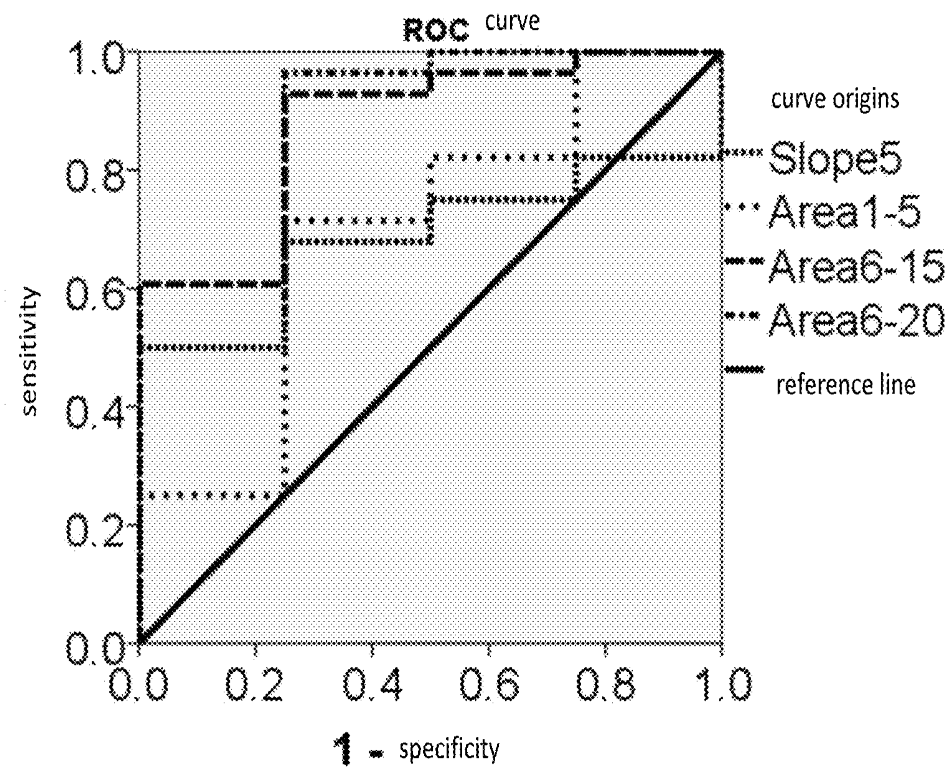

original inter-beat interval sequence
coarse grained processing
Scale 2
Scale 3
inter-beat interval multiscale sequences
calculating sample entropy
drawing a MSE curve combing scales with respect to sample entropies

Fig. 4



Slope 5
Area6-15
Area1-5
Area6-20
sample entropy
scale factor
1.5
1.4
1.3
1.2
1.1
1
0.9
0
2
4
6
8
10
12
14
16
18
20
21

Fig. 5



ROC curve
curve origins
Slope5
Area1-5
Area6-15
Area6-20
reference line
sensitivity
1 - specificity
1.0
0.8
0.6
0.4
0.2
0.0
0.0
0.2
0.4
0.6
0.8
1.0

Fig. 6

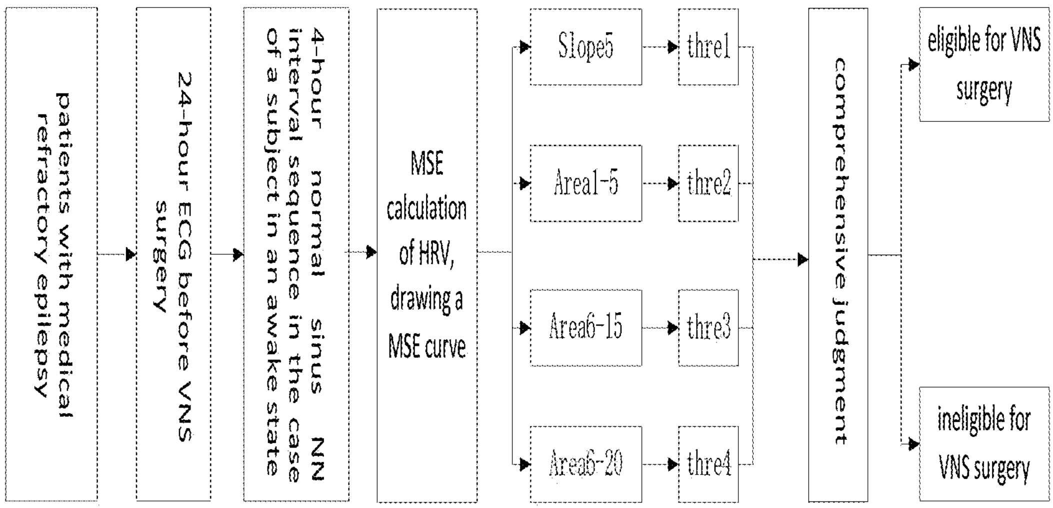

patients with medical refractory epilepsy
24-hour ECG before VNS surgery
4-hour normal sinus NN interval sequence in the case of a subject in an awake state
MSE calculation of HRV, drawing a MSE curve
Slope5
Area1-5
Area6-15
Area6-20
thre1
thre2
thre3
thre4
comprehensive judgment
eligible for VNS surgery
ineligible for VNS surgery

Fig. 7

MODELING METHOD FOR SCREENING SURGICAL PATIENTS

TECHNICAL FIELD

[0001] The invention relates to a modeling method for screening surgical patients, in particular to a modeling method 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 medical refractory epilepsy. As an adjuvant therapy, Vagus Nerve Stimulation (VNS) can effectively control epileptic seizures in patients with medical 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 medical 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 medical refractory epilepsy who were treated with VNS surgery. In view of uncertainties and large individual differences in the efficacy of VNS for treating medical 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 medical 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 medical 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 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.

[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 medical 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 modeling method for screening surgical patients, wherein, modeling is based on heart rate variability.

[0011] Further, the method comprises the following steps:

[0012] 1) collecting ECG data in vitro;

[0013] 2) selecting sinus NN interval data;

[0014] 3) performing MSE calculation on the selected sinus NN interval sequence;

[0015] 4) extracting parameters representing heart rate complexity by means of a MSE curve.

[0016] The specific method of steps 3)-4) is as follows:

[0017] i. performing coarse grained processing on the NN interval sequence $\{x_1, \ldots, x_i, \ldots, x_N\}$ in step 2), to obtain reconstructed sequences

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

$1 \le j \le N/\tau$ with different scales, r as a scale factor;

[0018] ii. calculating a sample entropy

$$S_E(m, r, N) = \ln \frac{\sum_{i=1}^{N-m} n_i'^m}{\sum_{i=1}^{N-m} n_i'^{m+1}}$$

for each scale's sequence

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

[0019] 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.

[0020] The characteristic parameters indicative of the heart rate complexity are acquired as follows:

[0021] For the curve in step iii, Slope n**1** is obtained by linearly fitting points with scales of 1–n**1**; scales n2-n**3** are segmented, and each area encompassed by each segment of the scale curve and the horizontal axis is calculated to obtain parameters Area**1**.

[0022] Further, n**1**<n**2**<n**3**, n**3**≤40; the number of parameters Area**1** is between 1 and 7.

[0023] Further, n1=5, the slope parameter Slope is Slope **5**, n2=6, n3=20. And parameters Area**1** are Area**1** **1-5**, Area**1** **6-15**, and Area**1** **6-20**.

[0024] Further, the selected sinus NN interval data is a NN interval data in an awake state.

[0025] Further, the selected sinus NN interval data is a 4-hour NN interval data in an awake state.

[0026] Further, the above-mentioned method is adaptable for vagus nerve-related diseases such as epilepsy or depression.

BRIEF DESCRIPTION OF DRAWINGS

[0027] FIG. **1** is a flow chart of the prior art for screening patients with VNS indications.

[0028] FIG. **2** is a diagram of 12-lead ECG acquisition.

[0029] FIG. **3** is a flow chart of ECG signal processing.

[0030] FIG. **4** is a flow chart of MSE analysis method.

[0031] FIG. **5** is a diagram of extracting indicators of MSE Complexity.

[0032] FIG. **6** is a threshold selection ROC curve

[0033] FIG. **7** is a flow chart for judgment.

EMBODIMENTS

Example 1

[0034] 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**.

[0035] 1) collecting and digitizing ECG signals;

[0036] 2) denoising and de-articulating digital signals;

[0037] 3) automatically detecting QRS waves thereof;

[0038] 4) manually inspecting QRS waves of the detected signals;

[0039] 5) removing ectopic exciting QRS wave signals;

[0040] 6) forming a sinus NN interval sequence;

[0041] 7) selecting 4-hour sinus NN interval sequences in the case of a subject in an awake state;

[0042] 8) calculating MSE based on the 4-hour sinus NN interval sequences;

[0043] 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;

[0044] 10) extracting characteristic parameters representing heart rate complexity, according to the MSE curve.

[0045] The MSE calculation method in the HRV analysis adopted in the present invention extracts characteristic parameters of Slope**5**, Area**1-5**, Area**6-15**, and Area**6-20** to represent the heart rate complexity.

[0046] The MSE method has the following steps (see FIG. **4**):

[0047] (1) performing coarse grained processing on the 4-hour normal sinus NN interval sequence $\{x_1, \ldots, x_i, \ldots, x_N\}$, to obtain reconstructed sequences

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

$1 \le j \le N/\tau$ with different scales, r as a scale factor;

[0048] (2) calculating a sample entropy

$$S_E(m, r, N) = \ln \frac{\sum_{i=1}^{N-m} n_i'^m}{\sum_{i=1}^{N-m} n_i'^{m+1}}$$

for each scale's sequence

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

[0049] (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 Area**1-5**, 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.

[0050] 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 4-hour normal sinus NN interval sequences during which the 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 Slope**5**, Area**1-5**, Area**6-15**, Area**6-20**, 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 Slope**5**, 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 Slope**5**, Area**1-5**, Area**6-15** and Area**6-20**, 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:

[0051] When Slope**5**=0.071, patients with a value higher than said value were considered eligible for VNS surgery. The screening accuracy was 67.9%.

[0052] 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%.

[0053] When Area**6-15**=10.57, patients with a value higher than said value were considered eligible for VNS surgery. The screening accuracy was 92.9%.

[0054] When Area**6-20**=15.85, patients with a value higher than said value were considered eligible for VNS surgery. The screening accuracy was 96.4%.

Example 2

[0055] The complexity indicator Area **6**-*n*, when the scale factor in the MES analysis method of Example 1 is expanded to n, could also be used for screening VNS patients as described above.

[0056] In the present invention, for patients with medical refractory epilepsy, 24-hours electrocardiogram acquisition before surgery and the MSE analysis of HRV were performed. In this way, patients with medical refractory epilepsy could be screened before surgery, thereby guiding patients who are not eligible for VNS therapy not to receive the surgery and to 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

[0057] 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.).

[0058] According to the above ECG signal processing method, the MSE analysis was performed, based on 24-hour dynamic electrocardiographic data. The corresponding characteristic parameters Slope**5**, Area**1-5**, Area**6-15**, and Area**6-20** were extracted based on each patient's MSE curve. At the end of 1-year follow-up, among 32 patients with medical 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 Slope**5**, Area**1-5**, Area**6-15**, and Area**6-20** before surgery could be adapted to predict efficacy. The results shown that, among the above four parameters, Area**6-20** was the most accurate parameter: when its threshold was set to 15.85, only one patient's Area**6-20** was 15.09 among the 28 effective patients, as shown in Table 1, and the rest patients' Area**6-20** 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

[0059] 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 modeling method, wherein modeling is based on heart rate variability.

12. The modeling method of claim **11**, comprising the following steps:

1) collecting ECG data in vitro;
2) selecting sinus NN interval data;
3) performing MSE calculation on the selected sinus NN interval sequence;
4) extracting parameters representing heart rate complexity by means of an MSE curve.

13. The heart rate variation analysis method of claim **12**, wherein the specific method of step 3)-4) is as follows:

i. performing coarse grained processing on the NN interval sequence $\{x_1, \ldots, x_i, \ldots, x_N\}$ in step 2), 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, ti as a scale factor;

ii. calculating a sample entropy

$$S_E(m, r, N) = \ln \frac{\sum_{i=1}^{N-m} n_i'^m}{\sum_{i=1}^{N-m} n_i'^{m+1}}$$

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.

14. The modeling method of claim **13**, wherein the method of acquiring characteristic parameters indicative of the heart rate complexity is as follows:

for the curve in step iii, Slope n**1** is obtained by linearly fitting points with scales of 1–n**1**; scales n**2**-n**3** are segmented, and each area encompassed by each segment of the scale curve and the horizontal axis is calculated to obtain the parameter Area**1**.

15. The modeling method of claim **14**, wherein n**1**<n**2**<n**3**, n**3**<40; and the number of Area**1** parameters is between 1 and 7.

16. The modeling method of claim **14**, wherein n**1**=5, the slope parameter Slope is Slope**5**, n**2**=6, n**3**=20, and parameters Area**1** are Area**11-5**, Area**16-15**, and Area**16-20**.

17. The modeling method of claim **12**, wherein the selected sinus NN interval data is NN interval data in an awake state.

18. The modeling method of claim **17**, wherein the selected sinus NN interval data is NN interval data in 4-hour during which a subject is in an awake state.

19. The modeling method of claim **11**, wherein a model is constructed for patients with vagus nerve-related diseases.

20. The method of modeling according to claim **19**, wherein the patients with vagus nerve-related diseases suffer from epilepsy or depression.

* * * * *

专利名称(译)	筛查手术患者的建模方法		
公开(公告)号	[US20190090803A1]()	公开(公告)日	2019-03-28
申请号	US16/086428	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		
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发明人	LI, LUMING LIU, HONGYUN YANG, ZHAO		
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摘要(译)

用于筛查手术患者的建模方法，用于心率变异性（HRV）的分析建模。低成本，便携式和可穿戴信号采集设备用于在手术前24小时获取癫痫的心电图（ECG）信号;通过编程的HRV分析方法计算ECG的多尺度熵（MSE），其中基于MSE曲线提取表示心率复杂度的特征参数，以及适合于迷走神经刺激（VNS）的医学难治性癫痫。准确有效地筛查手术，从而避免不必要的支出并避免延迟最佳治疗机会。同时，通过根据ECG的MSE复杂度的特征参数清楚地选择VNS手术指征患者，可以完全改善VNS治疗的疗效。