A Comparison of Brain Death Criteria between China and the United States

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Abstract

Background: Criteria for determining brain death (BD) vary between China and the United States. We reported the results of an investigation designed to compare procedures to determine BD in two countries.

Methods: The latest criteria in the United states were published in 2010. The latest criteria in China were published in 2009. We used these two types of BD criteria to evaluate patients who were considered to be BD. The time, cost, and accuracy of the diagnosis were compared.

Results: From January 1, 2012 to October 8, 2013, there were 37 patients which were applied for BD evaluation in the Neurological Intensive Care Unit of Beijing Tiantan Hospital. The cause of coma were known as subarachnoid hemorrhage (18 patients, 48.6%), intracerebral hemorrhage (8 patients, 21.6%), cerebral ischemia (9 patients, 24.3%), brain stem tumor (1 patient, 2.7%), and intracranial infection (1 patient, 2.7%). The clinical examinations were done for all of the patients except 1 patient who had low blood pressure. Three patients had brainstem reflexes that were excluded from BD. Twenty-five patients had apnea tests, and 20 tests were completed that were all positive. Confirmatory tests were completed differently: Transcranial Doppler (30 patients, positive rate 86.7%), electroencephalogram (25 patients, positive rate 100%), and somatosensory evoked potential (16 patients, positive rate 100%). Thirty-three patients were diagnosed BD by criteria of the United States. Only 9 patients were diagnosed BD by Chinese criteria. The use of time and money in the USA criteria was obviously fewer than those in Chinese criteria (P = 0.000).

Conclusion: Compared with BD criteria of the United States, Chinese criteria were stricter, lower positive rate, more cost in money and time, and more reliable by families and doctors.

Key words: Apnea Test; Brain Death Criteria; China; Diagnosis; the United States

INTRODUCTION

Brain death (BD) in the popular belief is that someone's brain stops functioning, even though their heart may be kept beating using a machine. Thus, the concept of BD is closely linked to the birth of modern intensive care medicine. After brain function had ceased, the somatic function being sustained by mechanical ventilation for a long time.^[1,2] Further treatment is inappropriate in a dead patient. So in many countries, the law provides that treatment can be legitimately removed from a patient who was diagnosed BD, and the donation of organs for transplantation can start. In this regard, the accuracy of diagnosis is very important.

In 1968, a definition of "irreversible coma" was presented for death by an *ad hoc* committee of the Harvard Medical School.^[3] Then in 1976, guidance on the diagnosis of

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brain (stem) death was published by the United Kingdom Conference of Medical Royal Colleges and their faculties.^[4] In 1979, a memorandum stated that BD equated with the death of the whole person by this commission.^[5] In 1995, the American Academy of Neurology (AAN) issued guidelines on the diagnosis of BD in order to standardize its practice parameters.^[6] This guidance was the basis for the development of the statutes of death in each state in the

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Received: 11-05-2015 Edited by: Xin Chen How to cite this article: Ding ZY, Zhang Q, Wu JW, Yang ZH, Zhao XQ. A Comparison of Brain Death Criteria between China and the United States. Chin Med J 2015;128:2896-901. United States and formed the basis of BD definitions in other countries.^[7] The latest criterion in the United States is the update of the 1995 AAN guideline on determining of BD, which was published in 2010.^[8]

Despite the general consensus on the concept of BD, its definition still varies widely between countries.^[9-13] In China, the diagnosis of BD and donation of organs are under development. In 2003, a draft of the determination of BD in adults was published in *National Medical Journal of China*.^[14] In 2009, the revised draft was published in *Chinese Journal of Cerebrovascular Disease*.^[15] In 2013, "Criteria and practical guidance for the determination of BD in adults (BQCC version)" was published in *Chinese Medical Journal*.^[16] The 2009 version of BD criteria is completely the same as the 2013 version.

In this study, we observed the application of the Chinese criteria of BD in a Neurological Intensive Care Unit (Neuro ICU). At the same time, we compare generally accepted BD criteria for diagnosis between China and the United States in order to know its diagnostic effectiveness.

METHODS

From January 1, 2012, we began to evaluate patients in the Neuro ICU of Beijing Tiantan Hospital, who were applied for BD diagnosis. The evaluations of BD were done by several neurologists who worked in the Neuro ICU. We used two criteria for BD diagnosis that were criteria of the United States and Chinese criteria.

In summary, the criteria of the United States consist of four steps: (1) Prerequisites: definite and irreversible coma whose cause should be excluded drug, hypothermia, alcohol, and other laboratory abnormal values; (2) examination: absence of brainstem reflexes; (3) the apnea test result is positive; and (4) ancillary tests can be used when uncertain about the clinical examination or when the apnea test cannot be performed.^[8]

The criteria in China also consist of four steps: (1) The clinical examination confirm the BD diagnose, including deep coma, absence of brainstem reflexes and no spontaneous (SPONT) respiration; (2) confirmatory tests should fulfill two of the three which include transcranial Doppler (TCD), electroencephalogram (EEG), and somatosensory evoked potential (SEP); (3) the apnea test is positive; and (4) a repeat determination should be done 12 h later after the 1st time.^[16]

If patients were in a coma and ventilated by nonautonomy breathing mode, they would be applied for the evaluation for BD and enrolled in this study. First of all, the cause of coma should be known and excluded drug, hypothermia, and alcohol. They should have normal body temperature and blood pressure (BP), no acidosis. Then the clinical examinations should be done including brainstem reflexes. The brainstem reflexes included corneal reflexes, pupillary reflexes, oculocephalic reflexes, oculovestibular reflexes, and cough reflexes. If the patients had no brainstem reflexes, we did apnea tests first. No matter what the test result was, confirmatory tests were done continuously which were SEP, EEG, and TCD. There were only 2 of 3 tests needed for one patient. If the results of tests for patients all fulfilled the criteria of BD, a repeat determination should be done 12 h later.

There are formal definitions of the apnea test. The patient is preoxygenated during the apnea test. Ventilator should be adjusted to provide normocarbia ($PaCO_2$ 34–45 mmHg) and hyperoxia ($PaO_2 \ge 200$ mmHg). The test is suspended if the patient become unstable or desaturases during the examination. If respiratory movements are absent in 10 min and $PaCO_2$ is ≥ 60 mmHg or 20 mmHg over a baseline, apnea can be confirmed.^[8]

The determination of BD in confirmatory tests as follows: (1) Short-latency SEP of median nerve shows that bilateral N9 and (or) N13 exist, while P14, N18, and N20 are absent; (2) EEG shows electrical silence; and (3) TCD sonography shows that the blood flows of intracranial anterior and posterior circulation demonstrate reverberating flow, small systolic spike, or absence of blood flow signal.

We used the two types of BD criteria to evaluate patients. Two doctors signed the BD reports separately. The results and the time for beginning and ending were recorded in the reports. Then the whole cost of money and time was calculated for each patient. The reactions of the physicians and families were recorded which meaning believes or unbelieves and the changes of treatment or not. At last we recorded the exact time when their hearts stopped beating.

The Chinese criteria of BD diagnoses have been officially published in the national journals which represent the legal status of this evaluation. At the same time, each steps of the evaluation have been already used in the clinical for years. Therefore, the approval of the Ethics Committee is not required. However, we informed the patients' families about the BD evaluation and obtained their consent before evaluations.

Statistical analysis

The age, time, and money were expressed as a mean \pm standard deviations (SD). The positive rates of each part of evaluation were expressed as a percentage. The diagnostic test accuracy was calculated by the four-fold table. Paired *t*-test was used to assess the statistical significance of changes in time and money. A *P* < 0.05 was considered statistically significant. All statistical analyses were used SPSS 19.0 software (SPSS Inc., Chicago, IL, USA).

RESULTS

From January 1, 2012 to October 8, 2013, there were 37 patients which were applied for BD evaluation in the Neuro ICU of Beijing Tiantan Hospital, who were a coma, being ventilated and no SPONT breathing. They were 21 males, 16 females, with a mean age of 58.86 ± 12.54 years (ranging from 37 years to 96 years). All patients were definite coma and excluded of

diseases due to drug, hypothermia, and alcohol. The cause of coma were known as subarachnoid hemorrhage (SAH, 18 patients, 48.6%), intracerebral hemorrhage (ICH, 8 patients, 21.6%), cerebral ischemia (CI, 9 patients, 24.3%), brain stem tumor (1 patients, 2.7%), and intracranial infection (1 patients, 2.7%). The data are summarized in Table 1.

Before the clinical examination, all patients had normal body temperature (core temperature >36°C) and BP (systolic BP \geq 100 mmHg) except 1 patient who had low BP. Clinical examinations were done for 36 patients. Three patients were excluded from BD because they had brainstem reflexes.

Although 33 patients needed to do apnea tests, only 25 patients did the tests because others could not provide normocarbia (PaCO₂ 34–45 mmHg) and hyperoxia (PaO₂ \geq 200 mmHg). Five patients' tests were suspended because they became unstable or desaturases. Twenty patients completed the tests, and all were positive. The mean PaCO₂ after 10 min stopping ventilators was 73.89 ± 11.51 mmHg (range 60.10–98.50 mmHg). There were 2 patients who seemed to be recovered in SPONT breathing. When the ventilator mode changed to SPONT mode, patients could remain SPONT breathing by machine. All the 2 patients repeated the apnea tests and got the positive results (PaCO₂ 61.6 mmHg and 77.6 mmHg, respectively). There were no respiratory movements observed in the test. So their apnea tests were decided to be positive.

Table 1: Features of the study population					
Cause of BD	Number of patients	Gender (male/ female), <i>n</i>	Age (years), mean ± SD (range)		
SAH	18	10/8	54.33 ± 11.02 (37-82)		
ICH	8	6/2	$58.38 \pm 10.01\;(4774)$		
CI	9	5/4	69.78 ± 13.01 (50–96)		
Brain stem tumor	1	0/1	53		
Intracranial infection	1	0/1	51		
Total	37	21/16	58.86 ± 12.54 (37–96)		

BD: Brain death; SAH: Subarachnoid hemorrhage; ICH: Intracerebral hemorrhage; CI: Cerebral ischemia; SD: Standard deviation.

Confirmatory tests were completed differently because it was only necessary to have 2 positive results of the 3 tests for BD diagnosis. But TCD was the first choice because 33 patients have planned to do that. Three patients could not get results because of the poor temporal windows. Twenty-six of the remaining 30 patients had positive results of TCD. Four patients had blood flow in the middle cerebral artery. The positive rate of TCD was 86.7%. Twenty-six patients arranged to do EEG. One patient who had decompressive craniotomy (DC) did not complete EEG because there were no places for the electrodes. Twenty-five patients had positive results of EEG, and the positive rate was 100%. Only 17 patients planned to do SEP. One patient who had DC could not complete the exam for the same reason. The positive rate of SEP was the same as EEG (16 patients, 100%). The data are summarized in Table 2.

As we know the evaluation of BD contains several steps, we followed the program one by one. After several steps, some patients were excluded from the diagnoses of BD. As we have described above in detail, in all 37 patients, 1 patient was excluded because of low BP. There were 33 left after the clinical examination. In all 33 patients, we need to complete one or more tests including the apnea test, TCD, EEG, and SEP. The highest selection rate of the test was TCD, and the rate was 89.2%. While the completed rates were higher in EEG and SEP than the other two test (96.2%, 94.1%, 90.9%, and 80.0%). The positive rats were 100% in patients who had completed the test except TCD. TCD had a poor positive rate which was only 86.7% [Table 2].

Thirty-three patients were diagnosed BD by criteria of the United States. According to the standards of the United States, 33 patients were diagnosed as BD without ancillary tests. Thirteen patients were confirmed BD with ancillary tests [Table 3]. Only 9 patients were diagnosed BD by Chinese criteria. As we showed in Table 3, 23 patients had two positive results of ancillary tests. There were 14 patients who had positive results of apnea test at the same time. Five patients did not wait for 12 h for another determination of BD. Two

Table 2: The each part of evaluation results of BD in 37 patients, % (n/N)					
Evaluations	Done	Complete	Positive	Negative	
Irreversible reason	100 (37/37)	100 (37/37)	100 (37/37)	0 (0/37)	
Clinical examination	97.3 (36/37)	100 (36/36)	91.7 (33/36)	8.3 (3/36)	
Clinical - repeat test	100 (9/9)	100 (9/9)	100 (9/9)	0 (0/9)	
Apnea test	67.6 (25/37)	80.0 (20/25)	100 (20/20)	0 (0/20)	
Apnea test – repeat test	100 (9/9)	100 (9/9)	100 (9/9)	0 (0/9)	
TCD	89.2 (33/37)	90.9 (30/33)	86.7 (26/30)	13.3 (4/30)	
TCD - repeat test	100 (7/7)	100 (7/7)	100 (7/7)	0 (0/7)	
EEG	70.3 (26/37)	96.2 (25/26)	100 (25/25)	0 (0/25)	
EEG - repeat test	100 (7/7)	100 (7/7)	100 (7/7)	0 (0/7)	
SEP	45.9 (17/37)	94.1 (16/17)	100 (16/16)	0 (0/16)	
EEG – repeat test	100 (7/7)	100 (7/7)	100 (7/7)	0 (0/7)	

In Chinese criteria, repeated tests should be done 12 h after the first evaluation. The items "repeat test" represented the second evaluations. "Done" means the selection rate of the test in all 37 patients. "Complete" means the finishing rate of the test in all patients who had done the test. "Positive" means the positive rate of the test in all patients who had completed the test. TCD: Transcranial Doppler; EEG: Electroencephalogram; SEP: Somatosensory evoked potential; BD: Brain death.

of them were chose to give up treatments after their families knowing about the BD diagnosis. That might be the reasons why the diagnose rate were such low in Chinese criteria.

The cost of time and money of each part of the evaluation was recorded. Thirty-three patients were diagnosed BD by criteria of the United States. The mean use of time was 52.27 min. The mean cost of each patient was RMB 235.76 Yuan. Nine patients were diagnosed BD by Chinese criteria. The mean use of time was 990 min. The mean cost of each patient was RMB 1333.33 Yuan. The use of time and money in the USA criteria was obviously fewer than that in Chinese criteria (P = 0.000) [Table 4].

In all 37 patients, 33 patients were diagnosed BD criteria of the United States. The positive rate was 89.2%. On the contrary, 9 patients were diagnosed BD by Chinese criteria (9/37, 24.3%). Two patients seemd to be recovered after the diagnoses of BD. But when we did the apnea test again, we confirmed that they were BD. Some doctors doubted if the criteria of the United States is right. The families of patients all believed the BD diagnosis while 8 patients' families could not believe that BD was equal to real death. Twenty-nine patients were died at last in the hospital. Five patients gave up treatments and went home. Sixteen patients chose palliative treatments. Six patients unchanged the treatments. Six patients lived on ventilators for 10 days. The mean time was 2.69 ± 2.42 days (range 1–10 days) [Table 4].

Table 3: The BD diagnostic procedures and positive cases in two criteria, n

Items	Criteria of the United States	Chinese criteria
Prerequisites	36	36
Examination	33	33
Ancillary testing	13	23
Apnea testing	20	14
Repeat test	0	9
Confirmed BD	33	9

The positive rate of Chinese criteria for BD was 24.3% and the criteria of the United States were 89.2%. BD: Brain death.

Table 4: Compare of the criteria of the United States and China in the practice

Items	Criteria of the United States	Chinese criteria
Positive rate in BD, $\%$ (<i>n</i> / <i>N</i>)	89.2 (33/37)	24.3 (9/37)
Time (min), mean ± SD (range)	52.27 ± 18.42 (45–105)*	990 ± 51.96 (930-1050)
Money (RMB, Yuan), mean ± SD (range)	235.76 ± 135.62 (110-620)*	1333.33±355.53 (880–1680)
Reliable by families, % (n/N)	100 (33/33)	100 (9/9)
Reliable by physicians, % (n/N)	93.9 (31/33)	100 (9/9)
Gave up treatments, % (n/N)	15.2 (5/33)	0.0 (0/9)
Active treatments, % (n/N)	24.2 (8/33)	33.3 (3/9)

*P = 0.000, there were a significant differential between two groups. SD: Standard deviation; BD: Brain death.

DISCUSSION

In China, the diagnosis of BD and donation of organs are under development. Although the Chinese criteria were published in the authoritative magazine since 2009, those were not used widely in the Intensive Care Unit (ICU). Some questions were put forward by the neurologists and physicians. Can a neurologist do the BD diagnosis? Is it difficult? Is it necessary for us to do that? So we did several BD evaluations in our Neuro ICU. We found that BD evaluations were safety and feasible. Then we had some other questions. Are the Chinese criteria for BD so difficulty? Can we just use the USA criteria? In order to answer the above questions, we compared the BD evaluations between criteria of China and the United States in a sequential series of patients in Neuro ICU of Beijing Tiantan Hospital. Each part of the BD evaluations was analyzed in the following sections.

The clinical evaluation seemed much easier than other tests. As a neurologist, he or she knew exactly what the irreversible coma was and how to make judgments to the cause of the coma. Also, they could do brainstem reflexes accurately. The pupillary, corneal, and cough reflexes were often tested, and doctors were skilled in checking them. The oculocephalic and oculovestibular reflexes were seldom done in practice. But they could be done well enough. So those above things did not matter for a neurologist. It should be noted that patient should have normal body temperature (core temperature >36°C) and BP (systolic BP \geq 100 mmHg). One patient did not do the BD evaluation because he could not reach the levels.

Confirmatory tests include TCD, EEG, and SEP. In our study, TCD seemed to be the first choice of doctors. But it was not always support the BD diagnosis. As we see, there were 4 patients had blood flow in the middle cerebral artery. That meant you cannot exclude BD even after blood flow found in TCD. And, there is another matter to consider. The brain condition could not complete TCD which included the poor temporal windows and craniotomy. In 33 patients who planned to have CD, 3 patients had poor temporal windows, and 3 patients had craniotomy. The rate was 9.1%. Ventricular drainages were seen in 6 patients and had no influences in TCD examination. EEG to determinate BD had some difficulties because the examination was done in the ICU. The environment exits too many electric inferences. When the sensitivity is increased to 2 μ V, it will take much time to get rid of inferences. It took at least 60 min to finish the exam. So the examiners would rather choose TCD than EEG. The actual use rate was 70.3% in the study. SEP is easier to do and less influences by the environment than EEG. But the use rate in our study was lowest. One of the probable reasons was that we used to do TCD and EEG. That was a problem of work habit. We can use more SEP to evaluate BD in the future. The positive rate of SEP was 100% in our study.

An apnea test is mandated by law or recommended by professional guidance in many countries.^[7] In fact, the

apnea test had some danger that 5 patients were suspended because they became unstable or desaturases in the test. But the complete rate was 80% that reflected most patients can afford the apnea test. There was one condition in our study. Two patients seemed to be recovered in SPONT breathing. When the ventilator mode changed to SPONT, patients could remain SPONT breathing by machine. Two patients were confirmed by Chinese criteria of BD. The repeated tests were positive too. All the 2 patients repeated the apnea tests and got the positive results (PaCO₂ 61.6 mmHg, and 77.6 mmHg, respectively). There were no respiratory movements observed by multiparameter monitor during the test. Thus, the results of the apnea tests were accurate.

Repeated assessments were chosen in many countries, presumably to minimize the risk of diagnostic errors.^[7] This is contrary to BD criteria of the United States which stipulate that only a single examination is required.^[8] In Chinese criteria, the repeated tests should be done 12 h later after the 1st time. Although the repeat tests increased accuracy, they prolonged the time of diagnoses. In our study, 5 patients did not wait for 12 h for another determination of BD.

We compared the determination of BD in China with that in the United States. In all 37 patients, more patients were confirmed BD by criteria of the United States than the Chinese criteria (89.2% vs. 24.3%). If the apnea test was positive, the patient can be diagnosed BD. As we showed in Table 3, more than half of patients were diagnosed BD. Further, only one ancillary test should be done to confirm BD. All of the above reasons make the diagnosis of BD by criteria of the United States more quickly, cheaper, and high diagnostic rate. The mean use of time in criteria of the United States was 52.27 min (<1 h). The mean cost of each patient was RMB 235.76 Yuan. The mean use of time in Chinese criteria was 990 min (16 h and 30 min). The mean cost of each patient was RMB 1333.33 Yuan. The use of time and money in criteria of the United States was obviously fewer than that in Chinese criteria (P = 0.000).

After comparing with criteria of the United States, can we draw the conclusion that Chinese criterion is poorer than criterion of the United States? Absolutely we cannot. In Chinese national condition, doctors are distrusted. So the accuracy is the most important thing. The second reason is that the organ donation is rare in the Neuro ICU. In our study, there were no cases of organ donation. Thus, the requirement for diagnose BD as soon as possible is few. The advantage of BD diagnosis is that the families and hospitals can stop unnecessary treatment. Yet, there were also some families who could not believe that BD was equal to real death. They asked for continuous active treatments. In our study, some patients lived on ventilators for 10 days.

Are there anything should we do about Chinese criteria of BD? The first thing is on the apnea test. In many countries, if a patient cannot complete apnea test, some ancillary test can be performed to determinate BD. In our study and other studies in China, there were a certain percent of patients

failing to complete the apnea test. When the confirmatory tests of these patients are all according with BD, we cannot exclude the diagnosis of BD. Although we need accuracy, can these patients be confirmed BD? Or we can use 3 confirmatory tests to take the place of apnea test.

The secondary thing is about the number of confirmatory tests. In order to be more accuracy, repeated tests must be done. But Chinese criteria are too complex to do. Patients in ICU usually have many things on treatment and nursing to handle. Its hard to find a block of time to complete the tests. The BD diagnosis will be difficult to finish in time when organ donations increase in the future. If patients have apnea test, and one confirmatory test can confirm BD, it will be more convenience than now.

There are some limitations in our study. The subjects in the study were most of the patients with cerebrovascular diseases since Beijing Tiantan Hospital is good at the treatment of cerebrovascular diseases. Our enroll subjects were from Neuro ICU that belongs to the Department of Neurology. The subjects we observed were SAH, ICH, and CI, who were older in age. The experience can only be applied to patients with the cerebrovascular disease. We are not sure whether our results can apply to the brain trauma and other neurological diseases.

In conclusion, we observed the application of Chinese criteria of BD in 37 patients from Neuro ICU. We found that BD evaluations in Chinese criteria were safety and feasible. A neurologist could fulfill the tests. Compared with the BD criteria of the United States, Chinese criteria were stricter, lower positive rate, more cost in money and time, and more reliable by families and doctors. Each of the two criteria has both advantages and disadvantages. With the more experiences we have in the future, the BD criteria will be more suitable for clinical practice.

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Conflicts of interest

There are no conflicts of interest.

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