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Brain death and effect of diagnosis on organ donation: a 10-year analysis

Beyin ölümü ve tanının organ bağışına etkisi: 10 yıllık bir analiz

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Abstract

Purpose: Brain death can be defined as the irreversible loss of brain functions. It is evident that a delay occurred in the diagnosis of brain death will result in the loss of many cadaveric organs and thus, the number of patients waiting for organ transplantation will increase. Despite there being many studies in the literature about the diagnosis and difficulties of brain death, family interviews, and organ donation, the studies regarding the effects of the regulation change in Türkiye on organ donation are limited. The present study includes 10-year retrospective data and it has been conducted to offer an insight to the scientists about the diagnosis of brain death and organ donation.

Material and method: The study was conducted by using data obtained from the examination of the retrospective files of patients diagnosed with brain death between 2011 and 2021 at Pamukkale University, School of Medicine after obtaining the approval of the ethics committee.

Results: After the study was initiated, the files of 71 patients diagnosed with brain death between 2011 and 2021, were accessed. Due to the missing information in the files of 4 patients, these patients were excluded from the study. Of 67 patients with registered brain death, 36 were male (53.7%) and 31 were female (46.2%). The age average was 49.07. When the treatment units of these patients were evaluated, 50 patients (74.6%) diagnosed with brain death were treated at the neurosurgery intensive care unit, 7 (10.4%) at the neurology intensive care unit, 6 (9%) at the anesthesia intensive care unit, and 4 (6%) at the cardiovascular surgery intensive care unit.

Conclusions: The study concluded that the importance of the diagnosis duration of brain death and the number of specialists who diagnosed brain death in the previous years may have affected this process. It is clear that the formal process, which changed after 2014, showed an acceleration in diagnosis. The importance of the interviews with family members besides the brain death diagnosis has emerged as a result of the study.

Key words: Brain death, organ donation, transplantation.

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Öz

Amaç: Beyin ölümü, beyin fonksiyonlarının geri dönüşümsüz kaybı olarak tanımlanabilir. Beyin ölümü tanısında yaşanacak bir gecikmenin birçok kadavra organının kaybına yol açacağı ve dolayısıyla organ nakli bekleyen hasta sayısının artacağı açıktır. Literatürde beyin ölümü tanı ve güçlükleri, aile görüşmeleri ve organ bağışı ile ilgili çok sayıda çalışma olmasına rağmen, Türkiye'deki mevzuat değişikliğinin organ bağışına etkilerine ilişkin çalışmalar sınırlıdır. Bu çalışma 10 yıllık retrospektif verileri içermekte olup, beyin ölümü tanısı ve organ bağışı konusunda bilim insanlarına ışık tutmak amacıyla yapılmıştır.

Gereç ve yöntem: Çalışma, etik kurul onayı alındıktan sonra Pamukkale Üniversitesi Tıp Fakültesi'nde 2011-2021 yılları arasında beyin ölümü tanısı alan hastaların retrospektif dosyalarının incelenmesi sonucu elde edilen veriler kullanılarak yapıldı.

Bulgular: Çalışma başlatıldıktan sonra 2011-2021 yılları arasında beyin ölümü tanısı alan 71 hastanın dosyalarına ulaşıldı. 4 hastanın dosyasında eksik bilgi olması nedeniyle bu hastalar çalışma dışı bırakıldı. Kayıtlı beyin ölümü olan 67 hastanın 36'sı erkek (%53,7), 31'i kadındı (%46,2). Yaş ortalaması 49.07 idi. Bu hastaların tedavi üniteleri değerlendirildiğinde beyin ölümü tanılı 50 (%74,6) hasta beyin cerrahisi yoğun bakım ünitesinde, 7 (%10,4) hasta nöroloji yoğun bakım ünitesinde, 6 (%9) hasta anestezi yoğun bakım ünitesinde ve 4 (%6) hasta da kalp damar cerrahisi yoğun bakım ünitesinde idi.

Sonuç: Çalışma, beyin ölümü tanı süresinin öneminin ve önceki yıllarda beyin ölümü tanısı koyan uzman sayısının bu süreci etkilemiş olabileceği sonucuna varmıştır. 2014 yılından sonra resmi prosedür değişikliğinin teşhiste hızlanma gösterdiği açıktır. Çalışma sonucunda aile bireyleri ile yapılan görüşmelerin önemi de ortaya çıkmıştır.

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Anahtar kelimeler: Beyin ölümü, donör organ, transplantasyon.

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Introduction

Brain death can be defined as the irreversible loss of brain functions [1]. It was primarily declared by the identification of clinical and pathological findings by French Mollaret and Goullon in 1959 [2]. Following the exclusion of reversible conditions mimicking this clinical status, brain death is a situation that includes the irreversible loss of all the brain activities, volitional acts, response to the painful stimulus, consciousness, lower brain stem functions, and spontaneous ventilation. There are differences between severe brain damage and brain death [3]. In order to detect such differences, the situation causing irreversible brain damage should be confirmed via neurological imaging methods. Pre-requisites include the exclusion of drug exposure that may cause coma, exclusion of serious metabolic disorders that are present in the patient, and close assessment of the absence of hypothermia that may cause this situation [4].

Brain death is an accepted medical and legal death criterion in many countries around the world [5]. Among the European countries, Finland is the first country that has accepted brain death as a manner of death since 1971. In Türkiye, the diagnosis of brain death has started to be made via No. 2238 Law on organ and tissue procurement, storage, vaccination, and transplantation, which has been in effect since 1979 [6]. Diagnosis of brain death is made by clinical assessment, apnea test, and radiological imaging triad in Türkiye. While the regulation on organ and tissue transplantation services dated 01.02.2012 and numbered 28191 stated that there was a requirement for the opinion of 4 specialist physicians for the diagnosis of brain death, the Ministry of Health amended this regulation in 2014 and entered the requirement of 2 specialist physicians for the diagnosis of brain death into effect [7, 8].

Although the criteria for the diagnosis of brain death vary in different countries around the world, the invariable criteria of brain death are coma, loss of brain stem reflexes, and positivity of the apnea test [3, 4]. In case an apnea test

cannot be conducted or no definitive diagnosis can be made, auxiliary imaging methods are applied. These methods are transcranial doppler, electroencephalography, cerebral tissue perfusion scintigraphy, and cerebral angiographic computerized tomography [4, 6]. After all the assessments, a diagnosis of brain death was made by 4 specialists in Türkiye before 2014 and since then, it has been made by 2 specialist physicians (anesthesiology and reanimation specialist or intensive care specialist and neurosurgery or neurology specialist) [6].

Since patients with brain death are the hope for multi-organ transplantation for the patients waiting for organ transplantation for a long time, careful diagnosis of brain death will also be a source of hope for such patients [9]. The stage of diagnosing brain death is a very critical process and this process should progress rapidly. In Türkiye, time spent on both diagnosis and documentation, and also the difficulties in family interviews regarding organ donation, are troublesome processes for the patients waiting for organ transplantation. In recent years, there has been an increase in organ transplantation from cadavers together with the importance given to donor care in intensive care units [10].

It is evident that a delay occurred in the diagnosis of brain death will result in the loss of many cadaveric organs and thus, the number of patients waiting for organ transplantation will increase. Despite there being many studies in the literature about the diagnosis and difficulties of brain death, family interviews, and organ donation, the studies regarding the effects of the regulation change in Türkiye on organ donation are limited. The present study includes 10-year retrospective data and it has been conducted to offer an insight to the scientists about the diagnosis of brain death and organ donation.

Material and method

The study was conducted by using data obtained from the examination of the retrospective files of patients diagnosed with brain death between 2011 and 2021 at Pamukkale University, School of Medicine after

obtaining the approval of the ethics committee (permission for the study was obtained from Pamukkale University Non-Interventional Clinical Research Ethics Committee. Patients, whose files could not be accessed or whose data were missing, were excluded from the study. In the light of this information, the following data (as of 2011) of the patients diagnosed with brain death was investigated in the study: Age, gender, department establishing the diagnosis, clinical diagnosis before brain death, apnea test applications, type of imaging methods applied at the time of diagnosis, the status of donating their organs, the degree of affinity of the interviewees, and if lack of donation, its reason. In addition, information on whether the patient was a judicial case and whether received vasopressor agents in intensive care units as well as the diagnosis dates of brain death were evaluated. After these evaluations, the units and numbers of the physicians making the diagnosis, who were responsible for the determination of brain death, were analyzed. As a result, times of cardiac death after the diagnosis of brain death were examined.

Statistical analysis

The behaviors of quantitative variables were specified by using centralization and variance measures. In order to show the behavioral differences of the group means, an Anova T-test was used; where normality and uniformity assumptions are met. Non-parametric methods, such as Kruskal-Wallis H Test (number of groups >2) and Mann Whitney U Test (number of groups=2), were used where those were not met. For all cases, statistical significance was specified as $p=0.05$. Statistical analyses were provided by IBM SPSS (Statistical Package for Social Sciences for Windows, Version 21.0, Armonk, NY, IBM Corp.) package program.

Results

After the study was initiated, the files of 71 patients diagnosed with brain death between 2011 and 2021, were accessed. Due to the missing information in the files of 4 patients, these patients were excluded from the study. Of 67 patients with registered brain death, 36 were male (53.7%) and 31 were female (46.2%). The average age was 49.07. When the treatment units of these patients were evaluated, 50 patients (74.6%) diagnosed with brain death were treated at the neurosurgery intensive care unit, 7 (10.4%) at the neurology intensive care

unit, 6 (9%) at the anesthesia intensive care unit, and 4 (6%) at the cardiovascular surgery intensive care unit.

Primary reasons for the hospitalization of the patients were assessed. The frequently seen reasons for hospitalization included: Subarachnoid hemorrhage (25, 37.3%), subdural hematoma (7, 10.4%), intracerebral hematoma (6, 9%), hypoxic encephalopathy (5, 7.5%), and cerebral aneurysms (4, 6%). Other reasons for hospitalization were found to be different diseases such as acute myocardial infarction, anaphylactic shock, disseminated intravascular hemorrhage, ischemic cerebrovascular cases, and intracranial mass (Table 1).

When the methods used for diagnosing brain death were examined, the number of patients with apnea tests was 54 (80.6%) and without apnea tests was 13 (19.4%). When auxiliary imaging methods used for diagnosis were observed, it was found that 53 patients (79.1%) were diagnosed by cerebral angiography computerized tomography, 9 (13.4%) by transcranial doppler, 3 (4.5%) by electro-encephalopathy (EEG), and 2 (4%) by brain Digital Subtraction Angiography (DSA). Of the patients, 14 (20.9%) were in judicial cases according to the assessment of the judicial statuses of the patients.

When the use of vasopressor agents in the intensive care follow-up of the patients was evaluated, only 16 patients (23.9%) did not need vasopressor drugs, while dopamine, dobutamine, and adrenaline were administered in various doses and combinations to other patients. In the evaluation of the specialties of the physicians determining brain death, 14 patients (20.9%) were diagnosed with brain death by 4 specialist physicians (anesthesiology, cardiology, neurology, and neurosurgery specialists). The number of brain deaths determined by the anesthesia and neurosurgery specialists was 46 (68.7%).

Documents of 4 patients could not be accessed and the brain death of the other 3 patients (4.5%) was diagnosed by anesthesiologists and neurologists. When organ donation of patients with brain death was evaluated, the organs of 48 patients (71.6%) were not donated by their families. While the cornea and both kidneys of 7 patients (10.5%) were donated; the heart, cornea, liver, and kidneys of 3 patients (4.5%) were donated. Only

the kidneys of 2 patients were donated, while the number of patients donating liver and both kidneys were 3 (4.5%). Other donations were 1 liver (1.5%), 1 liver and cornea (1.5%), and 1 liver, cornea, and both kidneys (1.5%). In one patient (1.5%), organs were donated, however,

the organs were not used as a donor. After the evaluations, when the periods between the diagnosis of brain death in the patients and the timing of the cardiac death were examined, the mean time elapsed was 4.24 ± 21.52 days (Table 2).

Table 1. Diagnosis of Brain death (Primary reasons for the hospitalization of the patients)

Diagnosis	Group n(%)
Acute MI	1 (1.5%)
Anaphylactic Shock	1 (1.5%)
Arteriovenous Malformation / Hemorrhage	4 (6%)
Dissemine Intravascular Coagulopathy	1 (1.5%)
Hypoxic Encephalopathy	5 (7.5%)
Intacranial Mass	1 (1.5%)
Intracerebral Hematoma	6 (9%)
Ischemic Cerebrovascular Disease	1 (1.5%)
Cardiac Arrest	1 (1.5%)
Perforating Trauma	1 (1.5%)
Subarachnoid Hemorrhage	25 (37.3%)
Subarachnoid Hemorrhage/ Arteriovenous malformation	2 (3%)
Subarachnoid Hemorrhage /Hematoma	1 (1.5%)
Cerebellar Mass Herniation	1 (1.5%)
Cervical Fracture	1 (1.5%)
Subdural Hematoma	7 (10.4%)
Cerebrovascular Disease	3 (4.5%)
Cerebrovascular Disease (Hemorrhagic)	1 (1.5%)
Intraventricular Hemorrhage	3 (4.5%)

Table 2. Mean age of patients and length of hospital stay during the brain death assessment process

	Mean $\pm$ SD	Median (Min-Max)
Age	49.07 $\pm$ 18.02	50 (9-87)
Day difference between brain death and cardiac death	4.24 $\pm$ 21.52	2 (-71-85)
Day difference between hospitalization and brain death	6.22 $\pm$ 14.09	3 (-20-92)
Day difference between hospitalization and cardiac death	10.76 $\pm$ 15.0	7 (1-87)

In the examination of the family interviews conducted during the organ donation process, organ donation interviews with the relatives of the patients were most frequently made with the spouses of the patients (27, 40.3%). The second-highest rate in the family interviews was found to be done with the sons of the patients (13, 19.4%). Other interviews included father (8, 11.9%), both father and mother (3, 4.5%), elder brother (1, 1.5%), elder sister (1, 1.5%), sibling (2, 3%), daughters and sons (1, 1.5%),

daughter-in-law and son-in-law (1, 1.5%), sister-in-law and brother-in-law (1, 1.5%) and uncle (1, 1.5%). When the reasons for not donating organs were examined, the most frequent answer of the families was the opposition to organ donation (28, 41.8%). Of the families who did not donate organs, 19 (28.4%) left this question unanswered; while 8 families (11.9%) did not want to accept that their patient had died. Table 3 shows the reasons for rejecting organ donation besides other reasons.

Table 3. Reason for rejecting organ donation

Reason for rejecting organ donation	Group n (%)
Empty	19 (28.4%)
Family rejects organ donation	28 (41.8%)
Brain death is not declared	3 (4.5%)
Patient Didn't Want To Have Organs Donated Before He/She Dies	5 (7.5%)
Inability to accept the death of the patient	8 (11.9%)
They Swore Not to Donate Organs/The Patient Was Alcoholic	1 (1.5%)
Left MCA flow was observed	1 (1.5%)
Conscientious discomfort	2 (3.0%)

Discussion

Establishing the diagnosis of brain death and following up with these patients as potential donors for organ transplantation have become a glimmer of hope for organ transplant patients in many centers in Europe and Türkiye. Statistics of brain death diagnosis have been shared by many countries in the literature. In a study conducted in England, the rate of diagnosis of brain death for potential organ transplantation was determined as 99%, while the rate of brain death diagnosis was only by using neurological criteria, which was 86%. In the same study, the rate of family interviews was 91% [11].

In the study of Karakoc et al. [12], 113 brain death diagnoses were made in Eskisehir, Türkiye in a 4-year examination and 25.7% of them resulted in organ donation. In another study, when 9-year retrospective brain death cases were analyzed, it was observed that 118 patients were diagnosed with brain death [6], and the time for the brain death diagnosis became easier after 2014.

The present study made a 10-year retrospective examination of brain death diagnoses in a university hospital, and similarly, it was found that the rate of brain death diagnosis and organ donation increased after 2014. This can be explained by the fact that the diagnosis was a more difficult process due to the legislation in the past, the awareness of organ donation increased, and the importance of communication in family meetings. However, it can also be observed that increasing the donation curve sometimes decreases in some situations. As an example, in a study conducted in Korea, despite the continued increase in Türkiye and the world until 2016, there was

a sharp decrease in 2017. The reasons for this were the maltreatment of the donor after the removal of organs, the elimination of compensation given to family members, the cancellation of the life-sustaining treatment protocol provided to family members, and the regulation changes in the working hours and conditions of the doctors [13].

These assessments show that brain death diagnosis, legal, and social interviews conducted with the family members are sensitive situations. They also remind us of the importance of donor care at the stage of organ procurement.

In a relevant study, new ways of communication between the family members and hospital staff were highlighted and the fact that the main theme was empathy stood out [14]. In a study conducted in Türkiye regarding this issue, the reasons for not donating organs in the interviews of brain death declaration and organ donation in pediatric patients were found to be the thought of the deterioration of body integrity and that they would suffer if their organs were procured [15]. This study is partially correlated with the current study about the rejection of organ donation. The reason for that was the family's disapproval of organ transplantation and not accepting that their patients died. These two studies bring the lack of knowledge and education about organ donation forth. In addition, the need for donor care and rapid organ procurement in case of organ donation is a need that should not be forgotten. Unfortunately, the time elapsed between brain death and cardiac death is not very long.

A study conducted suggests that donor care should not be performed before interviewing the families [16]. In another study, it was stated that

the diagnosis of brain death was made 3 days on average after hospitalization [17], while a Turkish study reported that the diagnosis period before 2014 was 4.8 days and the period after was 2.3 days [6]. In the assessments conducted in the current study, this period was found to be 6.2 days on average (Table 1). Any time elapsed to make a diagnosis means a delay in potential organ transplantation and it should be aimed to accelerate this process.

To that end, auxiliary imaging methods are frequently used both in Türkiye and throughout the world. In a study examining the brain death criteria [1], the brain death criteria of 80 different countries were compared and it was observed that auxiliary tests are compulsory in 40% of these countries. The conditions, when auxiliary tests are required, have been explained by the Ministry of Health in Türkiye [8]. In the present study, auxiliary imaging methods were applied to all the patients diagnosed with brain death. The reason was the difficulties in performing the apnea tests because most of our patients received vasopressor drug support. Evaluation of all these practices was conducted in a study including 492 hospitals in the USA in which the hospital procedures regarding brain death were examined. When the protocols of the hospitals included in the study were examined, it was found that the diagnosis of brain death should be made by specialist physicians, auxiliary imaging methods should be applied when necessary, and the conditions before diagnosis should be determined correctly (such as hypothermia and exclusion of drug exposures mimicking brain death...). Since this diagnosis should be 100%, the USA published a guideline in 2010 related to this issue and tried to standardize the diagnosis of brain death [18]. In Türkiye, the necessary legislation has been updated by the Ministry of Health, and these practices are carried out in a standard way at hospitals [8].

Limitations of the study

The present study was conducted by gathering retrospective data for 10 years and some of the data were affected by the change in the number of physicians making the diagnosis and the change in the physicians during this period. When this situation is evaluated and individual differences in physicians are considered, the diagnosis process of brain death may have been affected during the study.

In conclusion, the study concluded that

the importance of the diagnosis duration of brain death and the number of specialists who diagnosed brain death in the previous years may have affected this process. It is clear that the formal process, which changed after 2014, showed an acceleration in diagnosis. The importance of the interviews with family members besides the brain death diagnosis has emerged as a result of the study. The reality of both increasing the education regarding this issue and showing empathy and sensitivity in organ donation have emerged. Further studies regarding this issue are required both in Türkiye and in the world. Enlightenment together with sensitivity to this issue is required.

Conflict of interest: No conflict of interest was declared by the authors.

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Authors' contributions to the article

A.M.Y. constructed the main idea and hypothesis of the study. A.M.Y. and İ.K. developed the theory and arranged/edited the material and method section. A.M.Y., İ.K., B.E. and İ.H.A. have done the evaluation of the data in the Results section. Discussion section of the article written by A.M.Y., İ.K., İ.H.A., B.E. and S.K. reviewed, corrected and approved. In addition, all authors discussed the entire study and approved the final version.