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Current Status of Organ Donation in a University Hospital in İzmir: Identifying Obstacles and Possible Future Solutions

İzmir'de bir Üniversite Hastanesindeki Organ Donasyonunun Mevcut Durumu: Engellerin ve Gelecekteki Olası Çözümlerin Belirlenmesi

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ABSTRACT *Objective:* Although many new interventions including change in diagnostic policies are performed to increase the rates of diagnosis of brain death and organ donation within the recent years in Turkey, data about the longitudinal effects are limited. The aim of this study to understand the current status of organ donation in Izmir and find out whether new regulations have any impact on brain death and organ donation rates.
Materials and Methods: All patients diagnosed with brain death in a tertiary university hospital between january 2001 and december 2016 were included and patient data and organ donation status were collected from medical records.
Results: A total of 303 patients had brain death during the study period. In pediatric patients (n=42), the most common reason was traumatic brain injury (42.9%) and 12 patients (28.6%) were organ donors. For adult patients (n=261), the most common reason was intracranial hemorrhage (39.8%) and 97 patients (37.2%) were organ donors. The rate of brain death diagnosis was increased within years (from 0.59% to 0.67% after change in policy), there was no increase in organ donation rate (39.5 vs 26.5%). The most common cause of ineligibility for donation was refusal of patient's relatives both for pediatric and adult patients (83.3% and 86.6% respectively).
Conclusion: This study shows although the diagnosis of brain death is increasing slowly within years, but organ donation rates are still low in Izmir. New strategies aiming to increase awareness and change in perception for organ donation should be planned as soon as possible.
Keywords: Organ donation, brain death, refusal

ÖZ *Amaç:* Türkiye'de son yıllarda beyin ölümü teşhisi ve organ bağışını arttırmak amacıyla teşhis yöntemlerindeki değişiklikleri de kapsayan pek çok yeni uygulama yapılmasına rağmen bunların etkileri ile ilgili bilgilerimiz sınırlıdır. Bu çalışmanın amacı İzmir'de organ bağışının mevcut durumunu anlamak ve yeni düzenlemelerin beyin ölümü teşhisi ve organ bağışı üzerinde herhangi bir etkisi olup olmadığını öğrenmektir.
Gereç ve Yöntem: Bir üçüncü basamak Üniversite hastanesinde Ocak 2001 ve Aralık 2016 arasındaki beyin ölümü konan tüm hastalar, hasta verileri, organ nakli durumu tıbbi kayıtlardan elde edildi.
Bulgular: Çalışma süresince beyin ölümü teşhisi konan 303 hasta mevcuttu. Pediyatrik grupta (n=42) en çok görülen teşhis travmatik beyin hasarıydı (%42,9). Bu hastalardan 12 hasta (%28,6) donör oldu. Yetişkin hasta grubunda (n=261) ensık görülen teşhis intrakraniyal kanamaydı %39,8) ve 97 hasta (%37,2) donör olmuştu. Beyin ölümü teşhis hızı yıllar içerisinde artmıştı (yasal düzenlemeden sonra %0,59'dan %0,67'e yükselmişti), ancak organ nakil hızında artış yoktu (düzenlemeden önce%39,5, düzenlemeden sonra %26,5). Organ nakli yapılamamasının en sık görülen sebebi hem pediyatrik, hem de yetişkin hasta grubunda hasta yakını reddiydi (pediyatrik %83.3, yetişkin %86.6).
Sonuç: Çalışma İzmir'de beyin ölümü teşhisinin yıllar içerisinde artmasına rağmen organ naklinin hala düşük kaldığını göstermektedir. Farkındalığı arttıracak ve organ nakline bakışı değiştirecek yeni stratejiler en kısa zamanda planlanmalıdır.
Anahtar Kelimeler: Organ bağışı, beyin ölümü, hasta yakını reddi

Introduction

Although treatment options and technology in healthcare are growing exponentially, transplantation is still the main solution for organ failures. The disparity between the number of required organs for transplantation and the number of donor organs continues to be an important problem in many countries. Some countries such as Spain made comprehensive approaches with successful results and optimized performance in deceased donation, leading the country to an activity of 32–35 donors per million population (1,2). But these programs are still very limited to few countries in Europe.

Turkey is one of the countries with serious problems in organ donation. In 2017, around 25000 patients are in the waiting list for organ donation. However, amongst 12000 patients diagnosed between 2011-2017 years as brain death only 25% had organ donation (3). The current legal regulation for brain death and organ donation in Turkey was published in February 2012 and revised in January 2014 (4,5). The revision consisted of decreasing the need of four physicians (anesthesiologist, neurologist, neurosurgeon and cardiologist) to two (a neurologist or a neurosurgeon, and an anesthesiologist or an intensivist) to prevent delays in the diagnosis of BD. In addition to that, the Ministry of Health in Turkey started a project together with European Union which is aimed to develop quality and safety standards for human organ donation and transplantation, to harmonize of the EU acquis communautaire in the area cadaveric organ donation, to strengthen database structure and to increase donation rates (6). Other than those, Ministry of Health initiated an awareness campaign throughout the country in order to increase organ donation (7). The campaign consisted of information for not only the importance of organ donation but also religious perspective through media (television, radio and other social media channels) and in-hospital transplantation team services.

Although the aim of all these policies is to increase awareness and therefore the rates of diagnosis of brain death and organ donation, the longitudinal effects are not very well known. The objective of this study is to understand the current status of organ donation at a University Hospital in Izmir and find out whether these new regulations have any impact on brain death diagnosis and organ donation rates.

Materials and Methods

Study Population

The study was approved by local ethics committee (protocol number: 2017/04-19). and conducted in a tertiary reference university hospital with 73 intensive care unit (ICU) beds. All adult and pediatric patients diagnosed with brain death between January 2001 and December 2016 were included into the study. Data from medical records and hospital database were collected retrospectively. Patient demographics (age, gender), reasons for hospitalization, physical examination findings, tests performed for confirmation of brain death (Transcranial doppler [TCD], computed tomographic angiography [CTA], electroencephalography [EEG], single photon emission computed tomography [SPECT], cerebral scintigraphy), the final status for organ donation, reasons for ineligibility for organ donation (medical problems, patients relatives refusal and other reasons) were recorded. Patients were grouped according to age: pediatric group (<18 years) and adult group (≥18 years).

The Diagnosis of BD

The diagnostic criteria for brain death was same throughout the study period: Clinical evaluation of brain death was performed in the presence of a severe structural brain lesion, a Glasgow Coma Scale (GCS) score of 3/15, and absence of brainstem reflexes in normothermic patients who had no significant metabolic abnormalities, or residual effects of sedative drugs according to current legal regulations made by Ministry of Healt in Turkey (8). Ancillary methods were used in some patients for confirmation of brain death according to neurological evaluation. The study period was divided into two parts because of change in the criteria for the diagnosis of BD. According to regulatory laws for brain death and organ donation in Turkey, the diagnosis of brain death was made by a team of four physicians (anesthesiologist, neurologist, cardiologist and neurosurgeon) between January 2001 to December 2013 (Period 1). From January 2014, the diagnosis of BD was made by a team of two physicians (neurologist/neurosurgeon and anesthesiologist/intensivist) (Period 2). In order to understand the impact of regulatory change, we compared the rates of brain death and organ donation for both periods.

Statistical Analysis

We conducted a retrospective cohort study and reported its results in accordance with the STROBE (Strengthening

the Reporting of Observational Studies in Epidemiology) guidelines (9). The primary outcome of the study was whether the rate of BD diagnosis changed within years and new regulations made any impact on the diagnosis and organ donation. All categorical variables are expressed as numbers and percentages and continuous variables are expressed as mean and standard deviation (SD). Categorical variables between groups were compared with chi-square or Fisher's exact tests; continuous variables were compared with Student's t-test or Mann–Whitney U test. A two-tailed p value of <0.05 was considered statistically significant. Statistical analysis was performed with SPSS (Statistical Package for the Social Sciences Version 20; IBM Corporation, Armonk, NY, USA) program.

Results

During study period, 303 patients were diagnosed with brain death; 42 (13.9%) of them were in pediatric group, whereas 261 (86.1%) patients were in adult group (Figure 1).

Pediatric patients:

The mean ± SD age was 9.7 ± 6.1 years and 26 (61.9%) were male. The most common reason for brain death was traumatic brain injury (42.9%) followed by anoxic brain injury (14.3%) (Table 1). The apnea test was positive in 38 patients (90.5%) and 4 patients' data is unavailable (9.5%). Eighteen patients had the diagnosis of brain death with clinical evaluation only. An ancillary test was performed in the rest of patients (n=24, 59.5%) and the most commonly used ancillary method used in this age group was EEG (41.7%) (Table 2).

Twelve patients (28.6%) were organ donors and the rest of patients (n=30, 71.4%) were not eligible for organ donation. The most common cause of ineligibility for donation was refusal of parents/patient's relatives (n=23; 83.3%) (Table 3).

Adult Patients

In adult patients the mean ± SD age was 47.6 ± 18.3 years and 169 (64.8%) were male. The most common reason for brain death was intracranial hemorrhage (39.8%) followed by traumatic brain injury (19.2%) and ischemic stroke (15.3%). The apnea test was positive in 217 patients (83.1%) and couldn't be completed in 31 patients (11.9%). (In these patients, TCD was used in 8, CTA was used in 9 as an ancillary method. Other 14 patients' data is unavailable). TCD and CTA were the most commonly used ancillary method (44.6 and 39.3% respectively), followed by SPECT (8.9%).

Ninety-seven patients (37.2%) were organ donors and 164 patients (62.8%) were not eligible to organ donation (Table 3). The most common cause for ineligibility for organ donation was refusal of patients' relatives (86.6%).

The rate of brain death diagnosis and organ donation within study years:

The rate of diagnosis of brain death is increased throughout the study period but this increase was not accompanied by organ donation rates (Figure 2). During Period 1 (2001-2013), amongst patients admitted to ICU, the rates for brain death diagnosis and organ donation were 0.59% (220/36866) and 39.5% (87/220) respectively. During Period 2 (2014-2016), which is after the change in diagnostic approach, the rate of diagnosis for brain death was increased to 0.67% (83/12447) but organ donation rate was 26.5% (22/83) (Figure 3).

Discussion

The present study has two important results: First, the diagnosis of brain death is increasing within years in our center, however this was not accompanied by organ donation rates. Second, the main reason for ineligibility for

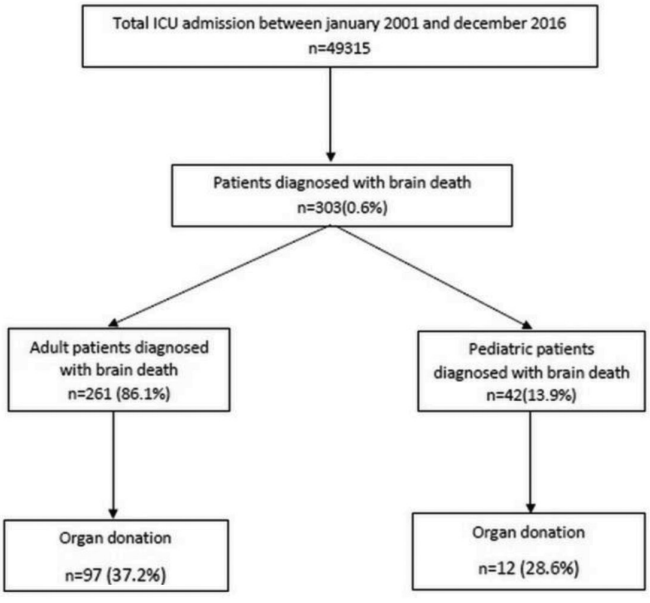

Figure 1. Study flow chart and distribution of patients according to age groups

organ donation was refusal from patient relatives in both pediatric and adult age groups.

Recently, Ministry of Health in Turkey declared important regulatory changes in order to increase organ transplantation rates. First, the reimbursements for the diagnosis of brain death and organ transplantation procedures are increased in order to encourage physicians. Second, the certification of brain death was performed with two physicians after policy changes in 2014. These regulatory changes were expected to facilitate the rate of diagnosis of brain death. In our study, although there is a huge variation between years, the number of diagnosis of brain death is slowly increasing within time in our center. This finding is consistent with Ministry of Health data in which the number of brain death diagnosis was increased from 1313 in 2011 to 2042 in 2017.

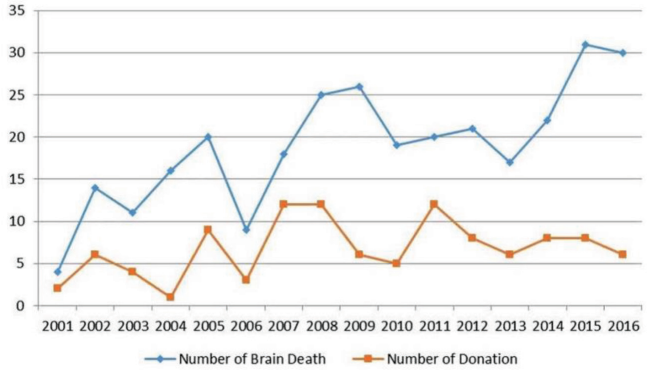

Figure 2. Annual numbers of patients for brain death and organ donation

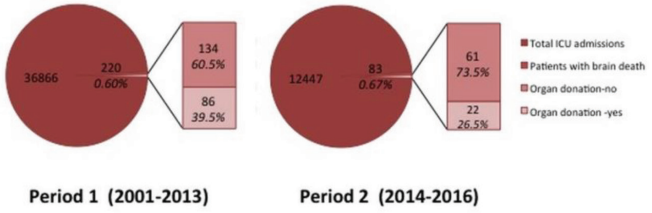

Figure 3. Total number of patients admitted to intensive care unit, number of patients diagnosed with brain death (%) and number of patients with organ donation (%) for each study period

Table 1. Demographic characteristics of patients

		Adult group (≥ 18 years)	Pediatric group (< 18 years)
n		261	42
Age (years)		47.6 ± 18.3	9.7 ± 6.1
Sex	Male	169 (64.8)	26 (61.9)
	Female	92 (35.2)	16 (38.1)
GCS (at ICU admission)		3.5 ± 1.4	3.1 ± 0.4
Duration of ICU admission to brain death diagnosis (days)		6.4 ± 4.1	5.8 ± 5.1
Hospital length of stay (days)		10.1 ± 8.7	11.9 ± 7.9
ICU length of stay (days)		7.3 ± 5.1	9.1 ± 6.2
Etiology of brain death			
Intracranial hemorrhage#		104 (39.8)	3 (7.1)
Traumatic brain injury		50 (19.2)	18 (42.9)
Ischemic stroke		40 (15.3)	3 (7.1)
Anoxic brain injury		17 (6.5)	6 (14.3)
Intracranial mass*		14 (5.4)	3 (7.1)
Multiple trauma		11 (4.2)	3 (7.1)
Arteriovenous malformation		3 (1.1)	-
Other causes¥		22 (8.4)	6 (14.3)

Categorical variables are expressed as n (%) and continuous variables are expressed as mean ± SD.
GCS: Glasgow coma score, ICU: Intensive care unit
#Intracranial hemorrhage group include all patients with intracerebral hemorrhage, subarachnoid hemorrhage and subdural hemorrhage.
*Include both pre and post-operative patients.
¥Intoxication (n=6), epilepsy (n=3), meningitis (n=3), acute renal failure (n=2), hemorrhagic shock (n=1), viremia (n=1), hepatic failure (n=1), septic shock (n=1), duraplasty (n=1), encephalitis (n=1), pneumothorax (n=1), cardiac failure (n=1), aspiration pneumonia (n=1), stomach cancer (n=1), retinoblastoma (n=1), venous sinus thrombosis (n=1), stabbing (n=1), unknown (n=1).

Harmancı-Seren et al also reported that the number of the diagnosis of brain death increased nearly 5 times between 2005 and 2015 in Istanbul province (10) and they commented that the increase is mainly due to increase in the number of transplant centers. Overall, the rate of brain death diagnosis is increasing but it still is very low than expected as Turkey's population is more than 80 million. Currently, similar to Spanish model, transplant coordinators are actively working in many tertiary reference hospitals in Turkey however we think that further improvements are needed to have successful networking between transplant team and ICU physicians which is definitely a key step to enhance brain death diagnosis. In addition interventions which aim to educate physicians and other health care personnel for assessment and determination of brain death should continuously be reinforced.

In Turkey two clinicians with specific departments are required to diagnose brain death. There is a huge variability of knowledge and practices for brain death declaration among physicians despite there are clear algorithms for the diagnosis (11-13). The diagnosis of brain death is primarily clinical and no other tests are required if the full clinical examination, including each of two assessments of brain stem reflexes and a single apnea test, is conclusively performed. It was reported that asynchrony between physicians may cause problems not only in the diagnosis of brain death but also organ donation. It was previously reported that the difference in attitude of physicians might be an obstacle for brain death diagnosis. A study of Kosieradzki et al showed that in Polish physicians difference in brain death diagnosis procedure was considered as an important barrier especially in centers with low rates of organ donation (14). Varelas et al reported that brain death certified with a single physician is easier, faster and more cost effective when compared to diagnosis with two physicians (15).

In this study, the overall organ donation rate was 37.2% in adults and 28.6% in the pediatric group, which is relatively lower than expected. Donor problem is still an important

Table 2. Diagnostic approaches for brain death

	Adult patient group n=261	Pediatric patient group n=42
Clinical diagnosis*	149 (57.1)	18 (42.1)
Positive apnea test	217 (83.1)	38 (90.5)
Ancillary methods	112 (42.9)	24 (57.9)
TCD	50 (44.6)	8 (33.3)
CTA	44 (39.3)	4 (16.7)
EEG	3 (2.7)	10 (41.7)
SPECT	10 (8.9)	1 (4.2)
Cerebral scintigraphy	5 (4.5)	1 (4.2)

Data were presented as n (%).
CTA: Computed tomographic angiography, EEG: Electroencephalography, SPECT: Single photon emission computed tomography. TCD: Transcranial doppler.
*Clinical diagnosis was established with presence of coma, complete loss of brain stem reflexes and positive apnea test with confirmed after waiting time specified for that age group (according to national guideline).

Table 3. Organ donation status in patients diagnosed with brain death

	Adult group n=261	Pediatric group n=42
Yes	97 (37.2)	12 (28.6)
No	164 (62.8)	30 (71.4)
Reasons for ineligibility for organ donation		
Refusal of patient's relatives	142 (86.6)	25 (83.3)
Ineligibility due to medical reasons	7 (4.3)	1 (3.3)
Could not interviewed with patient relatives	5 (3.0)	-
Data unavailable	10 (6.1)	4 (13.3)

Data were presented as n (%).

obstacle for organ transplantation in Turkey (16,17). Deceased donation rates per million population was 5.1 which is much lower than European Countries (16,17). According to 2017 data of Ministry of Health, only 26% of patients with brain death proceeded to organ donation (3). We have found that, family refusal seems to be the main obstacle for organ donation and refusal rate is much higher than previously reported. This finding is contrary to other countries data in which the most common reason for ineligibility for organ donation was medical problems (17-20). Matesanz et al reported that the donation rate in Spain between 1999 and 2008 was between 50 to 60%, and main obstacle in organ donation was due to medical contraindications whereas refusal from relatives was reported around 10-15% (2). Similar to that, in a study performed in 42 Spanish centers, Escudero et al reported overall family refusal rate as 13 % (18). We think that the refusal of patient's relatives for organ donation needs specific attention, as there was no much change throughout the study years. Although, there are many programs conducted by Ministry of Health, more effective comprehensive interventions for sustainability of deceased donor should be planned according to national needs (21). Moreover, we think that socio-cultural and religious characteristics of the country should be taken into account in order to establish successful organ donation models. Certain profession groups, such as health care professionals, teachers, religion officers, which are role models and have influence for changing the behavior throughout the society should be targeted to achieve a snowball effect for improved attitudes towards donation (22). In a study performed in health care professionals it was shown that only a quarter of them owned a donation card, whereas this rate was found as low as <1% in religion officers (23,24).

There is a strong relation between the attitude of the family toward donation and the willingness of the deceased person to be a donor. If the deceased's wishes are not known, it creates uncertainty for the family members during decision-making process, which also tends to result in a negative decision. The other important variable that affects the attitude of the family is giving them sufficient time to think during the decision-making process. Dissatisfaction with the health care system is another important factor that affects the family in the decision-making process. It is also necessary to improve the communication between doctor and patient or relatives to increase the satisfaction of patients, to increase the awareness of health professionals on the effect of their behavior. If the concept of brain death was not explained sufficiently to family members and uncertainty regarding the death increased, which affected the decision of the family negatively. An efficient protocol should be provide for organ donation request and health care professionals should be continuously trained about this protocol (25). In Turkey, Patient's relatives stated that they did not have sufficient knowledge about organ donation and they found overall knowledge of the community low. The ratio of organ transplants from living donors is high, the ratio of organ donation from deceased donor is still low and families are less willing. Sufficient resources, research, and education should be planned for reducing the refusal rate and increasing organ donation from deceased donor (26).

The study has limitations. First, the study was a retrospective study performed in a tertiary center therefore we think that our results may not be generalizable. Second, because of the retrospective nature of the study, detailed reasons for family refusals for organ donation is unknown. Third, we could not be able to analyze whether new policy for the diagnosis of brain death shorten the time needed for the diagnosis. However the present study have important strengths. First it gives a perspective about the trends for the last 16 years of brain death and organ donation in our Institution (in Turkey). Second we had the opportunity to better understand the effect of recent change in policy for the diagnosis of brain death. Finally we think that our study gives important insights for the main obstacles and possible future solutions for organ donation.

Conclusion

In conclusion, our study confirms that although changes in policies resulted to a positive impact to rate of BD diagnosis, this was not accompanied by organ donation in Izmir. New strategies which aim to increase population awareness and change in perception for organ donation/ transplantation should be planned as soon as possible. In addition, training of health care professionals for good, informative and crystal clear communications with patient relatives should be encouraged.

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