Investigating the Obstacles in the Process of Organ Donation from Patients with Brain Death in the Educational and Medical Hospitals of Northern Iran 2021-2023

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Abstract:

Background and Objective: Organ donation following brain death is an important way to provide organs for transplantation. This study was conducted in order to identify the obstacles in the organ donation process following brain death in the transplant center of northern Iran.

Materials & Methods: This cross sectional study was conducted on 195 patients with brain death admitted to educational and medical hospitals of Guilan University of Medical Sciences between March 20, 2021 and March 20, 2023. Based on the research criteria, the patients were divided into two groups suitable and unsuitable for organ donation. From the patient's files, information related to age, gender, underlying disease, smoking, level of education, the cause of brain death and in case of non-consent to donation, the reasons of family refusal of organ donation was extracted and recorded in the data collection form. Finally, the results were compared between the two groups. The recorded data was analyzed in SPSS software, version 21. The significance level was considered less than 0.05.

Results: In our study, the majority of patients were men with a number of 137 (70.30%) and an average age of 51.8 ± 20.92. The main cause of brain death in two groups suitable and unsuitable for donation was traumatic and cerebro vascular events, respectively (P = 0.0001). Also, there was a statistically significant difference between the two groups in terms of age (P = 0.0001), level of education (P = 0.0001), history of smoking (P = 0.0001) and underlying disease (P = 0.0001). The refusal rate of families to donate organ was 31% that the most important reason was not accepting brain death as the cause of death. The results of the study showed that after the inappropriateness of the conditions of brain dead patients and their organs for donation, the family, lack of consent is the most important factor that leads to organ donation failure. Although, in the investigation of the relationship between the factors of age (P = 0.380), gender (P = 0.304), level of education (P = 0.160), marriage (P = 0.060) and ethnicity (0.975) with consent to donation by relatives, no significant relationship was observed.

Conclusion: The results of the study showed that after the inappropriateness of the conditions of brain dead patients and their organs for donation, the family, lack of consent is the most important factor that leads to organ donation failure. Also, there are several factors that prevent the relatives of brain dead patients from organ donation, the most important of which is the lack of sufficient information on brain death and the organ donation process and the lack of appropriate educational interventions in this field.

Keywords: Transplantation, Brain Death, Organ Donation

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Background and Objectives

Organ transplantation is the preferred treatment for patients with advanced organ failure. Due to the medical and legal barriers associated with living donors, the use of organs from brain-dead patients has been increasingly adopted as a viable treatment method worldwide.[1,2] Brain death occurs when all brain functions cease, and irreversible brain damage ensues.[3,4] Despite the rise in brain death incidences in recent years, the current supply of transplantable organs remains significantly lower than the demand. This growing gap between the number of organ donors and recipients poses a serious challenge for countries globally.[3] Although one deceased donor has the potential to save eight lives, the rate of deceased organ donation in Asia remains disproportionately low.[5] Iran is among the countries facing a shortage of donated organs.[3] Annually, there are between 2,500 and 4,000 cases of brain death in Iran that could be potential candidates for organ donation. However, in 2017, only approximately 900 families of brain-dead patients consented to organ donation. With an organ donation rate of 10.9 per one million people, Iran ranks 27th globally.[6] Numerous barriers contribute to the shortage of donated organs. After identifying a potential donor and confirming brain death, the patient only becomes a candidate for organ donation if the organs are suitable and the relatives provide consent. However, only 30% of identified cases proceed to the donation process. Reasons for this dropout rate include unsuitable potential donors (due to infections, advanced age, malignancy, etc.), unsuitable organs (e.g., loss of glomerular filtration, elevated liver enzymes, etc.), lack of consent for organ donation by the next of kin, and cardiac arrest of the brain-dead patient before the organ donation process can be completed.[7,8] Among these barriers, the lack of family consent is one of the most significant obstacles to meeting the need for organ transplants in many countries.[9] The complexity of human nature, the influence of socio-cultural and religious factors, and the interplay between personal and social conscience play crucial roles in family decision-making for organ donation. Understanding the reasons behind family refusal to donate organs can aid the transplant team and family members in making informed decisions regarding organ donation. Moreover, the factors affecting the donation process vary from country to country and even across different regions within a country. Identifying these factors can help policymakers design targeted strategies and potentially increase the number of organ donations from patients with donation potential in the future. Given that Gilan is a transplant hub in northern Iran, where many patients hope for transplantation, we aimed to review the cases of brain-dead patients and identify the factors affecting organ donation at this center. By addressing the existing barriers, we strive to increase the rate of organ donation at this center.

Materials and Methods

This cross-sectional study was conducted following approval from the Deputy of Research and the issuance of ethics code number IR.GUMS.REC.1401.238. The study aimed to investigate the factors leading to the non-donation of organs from brain-dead patients in educational and medical centers in northern Iran from April 2021 to March 2023. The inclusion criteria encompassed all brain-dead patients hospitalized in the educational and medical centers of Gilan University of Medical Sciences during the specified period. Exclusion criteria included incomplete information in medical records and patient files. Data were obtained from the Ministry of Health's brain death case registration system and patient files. Based on evaluation criteria, patients were categorized into two groups: suitable and unsuitable for organ donation. The unsuitable donor group included patients for whom organ use was impossible due to medical conditions, legal issues, and cardiac arrest. Unsuitable medical conditions included age over 65, systemic infections

(sepsis), multi-organ failure, metastatic cancer, positive COVID-19 PCR test, and chronic transmissible infections (Hepatitis B, C, or HIV). The suitable donor group included patients who had at least one organ suitable for transplantation, and their legal heirs were counseled for brain death awareness and consent for organ donation. Patients initially considered suitable for donation but who experienced hemodynamic instability between brain death diagnosis and the donation process were also included in this group. Subsequently, suitable donors were divided into two groups based on family consent or non-consent for organ donation. Information such as age, gender, underlying disease, education level, marital status, ethnicity, organ donation card status, causes leading to brain death, and reasons for family non-consent for organ donation were extracted from all patients' files and recorded in the data collection form. Causes leading to brain death were categorized into: traumatic (traumatic brain injury from blunt and penetrating mechanisms), cerebrovascular (ischemic or hemorrhagic stroke, intracerebral hemorrhage due to high blood pressure, and rupture of brain aneurysm), cardiovascular (heart attack, arrhythmia, rupture of aortic aneurysm), malignancy and other causes. Reasons for family non-consent for donation were categorized based on Mojtabai and colleagues' study into: disbelief in brain death as death, fear of family blame and guilt, religious beliefs and hope for a miracle, denial, dissatisfaction with hospital care, deceased's negative opinion on organ donation during lifetime, opposition from influential negative individuals, ethnic and social issues, lack of trust in the organ donation system, concern about the fate of donated organs.[10] If family non-consent information was unavailable or unclear in the file, researchers contacted key family members with the help of a trained coordinator with acceptable communication skills and confirmed the reasons through semi-structured interviews. Subsequently, information on patients in the two groups (suitable and unsuitable for organ donation) was compared. Additionally, reasons for family refusal to donate organs were analyzed separately, and patient information in the two groups (consent-giving and refusing) was compared.

Statistical Analysis

All data were analyzed using SPSS software version 21, with a significance level set at less than 0.05. Data frequencies were expressed as numbers and percentages, and mean quantitative data were presented as mean ± standard deviation. The Chi-square and Fisher's exact tests were utilized to examine the relationships between variables, and the Odds Ratio was employed to indicate the strength of these relationships.

Table 1 - Frequency distribution of reasons why brain-dead patients under study are unsuitable for organ donation

Reasons why brain-dead patients are unsuitable for organ donation	*Number*	*Percentage*
Advanced patient age	*41*	*38.3*
Uncontrolled systemic infections - MOF	*28*	*26.2*
Malignancy	*11*	*10.3*
Covid_19	*10*	*9.3*
Hemodynamic instability	*9*	*8.4*
Legal prohibitions	*5*	*4.7*
Active brain infections (encephalitis)	*1*	*0.9*
HIV	*1*	*0.9*
Creutzfeldt-Jakob	*1*	*0.9*
Total	*107*	*100*

Table 2- Comparison of the distribution of personal characteristics variables in two groups: suitability and unsuitability of organs of brain-dead patients for organ donation

Variable	Organ suitability status	Organ suitability for donation status		Organ unsuitability for donation		Probability value
		Number	Percentage	Number	Percentage	
Gender	Male	69	50.4	68	49.6	P = 0.024
	Female	19	32.8	39	67.2	
Age (years)	Less than or equal to 30	26	14168	12	31.6	P < 0.001
	50-31	33	66	17	34	
	70-51	29	54.3	35	54.7	
	More than 70	0	0	43	100	
Education	Illiterate-Primary	7	13	47	87	P < 0.001
	To Diploma	17	47.2	19	52.8	
	Diploma	36	59	25	41	
	University	28	63.6	16	36.4	
Organ Donor Card	Yes	9	90	1	10	P = 0.003
	No	79	42.7	106	57.3	
Smoking and Alcohol Use	Yes	17	25	51	75	P < 0.001
	No	71	55.9	56	44.1	
Hypertension	Yes	18	19.1	76	80.9	P < 0.001
	No	70	69.3	31	30.7	
Heart Disease	Yes	2	6.2	30	39.8	P < 0.001
	No	86	52.8	77	47.2	
Surgery	Yes	6	12.2	43	87.8	P < 0.001
	No	82	56.2	64	43.8	
Diabetes	Yes	5	9.8	46	90.2	P < 0.001
	No	83	57.6	61	42.4	
Malignancy	Yes	0	0	10	100	P = 0.003
	No	88	47.6	97	52.4	
Causes of Brain Death	Trauma	52	71.2	21	28.8	P < 0.001
	Cerebrospinal causes	28	32.9	57	67.1	
	Malignancy	0	0	13	100	
	Cardiovascular causes	5	33.3	10	66.7	
	Unknown	3	33.3	6	66.7	

Table 3 - Examination of the frequency distribution of reasons for the family's dissatisfaction with organ donation among brain-dead patients under study

Reasons for dissatisfaction of families of brain-dead patients	*Number*	*Percentage*
Disbelief in brain death as death	*21*	*33.87*
Fear of family reprimand and feeling guilty	*12*	*19.35*
Religious beliefs and expectation of miracles	*10*	*16.12*
Denial	*5*	*8.1*
Dissatisfaction with hospital care	*5*	*8.1*
Declaration of the deceased's negative opinion of organ donation during life	*3*	*4.8*
Opposition of negative influential people	*2*	*3.2*
Ethnic and social problems	*3*	*4.8*
Distrust of the organ donation system and concern about the fate of donated organs	*1*	*1.6*
Total	*62*	*100*

Table 4- Comparison of the distribution of personal characteristics variables in two groups leading to donation and non-donation in brain-dead patients with healthy organs that can be donated

Variable	*Organ donation status / Status*	*Doing organ donation*		*Not doing organ donation*		*Probability value*
		Number	*Percentage*	*Number*	*Percentage*	
Gender	*Male*	*46*	*66.7*	*23*	*33.3*	*P = 0.304*
	Female	*15*	*78.9*	*4*	*21.1*	
Age (years)	*Less than or equal to 30*	*19*	*73.1*	*7*	*26.9*	*P = 0.380*
	31-50	*20*	*60.6*	*13*	*39.4*	
	51-70	*22*	*75.9*	*7*	*24.1*	
Education	*Illiterate-Primary*	*6*	*85.7*	*1*	*14.3*	*P = 0.160*
	Up to Diploma	*15*	*88.2*	*2*	*11.8*	
	Diploma	*22*	*61.1*	*14*	*38.9*	
	University	*18*	*64.3*	*10*	*35.7*	
Marital status	*Married*	*40*	*63.5*	*23*	*36.5*	*P = 0.060*
	Single	*21*	*74*	*4*	*16*	
Organ donation card	*Yes*	*8*	*88.9*	*1*	*11.1*	*P = 0.179*
	No	*53*	*67.1*	*26*	*32.9*	
Cause of brain death	*Trauma*	*20*	*71.4*	*8*	*28.6*	*P = 0.039*
	Cerebral vascular causes	*36*	*62.2*	*16*	*30.8*	
	Cardiovascular causes	*5*	*100*	*0*	*0*	
	Unknown	*0*	*0*	*3*	*100*	
Ehnicity	*Gilak*	*43*	*69.4*	*19*	*30.6*	*P = 0.975*
	Talesh	*11*	*64.7*	*6*	*35.3*	
	Turk	*2*	*100*	*0*	*0*	
	Persian	*4*	*66.7*	*2*	*33.3*	
	Kurdish	*1*	*100*	*0*	*0*	

Table 5 - Comparison of the distribution variable and odds ratio of causes leading to brain death in the two groups leading to organ donation and non-donation in brain-dead patients with healthy organs that can be donated

Cause of brain death	*Organ donation status / Status*	*Doing organ donation*		*Not doing organ donation*		*Probability value*	*Odds Ratio*
		Number	*Percentage*	*Number*	*Percentage*		
Trauma	*Yes*	*36*	*62.2*	*16*	*30.8*	*P = 0.983*	*Odds Ratio = 1.01*
	No	*25*	*69.1*	*11*	*30.6*		*CI95% = 0.4-2.53*
Cerebral vascular causes	*Yes*	*20*	*71.4*	*8*	*28.6*	*P = 0.764*	*Odds Ratio= 0.086*
	No	*41*	*68.3*	*19*	*31.7*		*CI95%=0.32-2.3*
Cardiovascular causes	*Yes*	*5*	*100*	*0*	*0*	*P = 0.318*	*Odds Ratio = 1.48*
	No	*56*	*67.5*	*27*	*32.5*		*CI95% = 1.27-1.7*
Unknown	*Yes*	*0*	*0*	*3*	*100*	*P = 0.027*	*Odds Ratio = 3.54*
	No	*61*	*71.8*	*24*	*28.2*		*CI95% = 2.52-4.97*

Findings

Out of 326 patients admitted with a level of consciousness below 5 in the educational and medical hospitals of Gilan Province during 2021-2022, 195 cases of brain death were investigated.

Among the brain-dead patients, 137 (70.3%) were males with an average age of 51.8 ± 20.92 years and an average body mass index (BMI) of 26.09 ± 3.11 kg/m².

In terms of ethnicity, the majority of patients were Gilaks, 147 (75.4%), and most were married, 158 (81%). Hypertension was the most common underlying disease among the patients. Regarding the causes of brain death, the highest percentages were: Cerebrovascular causes: 85 patients (43.6%), trauma: 73 patients (37.4%), cardiovascular causes: 15 patients (7.7%), malignancies: 13 patients (6.7%), unknown causes: 9 patients (4.6%).

Upon reviewing the outcomes of 195 patients clinically diagnosed with brain death, 107 patients (54.9%) were categorized as unsuitable donors due to inappropriate conditions and failure to meet donation criteria. Of the 88 patients (45.1%) deemed suitable for organ donation, 27 patients (13.8%) had families who refused organ donation for various reasons. Among the remaining 61 patients who consented to donate, 3 patients (1.5%) died before organ harvest, and ultimately, 58 patients (29.7%) successfully underwent organ harvest and donation.

In examining the causes of unsuitability for organ donation among the 107 brain-dead patients, the most prevalent reasons included advanced age, uncontrolled systemic infections, multi-organ failure (MOF), and malignancies (Table 1).

In assessing the suitability of brain-dead patients' organs for donation based on

certain personal characteristics, a statistically significant correlation was found between the suitability of organs for donation and factors such as gender, age groups, education level, smoking and alcohol consumption, underlying disease, and possession of a donor card (P < 0.05) (Table 2).

In investigating the reasons for families' refusal to donate organs, the most common reasons were disbelief in brain death as the cause of death (33.87%), fear of family blame and guilt (19.35%), and religious beliefs and hope for a miracle (16.12%) (Table 3).

In examining the correlation between relatives' approval of organ donation and the personal characteristics of brain-dead patients, it was found that there was no statistically significant correlation based on gender (P = 0.304), education level (P = 0.440), marital status (P = 0.060), age groups (P = 0.380), or ethnicity. However, a statistically significant correlation was observed between the approval of organ donation and the distribution of the causes leading to brain death (P = 0.039) (Table 4). Specifically, no statistically significant correlation was found between individual causes such as trauma, cerebrovascular causes, and cardiovascular causes with the approval of organ donation (P > 0.05), except for unknown causes of brain death, which showed a statistically significant correlation (P = 0.027) (Table 5).

Discussion

This study aimed to investigate the existing barriers in the organ donation process from brain-dead patients in teaching hospitals in northern Iran. The primary reason preventing the use of organs from brain-dead patients was found to be the unsuitability of the patient's condition and organs. If the organ is deemed suitable for donation, the lack of family consent remains the most significant barrier to organ donation. The results of this study also indicated statistically significant differences between brain-dead patients suitable and unsuitable for donation in terms of age, education level, smoking and alcohol consumption history, underlying disease, and the underlying cause leading to brain death. However, no statistically significant correlation was observed between family consent and factors such as age, gender, education level, marital status, or ethnicity.

Brain death occurs when all brain functions cease and irreversible brain damage is sustained. Organ donation is an altruistic decision that can be made by family members after brain death.[11] Various organizations and medical centers have implemented interventions and training courses to increase consent for organ donation.[12] However, the shortage of organs for donation remains a serious global issue, resulting in thousands of deaths each year for patients on the transplant waiting list.[13] After identifying a brain-dead patient, determining the eligibility of the potential donor with family consent and the absence of organ donation barriers, such as medical contraindications, cardiopulmonary arrest, and positive serology, is crucial. By understanding and overcoming family motivations, there is significant potential to increase the organ donation rate.

In the present study, 31% of the families of brain-dead patients refused to donate their patients' organs, with the primary reason being the non-acceptance of brain death as the cause of death. Many families did not have a clear understanding of brain death and the prognosis of their patients, leading to their refusal to accept the death of their loved ones and consequently not consenting to organ donation. A study conducted by Abbasi and colleagues on organ donation barriers in Iran similarly found that the non-acceptance of brain death as the cause of death due to a lack of awareness was the main reason for family refusal.[3] The medical and legal definition of brain death encompasses not only cardiopulmonary arrest but also the cessation of brain function. However, this concept is challenging for the general population and healthcare professionals alike, making it a significant barrier for families in deciding about organ donation.

Due to the lack of adequate public education about brain death and the necessity and process of organ donation in Iran, many individuals do not possess a clear understanding of it. Consequently, numerous families hold incomplete or incorrect information regarding brain death and organ donation, resulting in their reluctance to donate organs.

Another significant reason for families' refusal to donate organs is the fear of blame from others and feelings of guilt. Studies conducted by Abbasi and colleagues, as well as by Ghorbani and colleagues, identified fear and worry as barriers to organ donation.[3,14] Many participants believed that permitting organ donation would lead to being blamed by others. Consequently, making a decision in this regard was challenging for them. Cultural activities that foster a more positive attitude toward organ donation can be beneficial. Such families should be supported and honored by the community, rather than blamed, for their decision to donate organs.

Religious beliefs and the expectation of a miracle were also significant reasons for families' refusal to donate organs in our study. Studies conducted in Islamic countries have shown that the families of Muslim individuals believe that human organs will testify for or against the person on the Day of Judgment. Many participants believed that facilitating the death of patients is prohibited by their religion and considered a major sin. Additionally, many participants believed that death is in God's hands. Beliefs in bodily resurrection and God's will in the natural course of treatment were barriers to organ donation in several studies.[3,14-16] On the other hand, belief in God reinforces the idea that a miracle can happen. Therefore, for families who oppose organ donation, the lack of understanding of brain death diagnosis and the belief in the return of brain function are compelling reasons for refusing organ donation.

Denial of brain death by the patient's relatives was another reason for refusing organ donation in this study. In the study conducted by Bahrami and colleagues, the denial of brain death by the patient's relatives was also one of the main reasons leading to the refusal of organ donation.[16] A brain-dead patient creates a complex situation for family members, as they are saddened by the loss of their loved one and, simultaneously, must decide about organ donation. This situation causes significant emotional pressure and greatly affects their decision-making.[7] Given the vulnerability of families, the donation team must be able to instill a sense of honesty, compassion, and patience in the family. This approach enables the family to feel sympathy and empathy and provides sufficient time to accept the brain death of their loved one. Dissatisfaction with hospital care was another reason for relatives' refusal to donate organs. Other studies have also cited dissatisfaction with care teams and the lack of sufficient and effective communication between medical staff and families as barriers to organ donation.[17] Furthermore, awareness of the deceased's negative opinion on organ donation during their lifetime, ethnic issues, lack of trust in the organ donation system, and concern about the fate of donated organs were additional reasons leading to families' refusal to donate organs. In such cases, an experienced coordinator can resolve conflicts and uncertainties for the family and guide them toward making the right decision.[7]

In our study, the majority of patients were men. The primary cause of brain death was cerebrovascular accidents, followed by trauma, aligning with previous studies.[18,19] When comparing the causes leading to death, traumatic events and cerebrovascular accidents were the most common causes among the suitable and unsuitable donation groups, respectively. In the study conducted by Bertasi et al., which examined the relationship between traumatic and non-traumatic causes of brain death and organ donation, it was found that the ratio of donors to non-donors was higher in the traumatic group.[18]

Similarly, the study by De Oliveira et al. yielded comparable results, likely due to the increased availability of healthy organs in the

traumatic group. Age demonstrated a significant difference between patients with suitable organs for donation and those with unsuitable organs for donation. The average age in the unsuitable donation group was significantly higher than in the suitable group. Underlying conditions such as diabetes, hypertension, smoking, and alcohol consumption were more prevalent in the unsuitable donation group, explaining the higher incidence of cerebrovascular accidents as the cause of brain death in this group. In a study conducted by Bertasi et al. examining factors affecting organ donation, the prevalence of certain chronic diseases and lifestyle habits of donors was assessed. A relationship was shown between the absence of underlying diabetes and organ donation,[18] which was confirmed by other studies.[20] Additionally, these variables were evaluated in relation to causes leading to brain death, showing that underlying conditions such as diabetes, hypertension, and smoking were more common in the non-traumatic brain death group. Comparing variables such as age, gender, education level, and ethnicity between the consent and non-consent groups for donation revealed no significant statistical differences. Studies have shown that factors such as religion and ethnicity are influential in the organ donation process, with members of specific religious groups or ethnicities potentially having different views on organ donation.[11,21,22]

In our study, all brain-dead patients were residents of Gilan, and the majority were Gilak, so ethnicity did not affect our study results. When comparing the causes of brain death separately in the two groups, a statistically significant difference was observed only in cases of unknown causes of brain death, indicating families' unwillingness to donate organs when the cause of brain death is unknown.

Organ donation is a complex process where a positive attitude alone cannot be an effective factor. Instead, this factor, along with many others, can lead to achieving desired results. To increase the rate of obtaining consent from the relatives of brain-dead patients, it is recommended that educational programs and social activities be implemented to enhance the community's familiarity with brain death and the organ donation process. Improving communication between healthcare staff and families, making the brain death process, diagnosis, laws, and organ donation procedures transparent for families, continuing psychological support for families after the donation process, and taking actions to ensure families feel validated and satisfied after organ donation are advisable. In cases of family refusal, specialized counseling from experts in dealing with families should be employed. Ultimately, in the family interview session, all influential decision-makers should be considered to address fears and concerns.

Conclusion

The results of this study indicated that, after the factor of the unsuitability of the brain-dead patient's condition and organs, family refusal is the most significant factor leading to non-donation of organs. Additionally, several factors prevent the families of brain-dead patients from donating organs, the most important of which are the lack of sufficient information about brain death and the organ donation process, and the shortage of appropriate educational interventions in this area. Proper education in this field can eliminate existing barriers. The study also showed statistically significant differences between the groups of suitable and unsuitable brain-dead patients for donation in terms of age, education level, smoking and alcohol consumption history, underlying diseases, and the underlying factor leading to brain death. However, when examining the relationship between factors such as age, gender, education level, marital status, and ethnicity with consent to donation by relatives, no significant relationship was observed.

Limitations and Suggestions

Since this study was conducted on brain-dead patients hospitalized in the hospitals of Gilan University of Medical Sciences, the

sample size was limited. Additionally, this study was retrospective and based on recorded information in patients' files and hospital data. Therefore, it is recommended that future studies be multi-centered with a larger sample size and, if possible, conducted through face-to-face interviews with the relatives of brain-dead patients to obtain more accurate results.

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