The Effect of Using Protocol by Trained Nurses on Status of Brain-Dead Patients Candidate for Organ Donation

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ABSTRACT

Introduction: Due to the increasing number of patients in need of organ transplants and the limited number of qualified brain-dead patients, it is necessary to take steps to increase the number and performance of transplantable organs of brain-dead patients through optimal compliance with scientific protocols. **Methodology:** In this study, two groups of 32 eligible brain-dead patients were randomly assigned to two groups. In the first group, all orders were issued by the physician and the nurses did not have the right to interfere in the diagnosis and treatment processes. However, in the second group, the trained nurses used the protocol in caring for and treating patients and sought medical help when needed. **Findings:** There were no clear differences in the conditions of the patients in the two groups before the intervention. However, after the intervention, the mean serum sodium, potassium, and BUN levels, the mean arterial pressure, and the cardiac index were closer to normal values and the need for vasopressors was lower in the protocol group than in the non-protocol group. However, the two groups did not differ significantly in serum creatinine and liver enzymes (ALT, AST) levels or immortality rate of brain-dead patients and transplant rejection in the first 3 months after organ donation. **Discussion and Conclusion:** It seems that the use of the scientific protocol in caring for brain-dead patients by trained nurses can be effective in improving the physiological conditions of patients.

Key Words: brain death, organ transplantation, nursing care.

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INTRODUCTION

Annually, more than one million people worldwide undergo organ transplant surgery [1] and some survive for more than 25 years. However, a large number of patients are always on the waiting list for an organ transplant [2]. Due to the problems and high costs of maintenance therapies in people with organ failure, organ transplantation is considered a preferred method today [3] and has grown dramatically in the last three decades [4]. Despite extensive efforts to increase organ donation from brain-dead patients, there is still a significant shortage of donors [5].

In 1976, brain death was defined as the complete and irreversible loss of brainstem activity [6]. Brain death refers to the cessation of all brain and brainstem functions together with deep coma, without any evidence showing the use of central nervous system (CNS) depressant drugs, hypothermia, and metabolic, toxic, or endocrine disorders [7]. Patients meeting brain death criteria due to neurological problems who have transplantable organs should be introduced to the organ transplant system by the treating physician and, after obtaining consent and following the legal procedures, should receive the necessary care [8].

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One of the main limiting factors in organ donation from brain-dead patients is the shortage of suitable donors and organs. Brain death causes physiological changes that, if not well managed, will lead to organ degradation; however, the functional quality of transplanted organs can be increased by controlling the conditions [9]. In this regard, guidelines have been used to better care for brain-dead patients that have improved transplant outcomes and the number of transplantable organs [10]. These guidelines include protocols related to caring for brain-dead patients in such a way as to preserve the physiological conditions and improve the quality of transplantable organs [11].

Also, other studies aimed at investigating the effects of protocols in brain-dead patients by anesthesiologists, especially after cardiac arrest, showed that the use of these protocols led to an increase in the number of transplantable organs and improved organ function [12]. Application of specific protocols in caring for brain-dead patients who are a candidate for organ donation can increase the quality of transplanted organs including lungs [13].

Caring for brain-dead patients in ICUsis a multidisciplinary effort in which nurses play an important role [14], and Carlin *et al.* emphasized the role of nurses in caring for brain-dead patients [15].

Considering the increase in the number of transplants over the past years, it is necessary to improve the function of transplant organs by reviewing the methods of caring for brain-dead patients. The present study examined the effects of increased participation by trained nurses on the quality of caring for brain-dead patients.

MATERIALS AND METHODS:

This double-blind clinical trial was carried out on brain-dead patients in two separate ICUs at Bahonar Hospital in Kerman after receiving approval of the Kerman University of Medical Sciences Vice Chancellor for Research and obtaining the informed consent of the brain-dead patients' legal guardians. In one of the ICUs, the patient care protocol [11] was taught for two months theoretically and practically to the nurses involved in caring for brain-dead patients. After ensuring their readiness, the implementation stage of the study began.

Inclusion criteria

Patients aged 18 to 60 years without any underlying disease and infection who were candidates for organ donation due to brain death, and whose legal guardians signed the consent forms for their organ donation and participation in the study, were included in the research. Patients with infection symptoms or positive culture results were excluded from the study. The sample size (n=32) was calculated for the groups according to the results of a reliable pilot study and based on the effect size formula [16]. The eligible patients were divided into two groups using a simple randomization method. In the control group, the patients were admitted to ICU-1 and visited by the physician who issued the diagnostic and treatment orders. Nurses were not permitted to intervene in the diagnosis and treatment processes without the physician's permission. In ICU-2 (the case group), the nurses, based on the protocol related to caring for brain-dead patients they had already been taught, performed the diagnostic and therapeutic procedures and the attending physician issued the complementary orders (if needed). Serum sodium, potassium, urea, creatinine, AST, and ALT levels, mean arterial pressure, cardiac index, urine output, and heart rate were measured at specific intervals in both groups and charted. Also, the transplant rejection rate within 3 months after transplantation was recorded. The obtained data were statistically analyzed using descriptive statistics, Pearson correlation, and the independent *t*-test in SPSS 20 at the significance level of **<0.05**.

RESULTS:

In this study, the mean age of the patients was 36.068±17 years:37.12±18 years in the control group and 34.96±15 years in the case group with no significant difference between them in this regard (p=0.81). Each group had 32 members, and 30 patients in the protocol group and 28 patients in the non-protocol group received organs. 42 of the 58 evaluated patients were male and 16 female (23 male and 7 female in the protocol group and 19 male and 9 female in the non-protocol group). There was no significant relationship between the two groups in terms of gender (p=1.00) (Table 1).

In this study, the mean serum sodium level at baseline was 143.46±11.61 mEq/L in the protocol group and 139.29±8.07 mEq/L in the non-protocol group, with no significant difference between them(p=0.086). However, after the intervention, the mean serum sodium level was significantly closer to the normal values in the protocol group (147.86±7.62mEq/L) than the non-protocol group (156.54±14.29mEq/L) (p=0.002).

The mean serum potassium level at baseline was .357±0.67 mEq/L in the protocol group and 3.65±0.37mEq/L in the non-protocol group, with no significant difference between them (p=0.098). However, and the end of the research, the mean serum potassium level was significantly closer to the physiologic values in the protocol group (4.28±0.29mEq/L) than in the non-protocol group (3.31±0.67mEq/L) (p=0.00).

The mean serum BUNlevel at baseline was 13.88±3.86 mg/dl in the protocol group and 12.32±2.73 mg/dl in the non-protocol group, with no significant difference between them (p=0.056). However, at organ transplantation time, the mean serum BUN level was 13.22±3.19 mg/dLin the protocol group and 18.00±5.17 mg/dLin the non-protocol group (p=0.00).

The mean serum creatinine level at baseline was 0.98±0.04 mg/dL in the protocol group and 0.84±0.06 mg/dL in the non-protocol group, with no significant difference between them (p=0.55). However, at organ transplantation time, the mean serum creatinine level was 1.05±0.07 mg/dL in the protocol group and 1.12±0.08 mg/dL in the non-protocol group (p=0.521).

As can be seen, the mean serum BUN level in the protocol group was significantly closer to the normal level than in the non-protocol group. However, there was no significant difference between the two groups in terms of the mean serum creatinine level (p=0.521).

The mean AST level at baseline was in 43.34±20.06 U/L in the protocol group and 41.11±12.84 U/L in the-protocol (p=0.582). However, after the intervention, the mean AST level was 44.02±21.79 U/L in the group protocol and 42.91±13.41 U/L in the non-protocol group (p=0.798).

The mean ALT level at baseline was 46.48±19.67 U/L in the protocol group and 48.35±9.16 U/L in the non-protocol group (p=0.084). However, after the intervention, the mean ALT level was 48.68±22.76 U/L in the protocol group and 49.80±11.89 U/L in the non-protocol group (p=0.095).

The mean urine output at baseline was 2.71±0.82 mL/kg/min in the protocol group and 2.49±0.61mL/kg/min in the non-protocol, with no significant difference between them (p=0.384). However, at the end of the research, the mean urine output was 1.81±0.53 mL/kg/min in the protocol group and 2.33±0.24 mL/kg/min in the non-protocol group (significantly higher in the non-protocol group compared to the protocol group) (p=0.027).

The cardiac index at baseline was 2.69±0.51 L/min/m^2 in the protocol group and 2.74±0.73 L/min/m^2in the non-protocol group, with no significant difference between them (p= 0.07). However, at transplantation time, the cardiac index was 2.84±0.54L/min/m^2in the protocol group and 2.45±0.53 L/min/m^2in the non-protocol group, with a significant difference between them (p=0.004).

The mean arterial pressure at baseline was 6.49±0.94 mmHg in the protocol group and 6.72±1.10 mmHg in the non-protocol group, with no significant difference between them (p=0.357). However, at the end of the research, the mean arterial pressure was 7.10±1.13 mmHg in the protocol group and 6.36±1.39 mmHg in the non-protocol group, with a significant difference between them (p=0.017). (Table 2)

A comparison of the transplant outcomes showed that there was no significant difference between the protocol and non-protocol groups in this respect so that the transplanted organs were rejected in 3 cases in the protocol group and 4 cases in the non-protocol group (p=0.428) (Table 3).

In the protocol and non-protocol groups, twelve (40%) and sixteen (57.1%) of the patients needed vasopressors, respectively, and eighteen (60%) and twelve (42.8%) patients did not. According to these results, a significant relationship was observed between the two groups in terms of the need for vasopressors (p=0.016) (Table 4).

The mortality rate before transplantation was two (6%) in the protocol group and four (12.5%) in the non-protocol group, which was not statistically significant (p=0.084).

DISCUSSION:

The present study intended to investigate the effect that using the protocol by trained nurses in caring for brain-dead patients had on physiological conditions of the patients and short-term outcomes in organ transplantation. In this study, the mean serum sodium and potassium levels, the mean arterial pressure, the need for vasopressors, cardiac index and urine output were evaluated as physiological criteria, the mean serum BUN and creatinine levels as renal function indicators and the mean serum ALT and AST levels as liver function indicators.

The health status of the patients in the two groups did not differ significantly before the intervention, but at the end of the care period and just before the organ removal, the serum sodium and potassium levels significantly approached the physiological values in the protocol group, which could probably be attributed to more regular monitoring and compensation of electrolyte based on the protocol. In addition, the BUN levels and the mean arterial pressure were closer to normal in the protocol group, possibly due to better compensation for intravenous liquids so that the need for vasopressors was lower and the cardiac index was significantly higher in this group than in the non-protocol group (which probably resulted from more accurate use of the protocol by the nurses). However, the two groups had no significant difference in terms of mortality rate during the care period and in transplant rejection in the first 3 months after organ donation. Also, the serum liver enzymes (ALT, AST) and creatinine levels were within the physiological range in both groups at the end of the study and no significant difference was observed between them in this regard.

Guetti NR *et al.*reported that nurses were adequately aware of physiological changes resulting from brain death and, if this knowledge was applied, the role of nurses in changing the transplant scenario would be more prominent [17]. However in Iran, since nurses do not directly interfere in diagnosis and treatment processes, they must pass the educational course before interfering in these processes.

Luis FA *et al.* (2006) showed that the use of the protocol had a significant effect on improving the condition of the lungs donated by brain-dead patients [18], which confirmed the positive effect of the protocol on the outcome of organ donation from brain-dead patients.

Among the previous research, Glauco A. Westphal also demonstrated that the use of the VIP (Ventilation, Infusion, Pumping)care checklist could reduce the chances of cardiac arrest in brain-dead patients by 2 to 3 times and

increase the number of transplantable organs over time. It was also found that the number of items that were under surveillance had an inverse relationship with cases of cardiac arrest. Therefore, it seems that such a checklist was able to increase physicians' awareness in ensuring the "standard of care" of brain-dead patients. Also, a checklist was likely to improve the commitment of the staff with regard to the quality of care for brain-dead patients [19]. Although the mortality rate was not reduced in the present study, the use of the protocol increased patients'hemodynamic stability.

R. Abuanzehshowed that the use of an active management program in the care of brain-dead patients led to the recovery of more than half of the organs from potential heart donors, whereas the implementation of this program did not affect the outcomes of transplantation [20]. Our results also showed that the use of the protocol in the first 3 months after transplantation had no effect on the functional quality of the transplanted organs but was effective in stabilizing the patients' physiological conditions.

After interviewing the nurses in the ICUs in Sweden, Flodén*et al.*reported that there were numerous barriers to organ donation. They suggested that the formulation and implementation of a practical program including training in the diagnosis of brain death, interpersonal relationships, interaction with relatives, and regular follow-up regarding issues related to organ donation would help resolve these problems [21].

In the present study, increasing the awareness and knowledge of nurses and implementing a practical program by them were effective in improving the condition of brain-dead patients. Also, the condition of these patients improved significantly with increasing the involvement of trained nurses in the care of brain-dead patients. It seems that nurses can play an effective role in different parts of the organ donation system as Meyer K *et al.* showed that the provided pieces of training could develop the skills and professional performance of nurses and facilitate the organ donation process [22].

Z. Keshtkaran*et al.* showed that it was necessary to train nurses and support their performance in caring for brain-dead patients. They also noticed that it was essential to develop programs to promote the care of these patients in ICUs [23]. These results are consistent with ours.

Finally, it should be mentioned that the use of the protocol in caring for brain-dead patients by trained nurses can be effective in carefully controlling and adjusting variables such as serum sodium, potassium, and BUN levels, mean arterial pressure, cardiac index and urine output. Also, based on the results of this study, the number of patients using vasopressors in the protocol group was lower than the non-protocol group. This could reduce the complications caused by taking vasopressors.

Therefore, it seems that proper training of nurses in the use of the protocol and increasing their participation with physicians can improve the physiological conditions of brain-dead patients.

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Conflict of Interest:

Not declared

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Table 1: Comparison of gender differences between the protocol and non-protocol groups

P-value	Group			Sex
	No- protocol	Protocol	Total	
1	19(67.8%)	23(76.6%)	42(72.4%)	Male
	9(32.1%)	7(23.3)	16(27.5%)	Female

Table 2: Comparison of the variables between the protocol and non-protocol groups

p-value	Group		Variable
	Non-protocol	Protocol	
0.086	139.29±8.07	143.46±11.6	Mean serum Na at first of care
0.002	156.54±14.29	147.86±7.62	Mean serum Na at the end of care
0.098	3.65±0.37	3.57±0.67	Mean serum K at first of care
0	3.31±0.67	4.28±0.29	Mean serum K at end of care
0.056	12.32±2.73	13.88±3.86	Mean BUN level at first of care
0	18±5.17	13.22±3.19	Mean BUN level at end of care
0.55	0.84±0.06	0.98±0.04	Mean serum creatinine at first of care
0.521	1.12±0.08	1.05±0.07	Mean serum creatinine at the end of care
0.582	41.11±12.84	43.34±20.06	Mean serum AST at first of care
0.798	42.91±13.41	44.02±21.79	Mean serum AST at the end of care
0.084	48.35±9.16	46.48±19.67	Mean serum ALT at first of care
0.095	49.80±11.89	48.68±22.76	Mean serum ALT at the end of care
o.384	2.49±0.61	2.71±0.82	Mean urine output at first of care
0.027	2.33±0.24	1.81±0.53	Mean urine output at end of care
0.07	2.74±0.43	2.69±0.51	Mean cardiac index at first of care
0.004	2.45±0.53	2.84±0.54	Mean cardiac index at the end of care
0.357	6.72±1.10	6.49±0.94	Mean of MAP* at first of care
0.017	6.36±1.39	7.1±1.13	Mean of MAP at end of care

Mean arterial pressure*

Table 3: Comparison of transplant outcomes between the protocol and non-protocol groups

P-value	Group		The outcome of the transplanted organ
	Non-protocol	protocol	
0.428	4(17%)	3(10%)	Reject
	24(83%)	27(90%)	Successful

Table 4: Comparison of the protocol and non-protocol groups in terms of the need for vasopressors

P-value	Group		Need to vasopressor
	Non-protocol	protocol	
0.016	16(57.1%)	12(40%)	Yes
	12(42.8%)	18(60%)	NO