INTRODUCTION

The difference between the large organ demand and the low number of transplantations performed represents a serious public health problem worldwide.\(^1\,\,^2\) In Brazil, the loss of transplantable organs from deceased potential donors as a function of medical contraindications, family refusal, or cardiac arrest is notably high.\(^3\)

The strategies to improve the rate of transplants include the enhancement of living-donor programs, the adoption of donation after circulatory death programs, and the increase of donations from brain-dead individuals. This

### ABSTRACT

**Objective:** To assess the effect of the application of a managed protocol for the maintenance care of deceased potential multiple organ donors at two hospitals.

**Methods:** A before (Phase 1)/after (Phase 2) study conducted at two general hospitals, which included consecutively potential donors admitted to two intensive care units. In Phase 1 (16 months), the data were collected retrospectively, and the maintenance care measures of the potential donors were instituted by the intensivists. In Phase 2 (12 months), the data collection was prospective, and a managed protocol was used for maintenance care. The two phases were compared in terms of their demographic variables, physiological variables at diagnosis of brain death and the end of the process, time to performance of brain death confirmatory test and end of the process, adherence to bundles of maintenance care essential measures, losses due to cardiac arrest, family refusal, contraindications, and the conversion rate of potential into actual donors. Student's \(t\)- and chi-square tests were used, and \(p\)-value < 0.05 was considered to be significant.

**Results:** A total of 42 potential donors were identified (18 in Phase 1 and 24 in Phase 2). The time interval between the first clinical assessment and the recovery decreased in Phase 2 (Phase 1: 35.0±15.5 hours versus Phase 2: 24.6±6.2 hours; \(p = 0.023\)). Adherence increased to 10 out of the 19 essential items of maintenance care, and losses due to cardiac arrest also decreased in Phase 2 (Phase 1: 27.8% versus 0% in Phase 2; \(p = 0.006\)), while the conversion rate increased (Phase 1: 44.4% versus 75% in Phase 2; \(p = 0.044\)). The losses due to family refusal and medical contraindication did not vary.

**Conclusion:** The adoption of a managed protocol focused on the application of essential measures for the care of potential deceased donors might reduce the loss of potential donors due to cardiac arrest.

**Keywords:** Tissue donors; Brain death; Clinical protocols; Heart arrest
last option includes to improve brain death reporting, decreasing family refusal, adjusting the contraindication criteria, and reducing losses due to cardiac arrest.\(^{1,2,4-7}\)

In Brazil, the donation rate per million population (pmp) increased 43.6% in the last five years, reaching 10.6 donations pmp. The Brazilian state that exhibits the best performance in this regard is Santa Catarina, where the main reason for the increase in the donation rate is the professionalization and training of the coordinators of Transplant Commissions. Such training is in particular focused on the skills to communicate bad news to the relatives of potential organ donors, as well as on the revision of the criteria used to define the medical contraindications to donation.\(^{3,8,9}\)

The application of these measures began in 2008 and resulted in the reduction of losses by contraindication (2007: 10% versus 2011: 5.2%; p<0.02) and family refusal (2007: 44.9% versus 2011: 24.7%; p<0.001) with a net increase in the actual donations from 14.6 pmp in 2007 to 25.7 pmp in 2011. Nevertheless, the rate of losses due to cardiac arrest (27.8%) remained high.\(^{8,10}\)

The recent publication of Brazilian guidelines for multiple organ maintenance care in deceased adult potential donors represents an important step forwards to achieve uniform management criteria for intensive care teams and might reduce the loss of organs due to cardiac arrest.\(^{11-13}\) However, the wide-scale application of the best scientific findings available to clinical practice depends upon the dissemination and incorporation of such information, which might require many years to occur. Although the introduction of institutional protocols is crucial to reduce that time, the mere availability of such protocols is no guarantee that they will be actually applied.\(^{40}\) In addition to the protocols, healthcare professionals charged with their application play a crucial role by warning the attending staff during management and promoting real-time “course correction”.\(^{14}\) Thus, a managed protocol for potential organ donor maintenance care might reduce losses due to cardiac arrest and increase the number of actual donations.\(^{12,5-7,15}\)

The aim of the present pilot study was to investigate the impact of a managed multiple organ maintenance care protocol in potential deceased donors at two hospitals.

**METHODS**

**Study design and definitions**

An intervention (quasi-experimental) before-and-after study was conducted from January 2010 to January 2012 at the intensive care unit (ICU) of two general high-complexity hospitals in southern Brazil, one of which is public and includes 195 beds and 14 ICU beds, and the other is private with 164 beds and 15 ICU beds. All of the brain-dead patients admitted to both ICUs were consecutively included in the study. A diagnosis of brain death was established according to resolution 1,480/97 of the Federal Medical Council.\(^{16}\) The study was approved by the Research Ethics Committee of Hospital Municipal São José (No. 12,029). Informed consent was waived, as the study investigated the application of an institutional protocol.

**Maintenance care protocols**

The study was divided into two phases: in Phase 1, which lasted from January 2010 to April 2011, the measures for the maintenance care of potential donors were freely established by each intensivist. In that phase, data collection was retrospective using the patients’ clinical records and the documentation available at the In-Hospital Coordination of Organ and Tissue Donation for Transplantation (Coordenação Intra-Hospitalar de Doação de Órgãos e Tecidos para Transplantes - CIHDOTT).

In Phase II, which lasted from May 2011 to April 2012, the managed protocol for deceased potential donor maintenance care based on the Brazilian guidelines published in 2011 was implemented.\(^{11-13}\) The protocol consisted of the adoption of the guidelines,\(^{13}\) which describes the main clinical measures that must be taken in chronological order. Table 1 describes the physiological data and clinical goals that must be accomplished. The continuous assessment of the fulfillment of the various items in the guide was performed at the bedside by CIHDOTT nurses and/or ICU medical interns. The changes introduced in Phase 2 were exclusively organizational and did not demand additional human or structural resources.

**Data collection and analysis**

The data collected from the healthcare form were transferred to an Excel spreadsheet for later analysis. The groups of potential donors in Phases 1 and 2 were compared with regard to their age; gender; cause of brain death; physiological variables at the first clinical assessment of brain death (t0) and upon discontinuation of care – by family refusal, medical contraindication, or recovery (t1); time interval between the first clinical...
Table 1 - Goals and physiological variables analyzed during maintenance care

| Time goals                      | Ventilatory goals                                                                 |
|---------------------------------|-----------------------------------------------------------------------------------|
| a. Δt0 – first clinical assessment: | a. PEEP = 8–10 cmH₂O 60 e 110 |
| graphical complementary test < 6 hours | b. Tidal volume = 5–8 mL/kg 11 |
| b. Δt1 – first clinical assessment: | c. Plateau pressure >30 cm 11 |
| recovery < 24 hours             | d. PaO₂/FiO₂ > 300 11 |
| c. Fulfillment of all time goals| e. Fulfillment of all ventilatory goals |

| Hemodynamic goals              | Endocrine-metabolic goals                                                                 |
|--------------------------------|---------------------------------------------------------------------------------------------|
| a. PAM > 65 mm Hg 11           | a. Methylprednisolone 15 mg/kg every 24 hours |
| b. Urine output > 0.5 mL/kg/h and < 4 mL/kg/h 11 | b. Levothyroxine 300 μg every 24 hours |
| c. Fulfillment of all hemodynamic goals| c. Arginine > 180 mg% 11 |
| Physiological variables        | d. Fulfillment of all hormone replacement goals |
| a. pH, base excess, PaO₂/FiO₂ 60 e 110 | e. Fulfillment of all endocrine-metabolic goals |
| b. Heart rate, MAP 60 e 110     |                                                                                             |
| c. Fluid infusion, vasopressor agents, urine output, and fluid balance 60 e 11 |                                                                                             |
| d. Glycemia 60 e 110            |                                                                                             |
| e. Lactate, hemocrit, sodium, and creatinine 60 e 11 |                                                                                             |

Outcome indicators
- a. Losses due to cardiac arrest
- b. Actual donation
- c. Transplanted organs/donor
- d. Losses due to family refusal
- e. Losses due to medical contraindication

Table 2 describes the demographic and clinical variables of the sample at the time of the first clinical assessment (t0) and immediately before recovery (t1).

The losses due to cardiac arrest decreased with a concomitant increase in actual donations. The losses due to family refusal and medical contraindication did not exhibit variation (Table 3).

The time interval between the first clinical assessment and recovery decreased (Phase 1 = 35.0±15.5 hours versus Phase 2 = 24.6±6.2 hours; p<0.03), and the number of donors explanted in less than 24 hours was greater in Phase 2 (p<0.05) (Table 4). Adherence to the performance of the graphical complementary test within six hours from the first clinical assessment increased (p<0.05) (Table 4).

The central temperature exhibited a substantial increase in Phase 2, as did the global fulfilling of the temperature goals (Table 4).

Adherence to a mean arterial pressure (MAP) > 65 mmHg increased (Table 4), urine output increased, and the creatinine concentration decreased (Table 2). Despite the greater use of vasopressin in Phase 2 (Phase 1 = 22.2% versus Phase 2 = 54.2%; p<0.04), the uniform vasopressor doses were similar in both phases. With regard to the acid-base balance, the arterial pH increased, and the base deficit decreased, whereas the pH rose from t0 to t1 in Phase 2 (Table 2).

As observed in the case of vasopressin, adherence to the administration of methylprednisolone and levothyroxine was greater in Phase 2 (Table 4). Conversely, glyceremia increased in Phase 2 (Table 4).
Care with the adoption of protective ventilation was greater in Phase 2, where also the number of potential donors exhibiting PaO$_2$/FiO$_2$ > 300 was higher (Table 4).

| Characteristics | Phase 1 (N=18) | Phase 2 (N=24) | p value |
|-----------------|----------------|----------------|---------|
| Male gender     | 11 (61.1)      | 16 (64)        | 0.71    |
| Age (years)     | 39.4±15        | 49.8±19.6      | 0.07    |
| Cause of brain death |             |                |         |
| Brain trauma    | 9 (50)         | 8 (32)         | 0.27    |
| Stroke          | 6 (33.3)       | 14 (60)        | 0.21    |
| Other           | 3 (16.6)       | 2 (8)          | 0.41    |
| Temperature (°C) |              |                |         |
| t0              | 36.4±1.1       | 36.2±1.6       | 0.83    |
| t1              | 36.4±0.9       | 36.8±0.7       | 0.17    |
| HR (bpm)        |                |                |         |
| t0              | 107±25         | 106±27         | 0.83    |
| t1              | 104±28         | 106±23         | 0.82    |
| MAP (mmHg)      |                |                |         |
| t0              | 88±22          | 95±22          | 0.25    |
| t1              | 73±30          | 93±11          | <0.02   |
| Vasopressor (NA units*) |        |                |         |
| t0              | 0.14±0.16      | 0.18±0.23      | 0.63    |
| t1              | 0.12±0.23      | 0.07±0.10*     | 0.36    |
| Fluid infusion (mL) |        |                |         |
| t0 (24 hours before) | 4.972±5.096   | 4.759±4.224    | 0.88    |
| t1              | 2.897±3.604    | 5.247±4.073    | 0.07    |
| Urine output (mL/kg/h) |       |                |         |
| t0 (24 hours before) | 2.21±2.17     | 2.35±2.14      | 0.83    |
| t1              | 0.95±1.03      | 2.5±1.73       | <0.05   |
| pH              |                |                |         |
| t0              | 7.26±0.16      | 7.26±0.15      | 0.93    |
| t1              | 7.24±0.12      | 7.36±0.12**    | <0.02   |
| Base deficit    |                |                |         |
| t0              | -7.0±6.4       | -4.9±4.4       | 0.21    |
| t1              | -7.8±6.6       | -3.5±3.9       | <0.03   |
| PaO$_2$/FiO$_2$ |                |                |         |
| t0              | 209±77         | 304±182        | 0.08    |
| t1              | 194±116        | 388±334        | 0.10    |
| Glycemia (mg/dL) |            |                |         |
| t0              | 153±49         | 157±35         | 0.65    |
| t1              | 151±39         | 215±71**       | <0.008  |
| Lactate (mmol/L) | 1.4±0.5      | 1.9±0.9        | 0.24    |
| Hematocrit (%)  | 30.5±7.6       | 30.1±5.8       | 0.84    |
| Sodium (mEq/L)  | 147±8.7        | 149±7.2        | 0.46    |
| Creatinine (mg/dL) | 1.8±2.3     | 0.8±0.6        | <0.05   |

Table 3 - Main indicators of performance comparing phase 1 and 2 in the state of Santa Catarina and Brazil

| Indicators                  | Phase 1 (N=18) | Phase 2 (N=24) | p value |
|-----------------------------|----------------|----------------|---------|
| Actual donations            | 8 (44.4)       | 18 (75)        | <0.05   |
| Losses due to cardiac arrest| 5 (27.8)       | 0              | <0.007  |
| Losses due to family refusal| 3 (16.7)       | 4 (16.6)       | 1       |
| Losses due to contraindication| 2 (11.1) | 2 (8.3)        | 0.76    |

Table 4 - Adherence to goals during maintenance care

| Goals                                      | Phase 1 (N=18) | Phase 2 (N=24) | p value |
|--------------------------------------------|----------------|----------------|---------|
| Time goals                                 |                |                |         |
| ∆t$_1$ 1º clin assessmt – confirm test     | 3 (16.7)       | 11 (45.8)      | <0.05   |
| T _2 <6 h                                  |                |                |         |
| ∆t$_1$ 1º clin assessmt - explant <24 h    | 1/8 (12.5)     | 10/18 (55.5) * | <0.05   |
| Fullfillment of all goals                  | 1/8 (12.5)     | 7/18 (39.9) *  | 0.178   |
| Temperature goals                          |                |                |         |
| Measurement of central temperature         | 1 (5.6)        | 13 (52)        | <0.001  |
| Temperature >35 °C at 1º assessment        | 16 (88.9)      | 24 (100)       | 0.09    |
| Temperature >35 °C on ICU exit             | 16 (88.9)      | 21 (87.5)      | 0.89    |
| Fullfillment of all goals                  | 0              | 11 (45.8)      | <0.001  |
| Ventilatory goals                          |                |                |         |
| PEEP=8-10 cmH$_2$O                         | 2 (11.1)       | 10 (41.7)      | <0.03   |
| Tidal volume = 5-8 mL/kg                   | 0              | 9 (37.5)       | <0.004  |
| Plateau pressure <30 cm H$_2$O             | 0              | 11 (45.8)      | <0.001  |
| PaO$_2$/FiO$_2$ >300 on recovery           | 2 (11.1)       | 9 (37.5)       | 0.06    |
| Fullfillment of all goals                  | 0              | 4 (16.6)       | 0.07    |
| Fullfillment of goals without PaO$_2$/FiO$_2$| 0              | 7 (29.1)       | <0.02   |
| Hemodynamic goals                          |                |                |         |
| MAP >65 mmHg                               | 11 (61.1)      | 21 (87.5)      | <0.05   |
| Urine output >0.5 mL/kg/h - <4 mL/kg/h     | 6 (33.3)       | 15 (62.5)      | 0.06    |
| Fullfillment of all goals                  | 3 (16.7)       | 7 (29.1)       | 0.34    |
| Hormone replacement goals                  |                |                |         |
| Methylprednisolone 15 mg/kg every 24 h     | 6 (33.3)       | 24 (100)       | <0.001  |
| Levothyroxine 300 μg enteral every 24 h     | 0              | 21 (87.5)      | 0.09    |
| Urine output >0.5 mL/kg/h - <4 mL/kg/h     | 6 (33.3)       | 15 (62.5)      | 0.06    |
| Glucose <180 mg% on explant                | 8 (44.4)       | 8 (33.3)       | 0.46    |
| Insulin IV when glycemia >180 mg/dL        | 0              | 11 (45.8)      | <0.001  |
| Sodium 130-150 mEq/L on explant            | 12 (66.7)      | 16 (66.6)      | 1       |
| Fullfillment of all goals                  | 0              | 4 (16.6)       | 0.07    |

DISCUSSION

The present study shows that a managed treatment protocol for deceased potential donors reduces the incidence of cardiac arrest before organ recovery.

Although the present study was a pilot study conducted with a small sample, the causal association between the systematization and management of the maintenance...
measures and the results are undeniable. Recently, Salim et al. showed that the implementation of an aggressive strategy to handle deceased potential donors correlated with a 57% increase in brain death reporting (p<0.001), an 87% reduction in losses due to cardiac arrest (p < 0.001), and an 82% increase in the number of actual donors (p<0.001). Similarly, the measures implemented in our study resulted in a 100% reduction in losses due to cardiac arrest during the investigated period. As the losses due to medical contraindications and family refusal did not vary, the relative increase of 53.7% in the actual donors might be attributed to the reduction of losses due to cardiac arrest.

The time interval between the first clinical assessment and recovery decreased (Δtᵢₒ), and the adherence to the time-related goals increased, which show that the protocol made it shorter the maintenance and donation process. Diagnostic delay and correction of the physiological disorders associated with brain death most likely reduced the oxygen delivery to tissues (DO₂) and amplified the inflammatory response, thus affecting the use of organs in transplants and post-transplant survival.

In 2011, we investigated septic patients who were treated using a managed protocol that was similar to the one in the present study, and we found that a reduction in the time to diagnosis of severe sepsis reduced the mortality of that population. Although in severe sepsis, the main factor that influences mortality is early antibiotic treatment, many other therapeutic measures seem to influence a non-measurable variable that might be defining for the outcomes: greater attention paid to patients. Thus, the analogy between goal-managed care in sepsis and deceased potential donors seems quite appropriate. On these grounds, we might infer that the reduction in losses due to cardiac arrest resulted from the accomplishment of the basic protocol goals, such as maintenance of the temperature, hemodynamic conditions, electrolytic balance, hormone replacement, and an appropriate ventilatory regimen.

The control of the potential donors’ temperature was quite appropriate in both study phases, and in Phase 2, the monitoring of the central temperature by means of esophageal thermometer increased and there was complete adherence to the temperature goals. Due to the wide thermal lability of the skin temperature and its strong influence by the environmental temperature, the central temperature affords more precise data, especially when hypothermia occurs. The maintenance of normal temperature is crucial to ensure several biological phenomena, especially hemodynamic control.

Hemodynamic instability is the major challenge posed to the management of potential donors as hypotension is a common occurrence and reduces the perfusion of organs. The maintenance of a MAP>65 mmHg is one of the essential goals. Adherence to that goal was reached in 87.5% of the individuals in Phase 2, compared to 61.1% in Phase 1, and the MAP levels were also higher. With regard to that goal, attention must be paid to the appropriate volume expansion to reduce the risk of damage that is associated with vasoconstriction secondary to the use of vasopressor agents. In this regard, there was a tendency to increase the volume infused in Phase 2 compared to Phase 1 (p=0.068). This idea is reinforced by the increased urine output, reduced creatinine concentration, higher pH, and lower base deficit. The increase in the pH from t₀ to t₁ in Phase 2 might also denote improved perfusion.

Most brain-dead individuals requiring vasopressor agents are vasopressin-depleted. Thus, the greater use of vasopressin in Phase 2 might account for the increased pressure levels, despite the similarity between the uniform doses of vasopressor agents that were used in both phases.

The high rate of levothyroxine use in Phase 2 (87.5%) denotes a higher degree of care with regard to the potential donors; however, it is not possible to attribute pharmacological advantages to this drug, due to the lack of information on the action of its enteral administration and the overall lack of understanding of the actual role of thyroid hormones in the maintenance of potential donors. Conversely, methylprednisolone, which was administered in high doses to 95% of the potential donors in Phase 2, might have contributed to compensating for an eventual adrenal insufficiency and the consequent achievement of better hemodynamic control. Nevertheless, the use of that corticosteroid might have been the cause of the frequent occurrence of hyperglycemia in Phase 2 (Table 2). The detrimental effects of hyperglycemia on kidney function following transplantation and on the water-electrolytic balance emphasize the need for the strict control of the potential donors’ glycemia, especially following the administration of corticosteroids.

Although the benefits of protective ventilation for the use of lungs for transplantation are evident (27% increase; p=0.004), the rate of use of that strategy in the present study was low (0% in Phase 1; 16.6% in Phase 2).

The availability of clinical evidence, even in prestigious journals, does not ensure their transformation into actual care practices. The adoption of the protocol described in the present study induced changes to actual practice, as certain relevant actions and goals were pre-defined, provided opportunities to perform therapeutic adjustments, and decreased variation and subjectivity in the handling of deceased potential donors. The protocol is an adaptation of the medical...
early warning systems – MEWS, which are traditionally divided into (1) screening, (2) diagnosis, (3) treatment, (4) analysis of indicators, and (5) process revision.\textsuperscript{1,4,30} The published good practice guidelines by Spain’s National Transplant Organization (Organización Nacional de Transplantes - ONT) suggest several basic management principles, including a MEWS-based protocol. One year after the publication of such guidelines, the number of organ donors increased by approximately 15% in Spain.\textsuperscript{4,31} Even though a portion of the measures that were standardized by a given protocol might lack robust evidence, the management of activities and real-time “route corrections” place the healthcare staff at the bedside with a consequent improvement in assistance.

The present study had several limitations. In addition to the small sample, the retrospective data collection in Phase 1 might have impaired the quality of the information. Due to the disputable quality of the Phase 1 records, comorbidities were not assessed, which also impaired the analysis of the data.

Taking the study limitations into consideration and placing the results into the proper perspective, the findings of the present study are of paramount importance for the state of Santa Catarina. Despite the reduction in losses due to family refusal and medical contraindications, the rate of losses due to cardiac arrest during the clinical management of potential donors remains high.\textsuperscript{3,8} An analysis of the ten main multiple organ donation hospitals, which provide 75% (n=120/159) of the brain-dead donors in the state, showed that the rate of losses due to cardiac arrest was also high in 2011 (68/266; 25.5% of the brain deaths reported by those hospitals).\textsuperscript{8} Based on these findings and the results of the present study, one might infer that the large-scale application of similar systematics might reduce the loss of potential donors due to cardiac arrest, both in the state of Santa Catarina and in Brazil as a whole.

**CONCLUSION**

The results of the present study demonstrate the crucial role of coordinated actions in improving the quality of the maintenance of potential organ donors. The use of this protocol was correlated with the performance of essential measures in the maintenance of the potential donors, leading to a reduction in donation losses due to cardiac arrest.

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**RESUMO**

**Objetivo:** Avaliar o efeito da aplicação de um protocolo gerenciado de manutenção de potenciais doadores falecidos de múltiplos órgãos em duas unidades hospitalares.

**Métodos:** Estudo antes (Fase 1)/depois (Fase 2) realizado em dois hospitais gerais que incluiu, consecutivamente, os potenciais doadores ingressados em duas unidades de terapia intensiva. Na Fase 1 (16 meses), os dados foram coletados retrospectivamente e as medidas de manutenção do potencial doador foram instituídas a critério do intensivista. Na Fase 2 (12 meses), a coleta de dados foi prospectiva e a manutenção foi guiada por um protocolo gerenciado. As duas fases foram comparadas entre si de acordo com variáveis demográficas, variáveis fisiológicas no diagnóstico da morte encefálica e ao final do processo, tempo necessário para realização do exame confirmatório de morte encefálica e final do processo, aderência aos conjuntos de medidas essenciais de manutenção (pacotes), perdas por parada cardíaca, perdas por negativa familiar, perdas por contraindicação e taxa de conversão de potenciais doadores em doadores reais. Foram aplicados os testes de t-Student e do qui-quadrado, e o valor de p<0,05 foi considerado significativo.

**Resultados:** Identificaram-se 42 potenciais doadores (18 na Fase 1 e 24 na Fase 2). Houve diminuição do tempo entre a primeira exploração clínica e o explante (Fase 1: 35,0±15,5 horas versus Fase 2: 24,6±6,2 horas; p=0,023). Houve aumento na aderência em 10 dos 19 itens essenciais de manutenção, e redução nas perdas por parada cardíaca (Fase 1: 27,8 versus 0% na Fase 2; p=0,006) com aumento de doadores reais (Fase 1: 44,4 versus 75% na Fase 2; p=0,044). Não houve mudança nas perdas por negativa familiar ou por contraindicação médica.

**Conclusão:** A adoção de um protocolo gerenciado promove a aplicação de medidas essenciais no cuidado do potencial doador falecido e pode reduzir as perdas de potenciais doadores por parada cardíaca.

**Descritores:** Doadores de tecidos; Morte encefálica; Protocolos clínicos; Parada cardíaca
