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REPORTS OF ORIGINAL INVESTIGATIONS

Variability in deceased donor care in Canada: a report of the Canada-DONATE cohort study

Variabilité des soins prodigués aux donneurs décédés au Canada : un compte rendu de l'étude de cohorte Canada-DONATE

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Abstract

Purpose *Canadian donor management practices have not been reported. Our aim was to inform clinicians and other stakeholders about the range of current practices.*

Methods *This prospective observational cohort study enrolled consecutive, newly consented organ donors from August 1 2015 to July 31 2018 at 27 academic and five community adult intensive care units in British Columbia, Alberta, Ontario, and Quebec. Research staff prospectively recorded donor management data. Provincial organ donation organizations verified the organs donated. We formally compared practices across provinces.*

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Results *Over a median collection period of eight months, 622 potential donors were classified at baseline as having neurologic determination of death (NDD donors; n = 403) or circulatory death (DCD donors; n = 219). Among NDD donors, 85.6% underwent apnea testing (rarely with carbon dioxide insufflation), 33.2% underwent ancillary testing, and subsequent therapeutic hypothermia (34–35°C) was rare. Neurologic determination of death donors were more hemodynamically unstable with most having received vasopressin and norepinephrine infusions, with a large majority having received high-dose corticosteroids and intravenous thyroxine. Among DCD donors, 61.6% received corticosteroids, and 8.9% received thyroxine. Most donors did not receive lung-protective ventilation strategies. Invasive procedures after donation consent included bronchoscopy (71.7%), cardiac catheterization (NDD donors only; 21.3%), and blood transfusions (19.3%). Physicians ordered intravenous antemortem heparin for 94.8% of DCD donors. The cohort donated 1,629 organs resulting in 1,532 transplants. Case selection, death determinations, and hormone, nutrition and heparin practices all varied across provinces.*

Conclusion *These study findings highlight areas for knowledge translation and further clinical research. Interprovincial discrepancies will likely pose unique challenges to national randomized trials.*

Trial registration*: www.clinicaltrials.gov (NCT03114436); registered 10 April, 2017.*

Résumé

Objectif *Les pratiques canadiennes de prise en charge des donneurs n'ont pas été rapportées. Notre objectif était d'informer les cliniciens et autres parties intéressées quant à l'éventail des pratiques actuelles.*

Méthode *Cette étude de cohorte observationnelle et prospective a recruté des donneurs d'organes consécutifs ayant récemment consenti au don entre le 1er août 2015 et le 31 juillet 2018 dans 27 unités de soins intensifs universitaires et cinq unités de soins intensifs pour adultes en milieu communautaire en Colombie-Britannique, en Alberta, en Ontario et au Québec. Le personnel de recherche a enregistré de manière prospective les données de prise en charge des donneurs. Les organismes de dons d'organes provinciaux ont vérifié les organes donnés. Nous avons formellement comparé les pratiques d'une province à l'autre.*

Résultats *Sur une période médiane de collecte de huit mois, 622 donneurs potentiels ont été catégorisés au départ comme ayant un diagnostic de décès neurologique (donneurs DDN; n = 403) ou un décès cardiocirculatoire (donneurs DDC; n = 219). Parmi les donneurs DDN, 85,6 % ont subi un test d'apnée (rarement avec insufflation de dioxyde de carbone), 33,2 % ont subi des tests complémentaires, et une hypothermie thérapeutique subséquente (34-35°C) était rare. Les donneurs par diagnostic de décès neurologique étaient plus instables hémodynamiquement, la plupart ayant reçu des perfusions de vasopressine et de norépinéphrine, et une vaste majorité de ces donneurs ont reçu des corticostéroïdes à forte dose ainsi que de la thyroxine intraveineuse. Parmi les donneurs par DDC, 61,6 % avaient reçu des corticostéroïdes, et 8,9 % de la thyroxine. La plupart des donneurs n'avaient pas bénéficié de stratégies de ventilation protectrice des poumons. Les interventions invasives réalisées après le consentement au don comprenaient la bronchoscopie (71,7 %), le cathétérisme cardiaque (donneurs DDN seulement; 21,3 %) et les transfusions sanguines (19,3 %). Les médecins*

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ont prescrit de l'héparine intraveineuse ante mortem chez 94,8 % des donneurs DDC. La cohorte a donné 1629 organes, résultant en 1532 greffes. La sélection de cas, la détermination de décès et les pratiques hormonales, nutritionnelles et héparinques variaient toutes d'une province à l'autre.

Conclusion *Ces résultats soulignent des domaines propices à la transmission de connaissances et aux recherches cliniques plus poussées. Les différences interprovinciales poseront probablement des défis uniques pour les études randomisées nationales.*

Enregistrement de l'étude : *www.clinicaltrials.gov (NCT03114436); enregistrée le 10 avril 2017.*

Transplantation saves lives, improves quality of life, and is the treatment of choice for a growing number of advanced chronic diseases.[1] On a global basis, however, hundreds of thousands of people die annually in need of an organ transplant. In Canada alone, approximately every 1.5 days, another patient dies while waiting for an organ transplant.[2]

Organ donations typically originate from brain-injured patients who die in an intensive care unit (ICU). From the time of consent for organ donation to the time of organ retrieval—roughly 48 hr—their specialized care has surprisingly little foundation in clinical research.[3] Observational studies estimate that 20% of organs are unsuitable for transplantation because of suboptimal medical care of the donors.[4,5] Thus, to increase transplant rates, the World Health Organization called for research to improve donor management.[6] Recent clinical trials show that improved donor management can increase donation rates and also enhance transplant function.[7]

Donor management has three distinct aims. First, to maximize organ suitability, ICU clinicians strive to maintain hemodynamic stability (e.g., administering fluids, hormones, and vasopressors) and physiologic homeostasis (e.g., with electrolyte supplementation).[8] Second, to enhance organ function in recipients, clinicians may treat donors with methylprednisolone to mitigate pulmonary ischemia-reperfusion injury,[9] hypothermia to enhance renal graft function,[10] and intravenous heparin to prevent various postoperative thrombotic complications.[11] Third, clinicians investigate organ suitability for donation, which may include tests that carry intrinsic risks (e.g., organ biopsies) and/or potentially delay organ retrieval.

Donor management in Canada likely varies across provinces. While national guidelines for deceased organ donor management have been published,[12–14] specific processes are developed provincially by organ donation organizations or locally by institutions. Inappropriate variation in clinical practice occurs when non-evidence-based care is provided, or the care lacks wide acceptance, and often leads to disparate outcomes. The beneficial impact of standardization in healthcare, and specifically in deceased donation has been shown with increased donation and transplantation rates.[15]

We launched a prospective observational cohort study of deceased donor management in Canadian ICUs to describe national and provincial norms, as well as the variability in practices. Our aims were to provide donation clinicians and administrators with benchmarks for assessing their own practices; to inform clinicians about practices they might not have considered; to highlight opportunities for future education and knowledge translation initiatives; and to support the appeals for clinical research in this emerging field.

Methods

The complete study protocol details have been previously published.[16] This study includes adult donors from an earlier pilot study (n = 67), which has been published (NCT02902783).[17] This report follows STROBE and RECORD guidelines for the reporting of observational studies.[18,19]

Study participants

Eligible participants were those for whom a legal substitute decision maker had provided consent for organ donation following a neurologic determination of death (NDD donors) or circulatory death (DCD donors) at any of 32 adult ICUs in British Columbia, Alberta, Ontario and Québec. These provinces generate approximately 90% of all deceased donations in Canada. Hospitals were originally selected based on their high donation activity (ten or more per year). Upon request, we also included hospital sites that had an arrangement of sharing ICU research infrastructure with any of these original sites. Research ethics boards at all hospitals approved this study utilizing a waiver of research consent, as did the privacy office of participating organ donation organizations (ODOs). Each ODO developed a method to instantly alert study investigators about every new consent for deceased organ donation. Coupled with the waiver of research consent, this step enabled the enrollment of every consecutive potential donor at participating sites.

Data sources

Intensive care unit research staff recorded the medical history, hospital admission data, and ICU management details. To avoid inadvertent influence on donor care, research staff did not probe physicians about their decisions. Since neurologic death determinations typically preceded consent for donation, data related to brain death determinations were recorded retrospectively in the otherwise prospective study. We did not record the titration of palliative medications after withdrawal of life support. Organ donation organizations provided data related to the reasons that explained why transplant programs declined specific organs, and they identified which organs were donated and transplanted.

Statistical analysis

The endpoints of this descriptive observational study are the donor management interventions, including diagnostic tests and treatments. We also describe actual donation and transplant rates. Descriptive analyses generated means (standard deviation [SD]), medians [interquartile range (IQR)] or proportions, as appropriate. Because unique pathophysiologic considerations support some unique treatment strategies for NDD and DCD donors, we present these data separately. When descriptive analyses suggested that practices varied across multiple provinces, we tested for statistical significance in exploratory analyses. We compared means using an analysis of variance (Fisher's F-test), compared medians using the Kruskal–Wallis test, and compared proportions using a Chi squared or Fisher's exact test (for fewer than five counts), with a $P < 0.05$ denoting statistical significance. We did not adjust the significance level for multiple comparisons. All analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

To support these study analyses, we planned for each site to participate for 12 months (allowing for seasonal variation), aside from four vanguard sites that would participate for up to 24 months.[16] Based on reports of prior donation activity, we expected to enroll over 650 potential donors, with a distribution that would support interprovincial comparisons. Ultimately, we stopped enrollment before 12 months at 18 sites because of fixed funding and, in some instances, lengthy privacy office reviews or extended time to develop new research infrastructure.[16]

This report presents many analyses separately for NDD and DCD donor types. Baseline data reflects donor types as classified at the time of consent. These classifications changed for some participants (n = 29); therefore, some analyses necessarily include all donors *ever* considered as NDD donors (n = 419). Analyses of interventions unique to NDD donors include only those for whom the donor type classification never changed (n = 390).

Results

From August 1 2015 to July 31 2018, we screened 641 potential donors and enrolled 622 for whom ODOs could verify the existence of a formal consent for organ donation (Fig. 1).

Participating sites

The 32 participating sites varied with respect to the presence of hospital-based ODO staff (at 26 sites), support of a regional trauma program[14] or transplant program(s),[17] and their implementation of organ donation order sets[9] or checklists[19] (Appendix). There were 24 research centres of the Canadian Critical Care Trials Group with prior experience in the conduct of multicentre cohort studies, and eight with no existing research infrastructure. Four hospitals (Hamilton Health Sciences, London Health Sciences Centre, Centre Hospitalier Universitaire de Sherbrooke, Hôpital Sacré-Coeur de Montréal) participated in the vanguard phase and enrolled patients for 12–24 months. Participating sites enrolled a median [IQR] of 2 [1–4] donors per month, and participated for a median [IQR] of 8 [5–11] months.

Donor characteristics

Neurologic determination of death and DCD cohorts were comparable at the time of consent for donation aside from age (NDD donors were younger), and preceding duration of ICU stay (NDD donors had a shorter ICU stay) (Table 1). Donor type classification switched for 29 donors, and one was reclassified twice. Therefore, 419 were classified at some point as NDD donors, 407 were finally classified as NDD, and 215 were finally classified as DCD.

Neurologic death determinations

Among 419 participants ever classified as NDD donors, ten (2.4%) were quickly reclassified as DCD donors and 59 (14.1%) were judged medically unsuitable for apnea testing (e.g., acute lung injury, severe acidosis, or overdose of sedating substances). Among 350 donors who underwent apnea testing, 95 (27.1%) had more than one test, with a total of 466 documented apnea tests. Of these tests, 296 (63.5%) incorporated positive end-expiratory pressure (PEEP), with a mean (SD) level of 9 (3) cmH_2O.

Clinicians employed carbon dioxide insufflation during 35 apnea tests involving 28 donors at six sites in two provinces. Definite or questionable respiratory efforts during the test were rare (n = 13; 2.8%). Complications during apnea tests included hypotension (ten episodes), acute desaturation (five episodes), and cardiac arrest (one episode).

Among 419 donors ever classified as NDD donors, 139 (33.2%) had ancillary testing. The most common reasons included no apnea test (59/419; 14.1%), an equivocal apnea test (26/419; 6.2%), or a perceived need to confirm neurologic death (31/419; 7.4%). Confirmatory testing was requested according to local policy (16/31; 51.6%), physician preference (9/31; 29.0%), or family reassurance (4/31; 12.9%). Ancillary tests included nuclear scan (72/139; 51.8%), computed tomography (CT) angiogram (33/139; 23.7%), four-vessel angiogram (18/139; 12.9%), and others (16/139; 11.5%).

Practices in deceased donor management

Hemodynamic variables differed between NDD and DCD donors (Table 2). Most NDD donors received both vasopressin and norepinephrine infusions after consent for organ donation. One donor received extracorporeal membrane oxygenation.

Hormonal therapies varied between donor types. Among 407 participants with a final classification as NDD donors, 341 (83.8%) received corticosteroid therapy compared with 135 of 215 (62.8%) of DCD donors. The most common corticosteroid was intravenous methylprednisolone (n = 441; 97.6%) at a dose of 1,000 mg daily (n = 291; 79.5%). Meanwhile, 270 of 407 (66.3%) NDD donors received thyroid hormone supplementation, compared with 24 of 215 (11.2%) DCD donors. The most common thyroid supplement was intravenous levothyroxine (n = 269; 96.8%), at an initial dose of 100 μg (n = 206; 76.6%) followed by 100 μg daily (n = 175; 70.9%). Some NDD donors received a first dose of corticosteroid therapy (28.5%) or thyroid hormone (24.1%) prior to formal

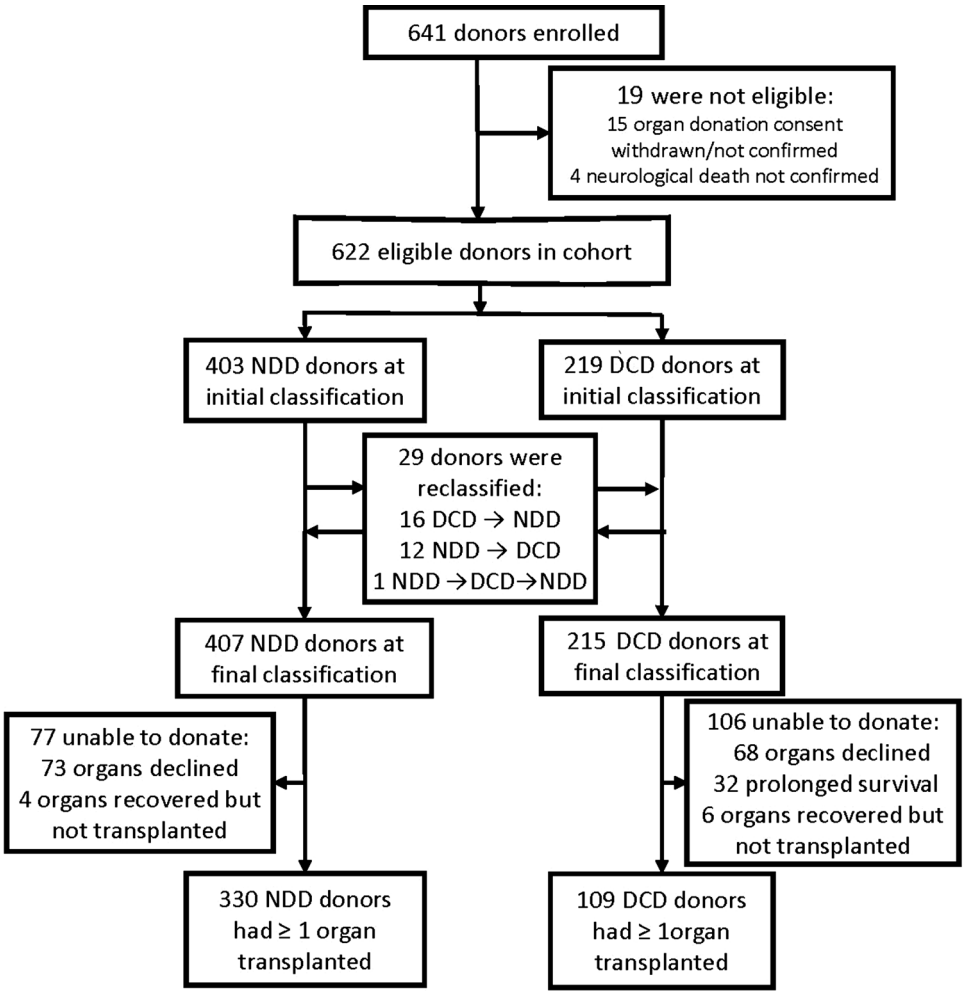

Fig. 1 Canada-DONATE study cohort. DCD = circulatory determination of death (DCD donors); NDD = neurologic determination of death (NDD donors)

consent for donation, for unspecified reasons, as did some DCD donors (11.8% and 4.4%, respectively).

Medical interventions changed following consent for donation (Table 3). Seventy-five percent of NDD donors had a temperature management order, and 24.7% had a core temperature of $\leq$ 35°C for some period of time after consent for donation. Infrequently, NDD donors received ongoing sedation and/or analgesia, for unspecified reasons. The proportion of DCD donors receiving nutrition decreased over time with 60.6% receiving nutrition the day after consent. In contrast, the proportion of NDD donors receiving nutrition increased with 41.7% on enteral nutrition one day post-consent.

Invasive or potentially time-consuming procedures were common. Nineteen percent of donors received a blood transfusion of red cells, platelets, or plasma; 71.7% underwent bronchoscopy; 17.4% underwent CT without contrast, 5.2% underwent CT angiography, and 21.3% of NDD donors underwent cardiac catheterization. Preoperative organ biopsies were rare and included 43 liver, nine lung, and seven kidney biopsies.

Withdrawal of life support

For 215 patients with a final DCD classification, 154 (71.6%) had one or more organs allocated to planned recipients. Physicians provided an order for a bolus of intravenous heparin for 146/154 (94.8%) of these donors around the time of the withdrawal of life sustaining therapies. The median [IQR] intravenous heparin dose was 511 [390–1000] $U \cdot kg^{-1}$ of body weight. No substitute decision makers declined consent for heparin, but three physicians did decline to order heparin in the context of a DCD donation. There was one episode of potential bleeding—the appearance of moderate blood in a rectal tube, for which the time of onset (before or after heparin) was uncertain. Research staff noted their limited assessments for new bleeding due to the removal of monitoring catheters and a desire to minimize their presence during palliation.

Withdrawal of life support usually started between 18:00 and 06:00 (59.7% of the time), and took place either in the ICU (n = 81; 52.9%), an operating room (n = 33; 21.6%), a surgical holding area (n = 24; 15.7%), or a

Table 1 Baseline characteristics

	Total	NDD	DCD	P value
n (%)	622	403 (64.8)	219 (35.2)	
Age (yr), mean (SD)	51.5 (16.6)	50.0 (17.7)	54.1 (14.1)	0.002
BMI ($kg \cdot m^{-2}$), mean (SD)	27.7 (6.4)	27.6 (5.6)	27.8 (7.6)	0.73
Male sex, n (%)	373 (60.0)	234 (58.1)	139 (63.5)	0.19
Comorbidities, n (%)	607	392	215	
Hypertension	196 (32.3)	127 (32.4)	69 (32.1)	0.94
Smoking history	168 (27.7)	116 (29.6)	52 (24.2)	0.16
Diabetes	87 (14.3)	54 (13.8)	33(15.3)	0.60
Coronary artery disease	59 (9.7)	43 (11.0)	16 (7.4)	0.16
Hepatitis B, C or HIV	37 (6.1)	22 (5.6)	15 (7.0)	0.50
Chronic thyroid therapy	30 (4.9)	17 (4.3)	13 (6.0)	0.35
Cancer	27 (4.4)	17 (4.3)	10 (4.7)	0.86
Chronic kidney disease	16 (2.6)	14 (3.6)	2 (0.9)	0.05
Peripheral vascular disease	12 (2.0)	6 (1.5)	6 (2.8)	0.36
Chronic steroid therapy	4 (0.7)	2 (0.5)	2 (0.9)	0.62
Principal cause of death, n (%)	622	403	219	
Anoxic brain injury	214 (34.4)	144 (35.7)	70 (32.0)	0.35
Brain hemorrhage	187 (30.1)	133 (33.0)	54 (24.7)	0.03
Brain trauma	147 (23.6)	92 (22.8)	55 (25.1)	0.52
Ischemic stroke	41 (6.6)	22 (5.5)	19 (8.7)	0.12
ICU days prior to consent for all donors, median [IQR]	1.6 [0.6–3.8]	1.0 [0.3–2.2]	3.8 [1.7–6.8]	< 0.001
ICU days prior to consent for transferred donors, median [IQR]	-0.1 [-0.2–0.7]	− 0.2 [− 0.2–0.5]	0.7 [− 0.1–1.3]	0.046
ICU days prior to consent for non-transferred donors, median [IQR]	2.1 [0.9–4.3]	1.4 [0.8–2.8]	4.0 [1.9–6.9]	< 0.001

Data presented as n (%), unless otherwise stated. BMI = body mass index; DCD = circulatory determination of death; ICU = intensive care unit; IQR = interquartile range; NDD = neurologic determination of death; SD = standard deviation.

Table 2 Evolution of hemodynamic variables and support

	NDD donors			DCD donors		
	Day prior to organ donation consent	Day of organ donation consent	Day after organ donation consent	Day prior to organ donation consent	Day of organ donation consent	Day after organ donation consent
n	316	390	369	186	203	180
Physiology						
Mean arterial pressure, mmHg, mean (SD)	-	89.4 (15.2)	89.1 (11.6)	-	88.2 (14.0)	88.2 (12.4)
Central venous pressure, mmHg, mean (SD)	-	9.7 (3.8)	9.9 (3.6)	-	10.3 (3.6)	10.7 (3.4)
Serum pH, mean (SD)	7.3 (0.1)	7.3 (0.1)	7.3 (0.1)	7.4 (0.1)	7.4 (0.1)	7.4 (0.1)
Lactate, $mmol \cdot L^{-1}$, mean (SD)	4.1 (3.7)	3.2 (2.7)	2.6 (1.8)	2.3 (2.5)	1.8 (1.5)	1.9 (1.7)
Creatinine, $\mu mol \cdot L^{-1}$, median [IQR]	88 [65–124]	86 [64–129]	79 [62–114]	66 [50–89]	66 [54–90]	64 [52–87]
Alanine aminotransferase (ALT), $U \cdot L^{-1}$, median [IQR]	60 [23–241]	40.5 [24–134]	38.0 [23–94]	53 [28–136]	47 [25–100]	47 [28–94]
Troponin I, $\mu g \cdot L^{-1}$, median [IQR]*	1.0 [0.2–10.9]	0.7 [0.2–3.4]	0.4 [0.1–1.6]	0.0 [0.0–0.3]	0.1 [0.0–0.3]	0.1 [0.0–0.2]
Ejection fraction, %, mean (SD), *n*	45.5 (18.6), 20	52.1 (13.9), 130	55.2 (11.3), 122	49.3 (12.9), 6	59.5 (22.3), 8	55.0 (0.0), 2
24-hr fluid balance, L, median [IQR]	1.5 [0.7–2.9]	2.2 [1.0–3.5]	1.7 [0.8–3.0]	1.3 [0.6–2.1]	1.3 [0.6–2.3]	1.2 [0.5–2.1]
Monitoring, *n* (%) donors						
Central venous catheter	211 (67.6)	319 (82.2)	309 (84.4)	110 (59.1)	131 (64.5)	122 (67.8)
Arterial catheter	259 (82.0)	384 (98.5)	364 (98.6)	158 (84.9)	190 (93.6)	176 (97.8)
Echocardiography	31 (9.8)	147 (37.7)	139 (37.7)	9 (4.8)	11 (5.4)	4 (2.2)
Pulmonary arterial catheter	6 (1.9)	18 (4.6)	27 (7.4)	1 (0.5)	1 (0.5)	1 (0.6)
Medications, *n* (%) donors						
Vasopressin	142 (44.9)	328 (84.1)	302 (81.8)	14 (7.5)	29 (14.3)	31 (17.2)
Norepinephrine	212 (67.1)	319 (81.8)	263 (71.3)	61 (32.8)	74 (36.5)	57 (31.7)
Other vasopressor agents	42 (13.3)	48 (12.3)	29 (7.9)	4 (2.2)	6 (3.0)	2 (1.1)
Other inotropic agents	14 (4.4)	19 (4.9)	21 (5.7)	5 (2.7)	6 (3.0)	5 (2.8)
Dopamine	7 (2.2)	6 (1.5)	10 (2.7)	1 (0.5)	1 (0.5)	3 (1.7)

Missing data were less than 1% for each item. DCD = circulatory determination of death; IQR = interquartile range; NDD = neurologic determination of death; SD = standard deviation

*Troponin I was the most frequently reported troponin type. Time trends and frequency distributions for other troponin measures were not substantially different to that of troponin I.

recovery room (*n* = 14; 9.2%). Family members were present for 123 (80.9%) patients. Ultimately, 120 (77.9%) died within a time frame that permitted organ donation.

Donation and transplantation outcomes

The mean (SD) time from donation consent to organ retrieval was 1.6 (0.7) days for NDD and DCD donors who ultimately donated organs.

From the original 622 potential deceased donors, 450 (72.3%) donated one or more organs and 439 (70.6%) had at least one organ transplanted (Table 4). This resulted in 1,629 organs retrieved (kidneys and lungs were counted individually) and 1,532 organs transplanted: 750 kidneys, 343 lungs, 276 livers, 111 hearts, and 52 pancreas transplants. Accounting for double-organ transplants, there were 1,337 organ recipients. We found that for many donors, ODOs did not clearly document the reasons that transplant programs had declined organs; therefore, we cannot report these data.

Interprovincial comparisons

Table 5 summarizes differences in donor case mix and management that we observed across the provinces. Figure 2 shows interprovincial variability in outcomes.

Discussion

In this first study of organ donor management practices in Canada, we recorded the scope of ICU practices in the care of 622 potential deceased donors at 32 sites. Some of the most interesting findings include differences in care across

Table 3 Routine ICU care

	NDD donors			DCD donors		
	Day prior to organ donation consent	Day of organ donation consent	Day after organ donation consent	Day prior to organ donation consent	Day of organ donation consent	Day after organ donation consent
n	316	390	369	186	203	180
Temperature management ordered	38 (12.0)	207 (53.1)	34 (9.2)			
Goal temperature, °C, median [IQR]						
Highest temperature	38.0 [37.3–38.0]	38.0 [37.0–38.0]	38.0 [37.0–38.0]			
Lowest temperature	35.8 [34.0–36.0]	35.7[35.5–36.0]	36.0 [35.5–36.0]			
Actual temperature, °C, median [IQR]	-	36.6 [36.1–37.2]	36.7 [36.3–37.0]			
Sedative agents	156 (49.4)	125 (32.1)	23 (6.2)	125 (67.2)	145 (71.4)	144 (80.0)
Analgesic agents	105 (33.2)	95 (24.4)	22 (6.0)	97 (52.2)	126 (62.1)	143 (79.4)
Tidal volume index, $mL \cdot kg^{-1}$ PBW, mean (SD)	8.2 (1.7)	8.2 (1.7)	8.1 (1.5)	7.9 (2.1)	8.1 (2.1)	8.2 (2.5)
Positive end-expiratory pressure, cmH_2O, mean (SD)	7.1 (3.0)	7.4 (2.9)	8.3 (2.9)	7.2 (2.7)	7.6 (2.8)	8.3 (2.7)
Lung recruitment maneuvers	36 (11.4)	216 (55.4)	213 (57.7)	10 (5.4)	87 (42.9)	83 (46.1)
Enteral nutrition	98 (31.0)	150 (38.5)	154 (41.7)	145 (78.0)	148 (72.9)	109 (60.6)
Parenteral nutrition	2 (0.6)	2 (0.5)	3 (0.8)	4 (2.2)	5 (2.5)	2 (1.1)

Data presented as *n*, % unless otherwise stated. Missing data were 0–4.2% for each item

DCD = circulatory determination of death; ICU = intensive care unit; IQR = interquartile range; NDD = neurologic determination of death; PBW = predicted body weight; SD = standard deviation.

provinces. We also observed the administration of NDD-specific therapies to DCD donors, perhaps mistakenly (e.g., thyroid hormone supplementation). Moreover, we observed some innovative practices that warrant further investigation in selected donor populations.

Findings from this study have enabled us to identify selected organ donor management practices that are ripe for knowledge translation initiatives. Based on randomized trial findings,[20] NDD donors should be ventilated using low tidal volumes (6–8 $mL \cdot kg^{-1}$ predicted body weight) and relatively high PEEP levels (at least 8 cmH_2O). In our study, mean tidal volumes and PEEP levels were out of range for NDD donors, suggesting less than half of potential lung donors were ventilated optimally. A recent multicentre randomized trial also supports mild therapeutic hypothermia (core temperature 34–35°C) for NDD donors, who achieved better post-transplant kidney function[10]; however, less than 10% of NDD donors in this cohort had a final core temperature in that range. Based on much weaker evidence, enteral feeding is a suggested consideration for NDD donors,[21] but this practice varied considerably across provinces. Previous Canadian guidelines did not address these three donor treatments, which may benefit from targeted knowledge translation initiatives.[12] Also important are current practices that are supported by limited evidence. Most notably, 41.8% of NDD donors in this study received thyroid hormone despite the absence of recognized clinical benefits.[22]

Interprovincial comparisons in this study are noteworthy. Though healthcare is a provincial domain in Canada, national initiatives underway to enhance organ donation include a body of donation physicians, donor management guidelines,[12,13] DCD heart donation protocols,[23] standardized data reporting,[24] and guidance for donation after medical assistance in dying.[25] Notwithstanding, we observed provincial differences in donor characteristics (e.g., age, cause of death, and donor types), neurologic death determinations (e.g., carbon dioxide insufflation during apnea tests, and ancillary testing rates), nutrition support, heparin administration, and other interventions. These differences may reflect the unique populations and cultural norms of Canadian provinces, but also the scarcity of randomized-controlled trials to guide donor care. Collectively, these findings highlight the need for clinical trials in organ donor management and highlight the need for regionally targeted knowledge translation initiatives.

Also noteworthy is the interprovincial variability in the conversion of potential to actual donors (Fig. 2). There was substantially more variability across provinces for DCD than NDD conversions, suggesting that the determining factors are unique to DCD donation. Potential DCD donors can only donate organs if they die promptly after the

withdrawal of life support: 30 min to three hours, depending on the type of organs allocated. When donors survive beyond that period, the many surgeons and transplant staff that travelled to the site will leave without organs for transplantation, and other limited hospital resources (e.g., operating rooms and staff) may be perceived as sub-optimally utilized. There are a few plausible explanations for relatively high rates of conversion of DCD donors in some provinces. First, the ICU physicians may be more selective in choosing patients for DCD. Second, the transplant teams may be understaffed for organ retrieval, and pushed to prioritize those donors most likely to die quickly. Third, individual physicians' practices with respect to palliative medications can influence the time to death. Investigating the importance of these varied explanations was beyond the scope of this study. A distinct group of donor interventions are those that have no anticipated value for ICU patients in achieving organ donation but rather have theoretical benefits for organ recipients post-transplantation. Large-dose intravenous heparin prior to the withdrawal of life support in DCD donors carries at least a theoretical risk to donors—the risk of hastening death through intracranial hemorrhage—and yet physicians ordered heparin for 94.8% of DCD donors who had organs allocated, with the aim of mitigating thrombosis and improving transplant function. Similarly, corticosteroid dosing generally surpassed the low doses required to address adrenal insufficiency of brain death and may reflect a desire to administer a higher anti-inflammatory dose to mitigate donor lung inflammation and recipient lung ischemia-reperfusion injury. These findings suggest appetite among many clinicians to administer transplant medicines to organ donors.

There are limitations to this study. Provinces and sites that participated for less than 12 months were relatively underrepresented. Fortunately, the high rate of enrollment in this study supported formal comparisons of donor management strategies across provinces. Additionally, with an explicit aim to observe and not influence practices, research staff did not probe the reasons for various management decisions, particularly those related to neurologic death determinations. Similarly, while variability in sedation practices during the withdrawal of life support in the context of organ donation is of great interest, it was not possible to observe these practices without influence; therefore, we did not record these data. Another limitation is the multiple comparisons undertaken in assessing interprovincial practice variability, which might have led to some spurious findings of statistical significance. Finally, we found that ODOs did not consistently record the reasons that individual organs

Table 4 Donation and transplant outcomes

	NDD donors	DCD donors
Potential donors*	407	215
Actual donors, *n* (%)	330 (81.1)	109 (50.7)
Organs recovered per potential donor†	3.2	1.5
Organs recovered per actual donor†	3.9	2.8
Organs transplanted per potential donor†	3.1	1.3
Organs transplanted per actual donor†	3.8	2.7
Transplant recipients, *n* (%)	1082	255
Single kidney	528 (48.8)	190 (74.1)
Double kidney	2 (0.2)	0
Kidney-pancreas	18 (1.7)	4 (1.6)
Liver	240 (22.2)	30 (11.8)
Liver-kidney	6 (0.6)	0
Single lung	17 (1.6)	0
Double lung	132 (12.2)	31 (12.2)
Heart	111 (10.3)	-
Pancreas	30 (2.8)	0

Data presented as *n*, % unless otherwise stated. *Denotes final classification

Actual donors = one or more organ recovered resulting in transplantation

† each lung, kidney, and liver represents a single organ, regardless of whether lungs or kidneys were transplanted in pairs, and regardless of whether livers were split to support more than one transplant. DCD = circulatory determination of death; NDD = neurologic determination of death.

Table 5 Interprovincial variability in deceased donation practices

	British Columbia	Alberta	Ontario	Quebec	*P* value
Donors, n (%)	58 (9.3)	72 (11.6)	299 (48.1)	193 (31.0)	
Donors per month, mean	7.0	6.2	8.6	8.1	
NDD donors*	32 (55.2)	56 (77.8)	158 (52.8)	161 (83.4)	< 0.001
DCD donors*	26 (44.8)	16 (22.2)	141 (47.2)	32 (16.6)	< 0.001
Inter-hospital transfer					
Among NDD donors	2 (6.3)	2 (3.6)	3 (1.9)	78 (54.5)	< 0.001
Among DCD donors	1 (3.8)	0 (0.0)	1 (0.7)	3 (10.0)	0.03
Age, mean (SD)	43.8 (16.9)	39.7 (14.9)	52.9 (15.3)	56.0 (16.4)	< 0.001
Neurologic determination of death					
Apnea test with CO_2 insufflation, no. of sites	0	0	3	3	
Ancillary testing among ever NDD	22/33 (66.7)	50/56 (89.3)	32/167 (19.2)	35/163 (21.5)	< 0.001
Donor interventions, n	58	72	299	193	
Pulmonary artery catheter in situ	1 (1.7)	0 (0.0)	5 (1.7)	26 (13.5)	< 0.001
Corticosteroids	56 (96.6)	44 (61.1)	241 (80.6)	135 (69.9)	< 0.001
Thyroid hormone supplementation					
Among NDD donors	28 (87.5)	51 (91.1)	142 (89.9)	49 (30.4)	< 0.001
Among DCD donors	1 (3.8)	0 (0.0)	22 (15.6)	1 (3.1)	0.05
Enteral nutrition	42 (72.4)	40 (55.6)	138 (46.2)	148 (76.7)	< 0.001
Parenteral nutrition	0 (0.0)	1 (1.4)	6 (2.0)	2 (1.0)	0.80
No nutrition	16 (27.6)	31 (43.1)	156 (52.2)	44 (22.8)	< 0.001
Withdrawal of life support, n	26	16	141	32	
DCD donors for whom organs were allocated, *n*	24 (92.3)	15 (93.8)	90 (63.8)	25 (78.1)	
Transfer from ICU for palliation to:					
Recovery room	0 (0.0)	0 (0.0)	14 (15.6)	0 (0.0)	0.01
Operating room holding area	0 (0.0)	0 (0.0)	24 (26.7)	0 (0.0)	< 0.001
Operating room	0 (0.0)	0 (0.0)	10 (11.1)	23 (92.0)	< 0.001
Intravenous heparin therapy					
Heparin ordered	22 (91.7)	13 (86.7)	88 (97.8)	23 (92.0)	0.10
Heparin administered	18 (75.0)	13 (86.7)	88 (97.8)	23 (92.0)	0.03
Physician declined heparin	0 (0.0)	2 (13.3)	0 (0.0)	1 (4.0)	0.02
Family declined heparin	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	.
Usual timing of heparin administration, *n*	18	13	76	22	
Before or same time of withdrawal of life support	6 (33.3)	5 (38.5)	76 (100.0)	20 (90.9)	< 0.001
After withdrawal of life support	12 (66.7)	8 (61.5)	0 (0.0)	2 (9.1)	< 0.001
Duration of donor care					
Duration NDD care (actual donors) in hours					
Mean (SD)	47.4 (4.2)	31.9 (12.2)	35.7 (15.0)	46.6 (17.7)	< 0.001
Median [IQR]	47.5 [32.8–55.2]	26.9 [24.2–37.3]	33.1 [26.1–42.8]	46.5 [31.4–56.2]	< 0.001
Duration DCD care (actual donors) in hours					
Mean (SD)	41.8 (13.7)	31.1 (10.5)	33.5 (16.7)	35.9 (16.4)	0.24
Median [IQR]	44.8 [29.5–50.6]	26.4 [24.0–40.7]	31.6 [25.7–39.6]	32.7 [26.9, 35.6]	0.10

Data presented as *n* (%), unless otherwise stated

*Denotes final classification

DCD = circulatory determination of death; IQR = the interquartile range; NDD = neurologic determination of death; SD = standard deviation.

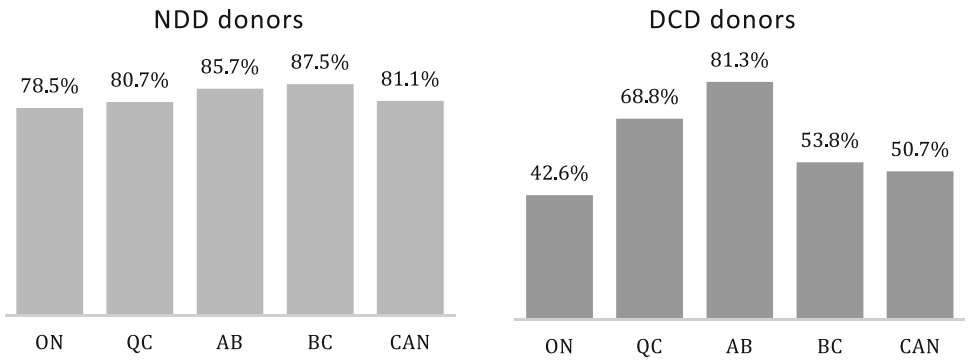

Fig. 2 Transplant rate among NDD donors and DCD donors. This figure shows the rate of conversion of potential (consented) donors to actual (transplanted) donors. DCD = circulatory determination of death (DCD donors); NDD = neurologic determination of death (NDD donors). AB = Alberta; BC = British Colombia; CAN = Canada; ON = Ontario; QC = Quebec

were declined—data that will be critical for future clinical trials—and efforts are underway to improve accessibility to this information.

Conclusions

Rigorous research to inform deceased donor management is limited. Investigators of two national research enterprises, the Canadian Critical Care Trials Group and the Canadian Donation and Transplant Research Program, aim to expand this evidence base through rigorous research that is national in scope. Based on the variability in practices we have identified, this study highlights many interventions suitable for randomized trials (e.g., heparin therapy in DCD donors, and high-dose corticosteroids for all donors). Our findings suggest that targeted knowledge dissemination activities and future clinical trials are warranted to clarify both NDD and DCD donor management.

Author contributions All authors have made material contributions to this manuscript according to the rules of authorship of ICMJE. All authors contributed to study conception and design, acquisition of data, analysis and interpretation of data, and drafting and revising the manuscript. Collaborators: Canadian Critical Care Trials Group, the Canadian National Transplant Research Program, Canadian Blood Services, British Columbia Transplant, the Northern Alberta HOPE Program, the Southern Alberta Organ Donation Program, the Trillium Gift of Life Network of Ontario and Transplant Quebec.

Conflict of interest None.

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Appendix

Thirty-two participating hospital sites

	Donors *n*	Months in study*	Trauma centre	Neuro surgery	Transplant centre	Donation referral centre	Permanent ODO staff on site	Donation order sets	Prior CCCTG centre
British Colombia									
Vancouver General	22	9.0	Y	Y	Y	N	N	Y	Y
Royal Columbian	15	5.4	Y	Y	N	N	N	Y	Y
St. Paul's	10	7.7	N	N	Y	N	N	Y	Y
Victoria General	6	7.2	Y	Y	N	N	N	Y	Y
Royal Jubilee	5	5.5	N	N	N	N	N	Y	Y
Alberta									
Foothills Medical Centre	32	8.2	Y	Y	Y	N	Y	Y	Y
University of Alberta	30	11.4	N	Y	Y	N	Y	Y	Y
Royal Alexandra	10	10.7	Y	Y	N	N	N	Y	Y
Ontario									
Hamilton Health Sciences -General Site	82	21.3	Y	Y	N	N	Y	Y	Y
Sunnybrook	28	8.6	N	N	N	N	Y	Y	Y

	Donors *n*	Months in study*	Trauma centre	Neuro surgery	Transplant centre	Donation referral centre	Permanent ODO staff on site	Donation order sets	Prior CCCTG centre
William Osler Health Centre -Brampton	28	10.7	N	N	N	N	Y	Y	N
The Ottawa Hospital Civic Campus	26	7.9	Y	Y	Y	N	Y	Y	Y
St. Michael's	25	6.9	Y	Y	Y	N	Y	Y	Y
London Health Sciences Centre -Victoria	24	11.1	Y	N	N	N	N	Y	Y
London Health Sciences Centre-University	21	10.7	N	Y	Y	N	Y	Y	Y
Kingston General	18	12.1	Y	Y	Y	N	Y	Y	Y
Windsor Regional - Ouellette Campus	16	4.3	Y	Y	N	N	Y	Y	N
Trillium Health Partners	11	5.2	N	Y	N	N	Y	Y	N
Hamilton Health Sciences – Juravinski Site	8	12.0	N	N	N	N	N	N	Y
St Joseph's Healthcare Hamilton	8	10.0	N	N	Y	N	N	N	Y
Windsor Regional - Metropolitan Campus	2	1.4	N	N	N	N	Y	Y	N
The Ottawa Hospital General Campus	1	2.6	N	N	Y	N	Y	Y	Y
William Osler Health System -Etobicoke	1	10.9	N	N	N	N	Y	Y	N
Quebec									
Sacré-Coeur de Montréal	51	13.3	Y	Y	N	Y	Y	N	Y
Hôtel-Dieu de Québec	41	11.8	Y	Y	Y	Y	Y	Y	N
Fleurimont	34	24.4	N	Y	Y	Y	Y	Y	Y
Saint-Luc	28	12.2	N	N	Y	Y	N	Y	Y
Maisonneuve-Rosemont	11	10.4	N	N	Y	Y	Y	Y	Y
Notre-Dame	11	9.2	N	Y	Y	N	Y	Y	Y
Royal Victoria	9	6.4	N	N	Y	Y	Y	Y	Y
Montreal General	6	4.4	Y	Y	Y	N	Y	N	N
Hôtel-Dieu de Montréal	2	5.2	N	N	N	N	Y	Y	Y

*Calculated from the date of first enrollment to the agreed upon site study completion date. CCCTG = The Canadian Critical Care Trials Group; ODO = organ donation organization.

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