Living Donor Nephrectomy: Is It as Safe as It Can Be? Analysis of Living Donor Deaths in the United States

Douglas Scott Keith, MD, FAST, Joe Brown, MAS, ATP, CFI,† and Kenneth Andreoni, MD‡*

Introduction: The reported 90-day rate of death from living donor nephrectomy is 3 in 10,000 donations. Although this risk is low, the important question is how many deaths are preventable?

Methods: To study this question, all living donor nephrectomy cases, 139,186 procedures, recorded in the Scientific Registry of Transplant Recipients database since its inception in 1987 were analyzed to determine the death rate and the number of deaths that were potentially preventable. Preventable deaths were defined as any death in the first 7 days except due to clearly unrelated events or death from hemorrhage, pulmonary embolism, infection, cardiovascular cause, or suicide in the first 90 days.

Results: The numbers of deaths at 7, 30, 90, and 365 days after donation were 16, 26, 38, and 86, which translated into 1.15, 1.87, 2.73, and 6.18 deaths per 10,000 donations, respectively. From 2000 onward, when coding was available for cause of death, 19 of the 30 deaths were deemed potentially preventable. The nonrisk-adjusted rate of death with laparoscopic donation was higher than open nephrectomy, but this difference did not reach statistical significance. Conversion from laparoscopic to open nephrectomy occurs in approximately 1 in 100 surgeries, and this rate has remained fairly steady since 2005.

Conclusions: This analysis suggests that up to two thirds of deaths are potentially preventable. The transplant community should consider additional safety strategies such as simulation training of rare complications to lower donor risk.

Key Words: living donor nephrectomy, mortality, laparoscopic surgery, open surgery, near misses, preventable deaths, safety

(*J Patient Saf* 2019;15: 274–281)

Living donation remains an important source of organs for transplant especially in kidney transplantation. The reported 90-day rate of death from kidney donation is 3 events in 10,000 donations.[1] Approximately 5500 living donor kidney surgeries occur annually in the United States in recent years.[2] That means that almost every year one or two donors die within 90 days of undergoing donor surgery. This rate of death is small compared with other surgeries, but this is for a procedure that has no direct medical benefit to the donor. The impact of these catastrophic events for the donor, donors loved ones, and recipient is enormous not to mention the impact on transplant programs and careers of transplant professionals. Table 1 is a comparison of the risk of donor nephrectomy compared with other risks an individual might consider taking. Among risk-taking behaviors, base jumping had the closest risk of death per event to living donor nephrectomy and that was only exceeded by laparoscopic cholecystectomy, living donor partial hepatectomy, and attempting to reach the summit of Mount Everest. Most people would agree that base jumping is a very risky endeavor. The point being made is that donor nephrectomy involves a small but significant short-term risk. The important issue that needs to be addressed with donor nephrectomy is "Can the risk be mitigated further and what steps would be needed to accomplish this?" The transplant community should not be complacent that donor nephrectomy is as safe as possible and that nothing further can be done to improve safety. Donors and recipients rely on us to ensure continual improvement.

To better understand the mortality risks of living donor nephrectomy, we analyzed the Scientific Registry of Transplant Recipients (SRTR) living donor database and identified all donors who died within 90 days of their living donor nephrectomy. The intent of the analysis was to identify the number of donor deaths that have been recorded in the database from its inception in 1987, estimate the number of potentially preventable deaths, to compare the risks of open versus laparoscopic donor nephrectomy, and to look at rates of conversion of laparoscopic donor nephrectomies to open procedures as a surrogate marker of near-miss events.

MATERIALS AND METHODS

Using the SRTR database, all patients who underwent a living donor nephrectomy were identified from its inception in 1987 until the end date of the data set, which included living donors in 2016. Death of a donor was determined from either the registration file status, follow-up file status, or dates from the Social Security Death file registry if present. For the purposes of the analysis, deaths within 365, 90, 30, and 7 days of the living donor nephrectomy date were determined. The type of procedure used was also determined from the coding in the data set. 1995 was the first year that laparoscopic living donation was reported in the U.S. literature.[3] Before that date, all donations were considered open if not coded otherwise. By 2004, more than 97% of donors had a coded procedure type. For the 9-year span between 1995 and 2004, the coding progressively improved from less than 1% of donors to more than 97%. Only two deaths during the follow-up period could not be assigned a procedure type either open or laparoscopic and were considered unknown for procedure. From 1995, the number of open versus laparoscopic donation was estimated by assuming the proportion without a code for procedure was proportional to the encoded procedures for each given year. For instance, if 80% of the encoded donors were laparoscopically donated, 80% of the donors without a procedure code were considered laparoscopically procured to determine the denominator for calculation of death rates by procedure.

Because coding for cause of death was absent before 2000, a separate cohort starting in 2000 until 2016 was analyzed to determine the causes of death during that period. This was used to

From the *Sacred Heart Kidney Transplant Program, Sacred Heart Hospital, Pensacola; †Clinical Integration Solutions, LLC, Health Safety Consultancy Company; and ‡Division of Transplant Surgery, University of Florida, Gainesville, Florida.

Correspondence: Douglas Scott Keith, MD, Sacred Heart Kidney Transplant Program, 5149 N 9th Ave, Suite 246, Pensacola, FL 32504 (e-mail: dkeith@renalus.com).

The data reported here have been supplied by the Minneapolis Medical Research Foundation (MMRF) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the SRTR or the U.S. Government.

Douglas Scott Keith, MD, has full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

TABLE 1. Death Rates of Activities

Risk of Death Per Event	Activity
1:10,000,000	Risk of death from lightening per year
1:10,000,000	Risk of fatal car accident in a 5-mile commute to work
1:4,700,000	Risk of death in commercial airline accident per flight
1:1,500,000	Risk of death per ski outing
1:500,000	Risk of death from bungee jump
1:200,000	Risk of death from an abortion
1:200,000	Risk of death per scuba dive
1:116,000	Risk of death per hang gliding flight
1:100,000	Risk of death skydiving per jump
1:100,000	Risk of death from general anesthesia in a healthy adult ASA 1
1:26,000	Risk of death driving a motorcycle for 100 miles per event
1:11,000	Risk of death during childbirth
1:10,000	Risk of dying rock climbing for 2.5 h
1:3000–5000	**Risk of death donating a kidney**
1:2300	Risk of death per base jump
1:1000	Risk of death from laparoscopic cholecystectomy
1:500–1000	Risk of death donating a lobe of your liver
1:25	Risk of death attempting to summit Mount Everest

Data in bold indicate surgical procedure of interest.

Approximate risks sourced from multiple Web sites listed hereinafter.

Risks sourced from the following Web sites and citations listed hereinafter: http://www.besthealthdegrees.com/health-risks/,

https://patient.info/health/anaesthesia-death-or-brain-damage,

https://www.guttmacher.org/fact-sheet/induced-abortion-united-states?gclid=CO3Luf6C3NMCFVM9gQod29QEDA,

https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html, and

https://www.facs.org/~/media/files/education/patient%20ed/cholesys.ashx

Soreide K, Ellingsen CL, Knutson V. How dangerous is BASE jumping? An analysis of adverse events in 20,850 jumps from the Kjerag Massif, Norway. *J Trauma*. 62(5):1113–7.

Cheah YL, Simpson MA, Pomposelli JJ, et al. Incidence of death and potentially life-threatening near-miss events in living donor hepatic lobectomy: a world-wide survey. *Liver Transpl*. 2013;19:499–506.

Firth PG, Zheng H, Windsor JS, et al. Mortality on Mount Everest, 1921–2006: descriptive study. *BMJ*. 2008;337.

determine the number of potentially preventable deaths. All deaths in the first 7 days, unless clearly not surgically related, and deaths from infection related to donation, cardiovascular causes, pulmonary embolism, hemorrhage, or suicide in the first 90 days were considered potentially preventable.

Finally, we identified all coded laparoscopic donations in the database with data on conversion and determined the number of conversions to open procedures as a surrogate marker of near miss events. From 2005 on, there was almost complete data (missing data for conversion only 5 cases of 66,167 coded laparoscopic donors) on conversions for laparoscopic donors and these data were used to determine the rates of conversion over time.

This study used data from the SRTR. The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration, U.S. Department of Health and Human Services, provides oversight to the activities of the OPTN and SRTR contractors.

RESULTS

Between the inception of the data set in 1987 until December 2, 2016, which was the final living donor recovery date in the file, 139,186 living kidney donors were identified. Table 2 shows the characteristics of the donors over time. For the 29-year span the mean donor age has increased by 7.5 years, the percentage of female, nonbiologic, and Hispanic donors have increased, whereas the percentage of white donors has decreased. The preference for left kidneys for donation has increased significantly coinciding with the increase in laparoscopic donation. The percentage of biologic donors has decreased over time with an increase in spousal and other nonbiologic donors. The emergence of laparoscopic donation as the preferred method of donation started in 1999. Now approximately 97% of donors are procured laparoscopically. The number of living donations increased progressively to its peak in 2004 and then began decreasing with another peak in donation in 2009. From 2009 onward, the numbers have slowly declined.

The numbers of deaths at 7, 30, 90, and 365 days were 16, 26, 38, and 86, respectively. This translated into 1.15, 1.87, 2.73, and 6.18 deaths per 10,000 donations, respectively.

Table 3 is a summary of all the deaths from 2000 onward when data regarding the causes of death were available in the data set. Thirty deaths occurred within 90 days of transplantation for this period of a total of 102,019 living donations. Before 2016 in only 1 year, 2012, there were no deaths. All but two of the deaths occurred in patients donating the left kidneys. Four deaths were in open donors, whereas one death occurred in a patient whose surgery was not specified, the remaining 25 deaths occurred in laparoscopically procured kidneys. Death occurred among all donor relationships except parental donors in this cohort. The most common cause of coded death was hemorrhage (n = 7). Two suicides occurred in the first 90-day posttransplant both among unrelated donors. Unfortunately, many of the cases listed "other" (n = 5) or "unknown" (n = 3) as a cause without specifying further in the data set. Of the 30 deaths, all deaths within 7 days of donation other than a homicide (n = 1), and any death due to hemorrhage (n = 7 total, 1 after day 7), cardiovascular (n = 3, 2 after day 7), infection related to donation (n = 2, 1 after day 7), pulmonary embolism (n = 2, 2 after day 7), or suicide (n = 2 after day 7) in the first 90 days were considered potentially preventable or 19 of the 30 deaths (Table 4). An additional three deaths occurred between day 8 and 10 that were coded either unknown or other. Deaths within 90 days considered unpreventable included two accidents, one homicide, and one ruptured brain aneurysm. Eight deaths were listed as either "other" (n = 5) or "unknown" (n = 3); 1 within 7 days of surgery, 3 between days 8 and 10, 1 between days 11 and 30, 2 between days 31 and 60, and one additional between days 61 and 90. All deaths occurred at different centers (data not shown).

To understand what background mortality rate of this population is in the absence of a donor nephrectomy procedure, the 90-day rate of death for the donor population was determined between 91 days and 1-year postdonation. The 90-day death rate was 1.15 deaths per 10,000 donors between 91 days and 1 year for this population. Assuming that this is the background death rate for the population, donor nephrectomy was associated with a 1.58 per 10,000 donors increase death rate in the 90 days after surgery.

TABLE 2. Characteristics of Living Donors

	Year of Donation													
	1987	**1988**	**1989**	**1990**	**1991**	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**
No. donations	n = 399	n = 1817	n = 1903	n = 2093	n = 2396	n = 2534	n = 2851	n = 3009	n = 3394	n = 3688	n = 3937	n = 4420	n = 4726	n = 5499
Age, mean ± SD, y	35.8 ± 10.7	36.1 ± 10.8	37.2 ± 10.9	37.1 ± 11.0	37.3 ± 10.7	37.2 ± 11.0	37.7 ± 10.9	38.0 ± 10.8	38.8 ± 10.6	38.8 ± 10.8	38.9 ± 10.9	39.3 ± 10.8	39.4 ± 10.7	39.7 ± 10.7
Female, %	57.9	54.7	54.7	55.7	55.6	55.7	56.5	55.4	58.1	58.3	57.2	57.8	58.1	57.0
Race/ethnicity, %														
White	77.4	76.2	76.2	76.1	73.8	72.7	70.8	71.1	72.6	70.8	70.6	71.0	70.0	70.4
African American	10.3	11.6	11.4	10.5	12.1	12.5	14.0	14.4	13.0	13.3	13.6	13.1	14.6	13.1
Hispanic	9.5	9.1	8.8	10.3	10.5	11.0	12.1	9.6	10.6	11.7	11.9	11.7	11.4	11.9
Asian	0.3	0.3	0.6	0.4	0.5	0.6	0.5	2.4	1.9	1.9	2.3	2.7	2.3	3.4
Other	2.5	2.9	3.0	2.8	3.0	3.2	2.7	2.6	1.9	2.3	1.7	1.6	1.6	1.2
Percent donor kidney left, %	58.6	61.7	65.3	66.8	69.2	70.8	69.2	71.5	73.5	73.0	74.3	75.3	80.7	81.4
Donor relationship, %														
Biologic	95.8	96.0	95.4	95.4	95.5	93.6	93.1	92.2	87.8	83.9	83.1	79.1	77.4	73.3
Spouse or life partner	3.1	2.3	2.9	3.1	2.5	3.2	4.4	4.9	7.7	10.0	9.8	12.5	12.3	12.2
Nonbiologic	1.0	1.8	1.7	1.6	2.0	3.1	2.5	2.8	4.6	6.2	7.2	8.4	10.3	14.5
ABO types of donors, %														
A	30.1	30.9	27.1	30.0	31.0	27.9	29.3	29.9	28.7	25.3	27.4	26.4	27.0	26.0
AB	0.8	0.9	0.8	1.4	1.3	0.8	0.8	0.8	1.2	1.1	0.9	1.2	1.0	0.9
B	8.3	7.6	9.1	8.8	8.3	8.4	8.9	8.4	8.3	8.5	8.7	7.6	8.1	7.7
O	60.9	60.6	62.9	59.7	59.4	62.9	61.0	60.8	61.8	65.1	63.0	64.9	63.9	65.4
Laparoscopically procured, %	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	1.8	2.4	7.7	27.9	48.9

2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
n = 6047	n = 6241	n = 6473	n = 6647	n = 6573	n = 6435	n = 6043	n = 5968	n = 6388	n = 6278	n = 5773	n = 5619	n = 5736	n = 5538	n = 5630	n = 5131
39.7 ± 10.7	39.9 ± 10.7	39.9 ± 10.8	40.0 ± 10.9	40.3 ± 10.9	40.5 ± 11.1	41.0 ± 11.3	41.2 ± 11.4	41.3 ± 11.6	41.6 ± 11.7	42.2 ± 11.6	42.0 ± 11.8	42.1 ± 11.8	42.3 ± 12.0	43.1 ± 12.2	43.3 ± 12.2
58.7	58.4	59.2	57.8	59.2	59.1	58.0	60.6	60.6	62.4	61.6	62.5	61.5	62.9	63.5	62.7
70.3	70.7	69.3	69.1	69.1	70.3	70.2	69.1	69.3	69.5	70.1	70.5	69.5	70.4	69.6	70.5
13.9	13.3	14.0	14.1	13.4	12.6	12.2	12.0	11.6	12.0	11.9	10.7	11.2	10.7	9.6	9.4
11.4	11.9	12.3	12.5	12.9	13.0	13.1	13.8	14.4	14.1	13.6	13.9	13.9	13.8	14.3	14.6
2.9	2.9	2.9	3.1	3.4	2.8	3.4	3.7	3.5	3.3	3.6	3.6	3.9	4.0	4.9	4.2
1.5	1.2	1.5	1.1	1.3	1.3	1.0	1.3	1.1	1.1	0.9	1.3	1.5	1.2	1.6	1.4
84.1	85.6	85.1	86.4	86.6	86.5	87.0	88.3	87.7	88.6	88.0	88.3	89.1	88.8	88.3	89.5
72.1	69.6	66.9	65.3	64.0	62.3	60.9	58.8	57.0	52.5	53.0	50.1	50.7	48.8	47.4	44.0
11.9	11.6	11.3	12.1	12.7	12.8	13.2	12.7	13.1	13.0	12.2	13.0	12.0	12.6	14.0	13.1
16.0	18.8	21.8	22.6	23.4	25.0	26.0	28.5	29.9	34.5	34.8	36.9	37.2	38.6	38.6	42.9
25.8	26.3	25.4	26.1	26.8	26.3	26.9	26.1	25.6	26.9	26.7	27.0	27.5	27.4	28.0	27.3
0.6	0.8	0.8	0.8	0.9	0.8	1.0	1.0	0.9	1.0	1.2	1.3	1.3	1.4	1.2	1.4
7.3	7.4	8.2	7.6	7.9	7.5	7.5	7.7	7.8	8.7	8.4	7.6	8.5	8.5	8.0	7.6
66.2	65.6	65.6	65.6	64.4	65.5	64.5	65.1	65.7	63.4	63.7	64.1	62.7	62.7	62.8	63.7
61.0	69.9	76.3	82.0	85.3	88.3	90.4	92.4	94.8	96.0	96.0	96.3	97.1	96.9	97.6	96.8

TABLE 3. Summary of Living Kidney Donor Deaths From 2000 to Present

Year of Donation	Age in Years	Sex	Race/ Ethnicity	Donor Relationship	Coded Cause of Death	Survival in Days From Surgery	Organ Recovered	Procedure	Conversion to Open Procedure	Reoperation	BMI	Recipient Cause of ESRD
2000	45	M	Black	Full or half sibling	Infection donation related	3	Left kidney	Lap unspecified	U	U	27.3	DM 2
2000	40	M	White	Other relative	Other	23	Left kidney	Lap unspecified	U	U	30.3	HTN
2001	25	M	Black	Child	Hemorrhage	1	Left kidney	Lap unspecified	U	U	29.8	FSGS
2001	39	M	Black	Full or half sibling	Other	8	Left kidney	Lap unspecified	U	U	22.8	HTN
2002	38	F	White	Full or half sibling	Pulmonary embolism	32	Left kidney	Lap unspecified	U	U	U	Obstructive uropathy
2002	27	M	White	Child	Other	57	Left kidney	Lap unspecified	U	U	27.1	HTN
2003	46	M	White	Full or half sibling	Other	2	Left kidney	Open	NA	U	U	Unknown
2003	32	F	Black	Child	Hemorrhage	2	Left kidney	Open	NA	U	28.3	HTN
2003	20	M	White	Other relative	Other	10	Left kidney	Open	NA	U	U	DM 1
2004	44	M	White	Anonymous	Cardiovascular	0	Left kidney	Open	NA	N	U	DM 2
2004	32	F	Black	Child	Accident	28	Left kidney	Lap no hand assist	N	N	23.3	Unknown
2004	50	F	White	Spouse	Accident	88	Right kidney	Lap hand assist	N	N	25.1	Amyloidosis
2004	40	F	White	Anonymous	Pulmonary arrest	0	Left kidney	Unknown	—	U	25.8	IgA nephropathy
2005	52	M	White	Unrelated directed	Cardiovascular	87	Left kidney	Lap hand assist	N	N	21.7	Unknown
2006	18	M	Hispanic	Full or half sibling	Infection donation related	13	Left kidney	Lap hand assist	N	N	20.1	FSGS
2006	41	F	White	Unrelated directed	Homicide	5	Left kidney	Lap hand assist	N	N	29.3	DM 2
2007	36	M	White	Unrelated directed	Unknown	88	Left kidney	Lap hand assist	N	N	24.5	DM 1
2008	29	M	Black	Spouse	Hemorrhage	1	Left kidney	Lap hand assist	N	Y	32.8	HTN
2008	65	M	White	Other relative	Hemorrhage	0	Left kidney	Lap hand assist	N	N	34.5	IgA nephropathy
2009	42	M	White	Full or half sibling	Pulmonary embolism	11	Left kidney	Lap no hand assist	N	N	30	Unknown
2010	46	F	White	Unrelated directed	Suicide	59	Left kidney	Lap hand assist	N	N	28.7	DM 1
2010	23	M	Black	Other relative	Cardiovascular	75	Left kidney	Lap hand assist	N	N	25	FSGS
2011	46	F	White	Full or half sibling	Ruptured brain aneurysm	64	Left kidney	Lap no hand assist	N	N	30	HTN
2011	41	F	Hispanic	Full or half sibling	Hemorrhage	0	Left kidney	Lap hand assist	N	Y	26.6	FSGS
2011	28	F	Hispanic	Unrelated paired donation	Hemorrhage	11	Left kidney	Lap hand assist	N	Y	28.5	DM 2
2013	45	M	White	Child	Unknown	42	Left kidney	Lap hand assist	N	N	27.3	DM 2
2014	44	M	Hispanic	Anonymous	Cerebrovascular accident	1	Left kidney	Lap hand assist	Y	N	35.4	HTN
2014	58	F	White	Unrelated directed	Suicide	29	Right kidney	Lap hand assist	N	N	28.6	Alport syndrome
2015	40	M	White	Child	Hemorrhage	1	Left kidney	Lap hand assist	N	Y	35	DM 2
2015	28	M	White	Full or half sibling	Unknown	10	Left kidney	Lap hand assist	N	N	21.1	HUS

Procedure: lap unspecified is laparoscopic donor nephrectomy but hand or no hand assist specified; open is an open donor nephrectomy regardless of approach either flank or abdominal incision; lap hand assist is laparoscopic donor nephrectomy with hand assistance; and lap no hand assist is laparoscopic donor nephrectomy without hand assistance.

Conversion to open procedure: U is unknown; N is no; Y is yes; and NA is not applicable open nephrectomy. One case the procedure was unknown and therefore conversion status could not be determined.

Reoperation: U is unknown; N is no; and Y is yes.

Abbreviations for cause of recipient ESRD: BMI is body mass index calculated by weight in Kg/ (height in Meters)^2; DM1 is type 1 diabetes mellitus; DM2 is type 2 diabetes mellitus; FSGS is focal segmental glomerulosclerosis; HTN is hypertensive nephropathy; and HUS is hemolytic uremic syndrome.

Donor relationships were the following: parent, child, full, or half sibling; other relative; spouse; life partner; anonymous; unrelated directed; unrelated paired donation.

TABLE 4. Summary of Causes of Death in First 90 Days

Cause of Death	n	Potential for Prevention
Hemorrhage	7	Potentially preventable
Cardiovascular	3	
Infection related to donation	2	
Pulmonary embolism	2	
Suicide	2	
Cerebrovascular accident	1	
Pulmonary arrest	1	
Other/unknown	8	Unsure
Accident	2	Not preventable
Homicide	1	
Ruptured cerebral aneurysm	1	

Deaths between 90 days and 1 year are shown in Table 5. There were two additional suicides and two overdoses in which the intent was unclear. Two of these donors were again unrelated, whereas the other two were related donors, a sibling and other relative. The most common cause of death was other or unknown. The most common coded cause of death was accidental. Four patients died of malignancy and three of the four were younger than 40 years. Three patients died of cardiovascular causes and two of three were in donors younger than 40 years.

Table 6 shows the death rate for open versus laparoscopic donation. Because coding for the procedure type was incomplete, assumptions were made about the denominator as discussed in the methods. In addition, three deaths occurred during the time of the transition to laparoscopic donation that had no code for the type of procedure and the rates of death for each procedure were estimated based on inclusion of these cases in each group on the table. For all assumptions, the rate of death was higher among laparoscopically procured donors but the difference did not reach statistical significance in any the assumed analyses.

Finally, the rate of open conversion of laparoscopic donor nephrectomy was determined from all the laparoscopically procured cases. A total of 68,971 laparoscopically procured donors were identified that had information about conversion to an open procedure. Among that group, 718 require open conversion for a conversion rate of approximately 1%. From 2005 onward, there was nearly complete data for conversion. Figure 1 shows the conversion rates for laparoscopic donations by year. Conversion rates did vary by year, but there was no definite evidence of a drop in the conversion rate over time.

DISCUSSION

The data from this study indicate that 19 of 30 events, or up to two thirds of donor deaths, were potentially preventable if one assumes that the surgical error rate and fatal pulmonary embolus rate should be 0. The analysis also suggests that laparoscopic donor nephrectomy may be slightly riskier with regard to patient death than open procedures although given the low event rate the differences did not reach statistical significance, and we are not able to risk adjust for any differences in donor risk factors, such as body mass index and age, due to low number of events. If we consider open conversion as a surrogate marker of a near-miss event, these events occurred at a rate that is several orders of magnitude higher than the death rate and are likely to occur a number of times in the surgical career of a donor surgeon.

Clearly, there are a number of weaknesses to this study. First, the event rate for donor deaths is very low, and it is possible that several missed events that were not recorded in the database or discoverable in the death master files could alter the conclusions. Donor deaths within 2 years of donation are now required to be reported to the OPTN, but that rule came into effect only in 2007.[4] It is certainly possible that programs might have been reluctant to report events before the rules mandating reporting and therefore were missed. The Social Security Death File dates were used to see whether additional deaths occurred that were not reported by the centers. Seven of the 38 deaths in the first 90 days were found using the Social Security Death file dates. All those deaths occurred before 1999. Second, defining conversions a near-miss event overestimates the frequency of serious complications during the surgery requiring conversion. There are a number of reasons to convert that are not emergent but because of technical reasons that do not allow safe laparoscopic donation, such as unanticipated anatomy or bowel adhesions. Third, coding for cause of death reveals only limited information on the events that led to a death, so determining what is preventable has limitations. Fourth, catastrophic outcomes such as a donor death usually have several factors that led to the final event. Without more detailed analysis of these events, remedial actions are speculative.

Keeping living donor nephrectomy as safe as possible is a priority for all programs. Deaths associated with donor surgeries are like plane crashes. They are rare, unlikely to occur more than once in any given center, and have devastating consequences particularly to the donors, the recipients, loved ones of the donor, and the transplant professionals and center. Because of this similarity, we believe that there is a great deal to be learned from the systems safety practices used in the aviation industry. The first safety strategy used by the aviation industry is through accident investigation performed by the government-sponsored National Transportation Safety Board (NTSB). After every airline accident, the NTSB performs a thorough investigation that results in a final public accident report complete with the accident's root cause and related causal factors. Furthermore, the NTSB publishes a "Most Wanted List of Transportation Safety Improvements." The NTSB Most Wanted List highlights safety issues identified from the NTSB's accident investigations to increase awareness about the issues and promote safety solutions.[5]

The second safety strategy used by commercial aviation is through a government and industry co-chaired Commercial Aviation Safety Team (CAST). The CAST has three main objectives.

TABLE 5. Living Kidney Donor Deaths Between 90 Days and 1 Year

Deaths Between 90 d and 1 y	No. Deaths	Notes
Malignancy	4	3 of 4 were in donors younger than 40 y
Accidental	10	
Homicide	3	
Suicide	2	1 unrelated and 1 sibling
Overdose intent unknown	2	1 unrelated and 1 other relative
Infection	1	
Cardiovascular	3	2 of 3 cardiovascular deaths were in donors younger than 40 y
Neurologic	1	
Other/unspecified	16	

TABLE 6. Rate of Death Based on Donor Surgery, Laparoscopic Versus Open Nephrectomy

	3 Unknown Deaths Added to Open and 0 Unknown Added Laparoscopic Donation	2 Unknown Deaths Added to Open Donations and 1 Unknown Added to Laparoscopic Donation	1 Unknown Death Added to Open and 2 Unknown Added Laparoscopic Donations	0 Unknown Deaths Added to Open and 3 Unknown Added Laparoscopic Donations
Laparoscopic rate of death per 10,000 donations	3.00	3.12	3.23	3.35
Open rate of death per 10,000 donations	2.28	2.09	1.90	1.71
P	0.43	0.26	0.15	0.07

The first objective is to perform an in-depth data analysis for a particular aircraft accident category. The CAST team analyzes the "accident chain" or specific events leading up to an accident and identifies methods to prevent or eliminate future occurrences. Each recommendation is further evaluated for effectiveness. The second objective is to develop specific safety enhancements by determining the feasibility of recommended intervention strategies identified by the initial data analysis. Lastly, CAST develops an integrated master safety plan to measure recommendation effectiveness and identify future areas of study.[6]

Like the NTSB, the Membership and Professional Standards Committee (MPSC) of the OPTN with surgical peer review does evaluate programs when a death occurs. General safety alerts have been released on one occasion regarding the Hem-o-lok clip (Teleflex Medical, Bannockham, IL) but in general, public disclosure of the root cause analysis is not shared with other centers.[7] Like lightning strikes, these events are unlikely to occur at the same institution twice; therefore, the remediation of a single program is not going to prevent further events if recommendations are not shared with the larger transplant community. Given this reality, it is incumbent on the transplant community to provide a mechanism to share information about these rare events among the transplant providers so that appropriate safety measures can be implemented. This may require national legislation to provide a protected mechanism for these investigations and for the disclosure of the findings with the transplant community that does not result in litigation. In addition, we believe that a committee, such as CAST, should review retrospectively in detail all the donor deaths within 90 days of surgery recorded in the OPTN/SRTR database. It is nearly certain that the MPSC already has those reviews, but a detailed report should be dispersed to transplant programs regarding the findings and best practices to avoid this tragic outcome. This release of information by the MPSC has been discussed at the MPSC meetings in the past, but no mechanism for the release of more granular information has been achieved.

This study suggests a number of specific recommendations could improve safety. First, laparoscopic donor nephrectomy, either hand assisted or not, has become the procedure of choice for donation. One of the challenges facing donor surgeons is preserving the skills needed to do open procedures. Less than 3% of donors are now done open. Having the skill to do an open conversion is very important because of the ability to skillfully and efficiently convert to an open procedure may be the difference between survival and death of a donor. Mechanisms to help surgeons maintain proficiency in this procedure may need to be considered. The American Society of Transplant Surgeons, as the body overseeing transplant surgeon qualifications, does mandate

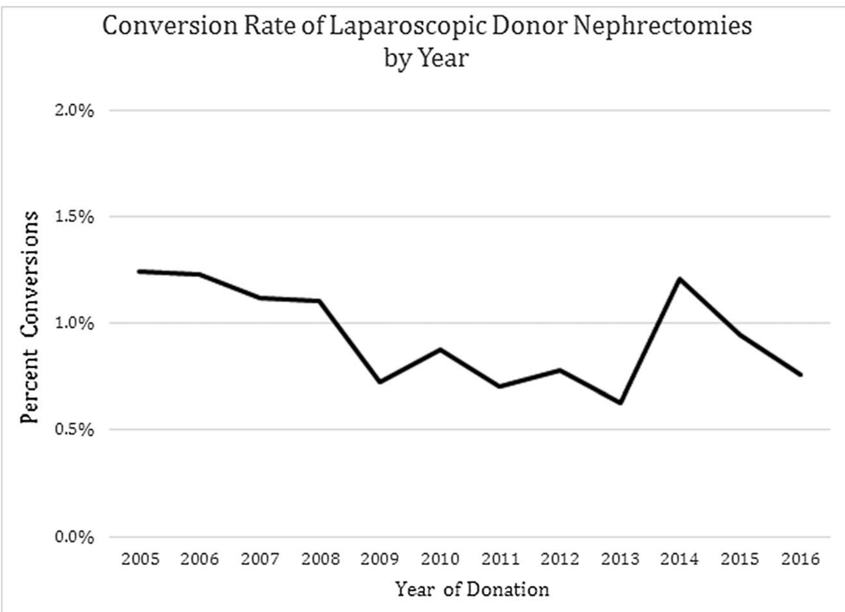

FIGURE 1. Conversion rate of laparoscopic donor nephrectomies by year of donation. Percent conversion rate of laparoscopic to open donor nephrectomy among donors based on year of donation.

that a donor surgeon be immediately available that has experience in open nephrectomy during either deceased donor procurement and/or native nephrectomy for donation or for disease.

Second, most early deaths were due to hemorrhage. Although some occurred in open donors, it seemed to predominate in laparoscopic donations. One of the clear risks of this type of donation is arterial or venous ligature failure or unrecognized arterial or venous injury at the time of donation.[8,9] Donor surgery is different than a native nephrectomy for disease in that the donor surgeon is attempting to preserve as much length to the artery and vein for subsequent transplantation. Failure of vascular stapling or clipping may be more likely when the length of the clipped artery and vein are short near the aorta or vena cava. In addition, potential inadvertent injury to the vena cava or aorta may be more frequent in this situation. The FDA put out a white paper alert regarding the potential for clip failure with Hem-o-lok vascular clip and the American Society of Transplant Surgeons have recommended stapling or suture ligature is the preferred method for vascular control now.[7] Between the original report of concern about the Hem-o-lok vascular clips in 2006, three additional deaths occurred in donors before the white paper alert.[9] A survey of European donor surgeons published in 2015 still reveals significant clip use among surgeons there, and it is unclear whether the abandonment of vascular clips has become standard operating procedure at all programs in the United States.[10] In the case of an arterial or venous remnant ligation failure, this could potentially occur after the patient returns to the floor postoperatively, and exsanguination from an arterial failure could occur within a very short period given the rate of blood flow through the renal artery and the potential space of the abdomen. Recognition of this complication needs to be very rapid if the patient is to be saved.

Third, although suicide of a donor is rare, it was documented in four cases in the first year. One common complaint of donors after donation is no one cares about them anymore, they are no longer the center of attention, and all the focus shifts to the recipient. This can lead to the donor having a negative emotional response to the donation. In the past, there has been less than ideal follow-up of donors. In an effort to improve this problem, the OPTN has mandated better follow-up and reporting of donor outcomes. Among the suicides, three of four were unrelated donors. The motivation to donate for someone not strongly emotionally related to the recipient is probably more complex, and they may expect some emotional reward from the gesture. If the predicted emotional reward is not forthcoming, a donor may feel disappointed, angry, or depressed, the typical antecedents to a suicide. Prevention of events like this requires careful screening of donor candidates and better follow-up not only of the patient's physical recovery from the donation but their emotional response to the donation. This may be particularly important for unrelated donors. Current policy from both Centers for Medicare and Medicaid Services and OPTN requires clear notification of the potential donor that they may have emotional reactions after donation, and these possibilities are to be probed during their predonation psycho-social evaluation. Tools for accurate prediction of postdonation emotional risk in all potential donors simply do not exist.

One issue that is apparent from this analysis is better data not only regarding deaths but also near misses needs to be collected and shared with the transplant community. For instance, a reporting mechanism needs to be developed that captures not only open conversions but also why they occurred. We have national data on how often laparoscopic donations are converted to open procedures, but we do not know the reasons why the conversion occurred. For instance, if it is due to adhesions, unanticipated anatomy, and an inability to get good exposure for the nephrectomy, it is not a near miss, whereas if a significant percentage is due to uncontrolled bleeding or bowel injury, that is something important to understand and is critical data if we are to improve safety.

Second, the rarity of these donor surgical emergencies mandates that improved simulation exercises be available for donor surgeons and operating room staff (surgical technicians, circulating nurses, and anesthesia team members). It also mandates that hospitals provide experienced operating room staff for these donor cases and not assume that only the surgeon needs to be experienced in the operative procedure and potential emergency procedures. Timely diagnosis, decision-making, and skills during critical events can potentially avert many bad outcomes. The aviation industry has invested in an enormous amount of training for their pilots and crew simulating rare critical events that can occur during a flight to help them learn and inculcate the proper knowledge needed to avert catastrophic outcomes. The medical profession is woefully behind in this type of training by comparison.

Finally, the approach to quality and safety in healthcare has generally been reactive rather than proactive. When considering quality, healthcare primarily focuses on outcomes only. Although outcomes are critical, they do not tell the complete story. Was good quality achieved by luck or through sound operating protocols, procedures, and evidence-based standards of care? Without formal, scientific data analysis, reporting, and investigative safety management strategies similar to the ones cited previously, opportunities for improvement in the reduction of living donor deaths will be difficult. It is incumbent of the transplant community to continue to improve the safety of these operations. We owe it to the donors who through their largess give the gift of life to so many patients that we do everything to ensure their safety during this operation.

REFERENCES

1. Segev DL, Muzaale AD, Caffo BS, et al. Perioperative mortality and long-term survival following live kidney donation. *JAMA*. 2010;303: 959–966.
2. Hart A, Smith JM, Skeans MA, et al. OPTN/SRTR 2015 Annual Data Report: kidney. *Am J Transplant*. 2017;17(suppl 1):21–116.
3. Ratner LE, Ciseck LJ, Moore RG, et al. Laparoscopic live donor nephrectomy. *Transplantation*. 1995;60:1047–1049.
4. Organ Procurement and Transplantation Network. Richmond, VA: United Network for Organ Sharing. Available at: https://optn.transplant.hrsa.gov/. Accesed April 30, 2019.
5. NTSB. 2016 Most wanted list of transportation safety improvements. Available at: https://www.ntsb.gov/safety/mwl/Documents/MWL2016_Brochure_web.pdf. Accessed April 27, 2017.
6. CAST The Commercial Aviation Safety Team. Available at: http://www.cast-safety.org/apex/f?*P*=180:1:7582805604460:NO:P1_X:organization Accessed April 27, 2017.
7. Weck Hem-o-Lok ligating clips contraindicated for ligation of renal artery during laparoscopic living-donor nephrectomy: FDA and HRSA Joint Safety Communication. 2011. Available at: https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm253237.htm. Accessed May 10, 2019.
8. Dekel Y, Mor E. Hem-o-lok clip dislodgment causing death of the donor after laparoscopic living donor nephrectomy. *Transplantation*. 2008; 86:887.
9. Friedman AL, Peters TG, Jones KW, et al. Fatal and nonfatal hemorrhagic complications of living kidney donation. *Ann Surg*. 2006;243:126–130.
10. Janki S, Verver D, Klop KW, et al. Vascular management during live donor nephrectomy: an online survey among transplant surgeons. *Am J Transplant*. 2015;15:1701–1707.