Attitudes toward Restored Kidney Transplantation among Dialysis Patients: Responses to a Questionnaire

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Abstract

By the end of 2012, more than 300,000 individuals across Japan were receiving dialysis for deteriorating kidney function. Approximately 38,000 patients begin dialysis each year, and approximately 30,000 die. After registering on the waiting list, patients wait for an average of 14 years to receive a kidney transplant because the number of cadaveric renal donors is extremely low in Japan. Between January 2012 and March 2013, we conducted a questionnaire survey with the cooperation of 70 hospitals in order to investigate the opinions of dialysis patients. Responses were obtained from 2727 dialysis patients, of which 91% had not enrolled in the kidney transplant recipient registry because of their advanced age, lower possibility of a transplant, or lack of knowledge regarding transplantation. In particular, the opinions of dialysis patients regarding the transplantation of surgically restored cancerous kidneys as a new donor source was investigated. Forty-five percent patients recognized restored kidney transplantation as medical care; nevertheless, restored kidney transplantation is currently not allowed in Japan. The ratio of patients accepting restored kidney transplantation is not worse than the number of patients who accept living donor renal transplantation as medical care (54.2%). In response to the question "When restored kidney transplantation becomes an available treatment, would you choose to undergo this type of transplantation," a total of 548 patients (20.1%) replied positively. When we subanalyzed dialysis patients who were applicants for living donor renal transplantation, 178 of 332 patients (53.6%) indicated that they would choose to undergo restored kidney transplantation, while 59 patients (17.8%) indicated that they would not. Even among the nonapplicants for living donor renal transplantation, 354 of 2283 patients (15.5%) indicated that they would accept this treatment. In countries like Japan, where the demand for donated kidneys far exceeds the supply, restored kidneys may be added to the donor pool to alleviate the long waiting time and easing the suffering of patients who require transplantation.

Keywords: shortage of organs, questionnaire survey, dialysis patients, restored kidney transplantation

1. Introduction

Chronic kidney disease (CKD) is a progressive loss of renal function over a period of months or years. The symptoms of worsening kidney function are unspecific and may include a general feeling of sickness and loss of appetite. Severe CKD requires renal replacement therapy. Although this may be in the form of dialysis, ideally, it involves renal transplantation. Dialysis is a process for removing waste and excess water from the blood and is primarily used as an artificial replacement for lost kidney function in patients with renal failure. The process takes 4–5 h, during which time abnormalities that have accumulated in the blood over the previous 2–3 days are eliminated. Many patients who receive dialysis are unable to work because of the time required for travel and treatment. Dialysis performs only 10–15% of the work of a functioning kidney; functions such as reabsorption, excretion, production of hormones, activating vitamin D, and metabolizing drugs are not performed.

Renal transplantation is a procedure involving the placement of a healthy kidney in the body, and it can replace complete kidney function. The quality of life of patients with end kidney disease is influenced by the disease itself and the type of replacement therapy. Dialysis must be repeated frequently and continued life-long until death or transplantation, whereas transplantation can positively alter quality of life.

Most patients report a better quality of life with renal transplantation than with dialysis, and those who receive renal transplantation typically live longer than those who remain on dialysis. The 5-year survival rate is 90% after renal transplantation and 60% with dialysis (Organ Transplant Factbook 2011, Japanese Society for Dialysis Therapy 2012)

However, there is a shortage of organs available for donation. Many candidates for renal transplantation are put on a transplant waiting list and require dialysis until an organ is available. At the end of March 2014, 12,875 recipients seeking renal transplantation were registered with the Japan Organ Transplant Network. These patients are waiting for transplantations from donors who are brain-dead or have succumbed to cardiac arrest. There were only 174 such procedures performed in Japan in 2012. Patients wait for an average of 14 years to undergo transplantation after they are registered on the waiting list, and approximately 300,000 patients across Japan must receive dialysis or depend on a living donor for survival (Japan Organ Transplant Network 2013). As such, approximately 30,000 dialysis patients are believed to die every year.

The number of cadaveric renal transplantations is extremely low in Japan compared with that in the United States and some European nations. Compared with that in Japan, the waiting period for transplantation in the USA and Europe is much shorter (3–4 years and 3 years, respectively) (UNOS 2013). The Japanese government has made efforts to increase the number of donors, such as revising the Organ Transplant Law in 2010. Under the reformed law, organ donation is possible with the agreement of the family, even if the intention of the donor cannot be confirmed. Although this policy has been established, considerable changes in organ donation trends have not yet been observed in Japan.

2. Method

Between January 2012 and April 2013, we distributed questionnaires to the doctors who played a key role in this survey. Subsequently, we collected answer sheets from 2727 patients in 70 hospitals where dialysis had been performed. A copy of the questionnaire is provided in the Appendix. Data were analyzed using descriptive statistics. This study was approved by the ethical review committee in the Medical Department of Nihon University.

Because the clinical studies of restored kidney transplantation were conducted at Tokusyukai Hospital Group, we balanced the number of patients who participated in the survey between Tokusyukai Hospital Group and Other Hospitals in order to prevent bias in the statistics. These included 1495 patients in the Tokusyukai Hospital Group and 1232 patients in the Other Hospitals group.

3. Results and Discussion

3.1 Sex Ratio of Dialysis Patients

In this study, the ratio of male to female dialysis patients was 60.4:33.4 (Table 1); this was similar to the sex ratio of dialysis patients in Japan at 63:37 (Assoc. of Kidney Support 2012). Diabetes is the main cause for dialysis, and it accounts for approximately 50% of dialysis patients. Because the frequency of diabetes is 14% in men and 8% in women in Japan (Itoh 2004), the sex difference in the number of dialysis patients may be attributed to this factor.

Table 1: Sex Ratio of Dialysis Patients

Response	n	%
Male	1647	60.4
Female	911	33.4
No answer	169	6.2

3.2 Age Distribution

As shown in Table 2, 68.3% dialysis patients were aged ≥60 years. With the aging of dialysis patients, the symptom of dementia also becomes a serious problem. Patients with dementia account for approximately 10% of all dialysis patients, and the concept of nursing care dialysis has now been proposed (Tsukasaki 2011).

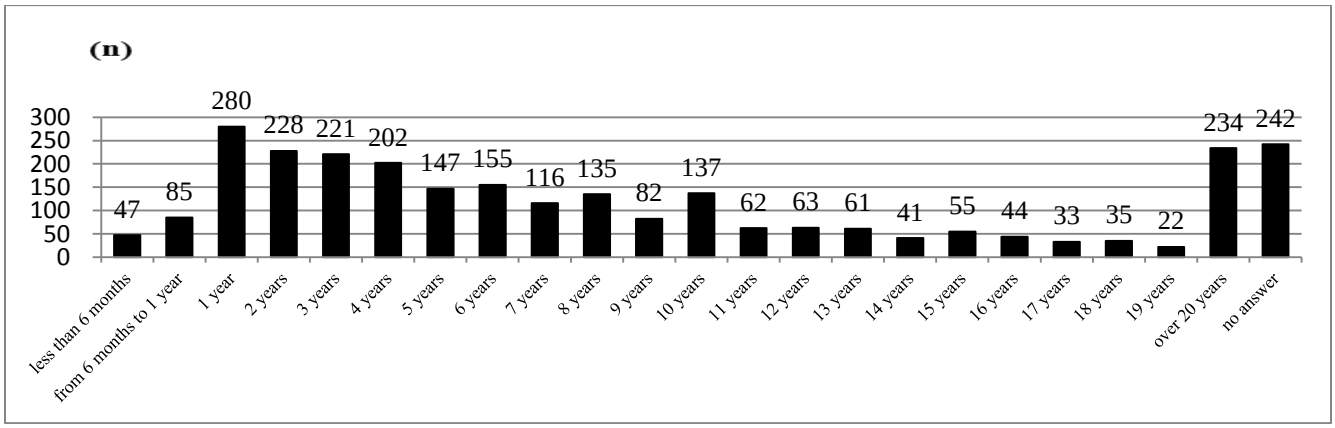
Table 2: Age Distribution of Dialysis Patients

Age	n	%
20–29	14	0.5
30–39	53	1.9
40–49	210	7.7
50–59	428	15.7
60–69	871	31.9
≥70	992	36.4
No answer	159	5.8

3.3 Dialysis Period

As shown in Figure 1, 28.9% continued dialysis for >10 years. The annual mortality in Japanese dialysis patients is the lowest in the world (The Japanese Society for Dialysis Therapy 2013). This depends on the development of the dialysis apparatus, cleanliness, and maintenance methods for dialysis systems. Significantly, almost all treatment expenses for dialysis are paid for by the Japanese National Health Insurance system. In comparison, in the United States, they focus on increasing the number of organ donors for transplantation, rather than on the development of new dialysis techniques (Suesawa 1998).

Figure 1: Dialysis Period for Patients



3.4 Patient Status for Enrollment in Kidney Transplant Recipient Registration

Surprisingly, 91.2% patients did not enroll in the kidney transplant recipient registry (Table 3-1). We questioned the patients for their choice in this respect (Table 3-2). The primary reasons were "The dialysis is enough for me" (42.0%) and "It is impossible even if I register" (31.9%). When these data were stratified by patient age of <60 years and ≥60 years, there was a significant difference in the response of "The dialysis is enough for me" between groups. Among the patients aged >60 years, 42.2%selected this reason; on the other hand, only 21.3%patients aged<60 years chose this option (Table 3-3). This suggests that many patients aged <60 years were not satisfied with dialysis therapy.

In a section of the questionnaire available for free answers, we obtained reasons for the lack of enrollment from 398 patients as follows: 1) advanced age, 2) low possibility of a transplant in patients >60 years old, 3)lack of transplant knowledge, 4) religious reasons, 5) personal reasons, and 6) expectations from regenerative medicine.

Table 3-1: Response of Dialysis Patients: Have you Enrolled in a Kidney Transplant Recipient Registry?

Response	n	%
Yes	199	7.3
No	2486	91.2
No answer	42	1.5

Table 3-2: If "No", Why Did You Not Enroll in a Kidney Transplant Recipient Registry?

Response	n	%
It is impossible even if I register	793	31.9
Registration fee is high	61	2.5
The dialysis is enough for me	1043	42.0
Other reasons	442	17.8
No answer	147	5.9

Table 3-3: If "No", why Did You Not Enroll in a Kidney Transplant Recipient Registry? (Subanalysis of Table 3-2 in Patients Aged < 60 Years or ≥ 60 years)

	< 60 years (%)	≥ 60 years (%)
It is impossible even if I register	26.4	29.2
Registration fee is high	3.6	2.3
The dialysis is enough for me	21.3	42.2
Others	26.7	14.9
No answer	22.0	11.4

3.5 Waiting Period of 14 Years before Transplantation

We asked the dialysis patients the following question: "It takes an average of 14 years for patients to undergo transplantation after registration in Japan. Are you aware of this?" The responses indicated that the majority of patients (78.9%) were not aware of this fact (Table 4). Because the patients did not want a transplant or believed that transplant was not possible, they may have been unconcerned in this regard and did not investigate the facts.

Table 4: Response of Dialysis Patients: It Takes an Average of 14 years for Patients to Undergo Transplantation after Registration in Japan. Are You Aware of This?

Response	n	%
Yes, I know	480	17.6
No, I don't	2151	78.9
No answer	96	3.5

3.6 Renal Transplantation from a Living Donor

During the 14-year wait after registration in Japan, patients may still undergo renal transplantation from a living donor, but in Japan, this must be a family member. Therefore, we posed the following question to patients: "Would you accept a kidney transplant from a living donor relative if possible?" The majority of patients (83.7%) responded that they did not want a kidney transplant from a living donor relative (Table 5-1). This may be because of patients being relatively well-conditioned under the best dialysis techniques in the world. Also, for patients undergoing long-term dialysis, their dialysis becomes their daily life, and they may no longer realize the inconvenience and disadvantages associated with it.

When these data were stratified by patient age of <60 years and ≥60 years, we found that 23.1% patients aged <60 years wanted a transplanted kidney from a living donor compared with only 9.2% patients aged >60 years (Table 5-2). These data show that younger patients with dialysis have greater expectations from transplantation compared with older patients.

Table 5-1: Response of Dialysis Patients: Would You Accept a Transplanted Kidney from a Living Donor Relative If Possible?

Response	n	%
Yes	332	12.2
No	2283	83.7
No answer	112	4.1

Table 5-2: Would You Accept a Transplanted Kidney from a Living Donor Relative if Possible? (Subanalysis of Table 5-1 in Patients Aged <60 Years or ≥60 Years)

Response	<60 years (%)	≥60 years (%)
Yes	23.1	9.2
No	74.0	86.7
No answer	2.9	4.1

3.7 Who Will Be a Living Donor?

We asked the following question to 332 patients who would accept living donor transplantation: "Who do you think the living donor would be?" The spouse was selected by 19.3% patients, and 15.4% patients suggested their sibling. Twenty-eight percent patients hoped for renal transplant, but unfortunately could not find a donor (Table 5-3). If the patient is single or has no siblings, they have little possibility of transplantation. In this sense, living donor renal transplantation may be unfair.

Table 5-3: If "Yes", Who Do You Think Will Be That Candidate?

Response	n	%
His or her parent	30	9.0
His or her sibling	51	15.4
His or her spouse	64	19.3
His or her child	32	9.6
Close relative	7	2.1
Uncertain	13	3.9
Nobody will become a donor	93	28.0
No answer	42	12.7

3.8 Opinions Regarding Living Donor Renal Transplantation

Living donor transplantation was recognized as ongoing medical care by 54.2% recipients, and 12.0% of recipients perceived it only as temporary medical care while 10.8% recipients perceived a problem with it as medical care (Table 6-1). Respondents were also provided with space to write a free answer. They responded as follows: "Family members may be pressurized to be donors", "Anxiety for the donor's health," "I do not intend to live with a kidney taken out of a living body," and "The recipient feels a psychological burden for the donor." For definition of terminology, "medical care" means regular medical care used for a long term and "temporary medical care" means medical care that is more likely to be changed to a different medical care in the near future.

For questions regarding medical care, 72.2% and 50.2% respondents aged <60 years and ≥60 years, respectively, perceived living donor transplantation as medical care (Table 6-2). Younger recipients more frequently recognized living donor renal transplantation as medical care compared with older ones. Because younger patients with dialysis had higher hopes of transplantation, this result would seem logical.

Table 6-1: Response of Dialysis Patients: What Do You Think About Living Donor Transplantation in Relatives?

Response	n	%
Recognized as medical care	1478	54.2
Recognized as temporary medical care	326	12.0
Had a problem as medical care	295	10.8
Others	246	9.0
No answer	382	14.0

Table 6-2: What Do You Think About Living Donor Transplantation in Relatives? (Subanalysis of Table 6-1 in Patients Aged <60 Years or ≥60 Years)

Response	<60 years (%)	≥60 years (%)
Recognized as medical care	72.2	50.2
Recognized as temporary medical care	12.6	10.8
Had a problem as medical care	4.3	12.0
Others	6.5	10.3
No answer	4.3	16.7

3-9. Innovative Practice in Japan (Restored Kidney Transplantation)

In the United States, approximately 14,000 renal transplantations were performed in 2013, primarily from brain-dead donors. However, the number of donors is still insufficient to meet the need because over 120,000 patients are on the waiting list for renal transplantation (Organ Donation and Transplantation Statistics USA 2014). Therefore, organs that were not previously used for transplantation are now being used, and these donors are defined as "marginal donors." The criteria for organ donation have been extended to include organs from elderly donors (double kidneys to a single recipient) and infectious organs (infected donor to infected recipient, e.g., hepatitis) (Sageshima 2013). The death rate for marginal donor kidney recipients shows a significant improvement in wait-listed patients still receiving dialysis; in addition, economic analysis suggests that transplantation with a marginal donor kidney is more cost effective compared with continued dialysis treatment (De Rosa and Muscogiuri 2013).

In Japan, different measures have been taken to increase the number of donors. The government urges citizens to declare their intentions regarding organ donation on their driver's licenses. In addition, the Organ Transplant Law was revised in 2010. Under the reformed law, organ donation is possible with the agreement of the family, even if the intention of the donor cannot be confirmed. Although these policies have been established, considerable changes in organ donation trends have not yet been observed in Japan.

Under these circumstances, one doctor in Japan (Dr. M) decided to use another source of kidneys. Between 1991 and 2006, he performed 42 restored kidney transplantations. Restored kidneys include cancerous kidneys (tumors must be ≤4 cm in diameter) removed from patients. The tumors are then carefully excised and the kidneys are surgically restored. Then, they are transplanted into individuals on the waiting list. However, these transplantations were performed only with oral informed consent (without documentation) and without approval from the Ethical Review Board of Uwajima Tokusyukai Hospital. Subsequently, the Japan Society for Transplantation released a statement that restored kidney transplantation was medically unacceptable. In view of this statement, the Ministry of Health, Labor and Welfare (MHLW) immediately revised its Organ Transplant Law and banned restored kidney transplantations. After strong opposition from a group of patients with kidney failure, in 2009, the MHLW permitted Uwajima Tokusyukai hospital to perform restored kidney transplantations as a medical trial. In this clinical trial, recipients were selected on the basis of blood group matching, high clinical evaluation scores, and negative results of cross-match testing. The term "match" refers to 6 possible HLAs. Before treatment with antirejection medications, 6 out of 6 antigens must match for successful transplantation. Since this time, Uwajima Tokusyukai Hospital has conducted 14 such transplantations, of which 12 involved unrelated donor–recipient pairs.

Many small renal tumors are nephrectomized in Japan, resulting in the disposal of an excessive number of discarded kidneys every year. Using discarded cancerous kidneys for transplantation may help in compensating for donor shortage. The issue of cancer recurrence is a concern in restored kidney transplantation, and the 5-year recurrence rate of cancer after restored kidney transplantation remains undetermined. Nicol et al. estimated that it may occur in less than one in 50 cases (0.5%) (Nicol and Fujita 2011). However, the recurrence rate after radical or partial nephrectomy is reported to be <6% (Poppel 2011). In our survey, we questioned dialysis patients on the assumption of a 5-year recurrence rate of 6% after restored kidney transplantation, a rate which is very high compared with the actual rate.

3-10. Opinions of Dialysis Patients Regarding Restored Kidney Transplantation

In response to the question "What do you think about restored kidney transplantation," the majority (45.1%) of recipients recognized restored kidney transplantation as medical care, and 14.2% of recipients perceived it as only temporary medical care while 19.1% recipients perceived a problem with it as medical care because of the risk of cancer recurrence (Table7-1). The ratio of patients accepting restored kidney transplantation (45.1%) is not worse than the number of patients who accepted living donor renal transplantation as medical care (54.2%). Perception of restored kidney transplantation as medical care was 50.3% in male patients and 37.3%in female patients (Table 7-2). Female patients may be more conservative and cautious about new treatment compared with male patients. As a free answer, patients expressed "I fear the recurrence of cancer," "If a patient understands the definition of a restored kidney, there is no problem," "A further clinical study is necessary," "One option for recipients, "and "The restored kidney should be returned to the person it originated from."

Table 7-1: Response of Dialysis Patients: What Do You Think about Restored Kidney Transplantation?

Response	n	%
Recognized as medical care	1229	45.1
Recognized as temporary medical care	386	14.2
Had a problem as medical care	520	19.1
Others	234	8.6
No answer	358	13.1

Table 7-2: What Do You Think about Restored Kidney Transplantation? (Subanalysis of Table 7-1 According to Sex)

Response	Male (%)	Female (%)
Recognized as medical care	50.3	37.3
Recognized as temporary medical care	14.9	13.4
Had a problem as medical care	17.9	22.2
Others	7.5	10.1
No answer	9.5	17.0

3-11. Dialysis Patients Want to Undergo Restored Kidney Transplantation?

In response to the next question "When it is introduced into medical care, do you want to undergo restored kidney transplantation?," 20.1% dialysis patients chose restored kidney transplantation (Table 8-1). When these data were stratified into patient age of<60 years and ≥60 years, we found that 27.8% patients aged <60 years requested restored kidney transplantation compared with only 17.4% patients aged >60 years (Table 8-2). Table 8-3 shows a subanalysis of Table 8-1 for patients who would accept living donor transplantation or those who would not. These data show that patients who would accept restored kidney transplantation were relatively young and living donor transplant applicants.

Because the clinical studies were conducted at Tokusyukai Hospital Group, we subanalyzed Table 8-1 by dividing patients into the Tokusyukai Hospital group and Other Hospitals group in order to secure the equity of the data (Table 8-4). The survey included 1495 patients from the Tokusyukai Hospital group and 1232 patients from the Other Hospitals group, with no significant difference between groups. We found that 22.5% patients in the Tokusyukai Hospital group wished for restored kidney transplantation compared with 17.1% patients in the Other Hospitals group. We concluded that patient decision was not affected by hospital.

Table 8-1: Response of Dialysis Patients: When It Is Introduced into Medical Care, Would You Accept Restored Kidney Transplantation?

Response	n	%
Yes	548	20.1
No	1228	45.0
Cannot decide	852	31.2
No answer	99	3.6

Table 8-2: When It Is Introduced into Medical Care, Would You Accept Restored Kidney Transplantation? (Subanalysis of Table 8-1 in Patients Aged <60 years or ≥60 years)

Response	<60 years (%)	≥60 years (%)
Yes	27.8	17.4
No	32.9	49.0
Cannot decide	38.6	29.6
No answer	0.7	4.1

Table 8-3: When It Is Introduced into Medical Care, Would You Accept Restored Kidney Transplantation? (Subanalysis of Table 8-1 in Patients Who Would Accept Living Donor Transplantation (LDT) or Those Who Would Not Accept Living Donor Transplantation)

Response	Want LDT (%)	Do not want LDT (%)
Yes	53.6	15.5
No	17.8	49.2
Cannot decide	27.1	32.8
No answer	1.5	2.8

Table 8-4: When It Is Introduced Into Medical Care, Would You Accept Restored Kidney Transplantation? (Subanalysis of Table 8-1 in Tokusyukai Hospital Group or Other Hospitals)

Response	Tokusyukai H.G. (%)	Other Hospitals (%)
Yes	22.5	17.1
No	41.5	49.4
Cannot decide	30.8	31.7
No answer	5.2	1.8

4. *Conclusions*

The ratio of total dialysis expenses to the national medical expenditure is roughly 5%. Because the national medical expenditure in 2013 was 38.4 trillion yen (US$384 billion) (Ministry of Health, Labor and Welfare. 2014), the total dialysis expense would be calculated at 1.9 trillion yen (US$19 billion). Recently the Japanese government significantly lowered the cost of dialysis treatment under the medical expenditure reduction policy. At present, a high standard of dialysis treatment is offered, but the dialysis quality may decrease in the near future because the number of dialysis patients increases year by year. The death rate of dialysis patients in the United States is much higher than that in Japan because of the shorter dialysis time and the low quality of dialysis efficiency, where the blood is circulated more speedily and in a larger volume (Suesawa 1998). Such dialysis methods decrease medical expenses.

Almost all treatment expenses for dialysis or transplant in Japan are paid for by the Japanese National Health Insurance system. The cost of dialysis averages 5–6 million yen (US$50,000–60,000) per patient per year (Dialysis Treatment Network 2010), and the cost of transplantation is much lower than that of dialysis. The average cost of transplantation, including the transplant surgery and medical care for the first postoperative year, averages 4 million yen (US$40 000). After the first year, the cost of transplantation averages 1.5 million yen (US$15,000), mostly for medications to prevent rejection (Novartis Pharma 2011).

In this survey, 28.0% patients among those expecting living donor transplantation could not find a donor, and more than 20% dialysis patients wanted to undergo restored kidney transplantation if possible. Guidelines on Renal Transplantation (2009) published by the European Association of Urology (European Association of Urology 2009) state the following: “Because of a low risk of recurrence, kidneys with small renal cell carcinoma (RCC) can be considered for local excision and transplantation after the recipient has provided informed consent. The risk of RCC transmission to the contralateral kidney and/or to other organs is even lower.” Medical transplantation originally started and has been developed on the basis of the assumption that human bodies are medical resources. In the current severe economic situation, we must analyze cost-effective plans for renal replacement therapy.

Appendix

1] The day when questionnaire was filled out.
2] Sex / How old are you? (20–29, 30–39, 40–49, 50–59, 60–69, ≥70 years)
3] How long are you on dialysis?
4] Have you enrolled in a kidney transplant recipient registry? / If “no”, why did you not enroll in a kidney transplant recipient registry? (1.It is impossible even if I register. 2. Registration fee is high. 3. The dialysis is enough for me. 4. Others)
5] It takes an average of 14 years for patients to undergo transplantation after registration in Japan. Are you aware of this?

6] Would you accept a transplanted kidney from a living donor relative if possible? / If "yes", who do you think will be that candidate? (1.your parent 2.your sibling 3.your spouse 4.your child 5.members of extended family 6.uncertain 7.nobody will become a donor)

7] What do you think about living donor transplantation in relatives?

8] Total nephrectomy is often performed as a treatment for small renal tumors (≦4 cm). Many of these nephrectomized kidneys could be successfully transplanted after surgical restoration with satisfactory results. However this is currently not allowed in Japan because of the lack of necessary evidence. The issue of cancer recurrence is a concern in restored kidney transplantation. The 5-year recurrence rate of cancer after restored kidney transplantation remains undetermined and we estimated it to be 6%. What do you think about restored kidney transplantations?

9] When it is introduced into medical care, would you accept restored kidney transplantation?

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