# Malignancies in Deceased Organ Donors: The Spanish Experience

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**Background.** To better define the risk of malignancy transmission through organ transplantation, we review the Spanish experience on donor malignancies. **Methods.** We analyzed the outcomes of recipients of organs obtained from deceased donors diagnosed with a malignancy during 2013–2018. The risk of malignancy transmission was classified as proposed by the Council of Europe. **Results.** Of 10076 utilized deceased donors, 349 (3.5%) were diagnosed with a malignancy. Of those, 275 had a past (n = 168) or current (n = 107) history of malignancy known before the transplantation of organs into 651 recipients. Ten malignancies met high-risk criteria. No donor-transmitted cancer (DTC) was reported after a median follow-up of 24 (interquartile range [IQR]: 19–25) mo. The other 74 donors were diagnosed with a malignancy after transplantation. Within this group, 64 donors (22 with malignancies of high or unacceptable risk) whose organs were transplanted into 126 recipients did not result in a DTC after a median follow-up of 26 (IQR: 22–37) mo, though a prophylactic transplantectomy was performed in 5 patients. The remaining 10 donors transmitted an occult malignancy to 16 of 25 recipients, consisting of lung cancer (n = 9), duodenal adenocarcinoma (n = 2), renal cell carcinoma (n = 2), extrahepatic cholangiocarcinoma (n = 1), prostate cancer (n = 1), and undifferentiated cancer (n = 1). After a median follow-up of 14 (IQR: 11–24) mo following diagnosis, the evolution was fatal in 9 recipients. In total, of 802 recipients at risk, 16 (2%) developed a DTC, which corresponds to 6 cases per 10 000 organ transplants. **Conclusions.** Current standards may overestimate the risk of malignancy transmission. DTC is an infrequent but difficult to eliminate complication.

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## INTRODUCTION

Organ shortage is the most important obstacle that precludes the full expansion of transplantation therapies.[1] One reason why possible donors do not transition to utilized deceased organ donors is medical unsuitability.[2] It is critical to minimize the risk of disease transmission, but also to avoid the unnecessary loss of organs.

A current or past history of malignancy in a donor needs to be carefully assessed before transplantation. The risk of transmission must be balanced with that of a particular recipient dying or dropping out from the waiting list.[3] Risk of transmission varies depending on the type of cancer, grade and stage at diagnosis, treatment and disease-free interval. Based on the limited evidence available, several organizations have classified donor malignancies in different risk levels.[4-7] A comparison of existing classifications has been recently published.[8] The Council of Europe considers 4 levels of risk of malignancy transmission: (1) minimal (eg, basalioma, central nervous system [CNS] neoplasia of the World Health Organization [WHO] grades 1–2, renal cell carcinoma [RCC] <1 cm and Fuhrman I–II); (2) low to intermediate (eg, colorectal cancer pT2N0 in complete remission ≥5–10 y, RCC 1–4 cm and Fuhrman I–II); (3) high (breast cancer in complete remission ≥5–10 y, glioblastoma); (4) unacceptable (eg, metastatic cancer).[7,8] Although a minimal risk of transmission is acceptable for any patient on the waiting list, a high risk is only considered acceptable after an individualized risk-benefit assessment and informed consent.[7] Although this guidance is of high value, there has been no prospective and standardized follow-up of recipients of organs obtained from donors with malignancies that could validate existing recommendations.[9]

A malignancy in the donor can also be identified after organ transplantation has taken place, when new information becomes available (eg, donor autopsy), or clinical manifestations in a recipient raise suspicion of a donor-transmitted cancer (DTC).

The risk of DTC was likely overestimated in reports from the Israel Penn International Transplant Tumor Registry (IPITTR), since its voluntary nature made it lack appropriate denominators.[10-13] Mandatory registries, where both numerator and denominator are known, reveal that the frequency of DTC ranges from 0 to 6 cases per 10 000 transplants, and that DTC is usually unknown in the donor before transplantation.[14-26] One of these studies described the Spanish experience during 1990–2006, reporting a rate of 6 DTCs per 10 000 solid organ transplants.[19] Since then, important changes have occurred in the profile of deceased organ donors in the country, who are becoming older.[27] As the risk of malignancy increases with age, it is likely that unknown malignancies in organ donors have become more frequent. Additionally, the transplantation of organs from donors with malignancy is being considered based on national recommendations that are aligned with those from the Council of Europe.[28]

The objective of the present study is to review the most recent Spanish experience on the outcomes of recipients of organs obtained from deceased donors with a malignancy identified either before or after transplantation. We aim at contributing to better define the risk of malignancy transmission through organ transplantation.

## MATERIALS AND METHODS

This is a nationwide, prospective study, focused on the outcomes of recipients of organs from deceased organ donors diagnosed with a malignancy. Information was derived from 2 sources: the nonstandard risk donor (NSRD) program and the biovigilance system, both managed by the Organización Nacional de Trasplantes (ONT).

The NSRD program was launched in 2013 to evaluate the safety of the transplantation of organs obtained from donors with a disease or condition (including a malignancy) that could be potentially transmitted to recipients, being such donor condition known and the risk assumed before transplantation. The program consists of the prospective follow-up of recipients at risk.

Donor coordination teams notify every potential donor to ONT providing all data required for donor and organ characterization and documented reports of any relevant diagnosis.[29] Donor coordinators and ONT make a first evaluation of potential donors, for ONT to then proceed with organ allocation and organ offers, transmitting all relevant information to transplant teams. ONT prospectively identifies all potential donors meeting NSRD criteria. Once a NSRD is identified and the transplant team decides to proceed with organ transplantation based on an individual risk-benefit assessment (supported by the aforementioned guidelines)[28] and recipient's informed consent, ONT activates an automatic systematized follow-up questionnaire for each recipient that must be completed at different time points (in case of donor malignancies, at 6 mo and 1 and 2 y after transplantation, with additional assessments when required). The follow-up questionnaire is completed at a secure web-based platform by designated personnel at transplant centers. Information is collected on whether there is an adverse outcome in the recipient that is suspicious of being related to the donor condition (including a DTC).[30] If this is the case, a form must be completed and reported to the national biovigilance system.

The biovigilance system is conceived to report, manage and analyze serious adverse events and reactions, including malignancies identified in the donor after the transplantation of organs and suspected cases of DTC (Table 1).[30] Reporting of cases is performed by donor transplant coordinators and transplant teams—or any professional identifying a reportable situation. Management of cases, including alerting centers involved to take preventive or therapeutic measures, is coordinated at a supra-hospital level by ONT and the regional coordination units. Information on all reported serious adverse events and reactions and on their management is compiled and analyzed by ONT. For recipients at risk or with suspected DTCs, a follow-up questionnaire identical to the one used in the NSRD program must be completed. In case of a suspected DTC and following the corresponding investigation, the case is assessed to determine the donor origin by using a tool inspired on the one developed by the Disease Transmission Advisory Committee in the United States (**Table S1, SDC,** http://links.lww.com/TP/C388).[31] The suspected DTC can be classified as having a definite/certain, probable, possible, or excluded relationship with the donor. A suspected DTC is considered confirmed when the likelihood of a donor origin is classified as definite/certain, probable, or possible.

**TABLE 1.**

**Scenarios that should raise reasonable suspicion of a donor-transmitted cancer, as described by Spanish National Guidelines**

| | Scenario |
|---|---|
| 1 | Cancer (other than posttransplant lymphoproliferative disorders) arising within the first 2 y after transplant |
| 2 | Cancer arising in the allograft organ in a patient with no history of carcinoma in the corresponding native organ |
| 3 | Metastatic carcinoma arising in an allograft recipient, particularly when a primary site cannot be identified |
| 4 | Metastatic carcinoma of allograft type (eg, RCC in a renal transplant recipient) in a recipient with no known history of that type of cancer |
| 5 | CNS neoplasia occurring outside the CNS, particularly in a transplant patient with no known CNS involvement |
| 6 | Sex-specific cancer (eg, choriocarcinoma) arising in a transplant patient of the opposite sex |
| 7 | Age discordant cancer (eg, pediatric cancer arising in an adult transplant recipient or vice versa) |
| 8 | Cancer in which there is specific suspicion of donor origin (eg, use of organs from a donor with a known history of cancer) |

CNS, central nervous system; RCC, renal cell carcinoma.

For the present study, we analyzed information from deceased donors with a malignancy diagnosed before transplantation (NSRD) and after transplantation (biovigilance), from January 2013 to December 2018. Donors diagnosed with benign neoplasia or with nonmelanoma skin cancer (basalioma or epithelioma) were excluded. Donors with any CNS neoplasia, regardless of the WHO grade, any type of in situ carcinoma and a variety of hematopoietic disorders, were included. Each donor malignancy was classified based on the risk levels proposed by the Council of Europe (**Table S2, SDC,** http://links.lww.com/TP/C388).[7] We also analyzed the outcomes of recipients of organs obtained from these donors, and the development of confirmed DTC, as previously defined. The assessment of risk levles and of the likelihood of donor-origin of suspected DTCs was performed by 2 separate physicians of the ONT team, with oncologist expert advice when required.

Quantitative data is presented as mean and SD or as median and interquartile range (IQR), depending on the dispersion of the sample. Qualitative data are presented as absolute numbers and percentages. We have used the statistical package IBM SPSS Statistics version 25.

The study was approved by the Institutional Review Board of ONT.

## RESULTS

During 2013–2018, 11 631 actual deceased organ donors were registered in Spain, of whom 10 076 transitioned to utilized deceased donors, providing 26 483 organs that were transplanted into 25 785 recipients. In total, 349 (3.5%) utilized organ donors were known to have a malignancy either before (n = 275) or after (n = 74) transplantation (Figure 1).

### Donor Malignancies Identified Before Transplantation

Of utilized deceased organ donors, 275 (2.7%) had a current or past history of malignancy known before the transplantation of organs into 651 recipients (354 kidneys, 193 livers, 42 hearts, 44 lungs, 1 pancreas, 11 combined pancreas-kidney, 6 combined liver-kidney).

Malignancies were identified in the donor's history in 168 (61%) cases and during the donation process in 107 (39%). In donors with a past history of malignancy, the median time between the diagnosis of cancer and death was 11 (IQR: 6–18) y and the median disease-free interval was 10 (IQR: 6–17) y. Types of donor malignancies and their classification according to the risk levels of the Council of Europe[7] are displayed in Table 2. The risk of malignancy transmission was considered minimal in 151 (55%) donors, low in 68 (25%), intermediate in 23 (8%), and high in 10 (4%). Additionally, 16 (6%) neoplasia were considered of minimal risk by radiological assessment with no confirmatory histology (all CNS neoplasia) and 7 (2%) of undetermined risk.

Malignancies deemed of high risk of transmission were a breast cancer (T2N0M0), 2 colorectal cancers (T3N1M0), a type I myelodysplastic syndrome, a cancer of the cavum (T2bN2bM0), a moderately differentiated liver cancer, and 2 prostate cancers (intra-prostate, Gleason 9), all diagnosed ≥5–10 y before death, appropriately treated and deemed disease-free at the time of donation. Two other high-risk malignancies were identified at the moment of donation and consisted of a glioblastoma (untreated) and an RCC (<4 cm, Fuhrman III).

At the moment of submitting this article, follow-up information was available from 554 of the 651 recipients at risk (85%), including all 19 recipients of organs from high-risk donors. After a median follow-up of 24 (IQR: 19–25) mo, 84 (15%) recipients had died and 46 (8%) had lost their grafts (censored for death). No patient death or graft loss was considered to be associated with the donor malignancy. There was no case of suspected DTC reported.

### Donor Malignancies Identified After Transplantation

During the study period, 74 (0.7%) utilized deceased organ donors were diagnosed with a malignancy after at least one of their organs had been transplanted, of whom 64 did not result in a DTC, whereas 10 did.

#### Donor Malignancies That Did Not Result in Transmission

Sixty-four donors diagnosed with a malignancy after transplantation provided organs to 126 recipients (57 kidneys, 39 livers, 10 hearts, 16 lungs, 3 combined kidney–liver, 1 combined kidney–pancreas). Donor cancers were identified at the back-table surgery of kidneys recovered for transplantation when other transplants were taking place or had concluded in 36 (56%) cases (all RCC), following a donor autopsy in 12 (19%), when receiving the definite pathology of a suspicious lesion intraoperatively informed as benign in 12 (19%) and when some new information became available from the donor's history

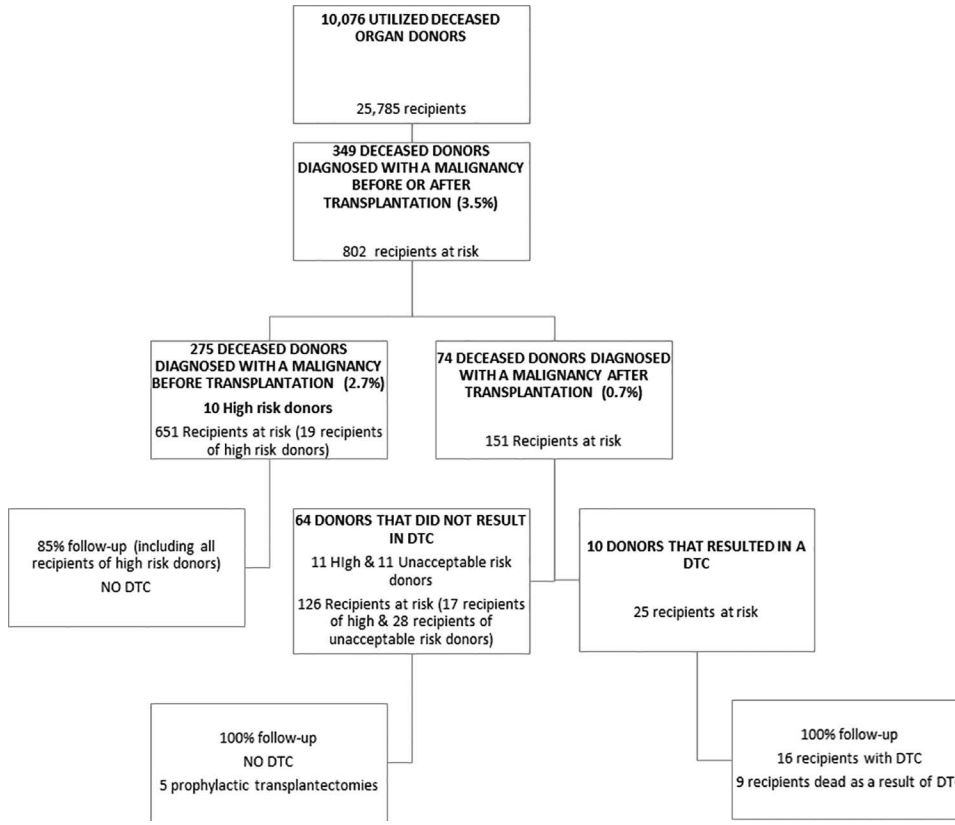


**FIGURE 1.** Utilized donors diagnosed with a malignancy before or after transplantation, recipients at risk and outcomes (Spain 2013–2018). DTC, donor-transmitted cancer.

**TABLE 2.**

**Classification of the risk of malignancy transmission in donors with a current or past history of malignancy known before transplantation**

| | Minimal risk | Low risk | Intermediate risk | High risk | Unacceptable risk | Minimal risk by image[a] | Undetermined risk | Total |
|---|---|---|---|---|---|---|---|---|
| Breast cancer | 0 | 3 | 4 | 1 | 0 | 0 | 0 | 8 |
| CNS neoplasia | 85 | 0 | 0 | 1 | 0 | 16 | 0 | 102 |
| Colorectal cancer | 4 | 2 | 1 | 2 | 0 | 0 | 0 | 9 |
| Gastric cancer | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 3 |
| GIST | 1 | 4 | 0 | 0 | 0 | 0 | 0 | 5 |
| Head and neck cancer | 1 | 7 | 5 | 1 | 0 | 0 | 0 | 14 |
| Hematopoietic neoplasia[b] | 0 | 0 | 7 | 1 | 0 | 0 | 6 | 14 |
| Liver cancer | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Neuroendocrine tumor[c] | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 3 |
| Ovarian cancer | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Prostate cancer | 27 | 6 | 1 | 2 | 0 | 0 | 0 | 36 |
| Renal cell carcinoma | 18 | 10 | 2 | 1 | 0 | 0 | 0 | 31 |
| Supra-renal tumor | 0 | 4 | 2 | 0 | 0 | 0 | 0 | 6 |
| Testicular cancer | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 2 |
| Thyroid cancer | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 3 |
| Urothelial cancer | 7 | 8 | 0 | 0 | 0 | 0 | 0 | 15 |
| Uterine cervix carcinoma | 3 | 5 | 0 | 0 | 0 | 0 | 0 | 8 |
| Uterus cancer | 0 | 7 | 0 | 0 | 0 | 0 | 0 | 7 |
| Other | 2 | 4 | 0 | 0 | 0 | 0 | 1 | 7 |
| Total | 151 | 68 | 23 | 10 | 0 | 16 | 7 | 275 |

[a]Minimal risk by image: CNS neoplasia diagnosed by neuro-radiological image, with no histological diagnosis available.
[b]Essential thrombocythemia (1), gastric mucosa-associated lymphoid tissue lymphoma (2), Hodgkin lymphoma (1), monoclonal gammopathy (3), lymphoma (1), myelodysplastic syndrome (1), non-Hodgkin lymphoma (3), polycythemia vera (2).
[c]Neuroendocrine tumors (2 lung, 1 colon).
CNS, central nervous system; GIST, gastrointestinal stromal tumor.

in 4 (6%). The diagnosis of donor cancer was made at a median of 1 (IQR: 0–9) d after transplantation.

Types of malignancies and their risk classification according to the Council of Europe[7] are displayed in Table 3. Twenty-two (34%) neoplasia were considered of minimal risk of transmission, 14 (22%) low, 5 (8%) intermediate, 11 (17%) high, 11 (17%) unacceptable, and 1 (2%) undetermined. Malignancies of high risk were a chordoma, a gastrointestinal stromal tumor (gastric, 4 cm, low mitotic index), and 9 RCC (4 mm to 5 cm, all Fuhrman III–IV). Malignancies deemed of unacceptable risk were an adenocarcinoma identified in a nodule in omentum, a breast cancer, a gallbladder adenocarcinoma (0.5 cm), a follicular lymphoma (grade 1), 2 liver cancers, 4 lung cancers, and an RCC (metastatic).

Follow-up information was available from the 126 (100%) recipients at risk, including 17 recipients of organs from donors of high risk of transmission and 28 recipients of organs from donors of unacceptable risk. After a median follow-up of 26 (IQR: 22–37) mo after transplantation, 23 (18%) patients had died, though no death was considered related to the malignancy in the donor. Thirteen (10%) patients had lost their graft (censored for death), with 5 graft losses related to the donor cancer. In these 5 patients, a prophylactic transplantectomy was performed to avoid the transmission of a malignancy deemed of unacceptable risk. No case of suspected DTC was reported.

### Donor Malignancies That Resulted in Transmission

During the study period, 10 other donors transmitted a malignancy to 16 (10 kidneys, 5 livers, 1 combined liver-kidney) of the 25 recipients of their organs. A summary of cases of DTCs is displayed in Table 4. DTCs consisted on lung cancer (n = 9), duodenal adenocarcinoma (n = 2), RCC (n = 2), extrahepatic cholangiocarcinoma (n = 1), prostate cancer (n = 1), and undifferentiated cancer (n = 1). Transmissions were diagnosed at a median of 14 (IQR: 11–24) mo after transplantation, incidentally in 6 patients and because of suspicious symptoms in the remaining 10. Of the 16 DTCs, 11 had disseminated beyond the graft, whereas 5 were confined to the graft at the moment of diagnosis.

None of the malignancies of these 10 donors had been identified before the transplantation of organs. A lung cancer had been diagnosed at a donor autopsy 6 mo after the transplantation of the 2 kidneys and the liver. After informing the recipients, the decision was made not to proceed with transplantectomy. Unfortunately, the 2 kidney recipients developed a DTC 4 y after transplantation and died as a result of a metastatic cancer. Notably, the liver recipient was disease-free at the last available follow-up. In the other 9 donors, the donor cancer was revealed when already transmitted.

After a median follow-up time of 30 (IQR: 17–52) mo following transplantation and 14 (IQR: 11–24) mo following diagnosis, 11 of the 16 patients with a DTC had died, with 9 deaths related to the malignancy in the donor, and 12 recipients had lost their graft, with 10 graft losses related to the donor cancer.

Nine other recipients of organs from these donors did not develop a DTC, though 3 died because of unrelated causes.

### Summary of Outcomes of Recipients of Organs From Donors With Malignancies

Table 5 and Figure 1 summarize the outcomes of all recipients of donors with malignancies identified either

**TABLE 3.**

**Classification of the risk of malignancy transmission in donors with a malignancy identified after the transplantation of organs**

| | Minimal risk | Low risk | Intermediate risk | High risk | Unacceptable risk | Minimal risk by image[a] | Undetermined risk | Total |
|---|---|---|---|---|---|---|---|---|
| Adenocarcinoma omentum | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| Breast cancer | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| CNS neoplasia | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 2 |
| Colorectal cancer | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Esophageal cancer | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| Gallbladder adenocarcinoma | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| GIST | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Hematopoietic neoplasia[a] | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 2 |
| Liver cancer | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 2 |
| Lung cancer | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 4 |
| Neuroendocrine tumor[c] | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| Pancreas tumor[d] | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| Prostate cancer | 3 | 1 | 0 | 0 | 0 | 0 | 0 | 4 |
| Renal cell carcinoma | 16 | 10 | 2 | 9 | 1 | 0 | 0 | 38 |
| Thyroid cancer | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| Urothelial cancer | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 3 |
| Total | 22 | 14 | 5 | 11 | 11 | 0 | 1 | 64 |

[a]Minimal risk by image: CNS neoplasia diagnosed by neuro-radiological image, with no histological diagnosis available.
[b]Follicular lymphoma (1), mycosis fungoides (1).
[c]Neuroendocrine tumor (1 ileocolic lymphadenopathy).
[d]Solid pseudopapillary tumor of the pancreas.
CNS, central nervous system; GIST, gastrointestinal stromal tumor.

**TABLE 4.**

**Description of cases of donor-transmitted malignancies and outcomes of recipients of organs from donors involved**

| | Donor demographics | Recipients at risk | Malignancy/status at diagnosis | Likelihood of donor origin | Time of malignancy diagnosis after transplantation (mo) | How the malignancy was discovered | Time of follow-up since transplantation (mo) | Transplantectomy/ excision | Recipient outcome | Death related to donor malignancy |
|---|---|---|---|---|---|---|---|---|---|---|
| Donor 1 | Male, 63 y | Kidney recipient right | Transmitted small cell lung cancer/D | Probable | 6 | Study after diagnosis in liver recipient | 9 | Transplantectomy | Deceased | Yes |
| | | Kidney recipient left | Transmitted small cell lung cancer/D | Probable | 6 | Study after diagnosis in liver recipient | 51 | Transplantectomy | Alive | |
| | | Liver recipient | Transmitted small cell lung cancer/D | Probable | 6 | Incidental (on routine ultrasound scan) | 10 | No | Deceased | Yes |
| Donor 2 | Male, 60 y | Kidney recipient right | Transmitted lung cancer/D | Definite | 16 | Graft dysfunction | 16 | No | Deceased | No |
| | | Kidney recipient left | Transmitted lung cancer/D | Definite[a] | 18 | Graft dysfunction | 21 | Transplantectomy | Deceased | Yes |
| | | Liver recipient | Transmitted lung cancer/D | Definite[a] | 7 | Graft dysfunction | 10 | No | Deceased | Yes |
| Donor 3 | Male, 42 y | Kidney recipient right | Transmitted lung cancer/D | Definite | 44 | Graft dysfunction | 46 | Transplantectomy | Deceased | Yes |
| | | Kidney recipient left | Transmitted lung cancer/D | Definite | 49 | Osteolytic lesions | 56 | Transplantectomy | Deceased | Yes |
| | | Liver recipient | No DTC | | | | 116 | No | Alive | |
| Donor 4 | Male, 61 y | Liver recipient | Transmitted small cell lung cancer/D | Definite[a] | 14 | Graft dysfunction | 26 | No | Deceased | Yes |
| Donor 5 | Male, 41 y | Kidney recipient right | Transmitted RCC/L | Definite | 5 | Incidental (on biopsy performed to assess graft dysfunction) | 81 | Transplantectomy | Alive | |
| | | Combined kidney-liver recipient | No DTC | | | | 27 | No | Alive | |
| | | Heart recipient | No DTC | | | | 23 | No | Alive | |
| | | Lung recipient | No DTC | | | | 3 | No | Deceased | No |
| Donor 6 | Male, 56 y | Kidney recipient right | No DTC | | | | 30 | No | Alive | |
| | | Kidney recipient left | Transmitted RCC/L | Definite | 1 | Incidental (on explant due to graft dysfunction) | 31 | Transplantectomy | Alive | |
| Donor 7 | Female, 57 y | Combined kidney-liver recipient | Transmitted extrahepatic cholangiocarcinoma/L | Definite[a] | 47 | Incidental (on explanted liver) | 60 | Transplantectomy and retransplantation | Alive | |
| | | Kidney recipient right | No DTC | | | | 9 | No | Deceased | No |
| | | Lung recipient | No DTC | | | | 59 | No | Alive | |
| Donor 8 | Male, 60 y | Kidney recipient right | Transmitted duodenal cancer/D | Definite[a] | 25 | Cutaneous lesions | 29 | No | Deceased | Yes |
| | | Kidney recipient left | Transmitted duodenal cancer/D | Definite[a] | 25 | Ascitis—peritoneal carcinomatosis | 33 | No | Deceased | Yes |
| Donor 9 | Male, 74 y | Kidney recipient right | No DTC | | | | 42 | No | Deceased | No |
| | | Kidney recipient left | No DTC | | | | 50 | No | Alive | |
| | | Liver recipient | Transmitted prostate cancer/L | Probable[a] | 5 | Incidental (on routine ultrasound scan) | 53 | Excision | Alive | |
| Donor 10 | Male, 83 y | Liver recipient | Transmitted undifferentiated cancer/L | Definite | 0.3 | Incidental (on protocol graft ultrasound) | 24 | Transplantectomy and retransplantation | Alive | |

[a]Molecular cytogenetic test was performed and consistent with donor origin.

D, disseminated; DTC, donor-transmitted cancer; L, localized; RCC, renal cell carcinoma.

**TABLE 5.**

**Outcomes of recipients at risk according to malignancy location in the donor**

| Malignancy (location in the donor) | Donors with malignancy[a] | Recipients at risk | Recipients at risk with follow-up information | Recipients with confirmed malignancy transmission[b] | Graft loss related to donor malignancy[c] | Death related to donor malignancy |
|---|---|---|---|---|---|---|
| Adenocar. omentum | 1 | 2 | 2 | 0 | 1 | 0 |
| Breast cancer | 9 | 28 | 20 | 0 | 0 | 0 |
| Cholangiocarcinoma | 1 | 3 | 3 | 1 | 0 | 0 |
| CNS neoplasia | 104 | 279 | 243 | 0 | 0 | 0 |
| Colorectal cancer | 10 | 18 | 17 | 0 | 0 | 0 |
| Duodenal cancer | 1 | 2 | 2 | 2 | 0 | 2 |
| Esophageal cancer | 1 | 4 | 4 | 0 | 0 | 0 |
| Gallbladder adenocarcinoma | 1 | 3 | 3 | 0 | 1 | 0 |
| Gastric cancer | 3 | 9 | 9 | 0 | 0 | 0 |
| GIST | 6 | 12 | 11 | 0 | 0 | 0 |
| Head and neck cancer | 14 | 25 | 20 | 0 | 0 | 0 |
| Hematopoietic neoplasia | 16 | 33 | 31 | 0 | 0 | 0 |
| Liver cancer | 3 | 5 | 5 | 0 | 0 | 0 |
| Lung cancer | 8 | 21 | 21 | 9 | 10 | 7 |
| Neuroendocrine tumor | 4 | 10 | 8 | 0 | 0 | 0 |
| Ovarian cancer | 1 | 2 | 2 | 0 | 0 | 0 |
| Pancreas tumor | 1 | 4 | 4 | 0 | 0 | 0 |
| Prostate cancer | 41 | 91 | 74 | 1 | 0 | 0 |
| Renal cell carcinoma | 71 | 116 | 110 | 2 | 2 | 0 |
| Supra-renal tumor | 6 | 18 | 17 | 0 | 0 | 0 |
| Testicular cancer | 2 | 5 | 4 | 0 | 0 | 0 |
| Thyroid cancer | 4 | 13 | 12 | 0 | 0 | 0 |
| Urothelial cancer | 18 | 39 | 31 | 0 | 0 | 0 |
| Uterus cancer | 7 | 16 | 14 | 0 | 0 | 0 |
| Uterine cervix carcinoma | 8 | 24 | 20 | 0 | 0 | 0 |
| Other | 7 | 19 | 17 | 0 | 0 | 0 |
| Undiff. cancer | 1 | 1 | 1 | 1 | 1 | 0 |
| Total | 349 | 802 | 705 | 16 | 15 | 9 |

[a]Includes 21 donors of high risk (breast 1, CNS 2, colorectal 2, gist 1, head and neck 1, hematopoietic 1, liver 1, prostate 2, renal cell carcinoma 10) and 11 of unacceptable risk (adenocarcinoma omentum 1, breast 1, gallbladder 1, hematopoietic 1, liver 2, lung 4, renal cell carcinoma 1). The follow-up information of all 64 recipients of organs from donors deemed of high or unacceptable risk is available.
[b]Donor origin of malignancy in the recipient classified as possible, probable, or definite/certain.
[c]Five prophylactic transplantectomies: adenocarcinoma omentum, gallbladder adenocarcinoma, lung cancer (2), renal cell carcinoma.
CNS, central nervous system; GIST, gastrointestinal stromal tumor.

before or after transplantation. Summaries by organ transplant type are presented as Supplementary material (**Tables S3–S5, SDC,** http://links.lww.com/TP/C388). Of 802 recipients at risk, 16 (2%) developed a DTC, which corresponds to 6 cases per 10 000 solid organ transplants performed during the study period. Of those, 9 patients died as a result of the transmitted cancer—1% of recipients at risk and 56% of recipients diagnosed with a DTC.

## DISCUSSION

DTC is a rare complication of solid organ transplantation but has devastating effects upon patients affected, the mental well-being of professionals involved (second victims), and the reputation of the transplant program. With better treatment of cancer and expansion of criteria for organ acceptance, it is likely that the frequency of donors with cancer and the risk of DTC increases. Different organizations have issued guidance for professionals to minimize the risk of DTC while avoiding the unnecessary loss of organs, but current recommendations are flawed by the limited evidence available. With this study, our intention was to contribute to increase such level of evidence through a study of a national scope based on a prospective and standardized follow-up of recipients at risk of DTC or with a suspected DTC.

The use of organs from donors with a current or past history of malignancy that was known before transplantation was surprisingly low in our series (2.7%) bearing in mind the advanced donor age in Spain. Additionally, most of these malignancies were associated with a theoretically reduced risk of transmission. The rather conservative approach in the assumption of risks associated with malignancy transmission may be explained by the high availability of organs in our country. The percentage of donors with malignancy in Spain was, however, similar to that described in other recent registry studies, ranging between 1% and 4%.[16,18,21-23] This makes us believe that the scarcity of organs for transplantation does not necessarily result in a higher assumption of risks of malignancy transmission.

Identifying a malignancy in the donor when at least 1 organ had been transplanted was infrequent (<1%) but could be an avoidable situation. In more than half of the cases, the malignancy was identified in the back-table surgery of kidneys when other organs were being transplanted.

The fact that the back-table surgery of kidneys in Spain is frequently performed at the transplant (not the donor) center, can explain this late identification of kidney lesions. Efforts should be made to ensure this information becomes available earlier in the process. The possibility of having expert pathologists on duty, ideally in the form of a specialized network, is envisioned as an approach to facilitate more accurate assessments of suspicious lesions identified during donor work-up or organ recovery. Finally, emphasis should be made on the need to thoroughly review the donor's medical history, with documented reports of any previously diagnosed cancer, as well as to process donor´s autopsies with urgency.

Notably, most of these donor malignancies were identified soon after the transplantation of organs and did not result in a DTC. It is likely that the early assessment of cancer and its potential risk of transmission allowed clinicians to make timely decisions (such as prophylactic transplantectomy) to avoid disease transmission when the risk was deemed high. This emphasizes the relevance of robust biovigilance systems, where prompt reporting of findings allows transplant teams to take measures on patients at risk.

The rate of DTC in our series was 6 cases per 10 000 solid organ transplants, similar to that reported by other mandatory registries and our previous experience.[19-21,23,24] As in other series, transmitted cancers were occult in the donor, were usually diagnosed late after transplantation when patients exhibited suspicious symptoms, and had frequently a fatal outcome.

In our experience, the most frequently transmitted malignancy was lung cancer. In some jurisdictions, performing a computed tomography systematically in all potential donors is an established practice that could potentially reduce malignancy transmission—particularly lung cancer.[32] However, it may also lead to the over-diagnosis of lesions, which assessment can slow down and increase the complexity of the deceased donation process. An in-between approach could be performing a computed tomography in potential donors with risk factors for malignancy, though such risk factors are difficult to define.[33]

The greatest value of this study is that it can contribute to confirm or modify existing recommendations on donor selection with regards to malignancies, though more evidence is warranted, and based on our experience, it is likely that current guidance overestimates the risk of malignancy transmission for certain types of cancer. When evaluating the entire series, the most frequent neoplasia in donors was CNS neoplasia, though except for 3 donors, all were considered of minimal risk. No suspected DTC was reported, including recipients of organs from the 3 donors with a CNS neoplasia of intermediate or high risk. Early reports from the IPITTR suggested a high transmission risk associated with CNS neoplasia, particularly WHO grades 3–4. This information was biased because of the voluntary nature of the IPITTR.[12] Subsequent registry studies, including ours, where both numerator and denominator are known, suggest that the risk of transmission is much lower than initially described, even for grade 4 CNS neoplasia.[8,17,18,34-37] In these more recent studies, there was only 1 donor who transmitted a glioblastoma to 3 recipients.[18,38] Still, caution is required, since these were likely highly selected donors and relevant details are unknown in most cases.

The second donor malignancy in frequency was RCC, usually identified in the donor before transplantation or during the back-table surgery of kidneys. Eleven cases were deemed of high (RCC confined to the kidney >7 cm and Fuhrman I–II or any size and Fuhrman III–IV) or unacceptable (extension beyond the kidney) risk of transmission. A prophylactic transplantectomy was performed only in the last of these cases, despite which no transmission of RCC was reported. The UNOS described no DTC in a series of recipients of organs obtained from 147 donors with an RCC suspected at the time of transplant.[39] This large experience confirmed previous data from registry studies[17-19,22,40-42] and single-center series,[43-45] as well as our own data. Precise RCC staging was lacking in most of these reports, but it is likely that nonrenal organs were accepted when RCC was diagnosed at an early stage or transplants were already being performed when information about the donor RCC became available. In our experience, 2 other recipients developed a donor-transmitted RCC: both kidney recipients. This is in accordance with what was reported in the literature, where most RCC transmissions have occurred in kidney transplantation, though transmission has also rarely been described after heart or lung transplantation.[11,46-48]

The third malignancy in frequency was prostate cancer. Of the 40 donors with this malignancy identified before or after transplantation, 2 were deemed of high risk (intraprostatic, Gleason >7). There was no case of DTC among 88 recipients at risk. Incidental prostate cancer has been described in up to 45% of donors >70 y of age.[49] Given that advanced age is no longer a contraindication, it is likely that organs from male donors with undiagnosed prostate cancer are being used for transplantation, with no major consequences. Additionally, several studies have reported no case of DTC after the transplantation of organs obtained from donors diagnosed with prostate cancer Gleason score ≤6 or 7.[21,23,43,44,50-53] In a literature review, Doerfler et al[54] identified 120 solid organ transplants from donors with confirmed prostate cancer without any case of DTC. More recently, an Italian group reported their experience with 5 liver transplants from deceased donors with Gleason scores 8 and 9, without DTC.[43]

The previous findings reassure us about the safety of using organs from selected donors with prostate cancer. However, a liver recipient was diagnosed with a transmitted prostate cancer 5 mo after transplantation.[55] There is only one further case of transmission of prostate carcinoma reported in the literature, involving a heart recipient.[56] The donor had a poorly differentiated metastasized prostate adenocarcinoma discovered during organ recovery. No abdominal organs were used but the heart transplant was too far advanced to stop, and the recipient died of a donor-transmitted metastatic prostate cancer.

The main limitation of our experience is that not all patients had follow-up information available, and that follow-up information was usually not reported beyond the 2 prespecified years after transplantation. Though most DTCs are diagnosed within this time frame, cases have been diagnosed after 2 y (31% in our series). Nevertheless, given the systematic approach that we have taken in Spain for the reporting of suspected cases of disease transmission, we consider that any suspected DTC of late diagnosis would have been reported to ONT even if the follow-up survey

was not systematically received by the centers after those 2 y. Still, under-reporting of donor malignancies and of DTC (eg, if professionals did not suspect a donor origin) is likely to have occurred, which further limits the value of this study.

Several important messages can be derived from our study. First, donors with a current and past history of malignancy can safely contribute to increase the donor pool after an individual risk-benefit analysis. Second, the Council of Europe classification is a good basis to guide decisions and inform potential recipients on the waiting list of the risk of DTC, but it may be overestimating the risk of transmission for certain types of cancer-based on our observation that most recipients of cancers deemed of high risk exhibited appropriate outcomes. Modifying existing standards will require to further increase the level of evidence upon which these recommendations are built. The systematic and prospective approach taken in Spain through the NSRD program and the biovigilance system can be of reference to other countries. By sharing a minimum data set internationally following this methodology, we should be able to better understand the risk that we are assuming when proceeding with the transplantation of these organs. Finally, recipients on the waiting list should be informed of the low but nonzero risk of transmission of occult donor cancers. Still, certain actions during donor characterization and organ recovery could help us to further minimize the risk of malignancy transmission and its deleterious effects upon recipients of organs.

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