

Safety of Donation From Brain-dead Organ Donors With Central Nervous System Tumors: Analysis of Transplantation Outcomes in Korea

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Background. This study aims to verify the condition of recipients of solid organs from donors with central nervous system (CNS) tumors and determine the risk of disease transmission due to transplantation. **Methods.** Twenty-eight brain-dead organ donors with CNS tumors and 91 recipients who received solid organs from January 1, 2005, to December 31, 2014 in Korea were investigated using the Korean Network of Organ Sharing data. **Results.** Of the 36 recipients of organs from the 11 donors whose pathological results were not verified, 4 developed the following tumors: renal cell carcinoma, carcinoma in situ of the cervix uteri, B-cell lymphoma, and colon cancer. Among 51 recipients from 17 donors with CNS tumor, no recipient had the same tumor as the donors. Six were classified as high-risk donors according to the World Health Organization classification, and 14 recipients from these donors did not develop tumor after transplantation. The remaining 11 donors were classified as low-risk donors according to the World Health Organization classification but as high-risk donors according to the Malignancy Subcommittee of the Disease Transmission Advisory Committee of the Organ Procurement and Transplantation Network/United Network for Organ Sharing. Of the 37 recipients, 3 had recurring hepatocellular carcinoma with lung and bone metastases, thyroid cancer, and Kaposi's sarcoma after transplantation. **Conclusions.** The risk of disease transmission due to organ transplantation from donors with CNS tumors was very low. Thus, organ donation from such donors should be promoted actively to expand the donor range.

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INTRODUCTION

The imbalance between organ supply and demand has become a global issue, and several countries are attempting to conduct a national measure to address organ shortage.^{1,2} The number of brain-dead organ donors in Korea was 52 in 2001, which steadily increased to 368 in 2011 and 573 in 2016 and then decreased to 515 in 2017 and 449 in 2018.^{3,4} However, the number of waitlisted solid organ transplant recipients has significantly increased

from 3628 in 2001 to 30544 in 2018. Thus, the supply of organs has not met the increase in demand. In addition, the number of patient deaths while waiting for an organ transplant has significantly increased from 308 in 2001 to 1909 in 2018.^{3,4} Accordingly, much effort has been made to expand the category of donors with the concept of the marginal donor to promote organ donation.⁵

In Korea, if donors have tumors, their organ donations after brain death are prohibited for the safety of recipients.^{6,7} Nonetheless, in case of a central nervous system (CNS) tumor, organ donation is allowed because this type of tumor is less likely to be transmitted to recipients through transplantation.^{8,9} Regardless of the tumor type, the risk of malignancy, or whether surgery or chemotherapy was administered, the decision on whether organs are donated is determined by the sole discretion and judgment of the hospital medical staff.

This study analyzed the characteristics of organ transplant donors with CNS tumors in Korea and observed the conditions of their solid organ transplant recipients. Further, the risks of tumor transmission from donors owing to the histological characteristics of CNS tumors and the safety of organ donation from donors with CNS tumors were investigated.

MATERIALS AND METHODS

This retrospective study analyzed data of 2804 brain-dead organ donors reported in the Korean Network for Organ Sharing (KONOS) from January 1, 2005,

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to December 31, 2014. During this period, a total of 28 donors were reported to have CNS tumors, and 91 recipients received solid organs from these donors. The recipients comprised 54 men and 37 women, with an average age of 46.3 ± 13.3 years (means \pm SD); their age ranged from 6 to 79 years. Additional data of these donors and recipients were collected by contacting organ transplant centers in medical institutions from March 1 to 31, 2017.

The pathological results could be verified for 17 brain-dead organ donors with CNS tumors, and 55 recipients underwent solid-organ transplantation. CNS tumors of the donors were classified into high- and low-risk groups according to the classification criteria of the Israel Penn International Transplant Tumor Registry (IPITTR) and the histological classification of the World Health Organization (WHO) and the Malignancy Subcommittee of the Disease Transmission Advisory Committee of the Organ Procurement and Transplantation Network/United Network for Organ Sharing (DTAC of the OPTN/UNOS).^{8,10,11} The histological classification used for the CNS tumors were as follows:

1. WHO classification¹⁰

Grade I: Tumors do not meet any of the criteria. These tumors are slow growing, nonmalignant, and associated with long-term survival.

Grade II: Tumors meet only 1 criterion, that is, only cytological atypia. These tumors are slow growing but recur as higher-grade tumors. They can be malignant or nonmalignant.

Grade III: Tumors meet 2 criteria, that is, anaplasia and mitotic activity. These tumors are malignant and often recur as higher-grade tumors.

Grade IV: Tumors meet 3 or 4 of the criteria, that is, anaplasia, mitotic activity with microvascular proliferation, and/or necrosis. These tumors reproduce rapidly and are very aggressive malignant tumors.

2. IPITTR classification

Low-risk category: WHO grade I or II

High-risk category: WHO grades III or IV

3. DTAC of the OPTN/UNOS classification

High-risk category: Any CNS tumor, regardless of grade, with a ventriculoperitoneal or ventriculoarterial shunt or extra-CNS metastasis, and a tumor that received prior surgery (excluding uncomplicated biopsy), chemotherapy, or radiotherapy.

The 17 donors whose pathological results were verified were grouped into the high- and low-risk groups according to the WHO classification based on data from the IPITTR and DTAC of the OPTN/UNOS classification. Thereafter, the incidence of cancer after transplantation among the recipients of solid organs from the donors was analyzed. The number of recipients who underwent solid organ transplantation from the 17 donors was 55. Although the number of donated solid organs was 60, the total number of recipients was 55 due to multiorgan transplantations. With the exception of 4 recipients whose conditions could not be observed, finally 51 recipients were analyzed. The occurrence of cancer in the recipients and the characteristics of the cancer occurrences (whether the cancer was

transmitted from the donor, whether the cancer that the recipient previously had recurred, or whether the cancer was a *de novo* cancer) were analyzed. Recipient survival and cause of death were also investigated.

This study was conducted after obtaining approval from the Institutional Review Board of Seoul National University Hospital.

All continuous data were expressed as means \pm SD; other data were reported as numbers (percentages).

RESULTS

Out of the 2804 brain-dead donors registered in the KONOS from January 1, 2005, to December 31, 2014, a total 28 donors were diagnosed with CNS tumors (15 men and 13 women, mean age: 37.3 ± 15.6 y, age range: 5–56 y). Among them, 11 donors (5 men and 6 women) were diagnosed using only image examination without verifying the pathological results; pathological results were available for the remaining 17 donors (10 men and 7 women). These 17 donors were classified according to the WHO classification as follows: Grade I, 8 donors; Grade II, 3 donors; Grade III, 3 donors; and Grade IV, 3 donors. The number of organs donated was 60, specifically 4 hearts, 2 pairs of lungs, 17 livers, 3 pancreases, 33 kidneys, and 1 small intestine (Figure 1).

The characteristics of the 17 donors whose pathological CNS tumor results were verified are presented in Table 1. The number of high-risk donors according to the WHO classification published based on the IPITTR data was 6/17 (28.6%). In addition, 14 donors (66.7%) belonged to the high-risk category according to the Malignancy Subcommittee of the DTAC of the OPTN/UNOS classification as follows: 9 patients receiving only intracranial surgery, 3 patients receiving chemotherapy or radiotherapy along with intracranial surgery, 1 patient receiving only chemotherapy and radiotherapy, and 1 patient receiving ventriculoatrial (VA) shunt surgery.

The number of donors in the high-risk groups according to the WHO classification based on the IPITTR data and the DTAC of the OPTN/UNOS classification was 3. The number of recipients of solid organs from these 3 donors was 5. The number of donors classified as high-risk donors according to the WHO classification but as low-risk donors according to the DTAC of the OPTN/UNOS classification was 3. The number of recipients of solid organs from these 3 donors was 9. All 14 recipients of the 2 donor groups had no tumors after transplantation (Table 2). No recurrence of cancer was found in 3 recipients who had tumors before the transplantation.

The number of donors classified as low-risk donors according to the WHO classification but as high-risk donors according to the DTAC of the OPTN/UNOS classification was 11; these donors comprised the largest donor group. The number of recipients of solid organs from these 11 donors was 37; these represented the largest proportion as well. The organs that the recipients received were 4 hearts, 2 pairs of lungs, 10 livers, 20 kidneys, and in 1 case, both liver and kidney (simultaneous transplant).

Among the recipients, 4 were diagnosed with tumors before the transplantation. Tumors occurred in 3 out of the 37 recipients after transplantation. One of them had cancer metastasis to the bone and lungs of hepatocellular

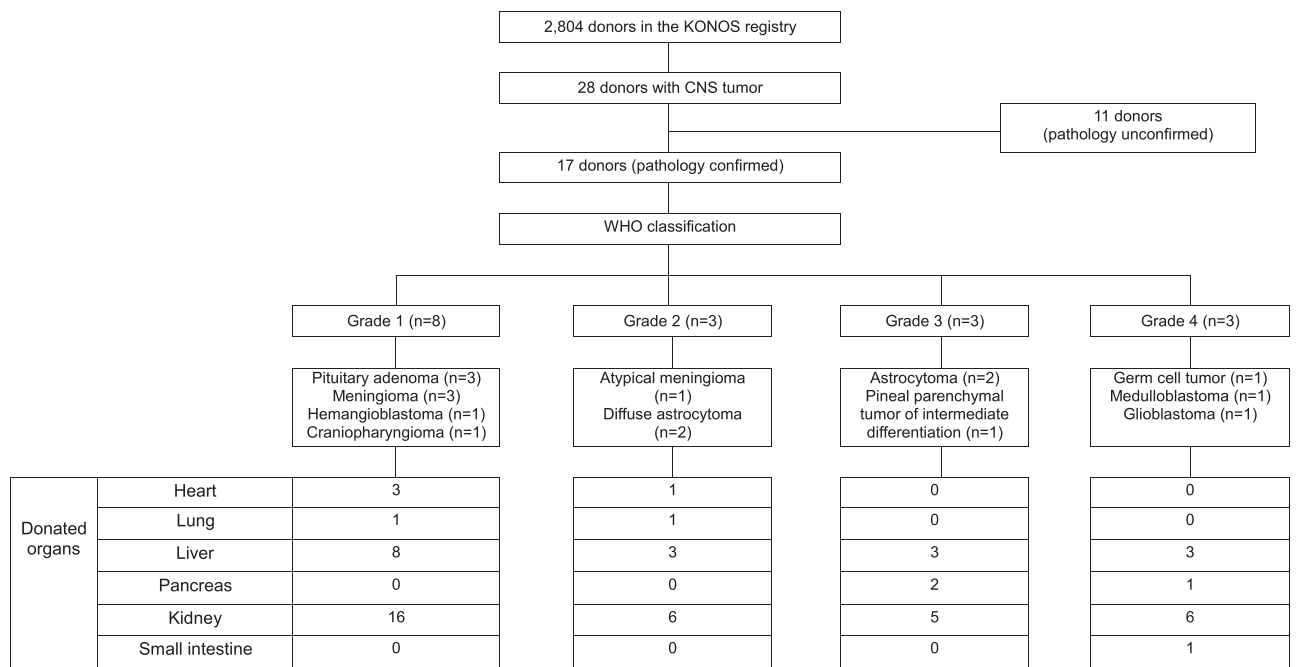


FIGURE 1. Diagram of enrolled donors with CNS tumors and donated organs. CNS, central nervous system; KONOS, Korean Network for Organ Sharing; WHO, World Health Organization.

carcinoma that existed before the transplant. This patient received organs from a donor who had a pituitary adenoma, which was a benign tumor. The other 2 patients who were kidney recipients were diagnosed with thyroid cancer after 7 years and 3 months and Kaposi's sarcoma after 2 years, respectively. Both patients had no CNS tumor but experienced occurrence of *de novo* malignancy.

The number of recipients of solid organs from the 11 donors whose pathological results were not verified was 36. This study analyzed 34 recipients, except for 2 patients whose condition could not be verified. Four recipients had tumors before transplantation, and none of the patients were diagnosed with tumors after transplantation. Out of the 30 patients who previously did not have tumors, 4 developed tumors after transplantation, and all of them received kidneys.

More specifically, they were diagnosed with renal cell carcinoma 3 years and 3 months after transplantation, carcinoma *in situ* of the cervix uteri after 3 years and 6 months, B-cell lymphoma after 5 years, and colon cancer after 4 years and 1 month, respectively. All the cancers were *de novo* cancers, and none of the patients had tumor transmission from the donors.

The survival rate of the recipients was analyzed, and the number of deaths out of the 51 recipients was 12 as of March 2017. Table 3 summarizes the number and cause of deaths due to transplantation. The average time to death of 9 patients was 23.3 months after transplantation. The dates of death of 3 patients could not be accurately verified. The causes of 10 deaths were sepsis ($n = 4$), intra-peritoneal bleeding ($n = 1$), hepatic insufficiency ($n = 3$), cardiovascular infarction ($n = 1$), and lung/bone metastasis of hepatocellular carcinoma ($n = 1$), and none of the deaths were related to the brain tumor of the donors. The cause of 2 deaths could not be verified.

DISCUSSION

Korea has enacted the "Organ Transplantation Law" from 1999 and enforced the law from February 2000 to address the issues of illegal organ trade, controversies of bioethics, and need for legal recognition on brain deaths after executing transplantations of organs from brain-dead patients for the first time since 1979.¹² In the same year of enforcement, the KONOS was launched to promote the fair and efficient distribution and management of organs and prevent illegal organ trafficking.^{12,13} Since then, the revision of the Organ Transplantation Law has been enforced from 2011. The law was focused on the legal basis of organ procurement organizations and notifications to such organizations when brain death occurs in patients to initiate the discovery and management of brain-dead patients.¹⁴

However, the Korean Society of Transplantation and the KONOS set very strict criteria regarding brain-dead donors with cancer history, considering their donation of organs as a contraindication. The criteria adhere to a strict policy in which donations from these donors are prohibited unless their cancers are early skin cancers and primary brain tumors not transmitted to other organs or if there is no cancer recurrence for ≥ 5 years after cancer treatment.⁶ In particular, there have been no specific criteria regarding the risk of transmission to recipients, such as cancer characteristics or performance of surgery or chemotherapy. Consequently, arbitrary decisions are currently made by the management of the medical institutions of the donor or by the medical staff of the recipient.

Thus, this study analyzed the risk of transmission of CNS tumors from brain-dead organ donors using the risk classifications proposed by the IPITTR and DTAC. When both of the classifications were taken into consideration, 17 brain-dead organ donors with CNS tumors verified on the basis of pathological results were classified as high-risk donors. In addition, 3 out of the 51 solid organ recipients

TABLE 1.**Characteristics of brain-dead organ donors with CNS tumor**

No. of pt.	Sex	Age	Pathology of CNS tumor	Risk factors according to the IPITTR classification		Risk factors according to the Malignancy Subcommittee of the DTAC of OPTN/UNOS classification					Donated organs
				Risk	Grade (WHO classification)	Risk	Hx. of V-P or V-A shunt	Hx. of surgery (excluding uncomplicated biopsy)	Hx. of chemotherapy	Hx. of radiotherapy	
1	M	17	Mixed germ cell tumor (immature teratoma plus yolk sac)	H	4	H	N	Y	Y	N	Liver Kidney
2	M	17	Astrocytoma, high grade	H	3	H	Unknown	Unknown	Y	Y	Liver Kidney (2) Pancreas
3	F	55	Pituitary adenoma	L	1	H	N	Y	N	N	Liver Kidney (2)
4	F	47	Meningioma	L	1	H	N	Y	N	N	Heart Liver Kidney (2)
5	M	47	Diffuse astrocytoma	L	2	H	N	Y	N	N	Liver Kidney (2)
6	M	25	Hemangioblastoma	L	1	H	N	Y	N	N	Heart Liver Kidney (2)
7	M	40	Astrocytoma, high grade	H	3	L	N	N	N	N	Liver Kidney (2) Pancreas
8	M	55	Pituitary adenoma	L	1	H	Y	N	N	N	Liver Kidney (2)
9	F	47	Pineal parenchymal tumor of intermediate differentiation	H	3	H	N	Y	Y	N	Liver Kidney (2)
10	F	46	Meningioma	L	1	H	N	Y	N	N	Heart Liver Kidney (2)
11	F	5	Medulloblastoma	H	4	L	N	N	N	N	Liver Pancreas Small intestine Kidney (2)
12	M	43	Pituitary adenoma	L	1	H	N	Y	N	N	Liver Kidney (2)
13	M	41	Craniopharyngioma	L	1	H	N	Y	N	N	Lungs Liver Kidney (2)
14	M	50	Glioblastoma	H	4	L	N	N	N	N	Liver Kidney (2)
15	F	39	Atypical meningioma	L	2	H	N	Y	N	N	Heart Lungs Liver Kidney (2)
16	F	56	Meningioma	L	1	H	N	Y	N	N	Liver Kidney (2)
17	M	52	Diffuse astrocytoma	L	2	H	N	Y	N	Y	Liver Kidney (2)

CNS, central nervous system; DTAC, Disease Transmission Advisory Committee; F, female; H, high; Hx., history; IPITTR, Israel Penn International Transplant Tumor Registry; L, low; M, male; N, no; No., number; OPTN, Organ Procurement and Transplantation Network; pt., patient; UNOS, United Network for Organ Sharing; V-A, ventriculoarterial; V-P, ventriculoperitoneal; WHO, World Health Organization; Y, yes.

TABLE 2.

Tumor occurrence in the recipients of organs from the brain-dead donors with CNS tumors according to the CNS tumor risks

Donors			Total recipient no.	Tumor existence before transplantation	Transplanted organs	Tumor occurrence after transplantation	Transplanted organ in the recipients with tumors	Period from transplantation to tumor occurrence	Pathology of occurring tumors in the recipients	Pathology of the donors' CNS tumor
IPITTR risk	OPTN/UNOS risk	No.								
High	High	3	5	2	Liver (3) Kidney (2)	–	–	–	–	–
High	Low	3	9	1	Liver (2) Liver + kidney + small intestine (1) Kidney (5) SPK (1)	–	–	–	–	–
Low	High	11	37	4	Heart (4)	3	Liver + kidney (1) Kidney (2)	1 y 1 mo ^a	HCC, lung/bone metastasis Thyroid cancer Kaposi's sarcoma	Pituitary adenoma Diffuse astrocytoma Meningioma
					Lungs (2)			7 y 3 mo		
					Liver (10)			2 y		
					Kidney (20)					
				Liver + Kidney (1)						
Low	Low	0	0	0	–	–	–	–	–	–
Not confirmed		11	34	4	Heart (3)	4	Kidney (4)	3 y 3 mo	Renal cell carcinoma Carcinoma in situ of the cervix uteri B-cell lymphoma Colon cancer	
					Lungs (1)			3 y 6 mo		
					Liver			5 y		
					(10) Kidney (20)			4 y 1 mo		

^aThis recipient had a tumor (hepatocellular carcinoma) before transplantation.

CNS, central nervous system; HCC, hepatocellular carcinoma; IPITTR, Israel Penn International Transplant Tumor Registry; OPTN/UNOS, Organ Procurement and Transplantation Network/United Network for Organ Sharing; SPK, simultaneous pancreas and kidney transplantation.

TABLE 3.

Analysis of deaths among the recipients of organs from the brain-dead donors with central nervous system tumors according to the transplanted organs

Transplanted organ	Total recipient no.	No. of death (%)	Year and month of transplantation	Date of death	Period from transplantation to death	Cause of death
Heart	4	1 (25)	2006.10	2007.07.02	9 mo	Sepsis
Lung	2	1 (50)	2012.11	Unknown	Unknown	Sepsis
Liver	15	5 (33)	2005.01	2005.12.13	11 mo	Unknown
			2006.03	Unknown	Unknown	Intra-abdominal bleeding
			2008.04	2008.04.13	0 mo	Liver failure
			2012.11	2013.03.21	4 mo	Sepsis
			2006.07	2009.07.11	36 mo	Liver failure
Kidney	27	3 (11)	2014.11	2014.11.08	0 mo	Cardiovascular infarct
			2013.12	Unknown	Unknown	Sepsis
			2008.04	2016.12.18	104 mo	Unknown
Liver + pancreas + small intestine	1	1 (100)	2011.10	2013.08.01	31 mo	Liver failure
Liver + kidney	1	1 (100)	2009.09	2010.12.31	15 mo	Hepatocellular carcinoma, lung/bone metastasis
Kidney + pancreas	1	0 (0)	–	–	–	–

from the high-risk group had cancers; there were 4 recipients lost to follow-up, of whom 1 patient had a recurrence of existing cancer (1.96%), and 2 patients had de novo cancers (3.92%). All of the tumors were non-CNS tumors,

indicating that the tumors were not transmitted from the donors to the recipients.

A retrospective study on data registered in the UK also verified that malignant tumors were not transmitted to all

448 recipients of organs from 177 donors with primary intracranial malignant tumors.⁹ In addition, Kauffman et al¹⁵ verified that tumors were not transmitted to recipients of solid organs from 642 donors with CNS malignant tumors. These included 175 organs donated from patients with glioblastoma multiforme based on the registered data from the OPTN.¹⁵ These results are consistent with those in our study, which proved that the possibility of tumor transmission from donors with CNS tumors was very rare. Thus, it is recommended to search for donors with CNS tumors actively to extend the range of donors. However, the risk of tumor transmission should always be considered. Thus, information, such as tumor characteristics and treatment details of donors, should always be shared during the donation process.

Although the risk of the same tumor transmission from donors with a CNS tumor is very low, much attention should be paid to the onset rate of de novo malignancy after transplantation. Studies performed in a Korea report suggest that the onset rate of malignant tumors is approximately 2%–5% after kidney transplantation. Kim et al¹⁶ reported that the incidence rate of malignant tumors was 4.2% during their observation period (27 y after kidney transplantation); further, Ro et al¹⁷ reported an incidence rate of 4.3% for malignant tumors from patients who received kidney transplantation (37 y of observation). Park et al¹⁸ reported an incidence rate of 2.9% for 18 years of observation. Thus, the incidence rates of malignant tumors tended to be higher in institutions whose observation period was longer than those with shorter observation periods. The occurrence of malignant tumors after kidney transplantation has been known to be closely related to the period of exposure to immunosuppressants, and the long-term use of immunosuppressants increases the cumulative incidence rate of malignant tumors.¹⁹ It is necessary to consider the observation period and the exposure period to immunosuppressants to compare and evaluate the incidence rate of malignant tumors. Thus, long-term follow-up observations on recipients are needed to evaluate the occurrence of de novo malignancy accurately in recipients of solid organs from donors with CNS tumors.

Despite the efforts made to secure safe organs for transplantation, the risk of transmission of malignant tumors and diseases from donors remains an ongoing concern. However, the risk of a malignant tumor or disease transmission should be compared with the risk of death for recipients who are on the organ transplant waiting list. The donor-related incidence rate in recipients was reportedly very low. In the United States, the rate was 0.017%, and in particular, the death rate owing to donor-related tumors was extremely low at 0.007%.²⁰ Moreover, this study had no case of transmission of the same tumor (malignant brain tumor) of donors to recipients.

Currently, it is not mandatory to report the accurate pathological results of donors who are diagnosed with tumors and their recipients in the KONOS database. The limitation of this study is that the pathological results of all donors and recipients could not be verified. Although it is important to check for the transmission of cancer or infection from donors after verifying the recipients' conditions after transplantation (eg, survival rate, cause of death, death date, diseases occurring after transplantation,

and diagnosed diseases) and manage the risk, no data that can verify the recipients' conditions after transplantation are presently available in Korea. This is because the data input is limited as it is not mandatory in the clinical fields, and specialized staffs have not yet been assigned to manage patient transplantation data. Thus, it is necessary to verify accurate statistics on malignant tumors and other diseases by reporting additional medical information to the national registry, which has been delayed due to lack of time and human resources. With these data, more accurate evaluation of tumor propagation risks from donors with malignant tumors can be performed. In this manner and under specific circumstances, including a careful selection process and analytical procedures, more donors may be transferred to the pool of acceptable donors, including donors with malignant tumors who were previously excluded due to their potential risk.²¹

The organ donation of brain-dead patients with CNS tumors is very safe in terms of cancer transmission risk. It is desirable to have more active organ donations from potentially brain-dead patients with CNS tumors in the future. Moreover, cancer transmission from donors with other malignant tumors must be studied closely to enlarge the pool of brain-dead organ donors. In addition, safer and more active organ donations by brain-dead donors could be promoted by enforcing long-term analyses on cancer transmission risks from donors after establishing a national level database of recipients.

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