Concurrent Trastuzumab Deruxtecan and Radiation Therapy in HER2-positive and HER2-low Metastatic Breast Cancer

Assessing the Efficacy

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Abstract: The combination in patients with HER2-positive and HER2-low metastatic breast cancer (MBC) of Concurrent Trastuzumab Deruxtecan (T-DXd) and Radiation Therapy (RT) is not enough studied. We conducted a retrospective study including patients treated between 11/2020 and 01/2024. Patients with HER2-positive and HER2-low MBC who received concurrent T-DXd and RT were identified. Data on patient demographics, treatment regimens, radiation doses, toxicity profiles, efficacy, and treatment discontinuations were collected. The toxicities were graded using CTCAE V5.0. Population of 33 patients with HER2-positive and HER2-low MBC who underwent concurrent T-DXd&RT, were studied. The median follow-up (FU) was 14 months. There were 39.4 partial remissions and 9.4 attained complete remission. In addition, 39.4% experienced stable disease, and 12.1% faced disease progression necessitating a change in therapy. Safety assessment revealed that acute toxicities were mainly associated with systemic treatment. Survival analysis showed 11 deaths (33.3%) during the FU period, with a median overall survival of 26 months and median progression-free survival of 12 months. The combination of T-DXd with RT in demonstrates promising efficacy with a manageable safety profile. Further studies are warranted to fully elucidate the potential synergistic effects of this treatment regimen and its impact on patient outcome.

Key Words: trastuzumab deruxtecan, radiotherapy, concurrent, breast cancer, efficacy, safety

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Metastatic breast cancer, particularly when it involves overexpression of human epidermal growth factor receptor 2 (HER2), represents a major therapeutic challenge in oncology due to its aggressive nature and often unfavorable prognosis. Approximately 15% to 20% of breast cancers have HER2 amplification, which has historically been associated with adverse clinical outcomes.[1] However, the introduction of therapies specifically targeting HER2, such as trastuzumab and other anti-HER2 drugs, has radically transformed the prognosis of patients with this subtype of cancer. Recent advances, such as trastuzumab deruxtecan (T-DXd), an antibody-drug conjugate (ADC) combining an anti-HER2 antibody with a topoisomerase I inhibitor, have demonstrated remarkable clinical efficacy, even in heavily pretreated patients.

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In DESTINY-Breast clinical trials, T-DXd showed a significant benefit in terms of progression-free survival (PFS) and overall survival (OS) in patients with metastatic HER2-positive breast cancer. For example, in the DESTINY-Breast01 trial, T-DXd demonstrated an objective response rate (ORR) of 62%, median PFS of 19.4 months (95% CI: 14.1-25.0), and median OS of 29.1 months (95% CI: 24.6-36.1) in patients who had received an average of 6 prior treatments.[2] These results were also confirmed in the DESTINY-Breast03 trial, comparing T-DXd to trastuzumab emtansin (T-DM1), where T-DXd showed a significant improvement in PFS.[3]

These results were also observed in patients with low HER2 expression (HER2-low), who have traditionally escaped the benefits of conventional anti-HER2 therapies. Notably, in the DESTINY-Breast04 trial, T-DXd improved overall survival compared with conventional chemotherapy in pretreated patients with HER2-low metastatic breast cancer, highlighting its potential even in subgroups of patients with lower levels of HER2 expression.[4]

At the same time, data from a large French real-world cohort reported median overall survival of HER2-positive metastatic breast cancer patients was 50.1 months (95% CI: 47.6-53.1) for the period spanning 2008 to 2016. This significant improvement in survival, particularly with the introduction of targeted anti-HER2 therapies, resulted in an increase in median overall survival from 39.1 months in 2008 to 58.0 months in 2013.[5]

Although these results have demonstrated the efficacy of trastuzumab deruxtecan alone, evaluating its efficacy when combined concomitantly with radiotherapy (RT) remains an under-explored area. Radiotherapy, a mainstay of local breast cancer treatment, can potentially synergize with antibody-drug conjugates to enhance the anti-tumor effect. However, the impact of this combination on tumor response and clinical outcomes remains to be clarified.

In a first approach, we primarily examined the toxicity profile (Bouziane et al, AJCO).[6] However, the objective of this article is to evaluate the efficacy of this combination in patients with HER2-positive and HER2-low metastatic breast cancer, with prolonged follow-up.

METHODS

We individualized the patients who received trastuzumab deruxtecan at our institution, then studied all patients with HER2-positive and HER2-low metastatic breast cancer who received trastuzumab deruxtecan concomitantly with radiation therapy. We conducted a retrospective analysis of this patient population.

The study was conducted in the Radiotherapy department of the Institut Curie in Paris between November 2020 and January 2024.

Patients were included if they met the following criteria: a diagnosis of metastatic breast cancer, prior treatments with other lines of chemotherapy, and trastuzumab deruxtecan in combination with radiation therapy. Patients were excluded if they had contraindications to any of the treatments or had received other concomitant investigational treatments.

Radiotherapy was administered to either locoregional sites or metastatic lesions, depending on clinical indications and tumor burden. Locoregional irradiation was performed if patients showed at least partial response at locoregional sites and disease stability at metastatic sites after several months of treatment. Metastatic irradiation was performed to relieve symptoms such as pain when systemic analgesic treatment was not sufficient, in cases of metastatic epidural spinal cord compression, or in patients with brain metastases.

The dose of trastuzumab deruxtecan administered was consistent with the recommended dose for breast cancer, that is, 5.4 mg/kg IV infusion every 3 weeks (21-d cycle).

Radiotherapy doses and target volumes were determined according to institutional guidelines, using Volumetric Modulated Arc Therapy (VMAT) for all locoregional treatments. For metastatic irradiation, clinical target volume (CTV) generally included macroscopic tumor volume with a variable margin. In this context, a VMAT technique was primarily used with prescribed doses of 20 Gy in 5 fractions (n = 16), 30 Gy in 10 fractions (n = 6), and 8 Gy in 1 fraction (n = 4). Brain metastases were mostly treated stereotactically according to various protocols (n = 8).

Trastuzumab deruxtecan was initially administered at the recommended dose of 5.4 mg/kg every 3 weeks (21-day cycle) concomitantly with radiotherapy. The duration of concomitant administration of trastuzumab deruxtecan and radiotherapy was recorded for each patient.

To assess the efficacy of the concomitant combination of trastuzumab deruxtecan and radiotherapy, we measured tumor response rates in terms of complete remission, partial remission, stable disease, and progression, based on imaging studies such as computed tomography (CT), magnetic resonance imaging (MRI), and PET scan, at the discretion of the treating physician.

We also collected survival data during the follow-up period. Patient follow-up began at the end of radiotherapy and continued until patients died or at the last visit.

RESULTS

There were 33 patients diagnosed with HER2-positive and HER2-low metastatic breast cancer, who had previously undergone multiple lines of chemotherapy. These patients were treated with trastuzumab deruxtecan (T-DXd) concurrently with radiotherapy between November 2020 and January 2024. The follow-up period was 14 months (1 to 42 mo). The baseline characteristics of the 33 enrolled patients are detailed in Table 1. There were 41 courses of radiotherapy concurrently with T-DXd in this population of patients, as following: in 4 cases the patients received locoregional irradiation and 1n 33: the RT was realized on 37 metastatic sites (concurrently with T-DXd) treated concurrently with trastuzumab deruxtecan. Trastuzumab deruxtecan was administered at the recommended dose, and radiotherapy was delivered per institutional protocols.

TABLE 1. Patients' and Tumors' Characteristics

Total, N (%)	33 (100)
Sexe	
Male	1 (3.03)
Female	32 (96.9)
Age	Median: 58.5 Range: 35-80
Histology	
Ductal carcinoma	28 (84.8)
Lobular carcinoma	3 (9.09)
Others	2 (6.06)
HER2 status	
0: 2	2 (6.06)
1+: 9	9 (27.2)
2+: 9	9 (27.2)
3+:12	12 (36.3)
Equivoque: 1	1 (3.03)
Hormone receptor expression (HR)	
HR+	25 (75.7)
HR-	8 (24.2)
Previous line of chemotherapy before T-DXd	
Yes	33 (100)
No	0 (0)
Site of metastases	
Bone	23 (63.6)
Brain	13 (27.2)
Chest wall	4 (12.1)
Nodal	2 (6.06)
Adrenal gland	1 (3.03)

T-DXd indicates Trastuzumab deruxtecan.

The mean overall treatment duration with trastuzumab deruxtecan for locoregional and metastatic irradiation was 9 months (range: 2 to 45 mo).

Regarding the efficacy of the combination of T-DXd and radiotherapy, 39.4% (ie, 13 patients) achieved *partial remission*, while 9.1% (ie, 3 patients) achieved complete *remission*. In addition, 39.4% (ie, 13 patients) presented with *stable disease*, while 12.1% (ie, 4 patients) experienced *disease progression* leading to a change in the therapeutic line.

In addition, we observed that 3 patients who achieved complete remission had received irradiation: 2 had received chest wall irradiation, each receiving a total dose of 40.05 Gy, administered in 15 fractions. The measured PTV volumes were 200.1 cc for one and 569.7 cc for the other. A third patient had received radiotherapy for the chest wall as well as for the lymph nodes (L2-L4, IP, MIS), with a dose of 50 Gy administered in 25 fractions, showing a PTV volume of 521.5 cc.

Regarding partial remissions, 13 patients were treated with radiation therapy for various metastatic locations. Of these, 10 received radiotherapy to bone sites, including lesions in the vertebrae and other long bones. One patient was treated for isolated brain metastases, while another had both bone and brain lesions. In addition, one patient was treated for adrenal metastasis.

The metastatic locations that responded to treatment, along with the volumes treated and the doses of radiotherapy administered, are summarized in Table 2.

With regard to treatment safety, we would point out that acute toxicities were mainly associated with systemic treatment. Nausea was reported as the most common Grade

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TABLE 2. Summary of Responding Metastatic Sites: Complete and Partial Responses with Treated Volumes and Radiation Doses

Case	Metastatic site	RT technique	Dose (Gy)/Fx	CTV volume (cc)	PTV volume (cc)	Response
1	Right chest wall	VMAT	40.05/15	183.7	200.1	Complete remission
2	Right chest wall	VMAT	40.05/15	538.1	569.7	Complete remission
3	Left chest wall and left lymph nodes (L2-L4, IP, IMN)	VMAT	50/25	337.3	521.5	Complete remission
4	WBI + left frontal lesion	• *WBI* :VMAT • *Frontal lesion* : SRT	• *WBI*: 30/10 • *Frontal lesion*: 27/3	• *WBI*: 370.8 • *Frontal lesion:* 3.6	• *WBI*: 1605.6 • *Frontal lesion:* 5.7	Partial remission
5	Left femur	3D	30/10	282.6	545.2	Partial remission
6	Right acetabulum	VMAT	20/5	136.6	277.8	Partial remission
7	Femur and brain lesions (left temporal, basifrontal and parietal)	• *Femur* : 3D • *Brain lesions* : SRT	• *Femur:* 20/5 • *Brain lesions:* 9/3 • *Left temporal lesion:* 30/5	• *Femur:* 477.8 • *Brain lesions:* (Parietal: 1, Basifrontal: 0.4) • *Left temporal lesion:* 2.4	• *Femur:* 900.6 • *Brain lesions:* (Parietal: 1.7, Basifrontal: 0.8) • *Left temporal lesion:* 3.9	Partial remission
8	Vertebrae T7-T10 + left hip and femur	3D	30/10	Not specified	Not specified	Partial remission
9	Adrenal gland	SBRT	46/5	51.9	110.5	Partial remission
10	Vertebrae L4-L5 and left acetabulum	VMAT	20/5	• *L4-L5*: 46.7 • *Left Acetabulum:* 114.8	• *L4-L5*: 270.1 • *Left Acetabulum:* 239.9	Partial remission
11	Vertebrae T7-T9	VMAT	20/5	111.3	204.7	Partial remission
12	Vertebrae T5-T8 and T10-L1	VMAT	20/5	• *T5-T8*: 102.7 • *T10-L1*: 210.6	• *T5-T8*: 198.5 • *T10-L1*: 340.6	Partial remission
13	Vertebrae C2, T6 and right Humerus	VMAT	• *C2 and T6*: 20/5 • *Right Humerus*: 8/1	• *C2:* 69.1 • *T6*:102 • *Right Humerus:* 85.9	• *C2:* 140.4 • *T6*:204.5 • *Right Humerus:*174.9	Partial remission
14	Vertebrae L4-L5	VMAT	20/5	52.2	72.7	Partial remission
15	VertebraeT12-L1 and S1	VMAT	20/5	• *T12-L1*: 118 • *S1*: 182.6	• *T12-L1*: 221 • *S1*: 327.8	Partial remission
16	Vertebrae T5	VMAT	20/5	66.9	117.4	Partial remission

CTV indicates Clinical target volume; dose (Gy)/Fx, total dose (gray)/number of fractions; Gr, grade; IMN, internal mammary node; IP, interpectoral (Rotter) nodes; L1–L4, axillary level 1 to 3 and supraclavicular region (level 4); PTV, planning target volume; RT technique, radiotherapy technique; SRT, stereotactic radiotherapy; VMAT, volumetric modulated arc therapy; WBI, whole brain irradiation.

1 toxicity, affecting 10 patients (30.3%). Grade 2 toxicities were observed in 7 patients (21.21%), including cases of asthenia and mucositi, along with a single occurrence of nausea accompanied by cardiac decompensation. It should be noted that no cases of grade ≥ 3 acute toxicity were reported, which is a positive indicator of treatment tolerance. In addition, trastuzumab deruxtecan had to be discontinued in 5 patients due to various complications, including thrombocytopenia and neutropenia.

With a median follow-up of 14 months, 7 (21.21%) patients reported late toxicities after completing radiation therapy. Among these cases, nausea, the most frequent late toxicity, was observed in 4 patients. Moreover, only 1 patient experienced drug-related grade 3 thrombocytopenia, which occurred 5 months after the completion of radiotherapy, with a favorable outcome.

Regarding survival outcomes, we recorded a total of 11 deaths (33.3%) during the follow-up period. With a median follow-up of 14 months (range: 1 to 42 mo), median overall survival was 26 months and median progression-free survival was 12 months. Overall and progression-free survival at 1 year was 80.1% (95% CI: 66.9%-95.9%) and 43.8% (28.5%-67.4%), respectively. Overall and progression-free survival at 2 years was 58.1% (95% CI: 37.2%-90.6%) and 18.8% (6.17%-57.1%), respectively. These data are shown in Figure 1, illustrating the survival curves for these 2 parameters.

DISCUSSION

Our study is one of the largest to evaluate the efficacy and safety of the concomitant combination of trastuzumab deruxtecan and radiotherapy for the treatment of HER2-positive and HER2-low metastatic breast cancer, encompassing a substantial number of patients who received irradiation at various sites. Although we have already published results regarding the toxicity profile,[6] it is essential to emphasize that we are now evaluating the efficacy of this combination treatment. We observed an acceptable tumor response and toxicity profile, but data on the efficacy of this combination remain limited. To date, there are no studies clearly establishing the impact of the concomitant combination of radiotherapy and T-DXd on clinical outcomes. This represents a major gap in the literature.

The results of the DESTINY-Breast03 trial, a randomized, multi-center, open-label, phase 3 trial, demonstrated promising efficacy results for trastuzumab deruxtecan in patients with HER2-positive metastatic breast cancer.[3] In a trial results update, 699 patients were screened for eligibility, and 524 were enrolled and randomized to receive either trastuzumab deruxtecan (n = 261) or trastuzumab emtansine (n = 263). The median duration of study follow-up was 28.4 months for trastuzumab deruxtecan and 26.5 months for trastuzumab emtansine. Median progression-free survival was significantly longer with trastuzumab deruxtecan at 28.8 months (95% CI: 22.4-37.9) compared with 6.8 months (95% CI: 5.6-8.2) with trastuzumab emtansine (hazard ratio [HR] 0.33, 95% CI: 0.26-0.43; nominal $P < 0.0001$). Median overall survival was not achieved in the trastuzumab deruxtecan group (95% CI: 40.5 months—not estimable) vs 34.0 months (95% CI: not estimable) in the trastuzumab emtansine group (HR 0.64, 95% CI: 0.47-0.87; $P = 0.0037$).[3]

In addition, recent data from the Destiny BREAST04 phase III trial confirmed the efficacy of trastuzumab deruxtecan in HER2-low metastatic breast cancer compared with standard chemotherapy.[4] Trastuzumab deruxtecan demonstrated a significant improvement in progression-free survival (HR = 0.50, $P < 0.001$) and overall survival (HR = 0.64, $P = 0.001$) compared with the control group, leading to its approval by the FDA for the treatment of HER2-low breast cancer in August 2022.[4] In addition, a number of ongoing phase III trials, such as Destiny-BREAST06, aim to further investigate the efficacy of trastuzumab deruxtecan in HR+, HER2-low metastatic breast cancer.[7] All of these findings highlight the efficacy of T-DXd as a second-line treatment in patients with HER2-positive breast cancer, providing significant benefits in terms of progression-free survival and overall survival compared with previous treatments.

On the other hand, according to the ESMO Expert Consensus Statements on the definition, diagnosis, and management of HER2-low breast cancer,[8] patients with metastatic HER2-low (IHC 1+ or IHC 2+/ISH-negative), hormone receptor-positive (HR+) breast cancer who have received prior CDK4/6 inhibitor therapy and at least one previous line of chemotherapy and are considered to have refractory endocrine disease, are candidates for T-DXd if they have no contraindications. In cases where both T-DXd

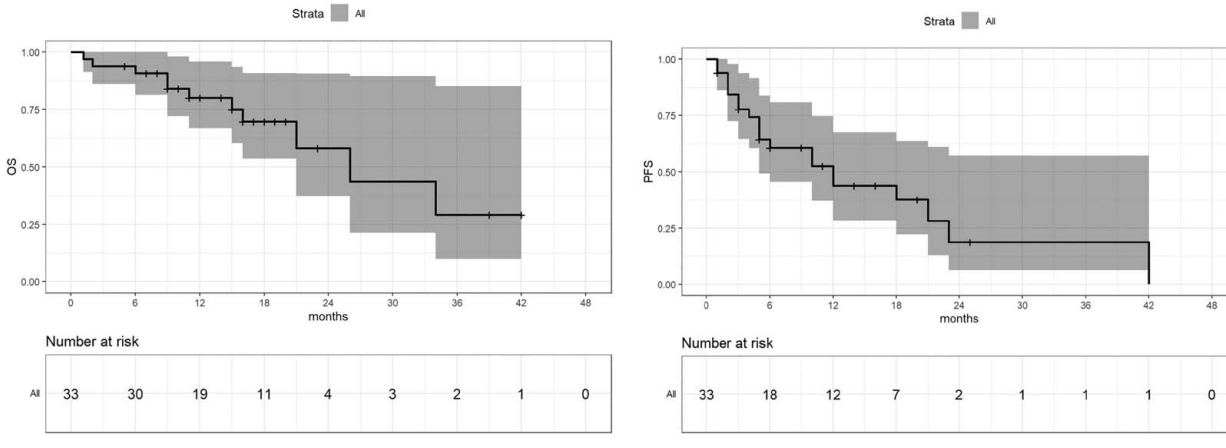

FIGURE 1. Overall survival (OS) and progression-free survival (PFS).

and OS are available options, T-DXd should be prioritized, as it has been studied in a less pretreated patient population.[8] In the DB-04 trial, 70% of patients with hormone receptor-positive disease had already received a CDK4/6 inhibitor, and subgroup analysis suggested that patients benefited from T-DXd regardless of prior therapy with a CDK4/6 inhibitor.[4] Subgroup analysis in DB-04 also showed a similar hazard ratio (HR) for disease progression or death in patients who received one or 2 lines of chemotherapy.[4]

On the basis of data currently available in pretreated patients with hormone receptor-positive HER2-negative metastatic breast cancer, T-DXd is the standard of care for HER2-low disease.[8] There is a greater body of evidence for the use of T-DXd in a less pretreated population (1 to 2 previous lines of chemotherapy), whereas SG has been tested in patients who have received 2 to 4 previous lines of chemotherapy in a metastatic setting, which justifies the preference for using T-DXd in an earlier line of treatment.[8,9]

For the treatment of patients with HER2-low metastatic triple-negative breast cancer (TNBC), study DB-04, whose primary objective was to compare PFS in patients with hormone receptor-positive breast cancer (n = 494), also included a cohort of 58 patients with HER2-low metastatic hormone receptor-negative breast cancer (ie, TNBC).[4] In the TNBC cohort, patients treated with T-DXd compared with physician-chosen chemotherapy had improved PFS (HR = 0.46, 95% CI: 0.24-0.89) and OS (HR = 0.48, 95% CI: 0.24-0.85). Since this was an exploratory objective, no *P*-value was assigned to the results.[4] However, this group was included in the full analysis population of the trial, where the results were again statistically significant in favor of T-DXd for PFS and OS, leading to FDA approval of T-DXd for patients with HER2-low metastatic TNBC who had received at least one prior line of chemotherapy.[4] It should be noted that patients with HER2-low metastatic TNBC were also included in the DAISY phase II trial[9] and the BEGONIA phase Ib trial,[10] demonstrating encouraging and more supportive response rates that T-DXd activity can be observed in HER2-low breast cancer, whether or not hormone receptors are expressed.

In addition, in France, the cATU program included patients with HER2-positive metastatic breast cancer who had received at least 2 prior lines of anti-HER2, with a median of 4 lines of metastatic treatment (range: 2 to 22). Before inclusion, 81.7% of patients had received radiotherapy and 76.5% had undergone surgery. At the start of treatment, 98.6% of patients received T-DXd at a dose of 5.4 mg/kg, thus meeting the admissibility criteria. The median age of the patients in this program was 58 years, comparable to the DESTINY-Breast studies, where the median age was 55 years in DESTINY-Breast01 and 54.2 years in DESTINY-Breast02, respectively.[5]

Unlike the cohorts of the DESTINY-Breast studies, which included > 99% of patients with a performance index of 0 to 1, 9.6% of patients in the cATU program had a performance index ≥ 2. This indicates that the patients in the cATU program were in a less favorable overall condition, which is an important factor to consider in the evaluation of treatment efficacy. Moreover, 28.1% of patients in the cATU program had active brain metastases, while the DESTINY studies excluded patients with this type of metastasis. This highlights that the results obtained under the cATU program may be more representative of real-world patients, although they are not directly comparable to clinical trial cohorts. At 6-month follow-up, the objective response rate (ORR) in the cATU program was 56.7%, while for patients with brain metastasis data, the ORR was 35.7%. In comparison, in the DESTINY-Breast01 phase II study, the ORR was 60.9% (95% CI: 53.4-68.0), and in the phase III study DESTINY-Breast02, the ORR was 69.7% (95% CI: 65.0-74.1). These data indicate that, although response rates in the cATU program are slightly lower, they remain encouraging given the more unfavorable characteristics of this population.[5]

In our study, the results showed that the concomitant combination of radiation therapy and T-DXd is both effective and safe. We observed complete remission rates of 9.1%, partial remission rates of 39.4%, and disease stabilization in 39.4% of patients, while 12.1% experienced disease progression. Overall survival (OS) was 26 months and progression-free survival (PFS) was 12 months. These data suggest that the simultaneous combination of radiotherapy and T-DXd could potentially enhance treatment efficacy. In addition, it appears that there is no need to interrupt T-DXd during radiotherapy.

It is also important to note that T-DXd was associated with an increased incidence of grade 3 or 4 adverse events compared with T-DM1 (45.1% vs. 39.8%, respectively). However, our study found that concomitant administration of T-DXd and radiotherapy did not result in a significant increase in treatment-related toxicity. The acute toxicities observed were mainly related to systemic treatment, with a low occurrence of grade 2 toxicities and no acute grade ≥ 3 toxicity reported.[6]

The preliminary results of our study, although encouraging and promising, would obviously require validation by larger, more controlled studies to allow definitive conclusions and a better understanding of the impact of this concurrent combination on survival and tumor response, in order to optimize the treatment of patients with HER2-positive and HER2-low metastatic breast cancer.

CONCLUSIONS

Although the results of our study support the efficacy and safety of this combined therapeutic approach, the lack of data on the efficacy of the concomitant combination of T-DXd and radiotherapy underlines the need for further clinical investigations. A better understanding of the impact of this combination on clinical outcomes is essential to optimize the treatment of patients with HER2-positive and HER2-low metastatic breast cancer.

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