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Adjuvant Chemotherapy Delay After Primary Debulking Surgery for Advanced Ovarian Cancer at a Teaching Hospital in Southern Nigeria

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Abstract

Background: Treatment of ovarian cancer involves a combination of surgery with optimal debulking surgery followed by chemotherapy, because many women are diagnosed at an advanced stage. The optimal timing of postoperative chemotherapy for ovarian cancer remains poorly defined.

Objectives: To determine the proportion of patient with delayed chemotherapy, the time-to-commencement of adjuvant chemotherapy, and to identify the predictors of delayed chemotherapy among women with advanced ovarian cancer at the University of Port Harcourt Teaching Hospital (UPTH).

Material and Methods: This was a prospective cross-sectional study of 57 patients who underwent surgery for advanced ovarian cancer between January 1, 2018, and December 31, 2022. A proforma was used to obtain the socio-demographic and clinical characteristics of the participants. Chemotherapy delay was defined as initiation of multiagent chemotherapy >42 days from primary debulking surgery. Associations of socio-demographic and clinical characteristics with adjuvant chemotherapy delay were evaluated with multivariate logistic regression.

Results: Most 20 (35.1%) were aged 45-54 years, with a mean age of 46.9 ± 11.3 years. Majority 37 (64.9%) were married and 31 (54.4%) had tertiary education. The most common histological type was serous 36 (52.6%) followed by mucinous 9 (15.8%). Almost all 55 (96.5%) the women had ascites on presentation, all the women were referred to the study centre, with many 33 (57.9%) of the referrals from private clinics. Many of these patients 46 (84%) had their adjuvant chemotherapy delayed, with 39 (69%) presenting with stage III disease. Financial constraint 35 (51.5%) was the main reason for delayed chemotherapy. Menopause was significantly associated with the delay in adjuvant chemotherapy (chi-square = 7.14, p = 0.01). However, multivariable logistic regression analysis did not identify any potential predictors as a factor for delay in commencing adjuvant chemotherapy. For every unit increase in age of these women, there was an insignificant 12% reduced odds of having delayed adjuvant chemotherapy.

Conclusion: Delay in starting adjuvant chemotherapy is known to be a risk factor for overall survival. Being able to identify the causes of these delays will assist healthcare professionals in understanding and mitigating the risk.

Keywords: Ovarian cancer; Adjuvant chemotherapy; Predictors of delay; Surgery; Nigeria

Introduction

Ovarian cancer is the third most common gynaecological cancer and has the worst prognosis. In 2020, about 313,959 new cases and 207,252 deaths were reported globally, with an age-standardized incidence rate of 6.6 per 100,000 person-years [1]. According to research conducted in Nigeria and Africa, ovarian cancer ranks as the second most common gynaecological cancer, comprising approximately 7 to 8.2% of all gynecological malignancies [2]. Unfortunately, around 75% of cases are diagnosed at advanced stages, which can be attributed to the absence of specific clinical manifestations and effective screening methods [3,4]. The survival rate of patients with ovarian cancer is highly dependent on the stage at diagnosis. For stages I and

II, relative survival at five years was 89% and 70%, respectively [5,6]. In contrast, for stages III and IV, relative survival at five years was much lower at 36% and 17%, respectively. At ten years, the survival rates were 84%, 59%, 23%, and 8% for stages I, II, III, and IV, respectively [7-9].

Primary debulking surgery (PDS) followed by adjuvant chemotherapy is the standard of care for advanced ovarian cancer. Adjuvant chemotherapy after PDS aims to eliminate residual cancer cells and reduce the risk of disease recurrence [10,11]. However, there is ongoing debate regarding the optimal timing of adjuvant chemotherapy after PDS. Some studies have suggested that delaying adjuvant chemotherapy after PDS may have a negative impact on patient outcomes [12,13]. The rationale behind this is that delaying chemotherapy may allow residual cancer cells to continue growing and potentially lead to disease progression [6,14]. On the other hand, there is also concern that starting chemotherapy too soon after surgery may delay wound healing and increase the risk of postoperative complications. Although many studies have been conducted, no consensus has been reached on the optimal timing for adjuvant chemotherapy after PDS for advanced ovarian cancer.

While the optimal timing of chemotherapy in ovarian cancer is unknown, it has been suggested that delaying chemotherapy beyond 4 weeks may have a negative prognostic impact [15]. However, most large studies have recommended adjuvant chemotherapy only after complete recovery from surgery, which takes an average of 42 days (6 weeks) after curative resection of ovarian cancer [16,17]. Feng et al. [18] concluded that a 6-week interval between surgery and chemotherapy had no effect on prognosis. A longer interval between surgery and the start of adjuvant chemotherapy resulted in a 22% decline in overall survival (OS) of ovarian cancer, with a 4% decrease in relative OS for each week of delay in starting adjuvant chemotherapy [19].

Uson et al. [20] reported in a meta-analysis that the time to adjuvant chemotherapy (between 20 and 40 days) after ovarian cancer surgery with curative intent was not associated with an increased risk of disease recurrence or death. This association, however, was influenced by the optimal debulking rate [20]. Clinicians must balance the potential benefits and risks of postponing chemotherapy with the potential benefits of commencing treatment sooner. Ultimately, the timing of adjuvant chemotherapy should be determined by individual patient factors and a multidisciplinary approach. Previous research focused primarily on locally advanced disease and found a significant reduction in OS if adjuvant chemotherapy was delayed for six weeks or more [4,12]. The current study was carried out to evaluate the proportion of patients with delayed chemotherapy and its predictors.

Materials and Methods

Study Area

This study was conducted at the gynaecological unit of the University of Port Harcourt Teaching Hospital (UPTH). The University of Port Harcourt Teaching Hospital is a 988-bed hospital in Alakahia, in Obio-Akpor Local Government Area of Rivers state. It is a tertiary hospital that serves as a referral centre for all levels of healthcare in Rivers state and other neighbouring states including Bayelsa, Imo and Abia. Every week, the gynaecology clinic is open from Monday to Friday, and each clinic session is led by a team of consultants. Patients are evaluated in the clinic before they are admitted into the gynaecogical ward for surgery.

Methods

This was a prospective cross-sectional study of 57 women with histologically confirmed ovarian cancer managed at the University of Port Harcourt Teaching Hospital between January 1, 2018, and December 31, 2022. The purpose of the study was duly explained to the women and an informed consent was obtained. A structured interviewer-administered questionnaire designed for this purpose was used to obtain socio-demographic, reproductive, and clinical characteristics. Tumour stage, histological type, serum levels of tumour markers, type of surgery, time to commencement of adjuvant chemotherapy, chemotherapy regimen, and reasons for delay were also evaluated. Chemotherapy delay was defined as initiation of multiagent chemotherapy >42 days from primary debulking surgery. The questionnaire for each patient was checked for completeness before it was entered into a spreadsheet and analyzed.

Statistical Analysis

Statistical Package for Social Sciences version 25 was used to analyze the data. Descriptive statistics were summarized using frequency, mean and standard deviation. The association of delayed chemotherapy with socio-demographic, reproductive, and clinical characteristics was assessed using the Chi-square test and multivariate logistic regression analysis, with statistical significance determined at $p < 0.05$.

Ethical Consideration

Ethical approval for the study was obtained from the research and ethics committee of the University of Port Harcourt Teaching Hospital. A written informed consent was obtained from the participants prior to inclusion into the study.

Result

Fifty-seven patients were recruited into the study. Most 20 (35.1%) were aged 45-54 years, with a mean age of 46.9 ± 11.3 years. Majority 37 (64.9%) were married, 31 (54.4%) had tertiary education, and 49 (85.9%) were still active in their respective occupation. This is shown in Table 1. Table 2a shows that the most common histological type was serous 36 (52.6%) followed by mucinous 9 (15.8%) and endometroid 8 (14%). Of the 57 women, 50 (87.7%) had symptoms for 1-2 years, and almost all 55 (96.5%) had ascites at presentation. Most 52 (91.2%) of the women had surgery and chemotherapy. All the women were referred to the study centre, with many 33 (57.9%) of the referrals from private

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clinics. The median pre-treatment serum CA-125 level was 286 (397) u/ml and a median platelet count of 308 (307) x 10^9/L, while the median number of adjuvant chemotherapy received was 6(2). This is shown in Table 2b.

Table 1: Socio-demographic Profile of Ovarian Cancer Patients (N=57).

Attributes	n (%)
Age (years)	
≤24	1 (1.8)
25-34	6 (10.5)
35-44	17 (29.8)
45-54	20 (35.1)
55-64	9 (15.8)
≥ 65	4 (7.0)
Marital Status	
Single	11 (19.3)
Married	37(64.9)
Divorced	2 (3.5)
Widowed	7 (12.3)
Education	
None	3 (5.2)
Primary	7 (12.3)
Secondary	16 (28.1)
Tertiary	31 (54.4)
Occupation	
#Technical/Associate Professional	7 (12.3)
$Professional	16 (28.1)
%Clerical Support	1 (1.8)
&Elementary	4 (7.0)
!Service/Sales Workers	11 (19.3)
>Skilled Workers/Farmers/Fishermen	4 (7.0)
<Craft/ Related Trade/Traders	14 (24.5)
Occupation	
Active	49 (85.9)
Inactive	5 (8.8)
Retired	3 (5.3)
Median Parity	3 (4)
Median No. of Living Children	3 (4)
Age at Menarche	13 (1)

Table 2a: Clinical Profile of Ovarian Cancer Patients (N=57).

Attributes	n %
Histological Type	
Serous	36 (52.6)
Mucinous	9 (15.8)
Endometroid	8 (14)
Granulosa	5 (8.8)
Endodermal sinus	5 (8.8)
Duration of Symptoms (years)	
1-2	50 (87.7)
≥ 2	7 (12.3)
Ascites	
Yes	55 (96.5)
No	2 (3.5)
Length of Diagnosis (years)	
<1	29 (50.9)
1-2	28 (49.1)
Hypertension	
Yes	14 (24.6)
No	43 (75.4)
Diabetes Mellitus	
Yes	2 (3.5)
No	55 (96.5)
Type of Treatment	
Surgery	5 (8.8)
Surgery + Chemotherapy	52 (91.2)
Menopausal	
Yes	22 (38.6)
No	35 (61.4)
Referred to the Facility	
Yes	57(100)
If yes, where	
Private clinic/maternity	33 (57.9)
Primary health center	4 (7)
Secondary health center	12 (21.1)
Tertiary health center	8 (14)
Hormonal Contraceptive Use	
Yes	8 (14.0)
No	49 (86.0)

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Table 2b: Clinical Profile of Ovarian Cancer Patients (N=57).

Attributes	Mean (SD)
Median Platelet Count (109/L)	308 (307)
Median CA125 µ/ml	286 (397)
Median CA199 g/l	9.8 (29.1)
Median CEA g/l	1 (92.8)
Median AFP g/l	3.6 (7.6)
Mean LDH g/l	285(64.9)
Median No. of chemotherapy received	6(2)
Median No. of chemotherapy delayed	2(1.8)

SD: Standard deviation

Figure 1 showed that most 46 (84%) of the patients commenced adjuvant chemotherapy more than 42 days after surgery, with financial constraints as the predominant reason for delay (Table 3). Many 39 (69%) of the women had stage III disease, while 15 (26%) of the women had stage IV cancer as shown in Figure 2. Tables 4 & 5 shows univariate analyses used to identify potential predictors of delay in adjuvant chemotherapy. The identified factors were age (median = 48 years, z=2.91 p-value = 0.004), CA 125 (median = 286 µ/ml, z=2.48, p-value = 0.008), platelet count (median = 308 G/L, z=2.46, p-value = 0.014) and menopausal status (X^2 = 7.148 p-value = 0.008). However, multivariable logistic regression analysis did not identify any potential predictors as a factor of delay in adjuvant chemotherapy commencement as shown in Table 6. For every unit increase in age, these women had a 12% lower chance of starting adjuvant chemotherapy later. There was no correlation between delayed adjuvant chemotherapy and each unit increase in CA125 in these women. Similarly, there was no association between having delayed adjuvant chemotherapy and every unit increase in platelet count in these women, and menopausal women had an insignificant 105% increased odds of having delayed adjuvant chemotherapy commencement.

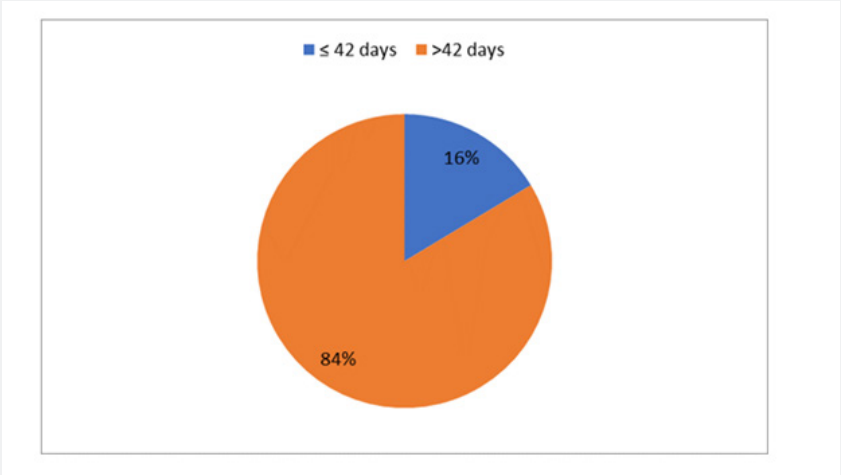

Figure 1: Time to commencement of Chemotherapy after surgery in women with Ovarian cancer.

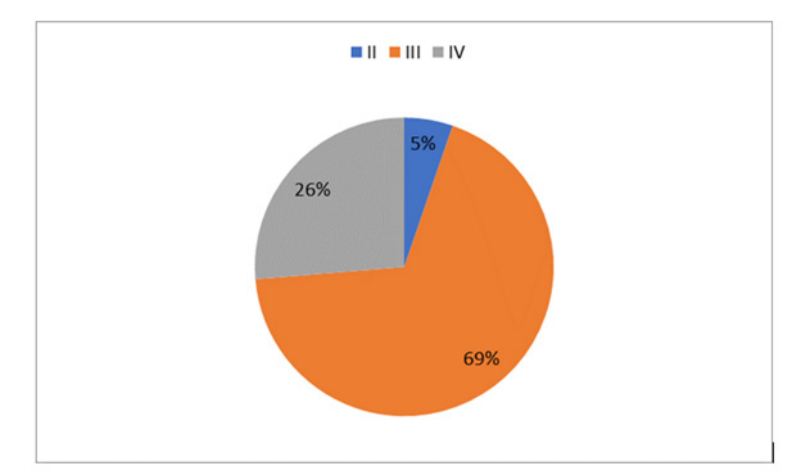

Figure 2: Distribution of Cancer Staging among Ovarian Cancer Women.

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Table 3: Reasons for delayed chemotherapy.

Attributes	n %
Financial constraint	35 (51.5)
Medical Comorbidity	4 (5.9)
Multiple reasons	29 (42.6)

Financial + anaemia + medical morbidity + low platelet + poor performance

Table 4a: Univariate Analysis of Predictors of Delay in Adjuvant Chemotherapy commencement in Ovarian Cancer.

Attribute	≤ 42 Days	> 42days	X2	P-Value
Marital Status				
Single	0 (0.0)	11 (100)		
Married	6 (17.1)	29 (82.9)	4.939	0.12
Divorced	1 (50.0)	1 (50.0)		
Widowed	2 (28.6)	5 (71.4)		
Occupation				
Technical/Associate Professional	4 (57.1)	3 (42.9)	8.44	0.14
Professional	3 (21.4)	11 (78.6)		
Clerical Support		1 (100)		
Elementary		4 (100)		
Service/Sales Workers	1 (9.1)	10 (90.9)		
Skilled Workers/Farmers/Fishermen		4 (100)		
Craft/ Related Trade/Traders	1 (7.7)	12 (92.3)		
Occupation Status				
Active	7 (15.6)	38 (84.4)		
Inactive		4 (100)	4.466	0.09
Retired	2 (66.7)	1 (33.3)		
Education				
None		2 (100)		
Primary		7 (100)	1.609	0.67
Secondary	3 (18.8)	13 (81.2)		
Tertiary	6 (20.7)	23 (79.3)		
Referred, Where?				
Private Clinic/Maternity	5 (16.1)	26 (83.9)		
Primary Health Centre	1 (25.0)	3 (75.0)	0.825	0.94
Secondary Health Centre	2 (16.7)	10 (83.3)		
Tertiary Health Centre	1 (12.5)	7 (87.5)		
Pap Smear Screening				
Yes	2 (40.0)	3 (60.0)	2.245	0.13
No	7 (14.0)	43 (86.0)		

* Significant at p<0.05 in Pearson's chi-square; ** significant at p<0.05 in Fischer's exact (>20%Cells <5) X2; Chi-square;

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Table 4b: Univariate Analysis of Predictors of Delay of Adjuvant Chemotherapy Commencement in Ovarian Cancer.

Attributes	>42days	≤ 42 Days	X2	P-Value
Hormonal Contraceptive use				
Yes	5 (71.4)	2 (28.6)		
No	40 (85.1)	7 (14.9)	0.821	0.37
Menopausal				
Yes	14 (66.7)	7 (33.3)		
No	32 (94.1)	2 (5.9)	7.148	0.01*
No. of Symptoms				
1-2	41 (83.7)	8 (16.3)		
Multiple	5 (83.3)	1 (16.7)	0	1
Stage of Cancer				
II	2 (66.7)	1 (33.3)		
III	33 (84.6)	6 (15.4)		
IV	11 (84.6)	2 (15.4)	1.221	0.54
Ascites				
Yes	44 (83.0)	9 (1.7)		
No	2 (100)		0.406	1
Histology				
Serous	28 (83.3)	5 (16.7)		
Mucinous	6 (85.7)	1 (14.3)		
Endometroid	5 (62.5)	3 (37.5)	3.435	0.46
Granulosa	5 (100)			
Endodermal sinus	5 (100)			
Length of Diagnosis (years)				
<1	23 (82.1)	5 (17.9)		
1-2	23 (85.2)	4 (14.8)	0.093	1
Reasons for delay				
Financial only	35 (97.2)	1 (2.8)		
Medical Comorbidity		1 (100)	7.533	0.13
Others	4 (100)			
Multiple reasons	29 (96.7)	1 (3.3)		

*Significant at p<0.05 in Pearson's chi-square; ** significant at p<0.05 in Fischer's exact (>20%Cells <5) X2; Chi-square

Table 5: Univariate Analysis of Quantitative Predictors of Delay of Adjuvant Chemotherapy Commencement in Ovarian Cancer.

Attributes	≤ 42 Days	>42days	Z	P-Value
Platelet Count (109/L)	586.5	289	-2.47	0.01*
CA125 µ/ml	851	271	-2.48	0.01*
CA199 g/l	6.3	9.8	-0.072	0.94
CEA g/l	16.4	1	-1.04	0.3
AFP g/l	46	3.4	-1.34	0.18
LDH g/l		281		
Age	59	44.5	-2.91	0.04*
Parity	3	2	-1.05	0.29
Age at Menarche	13	13.5	-1.06	0.29

*Significant at p<0.05 Z: Z-score

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Table 6: Multivariate Analysis of Predictors in Delay of Adjuvant Chemotherapy Commencement in Ovarian Cancer.

Attributes	AOR	95% C.I. for AOR		P-value
		Lower	Upper	
Age	0.88	0.07	1.02	0.1
Ca125	1	0.99	1	0.98
Menopausal				
Yes	2.05	0.08	55.14	0.67
+No				
Platelet count	1	0.99	1	0.06
Constant	16454.84	0.013		0.01

* Significant at p<0.05 AOR: Adjusted Odds Ratio, +: Reference

Discussion

There has been no large-scale research into the timing of adjuvant therapy after optimal debulking surgery. The timing of adjuvant chemotherapy in patients undergoing primary cytoreductive surgery has frequently been debated. Several studies have found that starting chemotherapy after immediate cytoreductive surgery is associated with poor outcomes [21]. However, there is no set time for starting postoperative adjuvant therapy in patients who have had primary cytoreductive surgery. The Gynaecologic Oncology Group (GOG) concluded in their study that patients with a therapy initiation time of more than 25 days had a worse prognosis than those who started therapy earlier [7].

A meta-analysis of 15 cohort studies concluded that starting chemotherapy early improved the overall survival of patients with ovarian cancer [19]. Each week that adjuvant chemotherapy was delayed resulted in a 4% decrease in relative OS. The GOG performed a post-trial ad hoc analysis on ovarian cancer patients from a phase III randomized control trial and found that when the time to chemotherapy exceeded 25 days, there was an increased risk of death in patients with Stage IV disease who had complete resection [7]. The time between surgery and the start of chemotherapy has varied between studies. Most studies investigated a 4-6-week delay. Although some research have been undertaken to determine the optimal time for initiation of adjuvant chemotherapy after interval cytoreductive surgery, no consensus has been reached.

Many of the women in the current study had delayed adjuvant chemotherapy, which was defined as a period of more than 42 days. This is consistent with previous reports from similar studies, which found that 60-90% of women had delayed chemotherapy after surgical removal of ovarian tumours, particularly in low and middle-income countries like Nigeria [7,10,12,22]. This is in contrast to reports from developed countries, which showed that approximately half of women who underwent optimal debulking surgery for advanced ovarian cancer had delayed chemotherapy [14,23]. The high proportion of women who had delayed chemotherapy in the study does not necessarily imply a causal relationship between delayed treatment and lower socio-economic status.

Chemotherapy delays may be influenced by factors such as age, patient comorbidities, cancer stage, treatment preferences, prolonged hospitalization, postoperative complications, or access to healthcare. Furthermore, the reasons for delayed chemotherapy may differ depending on the healthcare system, the patient's preferences, and the characteristics of the tumour [24,25]. However, only menopausal status was found to be significantly associated with adjuvant chemotherapy delay in the current study. The finding that many of the women had delayed adjuvant chemotherapy is a cause for concern, as treatment delays can have a negative impact on treatment outcomes and overall survival. Possible reasons for the delay in chemotherapy initiation should be investigated and addressed, including access to healthcare, patient education, and decision-making by physicians.

Many of the women had advanced cancer (stages III and IV). This is consistent with findings from similar studies, in which more than half of women undergoing primary debulking surgery (PDS) presented late [24,26]. This highlights the need for more effective early detection and screening methods to improve the chances of successful treatment outcomes and survival [4,27]. This could include raising awareness and educating women and healthcare providers about the symptoms of ovarian cancer and the importance of early detection. Further research is needed to understand the barriers to timely treatment in this group of women [24,26,28]. Strategies addressing the specific needs of ovarian cancer patients, such as managing treatment-related symptoms, may help to improve treatment adherence and outcomes.

The absence of significant predictors of delayed adjuvant chemotherapy initiation suggests that multiple factors may be contributing to treatment delays. This emphasizes the importance of a multidisciplinary approach to cancer care, including coordinated efforts among healthcare providers, patients, and their families to improve treatment adherence and outcomes. The findings of the current study emphasize the significance of ovarian cancer screening, early diagnosis, and timely treatment.

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Addressing the specific needs of women with ovarian cancer, as well as identifying and removing barriers to timely treatment initiation, are critical to improving treatment outcomes for women with ovarian cancer.

The limitations of our study were the small number of patients and the short duration of follow-up. A larger cohort could have achieved statistical significance. Given that this was not a randomized study, there was no prior calculation of sample size or power. The significance of our study was that it was the first time that delayed adjuvant chemotherapy was evaluated. Furthermore, as a single centre, a defined patient selection and optimal debulking surgery protocol was implemented.

Conclusion

The present study observed that majority of the women had delay in the initiation of adjuvant chemotherapy, which was mainly due to financial constraint. Concerted efforts should be made by the government, policy makers, and non-governmental organizations to subsidize cancer care, and make chemotherapy and radiotherapy part of the National Health Insurance Scheme. Furthermore, raising awareness and educating women and healthcare providers about the symptoms of ovarian cancer and the importance of early detection larger studies are needed to identify reversible risk factors that could impact on patient outcomes.

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