CANCER DIAGNOSIS & PROGNOSIS
4: 434-440 (2024) doi: 10.21873/cdp.10344

Tubular Carcinoma of the Breast: The Possibility to Omit Sentinel Lymph Node Biopsy

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Abstract. *Background/Aim: Tubular breast carcinoma, classified as a special type of invasive cancer, has a good prognosis. This study aimed to retrospectively investigate the clinical and pathological characteristics of 32 tubular carcinoma cases enrolled at our institution, with a focus on exploring the potential for treatment de-escalation. Patients and Methods: The study included all patients diagnosed with tubular breast carcinoma at our hospital between January 2005 and December 2021. In addition, 549 patients with ductal carcinoma in situ (DCIS) and 1,524 patients with stage I and II invasive cancers [not otherwise specified (NOS)] were selected for comparison. Results: All participants were female, with an average age of 54.4 years. The median follow-up duration was 64 months. The median tumor diameter was 7 mm, and all cases were Luminal A type. Moreover, no lymph vascular invasion was observed in any case, and no local recurrence, distant metastasis, or death occurred. The sentinel lymph node positive rate was 0% in the tubular carcinoma group, significantly lower than that in the NOS group (25.5%, p=0.0019) and not significantly different from that in the DCIS group (0.2%). The tubular carcinoma group tended to have better overall survival (OS) and disease-free survival (DFS) than the NOS group. Furthermore, the tubular carcinoma group was not inferior in OS and DFS compared to the DCIS group. Conclusion: Lymph node metastasis rate, OS, and DFS of the tubular carcinoma group are comparable to those of the DCIS group. Sentinel lymph node biopsy for tubular carcinoma can be omitted with an accurate preoperative diagnosis.*

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Key Words: Tubular carcinoma, de-escalation of treatment, sentinel lymph node biopsy.

The incidence rate of breast cancer in Japan is considerably increasing, with 1 in 10 women diagnosed with breast cancer in their lifetime. Advances in medications and surgical procedures for breast cancer have led to individualized approaches, and the 2019 Criteria and Classification guideline of the World Health Organization divides breast cancers into multiple categories based on pathological characteristics to optimize treatment. Notably, it is important to minimize the burden of treatment and maximize the benefits (1-5).

Tubular carcinoma (TC) is classified as a special type of invasive cancer, accounting for 1-4% of all invasive cancers and generally considered to have a good prognosis (1, 4-12). TCs are generally small in diameter, have minimal lymph node metastasis, are diagnosed early, and are mostly estrogen-dependent luminal A type (2, 6, 13-15).

For invasive breast cancer, confirming the presence of lymph node metastasis using sentinel lymph node biopsy in cases where clinical lymph node metastasis is negative at the time of diagnosis is recommended. On the other hand, for ductal carcinoma *in situ* (DCIS), sentinel lymph node biopsy is recommended only for extensive lesions requiring total mastectomy, considering the possibility of inclusion of invasive components (NCCN guidelines). Furthermore, sentinel lymph node biopsy can be omitted if breast-conserving surgery is performed for non-invasive cancer.

Despite having a good prognosis with minimal lymph node metastasis, sentinel lymph node biopsy, irradiation for the preserved breast, and postoperative endocrine therapy for five years are recommended for TC, similar to those for usual invasive cancers (16-19). Previous studies have reported that the treatment for TC is overloaded, and some

retrospective observational studies showed that the presence of lymph node metastasis does not affect recurrence-free survival or prognosis (20-23). In addition, a recent meta-analysis study on TC has reported that TC has a low recurrence rate and exhibited limited effects from endocrine therapy and radiation therapy (24).

In this study, we investigated 32 cases of TC, all of which were negative for lymph node metastasis and had a good prognosis compared with usual invasive ductal carcinoma. We aimed to explore the de-escalation of treatment for TC by retrospectively investigating the clinical and pathological characteristics of TC cases at our institution.

Patients and Methods

In this single-center retrospective observational study, we included all 32 patients who were diagnosed with TC and underwent treatment at the National Hospital Organization Tokyo Medical Center between January 2005 and December 2021. We also included 549 patients with DCIS and 1,524 patients with stage I and II invasive ductal carcinoma not otherwise specified (NOS) who underwent curative surgery at our hospital during the same period for comparison.

Clinical features. We collected the patients' demographic and clinical characteristics, including age, family history, history of contralateral or ipsilateral breast cancer, tumor size, lymph node metastasis, and distant metastasis.

Preoperative diagnosis. We investigated the detection rate of positive findings based on findings, such as tumor shadows, distortion, calcification, on preoperative mammography and positive findings on preoperative breast echography. In addition, we investigated the diagnostic accuracy of preoperative pathological diagnosis *via* needle biopsy and aspiration cytology.

Postoperative diagnosis. Using the excised specimens, we examined the positivity rates of estrogen receptor (ER), progesterone receptor (PR), and androgen receptor (AR), as well as the HER2 positivity rate and Ki-67 staining rate. The presence or absence of concomitant lesions of TC was also analyzed in detail, and we determined whether they were pure or mixed type. The type and presence of invasion for concomitant lesions were investigated, and the concordance rate between the preoperative biopsy and final pathological diagnosis was also examined. We confirmed the positive margin, lymph node metastasis, and lymphovascular invasion rates based on the type of surgical procedure. The details of postoperative treatments, such as endocrine therapy, chemotherapy, and radiation therapy, were investigated.

Prognosis analysis. Disease-free survival (DFS) and overall survival (OS) were compared between the TC and NOS or DCIS groups.

Statistical analysis. The chi-squared test (with Yates' correction) was used to analyze differences in the distribution of each factor between the TC and NOS or DCIS groups, whereas the *t*-test was used to compare the mean age. Kaplan–Meier curves were also created to compare postoperative recurrence and mortality. The Log-rank test was performed for statistical analysis, and SPSS (version 25.0; SPSS Inc., IBM Company, Armonk, NY, USA) was used for all statistical analyses, with a significance level of 5%.

Results

Clinical diagnosis. All patients were female with a mean age of 54.4±11.4 years, and 53% were premenopausal (Table I). The median follow-up period was 64 months (range=8-205 months).

Preoperative diagnosis. Except for one case, the tumor size was T1 with a diameter of 2 cm or less; mammography findings were detected in all cases. Of 32 patients in the study, no patients were clinically suspected with lymph node metastasis or distant metastasis. The clinical stage at diagnosis was stage I in 31 patients and stage IIa in 1 patient; 24 of 32 patients were diagnosed with TC *via* preoperative pathological examination (Table II).

Postoperative diagnosis. Regarding surgical treatment, partial mastectomy was performed in 81.2% (26 of 32) of patients, whereas total mastectomy was performed in 18.8% (6 of 32) of patients. Sentinel lymph node biopsy was performed in 31 patients with a metastasis rate of 0% (0/31); thus, axillary lymph node dissection was omitted in all cases. The median tumor size was 7 mm (range=1.1-34 mm). The ER, PR, and HER-2 positivity rates were 100% (32 of 32), 96.8% (31 of 32), and 0% (0 of 32), respectively; the Ki-67 staining rate was less than 15% in all cases. In addition, no lymphovascular invasion was observed in any case.

For breast-conserving surgery, we performed intraoperative pathological diagnosis of frozen sections for the stump, and 28.5% (8 of 28) of the patients had a positive or close margin. In two of the eight patients, the surgery was converted to total mastectomy, whereas one patient exhibited a positive final margin.

Regarding pathological diagnosis, mixed-type TC accounted for 37.5% (12 of 32) of cases, and the most common coexisting lesion was lobular carcinoma *in situ*, which accounted for 18.7% (6 of 32) of cases. The TC was multifocal in 12.5% (4 of 32) of cases, and other types of invasive carcinoma coexisted in 9.3% (3 of 32) of cases (Table III).

All patients underwent endocrine therapy for postoperative treatment, and irradiation of the conserved breast was performed for all 26 patients who underwent breast-conserving surgery. No patients required postoperative chemotherapy and experienced local recurrence, distant metastasis, or death during the follow-up period.

Prognosis analysis. Table IV and Table V show the results of comparison between 32 TC cases and 1,524 cases in the NOS group and 549 cases in the DCIS group. The rates of T1 and N0 were significantly higher in the TC group than

Table I. *Clinical characteristics of patients with tubular carcinoma (N=32).*

Characteristic	Total number (%)
Mean age (years±SD)	54.4±11.4
Menopausal status	
Premenopausal	17 (53.1)
Postmenopausal	15 (46.9)
Breast cancer family history	
Positive	4 (12.5)
Negative	28(87.5)
Breast cancer history	
Contralateral	3 (9.4)
Ipsilateral	0 (90.6)
Clinical Stage	
I	31 (96.9)
II	1 (3.1)
Regional lymph node involvement	
Negative	32 (100)
Positive	0 (0)
Distant metastasis	
Negative	32 (100)
Positive	0 (0)

SD: Standard deviation.

Table II. *Preoperative diagnosis of tubular carcinoma (N=32).*

Factors	Number (%)
Detected on Mammography	31/31 (100)
Mass/Density area	20/31 (64.5)
Distortion	8/31 (25.8)
Calcification	9/31 (29.0)
Detected on Ultrasound	
Mass/Hypoechoic area	27/31 (87.1)
Other	4 (12.9)
Preoperative pathological diagnosis	
Tubular carcinoma	24 (75.0)
Invasive ductal carcinoma	1 (3.1)
Invasive lobular carcinoma	1 (3.1)
DCIS	2 (6.3)
LCIS	1 (3.1)
Benign lesion	1 (3.1)
Cytology: Adenocarcinoma	1 (3.1)
Cytology: Benign cell	1 (3.1)

DCIS: Ductal carcinoma *in situ*; LCIS: lobular carcinoma *in situ*.

those in the NOS group ($p<0.0001$, $p=0.001$; Table IV). Additionally, the sentinel lymph node metastasis rate in the TC group (0%) was significantly lower than that in the NOS group (25.5%) ($p=0.0019$) and was not significantly different compared with that of the DCIS group (0.2%).

Regarding pathological diagnoses, there were significantly more cases with ER positivity (100% *vs*. 87.7% and 84.5%, $p=0.026$ and $p=0.009$) and PR positivity (96.8% *vs*. 79.7% and 77.9%, $p=0.017$ and $p=0.011$) in the TC group compared with those in the NOS and DCIS groups, indicating a higher prevalence of hormone receptor-positive cases in the TC group. Conversely, the HER2 positivity rate (0% *vs*. 12.8% and 15.7%, $p=0.027$ and $p=0.009$) and Ki-67 staining rate <15% (100% *vs*. 50.5% and 78.5%, $p<0.001$ and $p=0.009$) were lower in the TC group than those in the NOS and DCIS groups. Furthermore, the lymphovascular invasion rate (0% *vs*. 24% and 0%, $p=0.03$ and NS) and venous invasion rate (0% *vs*. 3.6% and 0%) in the TC group were lower than those in the NOS group and not significantly different from those in the DCIS group. However, the incidence of margin positivity in cases undergoing breast-conserving surgery did not differ significantly among the three groups (3.1% *vs*. 4.5% and 4.9%, $p=0.72$ and $p=1.0$).

Table III. *Postoperative pathological diagnosis of tubular carcinoma (N=32).*

Factors	Number (%)
Tubular carcinoma, pure type	20/32 (62.5)
Single lesion	16/32 (50.0)
Multiple lesion	4/31 (12.5)
Tubular carcinoma, mixed type	12/32 (37.5)
Coexisting lesion	
Invasive ductal carcinoma	1 (3.1)
Invasive lobular carcinoma	2 (6.3)
DCIS	3 (9.4)
LCIS	6 (18.8)

DCIS: Ductal carcinoma *in situ*; LCIS: lobular carcinoma *in situ*.

Treatment-related comparison results are shown in Table IV and Table V. No significant difference in breast conservation rates among the three groups were observed. The proportion of patients receiving postoperative endocrine therapy were significantly higher in the TC group than in the NOS and DCIS groups (100% *vs*. 83.7% and 5.1%, $p=0.0013$ and $p<0.0001$), indicating the higher prevalence of hormone receptor-positive cases in the TC group. In addition, the proportion of patients receiving postoperative chemotherapy in the TC group were significantly lower than those in the NOS group (0% *vs*. 34.8%, $p<0.001$) and similar to those in the DCIS group (0%). Postoperative radiation therapy did not significantly differ between the TC and NOS groups (81.2% *vs*. 68.2%, $p=0.12$) or DCIS group (81.2% *vs*. 75.8%, $p=0.48$).

The TC group showed a tendency toward better OS and DFS compared with the NOS group, although the difference was not significant. Similarly, the OS and DFS of the TC group were not inferior to those of the DCIS group (Figure 1, Figure 2, Figure 3, Figure 4).

Table IV. *Comparison of clinicopathological characteristics of tubular carcinoma with those of invasive ductal carcinoma (IDC) and not otherwise specified (NOS).*

Factor		Tubular carcinoma (N=32)	IDC and NOS (N=1,524)	*p*-Value
Age (years)		54.4±11.4	58.83±13.6	0.069
Stage	I	31 (21.4)	937 (34.6)	
	II	1 (27.3)	587 (26.9)	<0.001
Lymph node metastasis	Negative	31 (100)	1,096 (83.9)	
	Positive	0 (0)	377 (16.1)	0.001
Nuclear grade	1	32 (100)	540 (36.5)	
	2	0 (0)	328 (22.2)	
	3	0 (0)	612 (41.3)	<0.001
Estrogen receptor	Negative	0	186	
	Positive	32	1,338	0.026
Progesterone receptor	Negative	1	308	
	Positive	31	1,216	0.017
Androgen receptor	Negative	11	495	
	Positive	16	761	0.89
HER2 status	Negative	32	1,329	
	Positive	0	195	0.027
Ki-67 index	<15%	31	726	
	≥15%	0	795	<0.001
Surgery	Mastectomy	6	489	
	Conservation	26	1,035	0.10
Surgical margin	Negative	31	1,456	
	Positive	1	68	0.72
Lymphovascular invasion	Negative	32	1,157	
	Positive	0	367	0.001
Adjuvant endocrine therapy		32/32	1,276/1,524	0.013
Adjuvant chemotherapy		0/32	531/1,524	<0.001
Adjuvant radiotherapy		26/26	1,039/1,524	0.12

Table V. *Comparison of clinicopathological characteristics between tubular carcinoma and DCIS.*

Factor		Tubular carcinoma (N=32)	DCIS (N=549)	*p*-Value
Age (years)		54.4±11.4	56.6±13.2	0.60
Lymph node metastasis	Negative	30 (100)	404 (99.8)	
	Positive	0 (0)	1 (0.2)	1.00
Nuclear grade	1	32 (100)	159 (38.7)	
	2	0 (0)	176 (42.8)	
	3	0 (0)	76 (18.5)	<0.001
Estrogen receptor	Negative	0	85	
	Positive	32	464	0.009
Progesterone receptor	Negative	1	121	
	Positive	31	428	0.011
Androgen receptor	Negative	11	156	
	Positive	16	310	0.44
HER2 status	Negative	32	461	
	Positive	0	86	0.009
Ki-67 index	<15%	31	424	
	≥15%	0	125	0.003
Surgery	mastectomy	6	117	
	conservation	26	432	0.73
Surgical margin	Negative	31	522	
	Positive	1	27	1.00
Adjuvant endocrine therapy		32/32	28/549	<0.001
Adjuvant chemotherapy		0	0	1.00
Adjuvant radiotherapy		26/32	416/549	0.48

DCIS: Ductal carcinoma *in situ*.

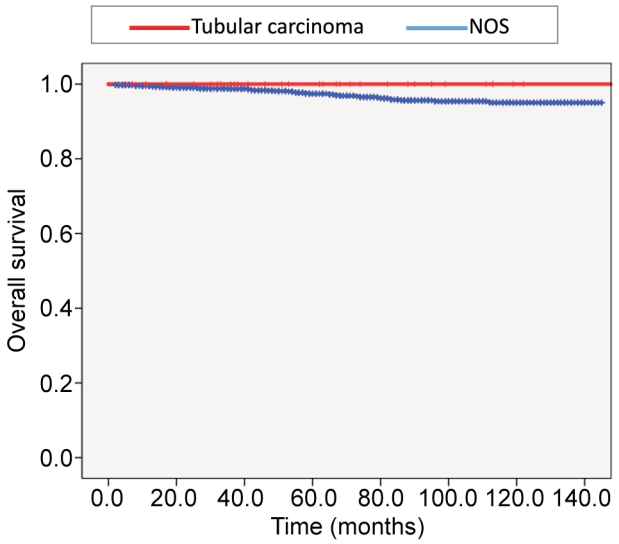

Figure 1. *Kaplan–Meier estimates of overall survival (OS) (log-rank test, p=0.35) comparing tubular carcinomas with the not otherwise specified (NOS) type.*

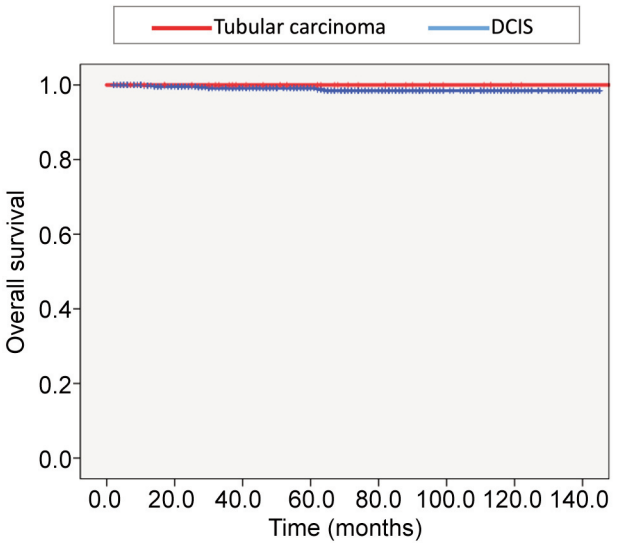

Figure 3. *Kaplan–Meier estimates of overall survival (OS) (log-rank test, p=0.55) comparing tubular carcinomas with ductal carcinoma in situ (DCIS).*

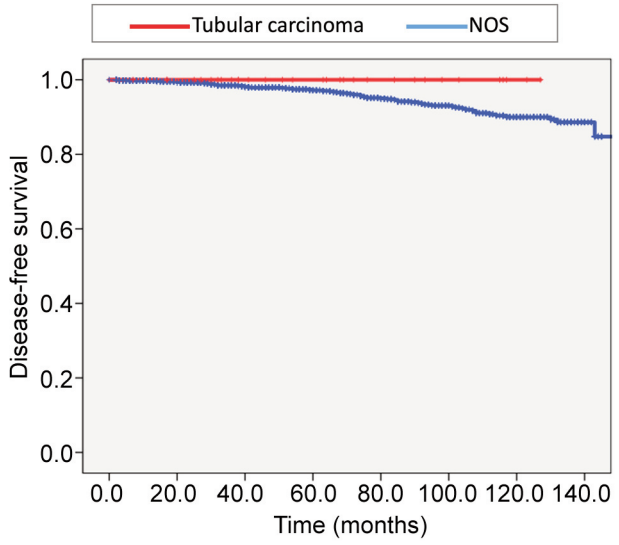

Figure 2. *Kaplan–Meier estimates of disease-free survival (DFS) (log-rank test, p=0.26) comparing tubular carcinomas with the not otherwise specified (NOS) type.*

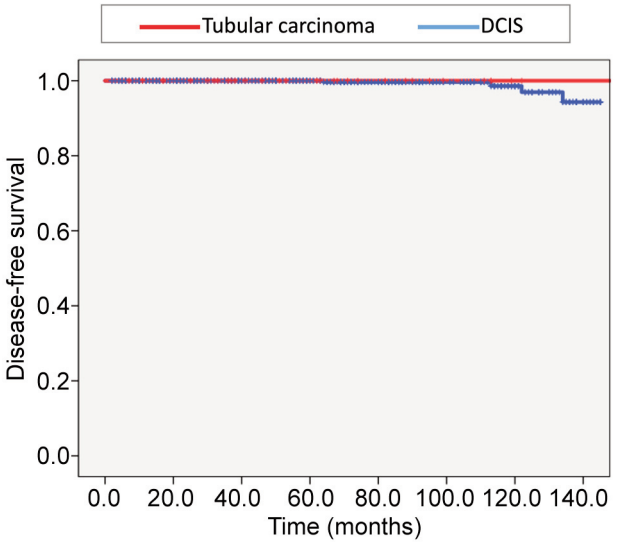

Figure 4. *Kaplan–Meier estimates of disease-free survival (DFS) (log-rank test, p=0.73) comparing tubular carcinomas with ductal carcinoma in situ (DCIS).*

Discussion

Among special types of cancer, TC is considered a cancer subgroup with favorable prognosis owing to its small tumor size, low lymph node metastasis rate, possibility of early diagnosis, and predominantly exhibiting the luminal-A subtype (2, 6, 13-15). Our study participants mostly comprised patients with low-grade, well-differentiated, early-stage breast cancers with no lymph node metastasis, high estrogen dependence, and low Ki-67 staining rate. Moreover, many patients had a favorable prognosis based on OS and DFS, similar to those of DCIS and better than those of invasive cancers. The current standard treatment for TC involves sentinel lymph node biopsy, radiotherapy for breast-

conserving surgery, and five years of postoperative endocrine therapy (16-19); however, there may be room to consider de-escalation for each treatment modality.

Surgical treatment. TC cases often have small tumor size and lack lymph node swelling on preoperative imaging (2, 6, 15). In this study, the lymph node metastasis rate, OS, and DFS of TC were not significantly different from those of DCIS; thus, omitting sentinel biopsy is reasonable to consider. Accuracy of preoperative diagnosis is an important issue for surgery, and TC was preoperatively diagnosed in 75% of cases in our study. Cases showing mass-like appearances may benefit from accurate diagnosis *via* needle biopsy. Finally, there were three cases (9.4%) with coexisting lesion of invasive lobular carcinoma or invasive ductal carcinoma, suggesting that close attention should be paid to the coexistence of invasive carcinoma, which has more influential impact on prognosis.

Furthermore, TC lesions are limited in extent by themselves but may be extensive owing to coexisting lobular carcinoma *in situ*, DCIS, or multiple tubular carcinomas. Thus, when planning conservative surgery, thorough verification of coexisting lesions or multiple foci is essential.

Even with sentinel biopsy alone, discomfort at the incision site, pain in the affected upper limb, swelling, and limited mobility way still occur in some cases. Therefore, the omission of sentinel biopsy for TC is a challenge that should be positively considered.

Endocrine therapy. In this study, all cases were Luminal A subtype, and their treatment included postoperative endocrine therapy. To omit endocrine therapy, conducting prospective controlled trials is necessary to demonstrate that omission does not result in a disadvantage. However, TC accounts for only approximately 1-4% of all breast cancers. Moreover, because TC has a good prognosis, accumulating adequate number of cases for comparative studies is difficult, and such studies often necessitate a prolonged duration to yield conclusive results. Even without waiting for trial results, there is room to consider omitting endocrine therapy in cases where disadvantages are anticipated because of therapy-related side effects, such as osteoporosis and various disorders from reduced estrogen levels.

Radiation therapy. In our study, radiation therapy for breast-conserving surgery was performed in most cases. Postoperative irradiation for TC reportedly does not lead to improvement in prognosis (24), and in our study, the incidence rates of mixed type multiple tubular carcinomas were 37.5% and 12.5%, respectively. Although the incidence rate of localized type was approximately 50% in cases with solitary TC, omission of radiation may be considered when sufficient free margins are secured. Omitting radiation may also be reasonable for limited cases, such as to avoid of burdensome clinic visits and acute skin disorders, lung inflammation, and late-stage cardiac or vascular complications associated with radiation therapy.

In conclusion, TC cases in this study were primarily early-stage well-differentiated malignancies, consistent with the findings of previous reports. No regional lymph node metastasis and distant metastasis was observed, and the postoperative course was comparable to that of DCIS. Regarding de-escalation of treatment, omitting sentinel lymph node biopsy may be feasible with accurate preoperative diagnosis, and omitting postoperative endocrine and radiation therapies for cases with confirmed pathological diagnosis seems reasonable.

Conflicts of Interest

The Authors have no conflicts of interest to declare in relation to this study.

Authors' Contributions

Sae Yamane: Contributed to conceptualization, methodology, formal analysis, writing – original draft preparation, writing – review & editing and visualization; Akira Matsui: Contributed to conceptualization, methodology, formal analysis, writing – original draft preparation, writing – review & editing and supervision; Yuya Murata, Ayako Nakashoji, and Manami Sasahara: Contributed to investigation and resources; Takayuki Kinoshita: Contributed to investigation, resources and supervision.

Acknowledgements

The Authors thank the technicians of the Pathology Department (Department of clinical laboratory pathology, National Hospital Organization Tokyo Medical Center, Tokyo, Japan) for sample preparation.

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Received February 27, 2024
Revised March 31, 2024
Accepted April 3, 2024