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Long-term survival of patients with T1bN0M0 esophageal cancer after thoracoscopic esophagectomy using data from JCOG0502: a prospective multicenter trial

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Abstract

Background Thoracoscopic esophagectomy (TE) is considered the standard surgery for esophageal cancer because of its superiority over open esophagectomy (OE) in terms of short-term outcomes. However, few prospective multicenter studies have evaluated its long-term survival after TE. This study aimed to investigate whether the prognosis for patients with T1bN0M0 esophageal cancer after TE is not inferior to OE using data from the Japan Clinical Oncology Group Study (JCOG0502), a prospective multicenter trial comparing esophagectomy with chemoradiotherapy.

Methods Data of patients in JCOG0502 after esophagectomy were used to compare the overall survival (OS) and relapse-free survival (RFS) after OE versus TE. OE or TE was selected at the surgeon's discretion. A hazard ratio and 95% confidence interval (CI) were calculated via Cox proportional-hazards model.

Results Of the 210 patients who underwent esophagectomy, 109 underwent OE, whereas 101 underwent TE. The 5-year OS was 88.9% after OE and 85.0% after TE. The hazard ratio of TE for OS was 1.53 (95% CI, 0.84–2.78; $p=0.16$) and 1.10 (95% CI, 0.52–2.35; $p=0.80$) in the univariable and multivariable analyses, respectively. The 5-year RFS was 85.3% after OE and 79.1% after TE. The hazard ratio of TE for RFS was 1.39 (95% CI, 0.81–2.38; $p=0.23$) and 0.88 (95% CI, 0.44–1.74; $p=0.70$) in the univariable and multivariable analyses, respectively.

Conclusion The prognosis for patients with T1bN0M0 esophageal cancer after TE was not inferior to OE.

Keywords Minimally invasive esophagectomy · Thoracoscopy · Laparoscopy · Esophageal cancer · Survival

Esophageal cancer is one of the most aggressive cancers affecting the gastrointestinal tract; oftentimes, it is known to have a poor outcome. In 2018, approximately 572,034 new cases and 508,585 deaths from esophageal cancer were recorded worldwide, ranking sixth as most common cause of cancer death [1]. In Japan, these numbers were estimated to include 21,900 new cases and 11,200 deaths in 2019, with

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5-year survival of 41.5% among all patients with esophageal cancer diagnosed from 2009 to 2011[2].

Esophagectomy remains to be the mainstay treatment for curable thoracic esophageal cancer. Thoracoscopic esophagectomy (TE), which was first introduced in 1992 [3], has been widely accepted as standard surgery [4, 5] because of its superiority over open esophagectomy (OE) for short-term outcomes, including better quality of life [6], less blood loss, and prevention of pulmonary complications [4, 7–9]. Indeed, TE now accounts for 52.8% and 61.0% of all esophagectomies performed in western countries [4] and in Japan [5], respectively. Despite its widespread use, only two prospective multicenter trials have evaluated its long-term survival after TE [10, 11]. One is the first phase II trial (ECOG2202) that reported 3-year OS of 58.4% after total minimally invasive esophagectomy (MIE) for patients with esophagogastric cancer ($n=95$) [11]. The other is the first phase III trial (TIME) that compared total MIE and open approach for patients with esophageal cancer ($n=115$) and showed no difference in 3-year OS between the two groups (total MIE: 42.9%, Open: 41.2%) [10].

The results of JCOG0502, which has been conducted by the Japan Clinical Oncology Group-Japan Esophageal Oncology Group (JCOG-JEOG), compare esophagectomy with definitive chemoradiotherapy for T1bN0M0 esophageal cancer, with a median follow-up time of 7.1 years [12]. The present study has used the data of these patients after esophagectomy ($n=210$) in JCOG0502 and compared overall survival (OS) and relapse-free survival (RFS) after TE versus OE to examine whether the prognosis after TE was not inferior to OE.

Materials and methods

Study design and patient selection

JCOG0502 is a four-arm prospective trial comparing esophagectomy with definitive chemoradiotherapy for patients with T1bN0M0 cancer, and it includes randomized and patient preference arms [12]. The present study used data of patients after esophagectomy in both arms (Fig. 1). Written informed consent was obtained from all enrolled patients. The study protocol was approved by the Clinical Trial Review Committee of the JCOG and by the review boards of all the participating institutions. The key eligibility criteria for JCOG0502 were as follows: age between 20 and 75 years; clinically staged as T1bN0M0 cancer; diagnosis of histologically proven squamous cell carcinoma, adenosquamous carcinoma, or basaloid cell carcinoma in the thoracic esophagus; and performance status of 0–1 according to the Eastern Cooperative Oncology Group.

Operative methods

After the patients were allocated to the surgery arms, transthoracic esophagectomy with lymphadenectomy was performed without preoperative chemotherapy and/or radiotherapy. The use of thoracoscopy and/or laparoscopy was at the surgeon's discretion without any intention to compare these approaches, regardless of the arm of the study. OE was then performed via a right thoracotomy in the lateral decubitus position, followed by gastric mobilization via either

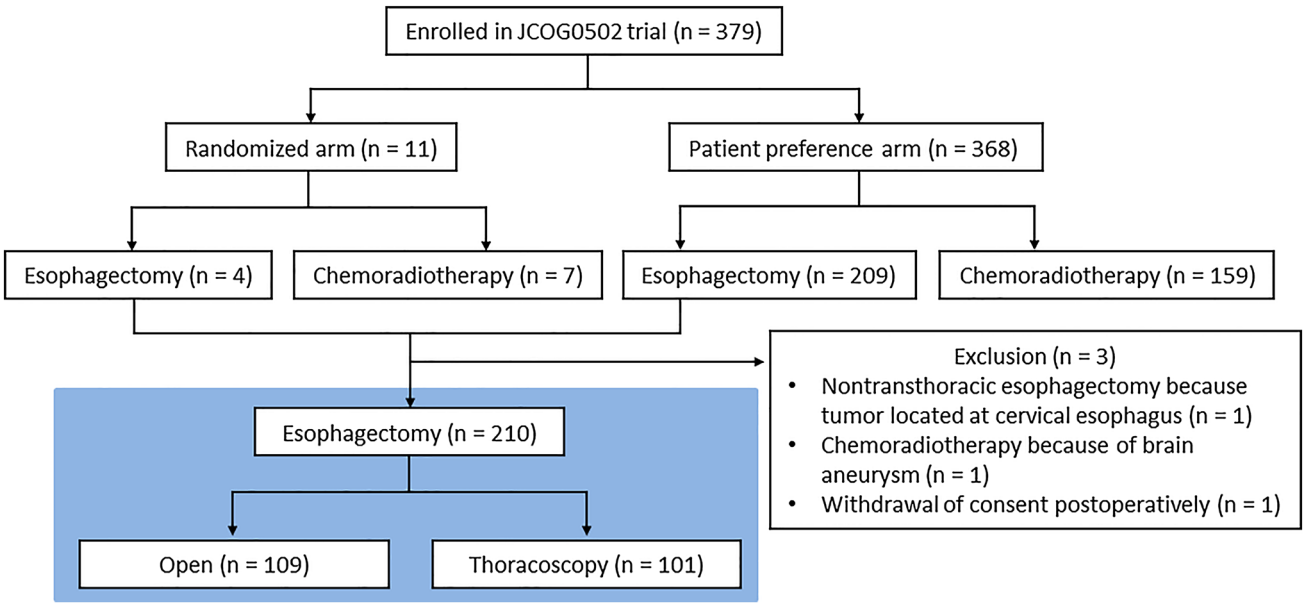

Fig. 1 Flow diagram for JCOG0502, with the present study highlighted in blue

laparotomy or laparoscopy. TE was performed through a right thoracoscopy in the lateral decubitus or prone position, followed by gastric mobilization via either laparotomy or laparoscopy. Patients with upper-thoracic disease underwent three-field lymphadenectomy, whereas patients with mid- or lower-thoracic disease underwent either two- or three-field lymphadenectomy at the surgeon's discretion.

Definitions and statistical methods

All clinicopathological parameters were expressed according to the *American Joint Committee on Cancer Staging Manual* (sixth edition) [13]. T1 tumor was further subcategorized into T1a (tumor invades lamina propria or muscularis mucosae) or T1b (tumor invades submucosa).

To compare OE and TE, the Wilcoxon rank-sum test was used for continuous data, whereas the Fisher's exact test was used for categorical data. OS was measured from the date of enrollment to the date of death or the last follow-up. RFS was measured from the date of enrollment to the date of the first evidence of relapse or death due to any cause. OS and RFS curves were estimated using the Kaplan–Meier method and were compared via log-rank test. A hazard ratio and 95% confidence interval (CI) were calculated using the Cox proportional-hazards model. Age, gender, tumor size, pathological T-factor, pathological N-factor, abdominal approach, and field of lymphadenectomy were included as explanatory variables in the multivariable analysis. The level of significance was set at a two-sided p-value of < 0.05. All analyses were then performed using SAS software, v9.4 (SAS Institute Inc., Cary, NC) at the JCOG Data Center. Data up to Feb. 2018 were presented in this article.

Results

Patient characteristics and operative details

In total, 379 patients with T1bN0M0 thoracic esophageal cancer from 37 institutions were enrolled in JCOG0502 between December 2006 and February 2013, wherein 210 of these patients underwent transthoracic esophagectomy (Fig. 1). However, three patients were excluded: one who underwent non-transthoracic esophagectomy because of tumor location at the cervical esophagus, one who received chemoradiotherapy because of brain aneurysm, and one who postoperatively withdrew consent. Of these 210 patients, 109 underwent OE, while 101 underwent TE. As shown in Table 1, no difference was noted between the two groups in terms of patient characteristics and operative details, except that the TE group was more often combined with a laparoscopic approach.

Table 1 Patient characteristics and operative details

	Open (OE) ($n=109$)		Thoracoscopy (TE) ($n=101$)		
	n	%	*n*	%	*P*[a]
Age (years)					
Median (range)	62 (41–75)		63 (48–75)		0.522[b]
Gender					
Male	93	85.3	82	81.2	0.462
Female	16	14.7	19	18.8	
Performance status[c]					
0	109	100	100	99.0	0.481
1	0	0	1	1.0	
Body mass index					
Median (range)	22 (13–29)		23 (17–28)		0.934[b]
Tumor location					
Upper thoracic	11	11.0	15	14.9	0.156
Midthoracic	66	60.6	67	66.3	
Lower thoracic	32	29.4	19	18.8	
Tumor size					
≤4 cm	76	69.7	70	69.3	1.000
>4 cm	33	30.3	31	30.7	
Lymphadenectomy					
Two-field	41	37.6	40	39.6	0.779
Three-field	68	62.4	61	60.4	
Abdominal approach					
Open	102	93.6	43	42.6	<0.001
Laparoscopy	7	6.4	58	57.4	

[a]Fisher's exact test

[b]Wilcoxon rank sum test

[c]Eastern Cooperative Oncology Group

Pathological characteristics of resected specimen

Most of the resected specimens in both groups were diagnosed with squamous cell carcinoma (Table 2). Pathological examination revealed that the TE group contained pT2 ($n=5$) and pT3 ($n=2$) cancers, while the OE group had no ≥ pT2 cancer ($p=0.04$) (Table 2). There was higher incidence of pathological lymph node metastasis in the TE group (29.7%) than the OE group (22.0%), although the difference was insignificant ($p=0.21$).

Overall survival

By the data cutoff date (February 20, 2018), 20 patients who underwent OE and 24 patients who underwent TE reportedly died, with a median follow-up time of 7.3 years among the 210 patients. OS curves are shown in Fig. 2. The 5-year OS was 88.9% (95% CI, 81.3–93.6) for the OE group and 85.0% (95% CI, 76.4–90.7) for the TE group (log-rank test; $p=0.16$). The hazard ratio for TE was 1.53 (95% CI,

Table 2 Pathological characteristics of resected specimen

	Open (OE) ($n=109$)		Thoracoscopy (TE) ($n=101$)		P^a
	n	%	*n*	%	
Histologic type					
Squamous cell carcinoma	106	97.2	95	94.1	0.187
Adenosquamous carcinoma	1	0.9	0	0	
Basaloid cell carcinoma	2	1.8	3	3.0	
Others	0	0	3	3.0	
Pathological T[b]					
pTis	1	0.9	2	2.0	0.044
pT1a	35	32.1	26	25.7	
pT1b	73	67.0	66	65.4	
pT2	0	0	5	5.0	
pT3	0	0	2	2.0	
Pathological N[b]					
pN0	85	78.0	71	70.3	0.211
pN1	24	22.0	30	29.7	
Pathological stage[b]					
pStage 0	1	0.9	3	3.0	0.346
pStage I	82	75.2	65	64.4	
pStage II	21	19.3	27	26.7	
pStage III	0	0	1	1.0	
pStage IV	5	4.6	5	5.0	
Residual tumor[b]					
R0	108	99.1	98	97.0	0.353
R1/2	1	0.9	3	3.0	

[a]Fisher's exact test

[b]According to 6th AJCC/UICC staging system (T1a: tumor invades lamina propria or muscularis mucosae, T1b: tumor invades submucosa)

0.84–2.78; $p=0.16$) and 1.10 (95% CI, 0.52–2.35; $p=0.80$) in the univariable and multivariable analyses, respectively (Table 3).

Relapse-free survival

During the follow-up period, 26 patients who underwent OE and 28 patients who underwent TE had reportedly relapse and/or died. RFS curves are shown in Fig. 3. The 5-year RFS was 85.3% (95% CI, 77.1–90.7) for the OE group and 79.1% (95% CI, 69.7–85.8) for the TE group (log-rank test; $p=0.23$). The hazard ratio for TE was 1.39 (95% CI, 0.81–2.38; $p=0.23$) and 0.88 (95% CI, 0.44–1.74; $p=0.70$) in the univariable and multivariable analyses, respectively (Table 4).

Prognostic factors affecting overall or relapse-free survival

Univariable analysis showed that age, tumor size, and pathological N-factor were associated with OS (Table 3). Multivariable analysis has also indicated age, tumor size, and pathological N-factor as the independent prognostic factors for OS.

For RFS, univariable analysis showed that age, pathological T-factor, pathological N-factor, abdominal approach, and lymphadenectomy were associated with RFS (Table 4). Multivariable analysis identified age, pathological T-factor, pathological N-factor, and lymphadenectomy as independent prognostic factors for RFS.

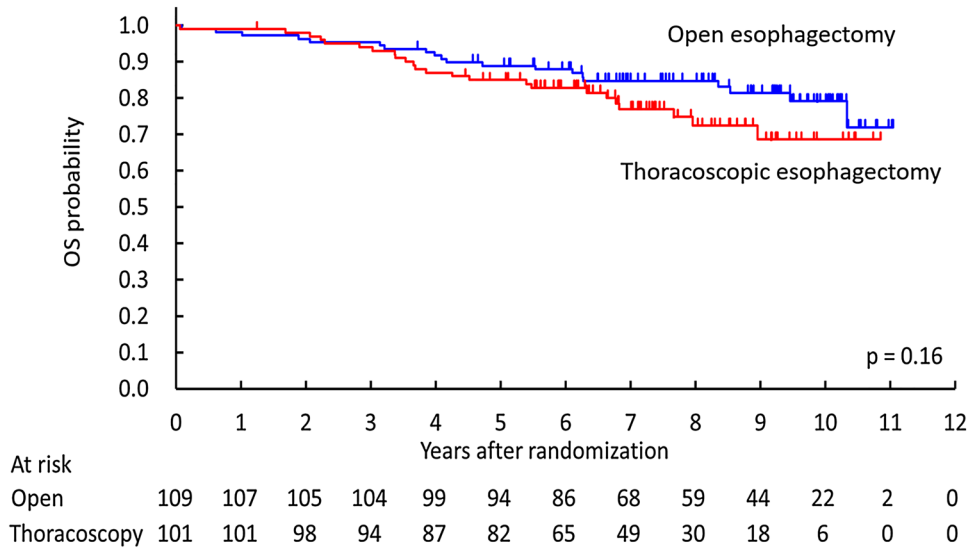

Fig. 2 Overall survival among patients undergoing open and thoracoscopic esophagectomy

Table 3 Univariable and Multivariable analyses for Overall Survival

		Total	Univariable analysis		Multivariable analysis	
		n	HR (95% CI)[a]	*P*[b]	HR (95% CI)[a]	*P*[b]
Age (years)	<65	129	1		1	
	≥65	81	2.00 (1.10–3.62)	0.022	1.92 (1.04–3.53)	0.036
Gender	Female	35	1		1	
	Male	175	1.12 (0.50–2.51)	0.787	1.15 (0.50–2.63)	0.740
Tumor size	≤4 cm	146	1		1	
	>4 cm	64	1.87 (1.03–3.40)	0.039	1.87 (1.02–3.42)	0.044
Pathological T	≤pT1a	64	1		1	
	≥pT1b	146	1.96 (0.94–4.08)	0.072	1.84 (0.86–3.93)	0.116
Pathological N	pN0	156	1		1	
	pN1	54	2.03 (1.10–3.78)	0.025	1.98 (1.03–3.81)	0.040
Thoracic approach	Open	109	1		1	
	Thoracoscopy	101	1.53 (0.84–2.78)	0.163	1.10 (0.52–2.35)	0.800
Abdominal approach	Open	145	1		1	
	Laparoscopy	65	1.71 (0.92–3.16)	0.088	1.52 (0.70–3.27)	0.290
Lymphadenectomy	Two-field	81	1		1	
	Three-field	129	0.67 (0.37–1.22)	0.193	0.66 (0.36–1.23)	0.191

[a]Hazard ratio (95% confidence interval)

[b]Two-sided p value by Cox regression

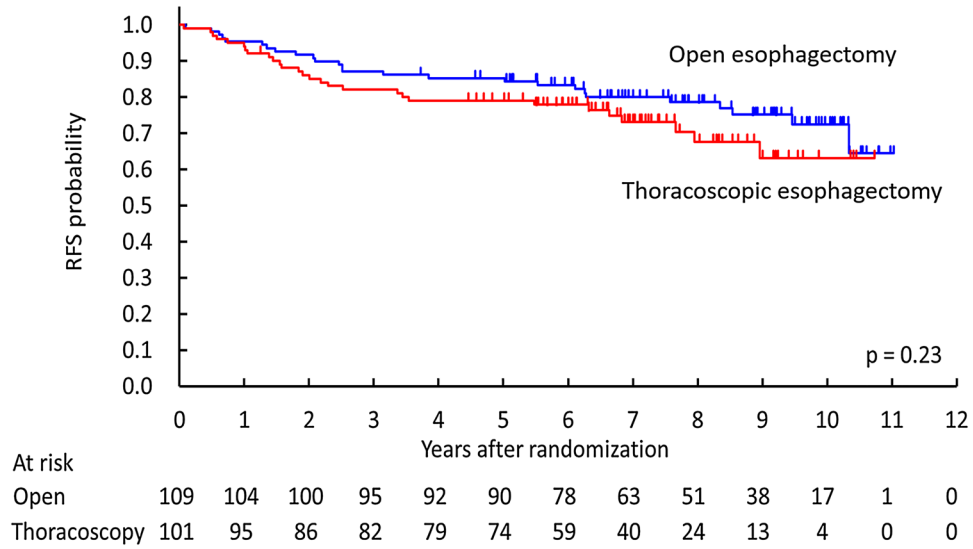

Fig. 3 Relapse-free survival among patients undergoing open and thoracoscopic esophagectomy

Discussion

Using data from a prospective multicenter trial (JCOG0502) for patients with T1bN0M0 esophageal cancer, our research on OE versus TE yielded no difference in long-term survival of patients. To the best of our knowledge, the present study is the largest analysis from a prospective multicenter trial to evaluate the long-term survival after TE.

The TIME trial comparing total MIE and open approach reported that there was no difference in both the 3-year OS and 3-year disease-free survival [10]. Retrospective studies using a large-scale nationwide database have reported that total MIE or hybrid MIE (any esophagectomy involving either thoracoscopy or laparoscopy) showed equivalent long-term survival compared with open approach [14–16]. A meta-analysis including 55 comparative studies concluded that all-cause and disease-specific mortalities were better after total MIE or hybrid MIE than after open approach [17].

In the present study, the 5-year OS and RFS were slightly shorter in the TE group than those in the OE group, and univariate analysis showed that the hazard ratio of TE was 1.53

Table 4 Univariable and Multivariable analyses for Relapse-free Survival

		Total	Univariable analysis		Multivariable analysis	
		n	HR (95% CI)[a]	*P*[b]	HR (95% CI)[a]	*P*[b]
Age (years)	<65	129	1		1	
	≥65	81	1.80 (1.05–3.06)	0.032	1.74 (1.01–3.00)	0.046
Gender	Female	35	1		1	
	Male	175	1.04 (0.51–2.12)	0.919	1.11 (0.53–2.30)	0.788
Tumor size	≤4 cm	146	1		1	
	>4 cm	64	1.64 (0.96–2.83)	0.073	1.61 (0.92–2.81)	0.093
Pathological T	≤pT1a	64	1		1	
	≥pT1b	146	2.04 (1.05–3.96)	0.035	2.05 (1.03–4.07)	0.041
Pathological N	pN0	156	1		1	
	pN1	54	1.95 (1.11–3.42)	0.021	1.85 (1.02–3.37)	0.043
Thoracic approach	Open	109	1		1	
	Thoracoscopy	101	1.39 (0.81–2.38)	0.230	0.88 (0.44–1.74)	0.704
Abdominal approach	Open	145	1		1	
	Laparoscopy	65	1.82 (1.04–3.18)	0.035	2.02 (0.99–4.12)	0.052
Lymphadenectomy	Two-field	81	1		1	
	Three-field	129	0.57 (0.33–0.98)	0.041	0.52 (0.30–0.90)	0.020

[a]Hazard ratio (95% confidence interval)

[b]Two-sided *p* value by Cox regression

for OS and 1.39 for RFS. This is probably because patients in the TE group had more advanced T- and N-stage cancers than those in the OE group (Table 2), which were associated with worse prognosis [18]. In multivariable analysis including pathological T- and N-factors, the hazard ratios decreased to 1.10 for OS and to 0.88 for RFS. Since the use of thoracoscopy was at the surgeon's discretion, the unequal distribution was probably by chance. To clarify whether thoracoscopic approach affected the incidence of cancer recurrence in the chest, we are now examining the first cancer recurrence site using data from JCOG0502 (JCOG0502-S8 study).

The phase III trial (MIRO) has shown that the laparoscopic approach prevented postoperative complications and did not shorten long-term survival after esophageal cancer resection [19]. However, a laparoscopic approach was identified as a prognostic factor for worse RFS in the univariable analysis of the present study. Since the total number of harvested lymph nodes in the laparoscopic approach was the same as in the open approach [20], it is unclear why the laparoscopic approach was identified as the prognostic factor. The JCOG0502-S8 study may elucidate this finding.

Multivariable analysis identified the number of fields of lymphadenectomy as a prognostic factor for RFS but not OS. In the present study, patients with upper-thoracic disease underwent three-field lymphadenectomy, whereas patients with mid- or lower-thoracic disease underwent either two- or three-field lymphadenectomy at the surgeon's discretion. Although the significance of prophylactic cervical lymphadenectomy remains controversial [21–23], the present study indicates that not performing cervical lymphadenectomy may cause lymph node recurrence in the neck. We are currently planning a new randomized trial (JCOG2013/MODERN3) to examine the omission of prophylactic supraclavicular nodal dissection.

The present study had some limitations. First, because it was designed as a nonrandomized comparison, the results may be affected by unmeasured confounding factors and low statistical power. Second, propensity score matching was not performed. Third, the first cancer recurrence site and subsequent treatments were not evaluated. Finally, the results may not be applicable to advanced esophageal cancer.

The TIME trial targeted the incidence of pulmonary infection as a primary endpoint; thus, it was underpowered for long-term survival analysis [10]. Our ongoing trial, JCOG1409 (MONET), is the world's first phase III trial to compare long-term survival between OE and TE as a primary endpoint [24].

In conclusion, a thoracoscopic approach for esophagectomy did not shorten the long-term survival of patients with T1bN0M0 esophageal cancer and was not inferior to open approach in terms of prognosis.

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Declarations

Disclosures Drs. Isao Nozaki, Ryunosuke Machida, Ken Kato, Hiroyuki Daiko, Yoshinori Ito, Takashi Kojima, Masahiko Yano, Masaki Ueno, Satoru Nakagawa, and Yuko Kitagawa have no conflicts of interest or financial ties to disclose.

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