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Association of Surgical Delay and Overall Survival in Patients With T2 Renal Masses: Implications for Critical Clinical Decision-making During the COVID-19 Pandemic

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OBJECTIVE	To test for an association between surgical delay and overall survival (OS) for patients with T2 renal masses. Many health care systems are balancing resources to manage the current COVID-19 pandemic, which may result in surgical delay for patients with large renal masses.
METHODS	Using Cox proportional hazard models, we analyzed data from the National Cancer Database for patients undergoing extirpative surgery for clinical T2N0M0 renal masses between 2004 and 2015. Study outcomes were to assess for an association between surgical delay with OS and pathologic stage.
RESULTS	We identified 11,848 patients who underwent extirpative surgery for clinical T2 renal masses. Compared with patients undergoing surgery within 2 months of diagnosis, we found worse OS for patients with a surgical delay of 3-4 months (hazard ratio [HR] 1.12, 95% confidence interval [CI] 1.00-1.25) or 5-6 months (HR 1.51, 95% CI 1.19-1.91). Considering only healthy patients with Charlson Comorbidity Index = 0, worse OS was associated with surgical delay of 5-6 months (HR 1.68, 95% CI 1.21-2.34, $P = .002$) but not 3-4 months (HR 1.08, 95% CI 0.93-1.26, $P = .309$). Pathologic stage (pT or pN) was not associated with surgical delay.
CONCLUSION	Prolonged surgical delay (5-6 months) for patients with T2 renal tumors appears to have a negative impact on OS while shorter surgical delay (3-4 months) was not associated with worse OS in healthy patients. The data presented in this study may help patients and providers to weigh the risk of surgical delay versus the risk of iatrogenic SARS-CoV-2 exposure during resurgent waves of the COVID-19 pandemic. UROLOGY 147: 50–56, 2021. © 2020 Elsevier Inc.

The current COVID-19 pandemic has disrupted systems of care. In these turbulent times, triage of clinical care delivery and appropriate calibration of care intensity have taken center stage. Oncology providers, in particular, are challenged to balance the risks of cancer progression versus the risks of COVID-19 morbidity and mortality, while potentially being constrained by limited healthcare resources.¹ In patients with localized

kidney cancer, for whom surgery presents an opportunity for oncologic cure, nuanced clinical decision-making is particularly critical.

Active surveillance for small renal masses (<4 cm in size) is a well-established and safe management strategy.²⁻⁶ Although larger renal tumors are known to harbor higher oncologic risks, it remains unclear to what extent a short to intermediate term delay in time to definitive management may impact survival. Prior studies on larger renal masses are limited by relatively small numbers from single institutions⁷⁻⁹ or describe preselected patients who were poor surgical candidates.¹⁰⁻¹⁵ There is a paucity of literature evaluating the impact of surgical delay on survival in the setting of large renal masses in contemporary patient cohorts.

In the setting of ongoing resource limitations and the risk of iatrogenic exposure of patients and providers to SARS-CoV-2, the decision to proceed with surgery for large renal masses pivots on the ability to assess the risk of

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surgical delay. As such, additional data are needed to guide these decisions. To this end, this study was designed to evaluate overall survival (OS) in patients with clinical stage T2 renal mass (≥ 7 cm; cT2) undergoing immediate versus delayed nephrectomy. We hypothesized that patients with a cT2 renal mass who experienced greater surgical delay would have worse OS when compared with patients who underwent immediate nephrectomy.

METHODS

Study Design

We conducted a retrospective review of patients undergoing extirpative surgery for clinical T2 renal masses in the National Cancer Database (NCDB) from 2004 to 2015. The NCDB, a hospital-based registry, harnesses clinical data from more than 1500 Commission on Cancer (CoC) accredited institutions in the United States and Puerto Rico. It is estimated that approximately 70% of all new cancer diagnoses in the United States are captured in the NCDB.¹⁶⁻¹⁹ The NCDB is a joint project of the CoC of the American College of Surgeons and the American Cancer Society. The data analyzed in the study were obtained from a de-identified NCDB file. The American College of Surgeons and the CoC have not verified and are not responsible for the analytic or statistical methodology employed nor the conclusions drawn from these data by the investigators. This study was deemed exempt from IRB review by the Wayne State University Institutional Review Board.

Study Population

Patients from the NCDB were included in this study if they had a clinical stage T2N0M0 renal mass and underwent radical or partial nephrectomy within 6 months of diagnosis during the period 2004-2015 ($n = 41,730$). Patients were excluded if they had nonrenal cell carcinoma histology ($n = 17,029$), uninterpretable date of diagnosis ($n = 8,924$), any neoadjuvant radiotherapy or systemic therapy ($n = 3,716$), or a mass larger than 20 cm ($n = 213$). The final analytic cohort included 11,848 patients.

Study Outcomes

The primary objective of this study was to test for an association between surgical delay and overall survival (OS). Surgical delay was calculated as the interval between the date of diagnosis (defined by the North American Association of Cancer Registries as the date of initial diagnosis by a recognized medical practitioner either *clinically* or *microscopically*) and the date on which the surgical procedure was performed. Patients were divided into categories based on time from diagnosis to surgery: ≤ 2 months, 3-4 months, and 5-6 months after diagnosis. To avoid immortal person-time bias, follow-up was calculated as the interval from surgery to death or last clinical contact.²⁰ A sensitivity analysis was performed with OS calculated as the interval from diagnosis to death or last clinical contact. Due to concern that comorbidity may be related to OS and surgical delay, a subgroup analysis was performed of patients with a comorbidity score of 0. Secondary outcomes of interest were to test for an association between surgical delay and upgrading to pathologic T3/4 disease or node positive (pN+) in patients who underwent a lymphadenectomy.

Statistical Analysis

The Kaplan-Meier method was used to estimate survival curves stratified by surgical delay. Multivariable Cox proportional hazard models with robust standard errors clustered by hospital were fit to assess for an association between surgical delay and overall survival. The main independent variable was surgical delay, treated as both a continuous variable and as an unordered categorical variable comparing categories of surgical delay against surgery within 2 months of diagnosis. The multivariable models were adjusted for factors available within the NCDB known or believed to be associated with surgical delay or overall survival: age, sex, year of diagnosis, race (white vs non-white), size of the renal mass in cm, urban/rurality index (metropolitan vs urban vs rural as defined by the USDA Economic Research Service), travel distance from the hospital (defined by the NCDB as distance from the center of the patient's zip code of residence and to the treating hospital's address), education status (as defined by the proportion of people age 25 and older without a high school degree in the patient's zip code of residence), income (as defined as median income of the patient's zip code of residence), Charlson-Deyo comorbidity score (calculated by the NCDB), hospital type (community cancer program vs comprehensive community cancer program vs academic/research program versus integrated network cancer program), and transfer status (as defined by whether the patient was treated at the diagnosing institution vs a different institution). The multivariable Cox proportional hazards model was used to estimate the adjusted 3-, 5-, and 7-year OS probability. Multivariable logistic regressions models were fit for the secondary outcomes of pathological upgrading and pN+ disease. Models for the secondary outcomes were adjusted for the same covariates as the primary outcome and clustered by hospital. All statistical tests were two-sided with significance set at 0.05, and statistical analysis was performed with Stata version 15.1 (Stata-Corp, College Station, TX).

RESULTS

Demographics

Median follow-up of the 11,848 patients in our study was 41.7 months (interquartile range [IQR]: 19.8-71.3). Median age of the cohort was 61 years (IQR: 52-69). Median renal mass size was 8 cm (IQR: 7-10 cm). The median time from diagnosis to surgery was 4 weeks (IQR: 2-7 weeks), with 10,146 (85.6%) patients undergoing surgery within 2 months, 1453 (12.3%) patients within 3-4 months, 249 (2.1%) patients within 5-6 months of diagnosis. Clinical, demographic, and oncological parameters for different categories of surgical delay are shown in [Table 1](#). We noted that patients with longer surgical delay tended to be older and less healthy.

Primary Outcomes

The Kaplan-Meier curves of unadjusted OS for patients with different categories of surgical delay are shown in [Figure 1A](#). There were 2,806 deaths during follow-up. In the multivariable Cox proportional hazards models, we detected a significant association between surgical delay and OS ([Table 2A](#)). Adjusted ORs for the covariates included in the model are shown in the Supplemental Table. Compared with patients treated within 2 months of diagnosis, patients treated within 3-4 months (hazard ratio [HR] 1.12, 95% confidence interval [CI] 1.00-1.25, $P = .042$) and 5-6 months (HR 1.51, 95% CI 1.19-1.91, $P = .001$)

Table 1. Clinical, demographic, and oncological parameters for patients treated within 1-2 months, 3-4 months, and 5-6 months of diagnosis. Categorical measures compared with the Chi-squared test and continuous measure compared with the Kruskal-Wallis test

	≤2 Months		3-4 Months		5-6 Months		P value
	N/Median	%/IQR	N/Median	%/IQR	N/Median	%/IQR	
Age	60	52-69	64	55-73	64	55-72	<.001
Sex							.876
Male	6362	62.7	914	62.9	160	64.3	
Female	3784	37.3	538	37.1	89	35.7	
Tumor Size (cm)	8	7-10	8	7-9	8	7-9	<.001
Race							<.001
White	9001	88.7	1211	83.3	190	76.3	
non-white	1145	11.3	242	16.7	59	23.7	
Distance (miles)	11.7	5.0-28.9	12.3	5.1-34.3	13.4	5.6-40.4	.0336
Insurance Type							<.001
Private	5352	52.8	500	34.4	75	30.1	
Government	4229	41.7	871	59.9	161	64.7	
Unknown/Not insured	565	5.6	82	5.6	12	5.2	
Education							<.001
≥17.6	1904	19.0	359	25.1	77	31.3	
10.9-17.5	2608	26.0	416	29.1	72	29.3	
6.3-10.8	2979	29.7	399	27.9	63	25.6	
<6.3	2545	25.4	254	17.8	34	13.8	
Income (\$/year)							<.001
<40,227	1776	17.7	322	22.6	67	27.2	
40,227-50,353	2284	22.8	353	24.8	70	28.5	
50,354-63,332	2509	25.0	354	24.8	50	20.3	
≥63,333	3449	34.4	397	27.8	59	24.0	
Comorbidity Index							<.001
0	7232	71.3	886	61.0	138	55.4	
1	2213	21.8	374	25.7	68	27.2	
≥2	701	6.9	193	13.3	43	17.3	
Facility Type							<.001
Community Cancer Program	785	8.1	82	5.8	14	5.8	
Comprehensive Community Cancer Program	4115	42.5	486	34.4	74	30.6	
Academic/Research Program	3430	35.4	645	45.6	120	49.6	
Integrated Network Cancer Program	1352	14.0	202	14.3	34	14.1	
Treated at Diagnosing Facility							<.001
Yes – No transfer in care	6950	68	827	56.9	123	49.4	
No – Care was transferred	3196	32	626	43.1	126	50.6	

*Cells for year of diagnosis and urban/rurality index suppressed per the NCDB data use agreement.

had worse overall survival. Surgical delay modeled as a continuous variable demonstrated a 10% increased hazard of all-cause mortality for each month interval between diagnosis and surgery (HR 1.10, 95% CI 1.06-1.14, $P < .001$). The estimated 3-, 5-, and 7-year OS probability for categories of surgical delay are shown in Figure 1B. The predicted 5-year OS for patients treated within 2 months of surgery was 78% (95% CI: 73%-82%) compared with 76% (95% CI 70%-81%), and 69% (95% CI: 59%-76%) for patients treated within 3-4 months and 5-6 months after diagnosis.

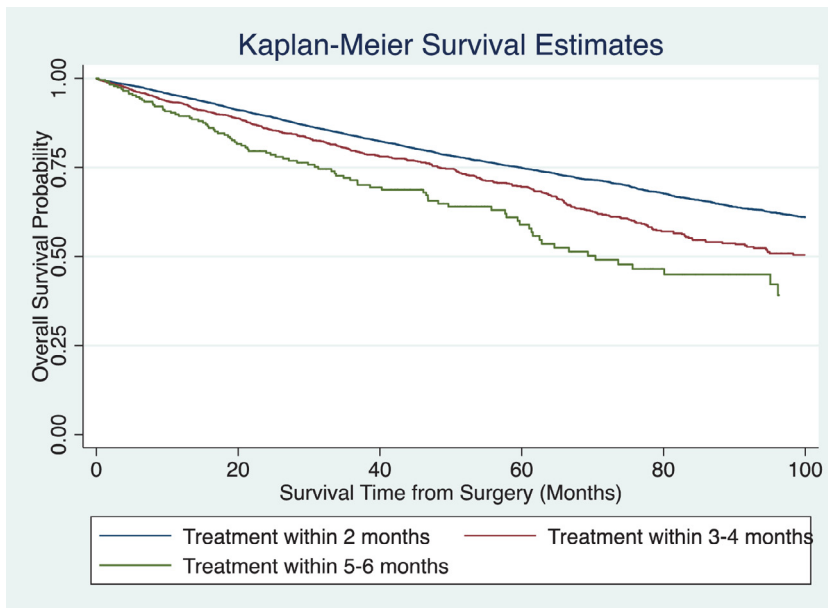
Surgical delay may be related to the presence of comorbidities. To address this potential bias, we repeated the analysis including only patients with a Charlson Comorbidity Index (CCI) of 0 ($n=8,256$). There were 1,806 deaths in this subgroup. We identified 7,232 patients (87.6%) treated within 2 months, 866 patients (10.7%) treated within 3-4 months, and 138 patients (1.7%) treated within 5-6 months of diagnosis. Multivariable Cox proportional hazard models restricted to patients with a CCI of 0 continued to show an association of surgical delay with OS (Table 2A). Patients treated within 5-6 months of diagnosis had worse OS compared with patients treated within 2 months of diagnosis

(HR 1.68, 95% CI 1.21-2.34, $P = .002$). However, healthy patients treated 3-4 months after diagnosis had similar OS compared with patients treated within 2 months of diagnosis (HR 1.08, 95% CI 0.93-1.26, $P = .309$). Surgical delay modeled as a continuous variable demonstrated a 11% increased hazard of all-cause mortality for each month interval between diagnosis and surgery in healthy patients (HR 1.11, 95% CI 1.06-1.17, $P < .001$).

Using the entire cohort and the subgroup of patients with a comorbidity index of 0, we performed a sensitivity analysis with OS measured as the interval from diagnosis to death or last clinical contact (Table 2B). These results demonstrated similar results as we continued to appreciate patients with surgical delay of 5-6 months had worse OS compared with patients treated within 2 months of diagnosis in the entire cohort (HR 1.38, 95% CI 1.10-1.73, $P = .006$) and in the cohort restricted to patients with a CCI of 0 (HR 1.52, 95% CI 1.11-2.08, $P = .009$).

Secondary Outcomes

We did not observe a significant association between surgical delay and upgrading or pN+ disease. Similar odds of upgrading



(A)

Figure 1A. Unadjusted Kaplan-Meier OS survival probability by category of surgical delay. (Color version available online.)

Table 2A. Multivariable Cox proportional hazards models of association of surgical delay and overall survival in the entire cohort and a subgroup of patients with CCI = 0. Surgical delay is treated as an unordered categorical variable in model 1 and a continuous variable in model 2. Overall survival was calculated as the interval from surgery to either death or last clinical contact

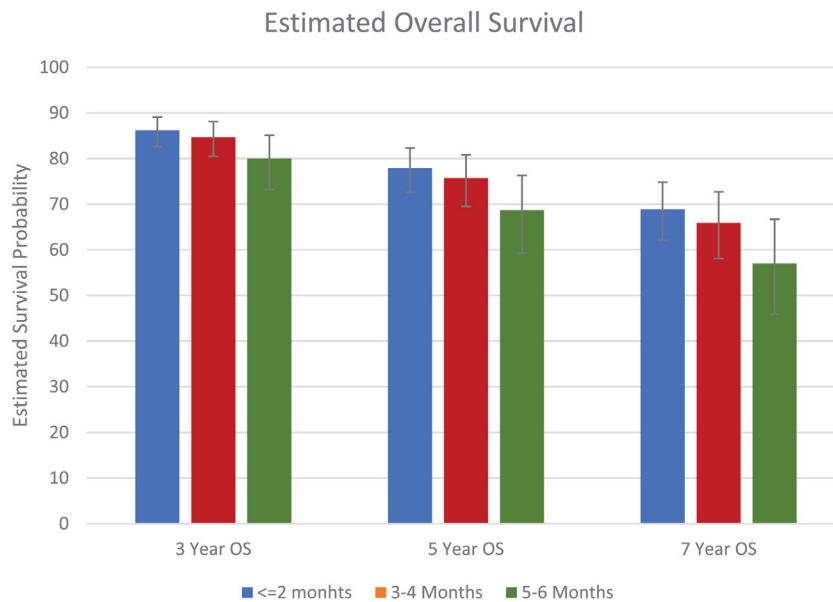
Time from Diagnosis to Surgery: Entire Cohort	HR	95% CI	P	Time from Diagnosis to Surgery: CCI = 0	HR	95% CI	P
Model 1:				Model 1:			
≤2 months	ref	ref	ref	≤2 Months	ref	ref	ref
3-4 months	1.12	1.00-1.25	.042	3-4 Months	1.08	0.93-1.26	.309
5-6 months	1.51	1.19-1.91	.001	5-6 Months	1.68	1.21-2.34	.002
Model 2:				Model 2:			
Continuous per month	1.10	1.06-1.14	<.001	Continuous per month	1.11	1.06-1.17	<.001

Adjusted for tumor size, age, sex, year of surgery, race, urban/rurality index, distance from the hospital, insurance type, education status, income, comorbidity index, hospital type, and transfer status.

Table 2B. Sensitivity analysis for the association of surgical delay and overall survival in multivariable Cox proportional hazard models for the entire cohort and a subgroup of patients with CCI = 0. Surgical delay is treated as an unordered categorical variable in model 1 and a continuous variable in model 2. Overall survival was calculated as the interval from diagnosis to either death or last clinical contact

Time from Diagnosis to Surgery: Entire Cohort	HR	95% CI	P	Time from Diagnosis to Surgery: CCI = 0	HR	95% CI	P
Model 1:				Model 1:			
≤2 Months	ref	ref	ref	≤2 Months	Ref	ref	ref
3-4 Months	1.06	0.96-1.18	.255	3-4 Months	1.05	0.90-1.21	.549
5-6 Months	1.38	1.10-1.73	.006	5-6 Months	1.52	1.11-2.08	.009
Model 2:				Model 2:			
Continuous per month	1.07	1.03-1.11	<.001	Continuous per month	1.09	1.04-1.14	.001

Adjusted for tumor size, age, sex, year of surgery, race, urban/rurality index, distance from the hospital, insurance type, education status, income, comorbidity index, hospital type, and transfer status.



(B)

Figure 1B. Estimated 3-, 5-, and 7-year OS probability adjusted for factors in the multivariable Cox model. Error bars display 95% CI. (Color version available online.)

Table 3A. Multivariable logistic regression model for the association of surgical delay and pathologic upgrading

Surgical Delay	OR	95% CI	P
≤2 months	ref	ref	Ref
3-4 months	0.9	0.77-1.04	.138
5-6 months	1.07	0.77-1.48	.673

Adjusted for tumor size, age, sex, year of surgery, race, urban/rurality index, distance from the hospital, insurance type, education status, income, comorbidity index, hospital type, and transfer status.

Table 3B. Multivariable logistic regression model for the association of surgical delay and pN+

Surgical Delay	OR	95% CI	P
≤2 months	ref	ref	Ref
3-4 months	0.82	0.47-1.43	.475
5-6 months	1.41	0.52-3.83	.504

Adjusted for tumor size, age, sex, year of surgery, race, urban/rurality index, distance from the hospital, insurance type, education status, income, comorbidity index, hospital type, and transfer status.

and pN+ disease were seen in patients treated 3-4 and 5-6 months after diagnosis compared with patients treated within 2 months of diagnosis (Tables 3A and B).

COMMENT

As resurgent waves of the COVID-19 pandemic continue to strain hospital systems' resources and personnel, non-emergent surgeries may be delayed.²¹ The goal of this study was to assess the association of surgical delay with OS in

patients with large renal masses. To this end, we report that patients with cT2 renal masses who experienced prolonged delays in surgical treatment exhibited decreased OS when compared to patients who underwent surgery soon after diagnosis. A similar association was seen when we restricted the cohort to patients with a comorbidity index of 0, although shorter surgical delay (3-4 months) was not associated with worse OS in healthy patients. We did not observe a significant association of surgical delay with the secondary outcomes of pathologic upgrading and pN+ disease.

The implications of treatment delay for patients with cancer is understandably on many patients' and clinicians' minds during these uncertain times.²²⁻²⁴ The literature is limited in addressing the association surgical delay with oncologic outcomes in patients with large renal masses. Published reports largely consist of retrospective single institution studies.^{7-9,25} or focus on poor surgical candidates undergoing observation of large renal masses.¹⁰⁻¹⁴ Similar to our results, Mano et al retrospectively reviewed 1,278 patients at a single center and found that increasing surgical delay for renal masses >4 cm (median tumor size, 6.2 cm) was significantly associated with decreased OS after adjusting for patient and tumor characteristics.⁸ Interestingly, these investigators did not find surgical delay to be associated with tumor upstaging, recurrence, or cancer-specific survival. In contrast, a study conducted by Kim et al retrospectively reviewed 319 patients with cT2 or greater renal cancer who underwent radical nephrectomy at a single institution and found no difference in survival or oncologic outcomes when comparing patients who underwent surgery within 1 month to those who had

surgery within 1-3 months after diagnosis, suggesting that the harm of a short delay, if it exists, may be difficult to detect in a small cohort.⁷

Furthermore, recent reports by Khorana et al and Turaga et al utilized the NCDB to evaluate the broader association of treatment delays and OS in multiple cancer types, including renal cancer.^{26,27} These studies included patients with renal masses of all sizes and demonstrated an association between prolonged treatment delay and decreased overall survival. In both studies, the median time to surgery was less than one week, suggesting possible inaccuracies in the recording of surgical delay. Indeed, a strength of our study was the inclusion only of patients in which surgical delay could be accurately characterized.

Our work continues to build upon the limited data regarding surgical delay in patients with cT2 renal masses by utilizing a large, contemporary, nationally representative cohort to suggest a small, but significant, absolute difference in OS in patients with prolonged surgical delay. We did not observe a significant association of the secondary outcomes of pathologic upgrading and pN+ disease with treatment delay. Furthermore, when restricting the analysis to healthy patients with CCI of 0, a short delay was not associated with worse OS. These data suggest that a short treatment delay due to the COVID pandemic may not affect survival nor worsen oncological outcomes of upgrading or node positivity. During the ongoing COVID-19 pandemic, the harms of surgical delay must be carefully weighed against multiple other considerations, including the risk of iatrogenic exposure to the virus, the compromise of social distancing during care delivery, and allocation of limited health resources.¹ This calculus must be individualized, informed by accurate estimates of the risks involved, and include active patient participation when deciding on the optimal timing of surgery. Furthermore, as the current pandemic resolves, these data may provide reassurance to patients who require a short delay to allow for medical maximization and improved control of chronic medical conditions prior to proceeding with surgery.

This study has several limitations. First, although we attempted to adjust for confounding variables in our multivariable models, no statistical adjustment of data obtained from preselected cohorts can fully account for both measured and unmeasured confounders. Granular details regarding specific comorbidities or oncologic characteristics, such as imaging findings or the health of the contralateral kidney, are not available in the NCDB. Second, the cause for delay in surgeries is unknown and the generalizability of these results to patients who have deferred surgery during the COVID-19 pandemic remains unclear. It remains possible that generally sicker and unhealthier patients may take longer to proceed to surgery due to more intense surgical clearance and medical optimization processes. Last, this study was limited by the variables collected by the NCDB. Oncologic outcomes such as disease recurrence, progression, and cancer specific

mortality were not available. Despite these limitations, this study uses current data from a national database with a large cohort providing a level of power that is otherwise not present in the current literature.

CONCLUSION

As the COVID-19 pandemic continues to strain health-care systems, delays in nonemergent surgery are inevitable. As gleaned from this large NCDB cohort, patients with cT2 renal masses may not have worse OS or oncological outcomes as a result of short surgical delay. Prolonged surgical delay was associated with worse OS and should be minimized when possible. These data can help inform patient counseling when deciding on the timing of nephrectomy by weighing the risk of surgical delay against the risk of iatrogenic SARS-CoV-2 exposure.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urology.2020.09.010>.

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