Original Article

Diagnostic Accuracy Of Tokyo Guidelines 2018, In Acute Cholecystitis, Taking Histopathology As Gold Standard

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Abstract

Objective: To evaluate the diagnostic accuracy of the 2018 Tokyo Guidelines for acute cholecystitis by comparing clinical diagnosis with histopathological findings in patients undergoing cholecystectomy.

Methods: This prospective observational study was conducted on 71 patients undergoing cholecystectomy with a preoperative diagnosis of acute cholecystitis based on TG18. The diagnostic criteria included clinical features (right upper quadrant pain, Murphy's sign), laboratory parameters (leukocytosis, elevated CRP), and imaging findings on abdominal ultrasonography (gallbladder wall thickening, pericholecystic fluid). Postoperative histopathological examination of the resected gallbladders was used as the gold standard for confirming the diagnosis. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated.

Results: Out of 71 patients, histopathology confirmed acute cholecystitis in 64 cases and ruled it out in 7. The Tokyo Guidelines demonstrated a sensitivity of 93.4%, specificity of 40%, positive predictive value of 90.47%, negative predictive value of 50%, and an overall diagnostic accuracy of 85.91%. Six patients had discordant results, showing false-positive diagnoses according to the Tokyo Guidelines, which were not supported by histopathology.

Conclusion: The 2018 Tokyo Guidelines are highly sensitive and have good diagnostic accuracy for acute cholecystitis, making them valuable in clinical settings. However, the low specificity and modest NPV indicate a potential for overdiagnosis. Refinement of diagnostic criteria is warranted to reduce false-positive rates and improve the detection of true negative cases.

Keywords: Acute Cholecystitis; Tokyo Guidelines; Diagnostic Accuracy; Cholecystectomy; Histopathology; Sensitivity and Specificity.

Introduction

Acute Cholecystitis is a condition characterized by inflammation of the gallbladder, primarily caused by the obstruction of the cystic duct by existing gallstones, which leads to the accumulation of bile within the gallbladder and triggers the onset of inflammatory symptoms. This condition is relatively common, affecting 3 to 10 percent of individuals with gallstones. Typical symptoms include abdominal pain, often in the right upper abdomen or occasionally in the epigastric region, as well as nausea, bloating after meals, and vomiting. The primary anatomical reason behind acute cholecystitis is the blockage of the narrowest structure leading into or out of the gallbladder, the cystic duct, due to impacted gallstones. To diagnose this condition, clinicians have traditionally followed the Tokyo Guidelines, which were first introduced in 2013 and later updated in 2018.[1] These guidelines incorporate various clinical, biochemical, and radiological parameters to aid in the accurate diagnosis of acute cholecystitis.

The Tokyo Guidelines for the diagnosis of acute cholecystitis have played a crucial role in improving the accuracy of diagnosis and ensuring that patients receive appropriate treatment promptly. By combining clinical symptoms, laboratory tests, and imaging techniques, healthcare professionals can better identify cases of acute cholecystitis, allowing for more effective management and reducing the risk of complications. These guidelines represent an important advancement in the field of gastroenterology, helping clinicians make informed decisions about treatment options, including medical management or surgical intervention like cholecystectomy.[2] Tokyo Guidelines 2018, as a modified and updated version of the original 2013 guidelines, reflect the ongoing efforts of medical experts to refine and enhance diagnostic approaches for this condition. They underscore the significance of a multidisciplinary approach in the diagnosis and management of acute cholecystitis, ultimately leading to improved patient outcomes and quality of care in cases of gallbladder inflammation.

The clinical parameters that were added in the guidelines included: pain in the right hypochondrium, mass in the right hypochondrium, tenderness in the right hypochondrium and the presence or absence of Murphy's sign i.e. rebound tenderness that is elicited upon palpation of the right hypochondrium and upon asking the patient to take deep breaths which causes the inflamed organ to touch the examiners palpating hands.[3]

The biochemical parameters that were introduced in the Tokyo guidelines 2018 were the measurement of serum levels of CRP (C- C-reactive protein) and raised levels of TLC (total leukocyte count).

The third parameter of diagnosis that was introduced as a mandatory modality of diagnosis was the use of ultrasound in order to confirm the diagnosis; any of the three signs present were considered diagnostic. Firstly,

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MUR, AD, KB - Acquisition, Analysis, Interpretation
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the presence of stones/sludge in the Gall bladder lumen or cystic duct, secondly, the increased wall thickness of the gall bladder up to 3mm, and thirdly, the presence of pericholecystic fluid were considered as acceptable findings in the diagnosis of acute cholecystitis.

Table: Diagnostic Criteria and Severity Grading of Acute Cholecystitis (Tokyo Guidelines 2018)[13]

Category	Criteria	Examples / Notes
A. Local Signs of Inflammation	**1.** Murphy's sign (elicited tenderness on inspiration) **2.** Right upper quadrant (RUQ) mass/pain/tenderness	Indicates local gallbladder inflammation
B. Systemic Signs of Inflammation	**1.** Fever **2.** Elevated C-reactive protein (CRP) **3.** Elevated white blood cell count (WBC)	Reflects systemic inflammatory response
C. Imaging Findings (Supportive)	Imaging findings characteristic of acute cholecystitis on: – **Ultrasound:** gallbladder wall thickening (>3 mm), pericholecystic fluid, enlarged gallbladder, sonographic Murphy's sign, gallstones/sludge – **CT/MRI:** confirmatory findings	Imaging confirms local inflammation.
Diagnostic Confirmation	**Suspected diagnosis:** One item from **A** + one item from **B** - **Definite diagnosis:** One item from **A** + one from **B** + imaging findings (C)	Combines clinical, systemic, and imaging data
Severity Grading (TG18)	**Grade I (Mild):** No organ dysfunction, mild local inflammation. **Grade II (Moderate):** Marked local inflammation (e.g., elevated WBC ≥18,000/mm³, palpable tender mass, >72 hrs symptoms). **Grade III (Severe):** Organ dysfunction (cardiovascular, neurological, respiratory, renal, hepatic, or hematological).	Guides the management and intervention level

The revised guidelines are made up of evidence-based diagnostic approaches so that the accuracy of the diagnosis can be increased significantly and attain a higher quality of patient care in the hospitals. After every five years, the Guidelines are modified so that accuracy in the diagnostic protocols and the expected results can be enhanced accordingly. However, during the process of modifications and improvements in the diagnostic criterion, it was observed that two major issues came up in the process of diagnosis of the disease during the clinical executions which include the lack of specific criteria of the diagnosis and the use of a combined approach of diagnosis, which results in the lack of important justification of the process and adds up ambiguity in the data.[4]

The results from the large amount of data on acute cholangitis severity were very promising and widely accepted by the medical community worldwide, so much so that the Tokyo guidelines were being mentioned in the textbooks of surgery worldwide. The committee hoped that after the large amount of research carried out in the world, the effectiveness of the guidelines in diagnosing acute cholecystitis would also be thoroughly accepted.[5]

Materials And Methods

The study design pertains to the methodological framework of the research, integrating all components to maintain coherence and alignment with the stated objectives. The design guided the data collection and analysis procedures to ensure consistent and valid conclusions. In this prospective observational study, the research population comprised 71 patients who were preoperatively diagnosed with acute cholecystitis using the Tokyo Guidelines 2018 and later underwent cholecystectomy. The study aimed to evaluate the diagnostic accuracy of the guidelines using histopathology as the gold standard.

These patients were admitted for over one year in Surgical Unit I and Surgical Unit II of Benazir Bhutto Hospital, affiliated with Rawalpindi Medical University. Ethical approval was obtained from the Board of Advanced Studies and Research (BASR) and the Institutional Review Board before initiating the study. All patients included were diagnosed with acute cholecystitis and scheduled for same-admission cholecystectomy within 72 hours. Clinical assessment was initially performed by surgical registrars and later confirmed by consultant surgeons. Ultrasonographic evaluation was carried out by consultant radiologists using MyLAB model X9 ultrasound machines available in the hospital's radiology department. The study was designed to achieve a 95% confidence level with a 7% margin of error, and an anticipated diagnostic sensitivity of 90%. Recognizing that acute cholecystitis is not gender-specific, both male and female patients were considered to ensure generalizability of the results.

A total of 71 patients were selected through purposive sampling, with inclusion based on the diagnostic criteria of the Tokyo Guidelines. Among them, 4 were male and 67 were female. Patients included were aged between 20 and 70 years, had received prior care within the same hospital, were diagnosed with acute cholecystitis per Tokyo Guidelines, and underwent same-admission cholecystectomy. All patients provided informed consent to participate in the study. Patients were excluded if they had acute pancreatitis, obstructive jaundice, gallbladder carcinoma, chronic or terminal systemic illnesses, were deemed unfit for anesthesia, or refused same-admission cholecystectomy.

The data collection for the current research was conducted along the lines of the inclusion criteria of the patients. In the first stage, ethical approval was taken from the Ethical Review Board RMU (Rawalpindi Medical University). Patients presenting with acute Cholecystitis were considered as potential fit for the study. Once a patient had been selected, complete data, including their detailed history with medical examinations to date, was taken from them. All other relevant examination reports were also taken. Afterwards, written consents were taken from the selected participants, and only those who were cleared fit for cholecystectomy. The technique of the surgery was standardized as open or laparoscopic cholecystectomy. Histopathological data were collected from all the patients who underwent cholecystectomy. The data reports of the ultrasound, white blood cell counts, and serum CRP levels as relevant blood work.

Data analysis pertains to the specific techniques of analysis that the researcher used to obtain specific information from the data examined. Comparative analysis was conducted for which the base used was the TG18 guidelines against which, histopathological data of the patients were analyzed on SPSS v.22. In this particular research as the patients who were diagnosed as having acute cholecystitis based on Tokyo guidelines were

admitted and then operated, all the patients with suspected diagnosis of acute cholecystitis in TG 18 criteria were considered negatives as is the case in the parent research.

Results

A total of 71 patients were enrolled in this study. The mean age was 44.9 ± 11.5 years, with a range of 38 years (minimum 27, maximum 65). The median age was 35.5 years, while the mode was 43 years. Among the total, 67 (94.4%) were female and 4 (5.6%) were male.

Table 1: Descriptive Statistics of Study Population

Parameter	Value
Sample size (n)	71
Mean age (years)	44.9 ± 11.5
Median age (years)	35.5
Mode age (years)	43
Range (years)	38 (27–65)
Gender (Female: Male)	67:4

Based on Tokyo Guidelines 2018 (TG18), 67 patients were diagnosed as having acute cholecystitis, while 4 were negative. Histopathological analysis confirmed acute cholecystitis in 61 cases and ruled it out in 10.

Table 2: Diagnostic 2×2 Table Comparing TG18 with Histopathology

	Histopathology Positive	Histopathology Negative	Total
TG18 Positive	57 (True Positive)	6 (False Positive)	63
TG18 Negative	4 (False Negative)	4 (True Negative)	8
Total	61	10	71

From this data:

Sensitivity = 57 / (57 + 4) × 100 = 93.4%
Specificity = 4 / (4 + 6) × 100 = 40%
PPV = 57 / (57 + 6) × 100 = 90.47%
NPV = 4 / (4 + 4) × 100 = 50%
Diagnostic Accuracy = (57 + 4) / 71 × 100 = 85.91%

A Chi-square test of independence was applied to examine the association between TG18 diagnosis and histopathological findings. The test result was $\chi^2(1) = 20.56$, $p < 0.001$, indicating a statistically significant association between TG18-based diagnosis and histopathology (Table 3).

Table 3: Chi-square Test for Association Between TG18 and Histopathology

Test Used	χ^2 Value	df	p-value
Pearson Chi-square	20.56	1	<0.001

Table 4: Comparison of TG18 and Murphy's Sign

Diagnostic Tool	Sensitivity (%)	Specificity (%)
TG18	**93**	**44**
Murphy's Sign	**20.5**	**87.5**

Of the 61 patients confirmed positive by histopathology, 14 had a raised Total Leukocyte Count (TLC >10×10^9/L) and only 4 had elevated C-Reactive Protein (CRP). This indicates that while clinical and radiological features were consistent, inflammatory markers were less frequently elevated. These findings affirm the high sensitivity but modest specificity and negative predictive value of TG18. The results further highlight the limitation in detecting true negatives, stressing the need for enhanced diagnostic criteria for such cases.

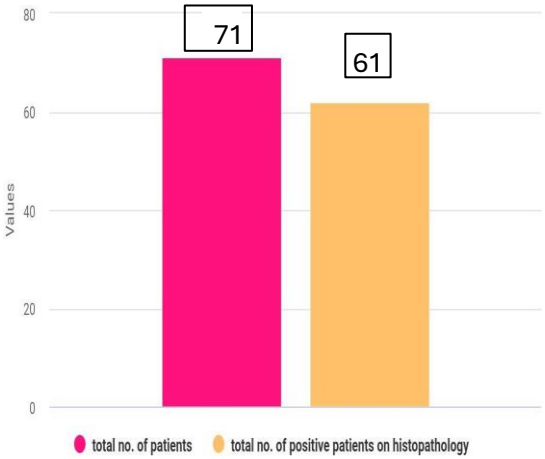

Figure 1: Comparison of TG18 vs. Histopathology (Positive Cases)
(bar graph showing 67 TG18 positives vs. 61 histopathology positives)

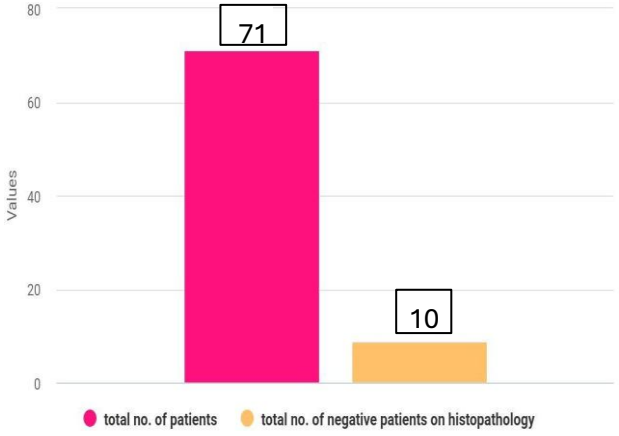

Figure 2: Comparison of TG18 vs. Histopathology (Negative Cases)
(bar graph showing 4 TG18 negatives vs. 10 histopathology negatives)

Discussion

Inflammation of the gallbladder, known medically as acute cholecystitis, may occur when gallstones block or constrict the cystic duct.[3] According to a large body of clinical evidence, gallstones are mostly caused by high cholesterol and triglyceride levels.[7] Anatomical research has shown that the cystic duct is the principal conduit linking the gallbladder; nevertheless, bile juice cannot be properly transported to the liver for processing if there is an excess of cholesterol that forms stones inside this duct.[7] About 10% of the population is at risk for developing acute cholecystitis, and the condition's severity and course may vary depending on available treatments and the body's tolerance for the infection, according to clinical data.

When gallstones block or narrow the cystic duct, an important part of the gallbladder's structure, they cause inflammation of the gallbladder, a disease known as acute cholecystitis.[3] Over time, the gallbladder may get clogged with these stones, which are often made of cholesterol and other chemicals, and cause a host of problems. Research in humans has repeatedly shown that high cholesterol and triglyceride levels precede gallstone formation. These chemicals may crystallize and become gallbladder stones when concentrations go too high.[7]

The cystic duct's role in gallbladder function has become better understood thanks to anatomical studies. The principal route for the liver's bile to go from the gallbladder to the rest of the biliary system is this duct. Cholesterol builds up in the cystic duct and forms stones, which may block the bile ducts and prevent the bile from reaching the liver for metabolism and then the digestive system. The buildup of bile inside the gallbladder, which may aggravate its inflammation, might result from this disturbance in the usual flow of bile.

From what we can tell from clinical studies, acute cholecystitis is very common; in fact, it affects around 10% of the population. Factors such as gallstone size and location, underlying medical disorders, and the body's inflammatory response all play a role in how acute cholecystitis develops and how severe it might be for afflicted people. Severe consequences, such as gallbladder rupture or infection, may develop from untreated acute cholecystitis; thus, it is crucial to diagnose the condition early and treat it appropriately. Therefore, it is critical for healthcare practitioners and people at risk of developing acute cholecystitis to grasp the anatomical aspects of this condition's development and the variables that contribute to gallstone production.

Since almost 7% of instances of acute cholecystitis may progress to severe forms, significantly increasing morbidity later, it is crucial to diagnose the condition promptly and accurately, in line with the American Association for the Surgery of Trauma (AAST) emergency general surgery guidelines for acute cholecystitis.[6] The morbidity and death rates are considerably greater in situations of patients who already have several comorbidities, and in certain circumstances, this may lead to emergency cholecystectomies in these individuals, who have a fatality rate of around 3%. In order to assess the goals of screening for acute cholecystitis prevalence in accordance with the diagnostic accuracy criteria outlined in the 2018 Tokyo guidelines, this study compared the screening accuracy to that of histopathological gold standards for evaluating the disease. This research examined 71 individuals, mostly male and female, admitted to the surgery wards of healthcare facilities for the cholecystectomy operation to evaluate and validate the severity of acute cholecystitis. The majority of cases of acute cholecystitis are thought to be the result of gallstones inside the gall bladder; surgical operations are the most effective interventional methods for treating this condition.[4,8] Due to the paucity of literature on the topic, this study fills a significant gap in our understanding of the diagnostic accuracy of Tokyo recommendations compared to histological examination for the screening of acute cholecystitis.

Based on an analysis of the available data, the Tokyo recommendations have been recognized as the gold standard for the diagnosis and treatment of cholecystitis worldwide.[5] The 2007 International Consensus Meeting in Tokyo was the primary forum for the introduction and presentation of the Tokyo guidelines, which required expert approval. By following the rules, we can be confident that it is reflective of and compatible with the most current developments in healthcare and clinical practice.[3] Acute cholecystitis imaging findings, systemic inflammation indicators (such as fever, elevated C-reactive protein, and prevalence of elevated white blood cell count), and local inflammation indicators (such as Murphy's sign, pain, and prevalence of tenderness in the upper right abdominal quadrant mass) are the three main components that make up the revised Tokyo guidelines for cholecystitis diagnosis [8,9]

The research found that when utilizing the Tokyo criteria for a conclusive diagnosis of cholecystitis, the specificity was 40%. According to the 2018 Tokyo criteria, the diagnostic accuracy was 85.91%, while the sensitivity for the definite diagnosis was 93%. This research's findings are comparable to those of a 2018 study published in the Journal of Hepato-Biliary and Pancreatic Sciences,[10] that found the 2018 Tokyo

recommendations to have a sensitivity of 91% and a specificity of 96%. There is a notable discrepancy in the specificity findings between the two trials, although the sensitivity values are similar. It is quite probable that the variation in test sensitivity is caused by the patients' selection criteria.

One major drawback of using the Tokyo standards for diagnosis is that previous research has not provided clear criteria for choosing genuine negative instances. Since most of these studies only included symptomatic patients, there is currently no standard method for determining if a patient does not have acute cholecystitis. This is a major concern since the histological analysis of the gallbladder sample becomes meaningless if a patient who does not fit the diagnostic criteria is incorrectly classified as a true negative. Patients without a confirmed diagnosis would not have their gallbladders removed during surgery, and the resulting tissue samples would not be submitted for analysis. In order to ensure accurate diagnosis and suitable medical actions, it is necessary to establish more exact rules and criteria to differentiate between instances that are really negative and those that may have an underlying disease.

True negative instances are not well-defined, which might cause doctors to miss symptoms of acute cholecystitis and put off treating patients who do not have the disease for too long. Acute cholecystitis may develop quickly, leading to problems including infection or gallbladder perforation; therefore, any delay in treatment might be disastrous. The lack of clarity around the selection of real negative instances also casts doubt on the reliability of results from research that uses the Tokyo guidelines for its diagnostic procedures. More thorough and accurate criteria for detecting real negative instances should be the goal of future research and clinical practice in order to overcome this restriction. In addition to lowering the likelihood of complications and improving healthcare outcomes generally, this would make acute cholecystitis diagnoses more accurate and guarantee that patients get the treatment they need promptly. It shows how important it is for gastrointestinal diagnostic guidelines to be continuously improved and validated so that they can meet the demands of both patients and doctors.

Addressing the correctness or conclusive diagnosis of acute Cholecystitis is complicated in light of the data collected from the research study. These findings put the reliability of the diagnostic process into question, but they also provide strong evidence that supports the Tokyo recommendations' preference for histopathological examination of Cholecystitis over other methods. Based on the results of this study and the information gathered from the most popular sources of literature, it has been concluded that not all patients should be encouraged to follow the Tokyo guidelines. This is particularly true for adults with acute cholecystitis who do not fully meet the criteria [9,11]. The reason is, each patient has unique needs and potential health issues. This guarantees that every patient may need a descriptive examination of their ailment in line with the recommended diagnostic procedures advocated by the doctor, experts, or advisors. The incidence of carcinomas and other metabolic problems and health effects, among people whom the Tokyo recommendations 2018 do not adequately analyze, has also been noted.[11]

Since no worldwide agreement has been reached on the long-term viability and dependability of the criteria of the Tokyo guidelines for the evaluation of cholecystitis, the results-based evaluation has addressed the tremendous need for additional research into the diagnostic accuracy of these guidelines.[4,5] Research has shown that when additional diagnostic techniques are adequately compared to the conventional Tokyo diagnosis, there is no need to keep comparing histological evaluations of acute cholecystitis to the gold standards as the major step of analyzing accuracy.[12] The present validations must be conducted on ways, techniques, and scenarios in which the related Tokyo criteria must be applied to assess patients, which was a strong and significantly noticeable worry in this research. Because imaging procedures and other forms of pathophysiological analysis are often used to diagnose the prevalence of acute cholecystitis, this is necessary.[9] Health care providers typically prefer and prescribe these methods after keeping careful clinical observations.

The consideration rate of the 2018 Tokyo rules across various locations and races is also quite small; therefore, genuine evidence cannot be supplied. As a result, most healthcare institutions steer clear of its implications for thorough patient assessment. The reliability and consistency of using the Tokyo criteria for the diagnosis of acute cholecystitis were confirmed throughout the creation of this study.[3,5] To evaluate and validate the validity and dependability of the Tokyo recommendations, its practical implications will be useful. Subsequent assessment in various healthcare settings and environments is necessary to sustain the improvement and reliability analysis of these recommendations.[5] To improve the diagnostic accuracy of the Tokyo recommendations, this research was focused on assessing the sensitivity and specificity. The specific criteria for the clinical examination and diagnosis of acute cholecystitis have been uncovered by a comprehensive review of the relevant research.

The clinical study, which followed the normal parameters set forth by Tokyo, found that individuals had varying degrees of discomfort. All things considered, the participants' pain levels were really high. Although the patients also reported discomfort in the upper right abdominal region. Some patients additionally made sure that their stomach ache extended to their right shoulder. The clinical assessment also noted that some patients were sweating, that they were experiencing a lack of appetite, nausea, bloating, and a high to moderate temperature. Evidence based on ultrasound of the abdomen, clinical symptoms, and blood tests is often used to diagnose cholecystitis, according to the research. Patients were chosen based on their history of cholecystectomy procedures.[9,12] In order to choose the participants for the study, researchers looked at both open and laparoscopic cholecystectomy as possible surgical methods.

The 2018 Tokyo recommendations found that stomach discomfort was experienced by about 82% of the patients. In contrast, preoperative Murphy sign positivity was present in 51% of the individuals who were ultimately chosen for the study. Although a prospective analysis indicated that the positive predictive values for the Tokyo recommendations were 90.47 percent. Conversely, 50% negative predictive values were noted, which deals with the dependability of using the 2018 Tokyo standard standards to a certain degree.

Conclusions

In Tokyo, Guidelines demonstrate relatively high sensitivity but lower specificity and negative predictive value in the diagnosis of acute cholecystitis compared to histopathological findings. Significant discordance between preoperative Tokyo Guideline diagnosis and postoperative histopathology was found in 6 patients out of the 71 studied. This indicates there is room for improving the accuracy and reliability of the Tokyo Guidelines, especially when it comes to defining standards and criteria for true negative cases where acute cholecystitis is absent. Without clear true negative criteria, there is a risk of delayed diagnosis and treatment in some patients. More research is needed to refine and validate the Tokyo Guidelines across diverse populations and practice settings worldwide. Continued efforts to improve clinical diagnostic guidelines for gastrointestinal conditions like acute cholecystitis are crucial for meeting the needs of both patients and healthcare providers.

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