e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(11); 01-08

Original Research Article

A Study on the Complications Occurring During and After Intubation in Relation to The Predictive Assessment of Difficult Intubation in Heaven Criteria versus Modified Lemon Criteria

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Received: 28-08-2026 / Revised: 27-09-2026 / Accepted: 27-10-2026

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Conflict of interest: Nil

Abstract:

Objectives: The present study was to evaluate the complications occurring during and after intubation in relation to the predictive assessment of difficult intubation in Heaven Criteria versus Modified Lemon Criteria.

Methods: All patients were evaluated for difficult intubation using both HEAVEN criteria and Modified LEMON criteria before performing the procedure. Intubation was performed following the standard rapid-sequence or delayed-sequence protocol. Vitals including heart rate, blood pressure, oxygen saturation (SpO_2), and respiratory rate were recorded pre- and post-intubation. Peri-intubation and post intubation complications, such as: Hypoxia (SpO_2 < 93%), multiple attempts at intubation (> or = 2) and hemodynamic instability (SBP < or = 90 or use of Vasopressor agents) were recorded.

Results: A total of 200 patients were enrolled for intubation. The gender distribution showed a male predominance, with 122 males (61%) and 78 females (39%). The mean age of participants was 55 years, with a range from 18 to 86 years. Most common comorbidity was hypertension followed by diabetes mellitus and Cardiac condition. Mean Intubation time for successful 1st attempt was 23.57± 8.34 but it increases significantly ($p<0.001$) by 118.57% with multiple attempts. The slope of the graph of successful intubation is higher for HEAVEN score (0.0294) as compared to Modified LEMON score (0.0206). Out of total 200 patients, 60 developed post intubation hypotension (SBP < 90 mmHg or requiring vasopressor support) and 4 developed post intubation hypoxia (SpO2<93%).

Conclusions: Hypoxia and hypotension were the most common post intubation complications. The number of attempts was directly proportional to the incidence of complications such as hypoxemia, bradycardia and aspiration associated with hypotension during intubation. HEAVEN criteria scores significantly increased the number of attempts for successful intubation as compared to modified Lemon criteria.

Keywords: Intubation, Heaven Criteria, Modified Lemon Criteria. Complication.

DOI: 10.25258/ijcpr.18.11.1

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Introduction

Difficult airway management is a problem for healthcare professionals. Complications of intubation are failed intubation, repeated intubation attempts, airway trauma, and hemodynamic instability. Precise prediction of difficult intubation is therefore crucial in optimizing patient outcomes and reducing related complications (Mort,2004) [1].

Encountering a difficult airway is relatively a rare event, ranges from 0.07 to 16%. Difficult tracheal intubation ranges from 5 to 8% and failed tracheal intubation from 0.05 to 0.35%. The success rate for tracheal intubation with video laryngoscopes is between 97.1 and 99.6% overall and between 95.8

and 100% when a prediction of difficult airway is established [2].

Intubation is commonly performed in emergency departments (EDs), intensive care units (ICUs), and operating rooms to ensure adequate oxygenation and ventilation. In medical emergencies, surgical, and critical care settings, Intubation is used to secure an airway; ensure ventilation of the patient and prevent aspiration of oropharyngeal or gastric contents into the lungs by the passage of an endotracheal tube (ETT) into the trachea. It is a critical procedure in emergency medicine, anaesthesia, and intensive care units ensuring that the airway remains open, especially in cases of obstruction, trauma, or during surgery. The most significant purpose of intubation is to establish a clear pathway for oxygen to reach the lungs and facilitate effective mechanical ventilation. Intubation in emergency departments is performed mainly in critically ill patients, including respiratory failure, trauma, and cardiac arrest, for whom immediate airway management can mean survival (Brown et al.,2015) [3]. The procedure is often performed with the usage of either "direct laryngoscopy or video laryngoscopy". VL provides a better visualization of the airway and reduces the risk of complications [3].

Various airway assessment tools have been developed in the past to predict difficult intubation. Of these, the "LEMON (Look externally, Evaluate 3-3-2 rule, Mallampati score, Obstruction, Neck mobility) score" is most well-known, with widespread use in preoperative settings [4]. Its application in emergency airway management is limited, however, by the requirement for patient cooperation in some of its components, notably the Mallampati score. In an attempt to overcome these, "Modified LEMON score" [5] was created, removing the Mallampati component to make it more feasible in the ED. While these instruments are intended to concentrate on anatomical predictors of difficult intubation, they fail to consider physiological factors that may influence intubation difficulty, particularly in critically ill or trauma patients [6,7]. The present study was to evaluate the complications occurring during and after intubation in relation to the predictive assessment of difficult intubation in Heaven Criteria versus Modified Lemon Criteria.

Material & Methods

Study Design: This study was a Prospective cross-sectional Study conducted over a period of two years to evaluate the complication during and after intubation in HEAVEN criteria versus Modified LEMON criteria" in predicting difficult intubation.

Study Setting: The study was conducted in the Department of Emergency Medicine at Kalinga Institute of Medical Sciences (KIMS), PBMH, KIIT Deemed to be University, Bhubaneswar, Odisha.

Ethical Considerations: Ethical approval was obtained from the Institutional Ethics Committee (IEC). Informed consent was taken from all participants before their inclusion in the study. The confidentiality of patient data was maintained, and the study adheres to the ethical guidelines set by the Declaration of ICMR 2017.

Study Duration: The study was conducted over a period of two years 2022-2024.

Sample Size: A total of 200 patients requiring "rapid-sequence or delayed-sequence intubation" were enrolled in the study. All the consecutive cases requiring endotracheal intubation in the Emergency department were included.

Selection of Cases:

Inclusion Criteria:

- Patients meeting the following criteria were included in the study:
- Patients requiring rapid-sequence or delayed-sequence intubation in PBMH, KIMS, Bhubaneswar.
- Patients aged ≥18 years, irrespective of gender.

Exclusion Criteria:

- Patients undergoing intubation during Cardiopulmonary Resuscitation (CPR).
- Patients intubated by a provider with less than three months of experience.

Patient Enrolment: Patients who met the inclusion criteria were enrolled in the study after obtaining informed consent.

A pre-designed case record form (CRF) was used to collect demographic and clinical data.

Method:

Pre-Intubation Assessment: All patients were evaluated for difficult intubation using both HEAVEN criteria [77] and Modified LEMON criteria [6] before performing the procedure.

Intubation Procedure: After appropriate patient selection and informed consent, intubation was performed following the standard rapid-sequence or delayed-sequence protocol. Vitals including heart rate, blood pressure, oxygen saturation (SpO_2), and respiratory rate were recorded pre- and post-intubation.

The intubation procedure consisted of following critical steps:

Preparation:

- This phase included assessment of patient's airway, airway equipment and medication

check and team debriefing about further plan if airway was difficult or failed.
- It was ensured that pulse oximetry, BP cuff and other monitors were connected to patient.
- The airway provider ensured that there were at least two functioning iv lines in place.
- Appropriate size of Endotracheal tube (ETT) was selected, one size smaller and one size larger ETT and these were checked for any cuff leaks and were kept ready.
- Yankauer suction was connected to the suction apparatus, and oxygen source was checked.
- Airway adjuncts like stylet, bougie, LMA, and VL were kept ready along with a tight-fitting mask and bag and valve device for preoxygenation.
- Appropriate induction agents and paralytics were selected by the airway provider based on the patient's requirement.

Preoxygenation:

- Preoxygenation was attained using an appropriately sized tight-fitting mask and bag valve mask connected to an oxygen source.
- Preoxygenation was done for 8 vital capacity breaths or 3 mins if situation permitted.

Pre-treatment: Pre-treatment was administered wherever it was applicable.

Paralysis with Induction:

Table 1: Drugs using in paralysis with induction.

Drug	Dose	Onset of action	Duration of action
Induction Agents			
Etomidate	0.3 mg/kg IV, max 40 mg, use adj BW	Immediate, 5–15 s	5–15 min
Ketamine	1–2 mg/kg IV, 4–6 mg/kg IM, max 200 mg IV or 500 mg IM, use adj BW	30–90 s	10–30 min IV 25–45 min IM
Propofol	1–2 mg/kg IV, max 200 mg, use adj BW	Immediate, 15–30 s	5–10 min
Midazolam,	0.1–0.3 mg/kg IV or IM adj BW recommend no weight-based dose of 5–10 mg	1–3 min IV 5–15 min IM	10–30 min
Neuromuscular blockade			
Succinylcholine	1.5 mg/kg IV, use TBW	30–45 s	5–15 min
Rocuronium	1–1.2 mg/kg IV, max 150 mg, use IBW	45–60 s	45–120 min
Vecuronium	0.1 mg/kg IV, max 15 mg, use IBW	Delayed, 2–4 min	40–60 min

Positioning: Laryngoscopy is performed in "Sniffing position (SP)" (neck will be flexed [flexion of 35°] on the chest with a cushion under the occiput and extending [extension of 15°] the head at the atlanto-occipital joint has been considered as the ideal position for direct laryngoscopy [16].

The marker used for proper SP is "alignment of the external auditory meatus with the sternum of the patients". Greenland et al (2010) [17]. described that alignment of external auditory meatus and sternal notch in same horizontal plain in supine makes it an optimum position for endotracheal intubation.

Collins et.al (2004) suggested the "RAMP" position for intubating obese patients, as it improved the glottis view during direct laryngoscopy [18, 19].

The "ramped position" is achieved by arranging blankets under the patient's upper body and head to obtain a horizontal alignment between the external auditory meatus and sternal notch [88].

Placement with proof: 5-point auscultation was done, i.e. Bilateral axillary region, bilateral chest, and epigastrium.

Wherever time permitted USG guided confirmation of ETT placement was done.

Post-intubation management: Post intubation management included recording of vital signs, continued monitoring, ensuring adequate oxygenation and ventilation, administering adequate sedation and analgesia using appropriate medications.

The "time taken for successful intubation" was measured. It was defined as "the time from inserting the tip of the laryngoscope blade into the oral cavity to confirmation of tracheal intubation through visualization and five-point auscultation.

Time taken for intubation was recorded by an assistant using a stopwatch. The physician intubating would say out loud to "start" when he/she attempted to pass the tip of laryngoscope into the oral cavity and would say "stop" when he/she confirmed placement with 5-point auscultation. Intubation was considered successful if achieved in the first attempt.

In case of failed attempt, the patient would receive oxygenation using bag and mask followed by usage of "Bougie" to assist intubation or changing the provider if more than two attempts were made.

Outcome Measures: Assessment of peri-intubation and post intubation complications, such as:

- Hypoxia (SpO_2 < 93%)
- Multiple attempts at intubation (> or = 2)

- Hemodynamic instability (SBP < or = 90 or use of Vasopressor agents)

Statistical Analysis: Data was analysed with the help of IBM SPSS software. Mean and standard deviations were observed. Unpaired Student's t-test and correlation test were applied. P value was taken less than or equal to 0.05 ($p \leq 0.05$) for significant differences.

Results

A total of 200 patients were analysed, revealing significant insights into the factors influencing successful intubation. The gender distribution showed a male predominance, with 122 males (61%) and 78 females (39%). The mean age of participants was 55 years, with a range from 18 to 86 years. Mean age of males was 55.05 ± 14.55 and females was 55.92 ± 16.21 respectively.

Most common comorbidity was hypertension followed by diabetes mellitus and Cardiac condition.

Mean Intubation time for successful 1st attempt was 23.57± 8.34 but it increases significantly ($p<0.001$) by 118.57% with multiple attempts.

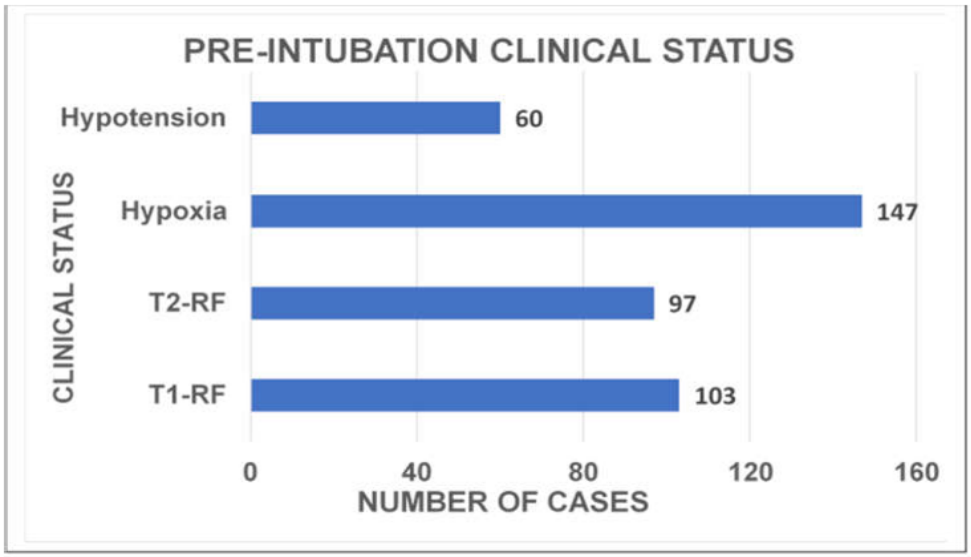


Figure1: pre-intubation clinical status of the participants, 147 had hypoxia and 60 had hypotension.

Table 2: Intubation Outcome

Outcome	Total	Percentage
Successful First Attempt	151	75.5%
Failed First Attempt	49	24.5%

75.5% of the intubations were successful in the first attempt whereas 24.5% intubations failed in first attempt.

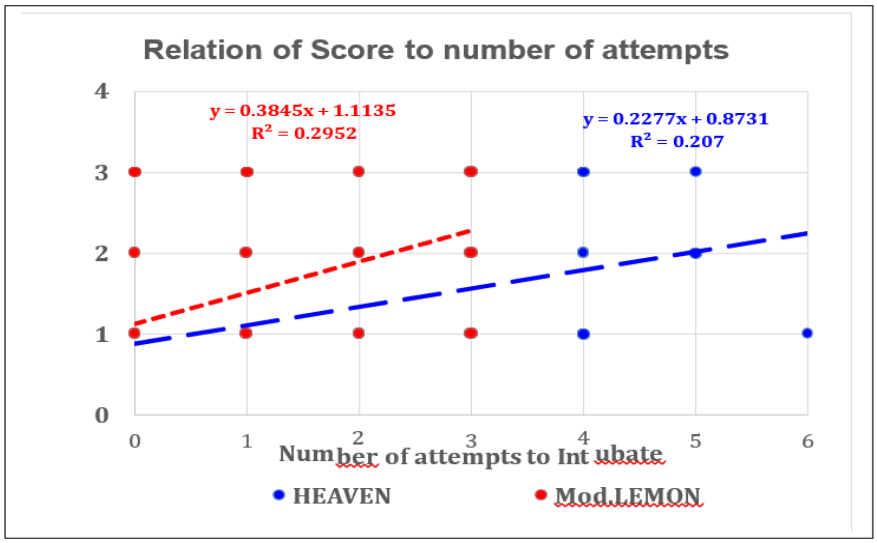


Figure 2: Correlation of score to number of attempts

Fig.2 depicts the linear co-relation between HEAVEN score and Modified LEMON score with the number of attempts for successful intubation. As the score increases the number of attempts also increases. The slope of the graph is higher for Modified LEMON score (0.3845) as compared to HEAVEN score (0.02277).

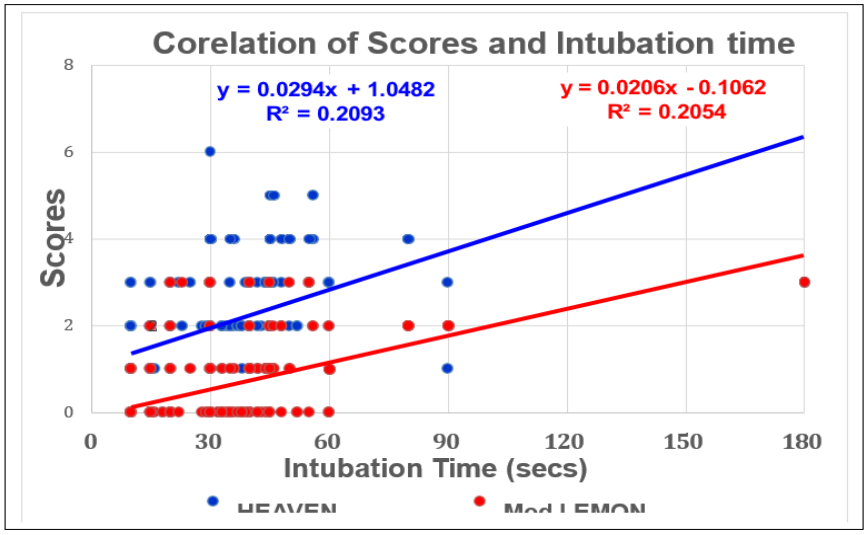


Figure 3: Correlation of score to intubation time

Fig. 3 depicts the linear co-relation between HEAVEN score and Modified LEMON score with the "time for successful intubation". As the score increases the time taken for successful intubation also increases. The slope of the graph is higher for HEAVEN score (0.0294) as compared to Modified LEMON score (0.0206) indicating that HEAVEN score co-relates more with time for successful intubation; that means if the score increases the time taken for successful intubation increases.

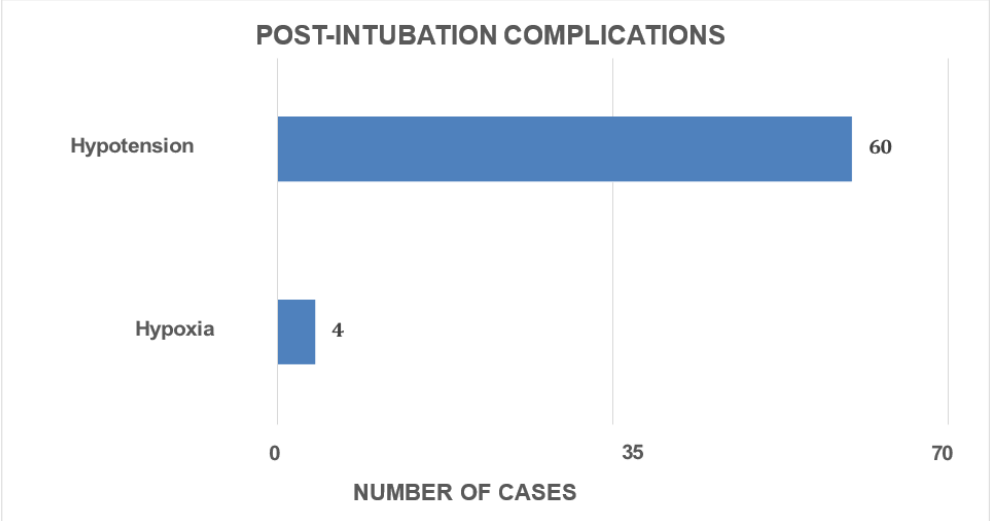


Figure 4: Post-Intubation Complications

Post intubation complications like hypoxia and hypotension were estimated. Of the total patients included in the study, 60 developed post intubation hypotension (SBP < 90 mmHg or requiring vasopressor support) and 4 developed post intubation hypoxia (SpO_2 < 93%).

Discussions

In the present study, a total of 200 patients were included. There were total 61% males (n = 122) as compared to 39% females (n = 78). The mean age of participants was 55.41, with the range being 18 to 86. This is in agreement with Tan et al (2022) [8].

Comorbidities noted among patients in this study were hypertension, diabetes mellitus, chronic kidney disease, cerebro-vascular accidents, respiratory disorders and others. Among the comorbidities the most common comorbidity was hypertension followed by diabetes mellitus.

Indications for intubation were airway protection, altered mental status with threatened airway, respiratory distress and failure, shock and others. Among all the indications, most common indication was airway protection (n = 139) and altered mental status with threatened airway (n = 121). Pre-intubation clinical status was estimated and the total number of patients with hypotension and hypoxia were estimated, 147 patients had pre-intubation hypoxia and 60 had hypotension prior to intubation. The PO_2 status and PCO_2 status was estimated from pre-intubation ABG analysis. Total 103 patients had type 1 respiratory failure (PO2 < 80) and 97 patients had type 2 respiratory failure (PCO_2 > 45). All patients received neuromuscular blockade with either Rocuronium or Succinylcholine.

The outcome was the demonstration of the HEAVEN criteria showing high Positive predictive value (96%) and specificity (94%) when predicting difficult intubations, the same finding was also observed in the study of Kuzmack et.al [9]. The Modified LEMON criteria, though effective, were found to have slightly less specificity (45%) and positive predictive value (40%). In this regard, the result is consistent with previous studies such as the work by Nausheen et al. [10] where it highlighted the application of the HEAVEN criteria in emergency settings particularly for the prediction of laryngoscopic view and first-attempt intubation success.

The two main outcomes from the study were the rate of "successful intubation in the first attempt and the time taken for the intubation". They were both closely related to the ability of the criterion to predict difficult airways. The overall first-attempt success rate was 75.5%. This finding is consistent with the study done by Nausheen et.al (2019) [10]. The first attempt success was significantly higher for cases identified to have low difficulty according to the HEAVEN criteria and Mod LEMON criteria. As the scores increased, the number of successful intubation in first attempt decreased significantly ($p< 0.05$). This finding is in tandem with the results of Kuzmack et. al & others [9,11,10] & Sakles et al. [6], who highly emphasized the critical importance of achieving "first-pass success" in emergency intubations, thereby reducing the incidence of adverse events, such as oxygen desaturation and hypotension. This had the concomitant effect of a higher incidence of complications, as observed by Mort [1] with his study on repeated intubation attempts and its associated complications such as hypoxemia, bradycardia, hypotension and aspiration. The number of attempts was directly proportional to the incidence of complications, as observed in our study with hypotension. In our study there were total 4 incidences of post intubation hypoxia as it was ensured that if the first attempt failed the patient should receive re-oxygenation before attempting a second attempt, also the patients received apnoeic oxygenation [12]. The mean intubation time (in sec) for successful 1st attempt was 23.57 ± 8.34 but it increases significantly ($p<0.001$) by 118.57% with multiple attempts.

Comparison between the HEAVEN and Modified LEMON criteria shows that both sets of criteria are useful tools for predicting difficult airways in emergency situations. However, the HEAVEN criteria showed better overall accuracy in that it included physiological factors like hypoxemia and exsanguination, which are more relevant to the critical condition of patients who have been subjected to rapid-sequence intubation in emergency settings. This is in agreement with the validation of the HEAVEN criteria by Kuzmack et al. [9], however the finding of Tan et.al [8] are different. The study by Ji et al (2018) [6] also concurred with this, where there was a good correlation between the modified LEMON score and intubation difficulty, further emphasizing the need for pre-intubation airway assessment.

The incidence of complications found in our study also corresponds with those in the literature. The association between the number of criteria met and the chance of having a difficult intubation is also the same as that observed by Reed et al. [7], where it was seen that the patient with a higher score of airway assessment through LEMON method was at higher risk for having a difficult intubation. Further, the data from our study support the idea that predictive airway scoring systems, such as HEAVEN, can make the risk of complications significantly reduced in association with emergency intubations by permitting clinicians to better prepare and select appropriate techniques.

In addition, the findings susggest the importance of limiting attempts during intubation. Though the first intubation attempt remains essential to successful airway management, subsequent attempts have increased the risks of adverse outcomes [13,14]. Hence, the HEAVEN criteria are of high specificity in identifying a difficult airway, enabling clinicians to prioritize alternative approaches and equipment early on to reduce complications [9]. This is in line with the recommendations of the "ASA Task Force on the Management of the Difficult Airway [15], which limits the number of intubation attempts to minimize harm to the patient.

The HEAVEN criteria, which incorporate both anatomical and physiological predictors, are more comprehensive than the Modified LEMON criteria in determining airway difficulty. This study underscores the need to have accurate pre-intubation airway assessments as a means of improving outcomes for patients by ensuring the right intubation technique is used at the appropriate time. As emergency airway management evolves, the

HEAVEN criteria appear to be an encouraging approach toward better intubation success rates and reducing complications in general, ultimately improving patient care in critical settings.

Conclusions

The present study concluded that the hypoxia and hypotension were the most common post intubation complications. The number of attempts was directly proportional to the incidence of complications such as hypoxemia, bradycardia and aspiration associated with hypotension during intubation. HEAVEN criteria scores significantly increased the number of attempts for successful intubation as compared to modified Lemon criteria.

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