5 Is it Time for REBOA to be Considered as an Equivalent to Resuscitative Thoracotomy?

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Introduction

According to estimates, hemorrhage is responsible for 40% of civilian trauma-related deaths and greater than 90% of military deaths from potentially survivable injuries [1]. While mortality from compressible hemorrhage can be temporized in the field with rapid hemostasis from direct pressure, non-compressible torso hemorrhage (NCTH) remains lethal and requires timely access to an operating room (OR) for definitive hemostasis, equipment, and blood bank resources [2, 3]. To prevent immediate exsanguination before achieving definitive hemorrhage control, aortic cross-clamping remains the primary method for hemorrhage control in these settings [4]. This is typically achieved with an American College y (RT), descending aortic clamping, coupled with emergency surgery to control hemorrhage. [5] The feasibility of RT was first demonstrated in 1976 by Dr. Anna Ledgerwood in a landmark study evaluating the role of thoracic aortic occlusion for massive hemoperitoneum. This study demonstrated that aortic cross-clamping before an exploratory laparotomy in patients in extremis experienced improvement of vital signs, perfusion to the brain and myocardium, and prevented sudden cardiac arrest as the abdominal wall tamponade was released [6]. Despite the morbidity associated with a thoracotomy, selective use in hemorrhaging trauma patients is driven by organized and evidence-based algorithms [7].

The use of resuscitative endovascular occlusion of the aorta (REBOA) was first described in 1954 by Colonel Hughes to address the challenges of traumatic hemorrhage under austere conditions [8]. He utilized aortic balloon occlusion in two

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patients during the Korean War to non-invasively gain control of intra-abdominal hemorrhage. This was one of the first documented instances for aortic balloon occlusion to stem hemorrhage. Though both patients died, he was able to improve central perfusion in one patient temporarily [8].

The past decade witnessed an evolution in resuscitation paradigms with the greater extracorporeal capability and the introduction of more precise and selective technology. As endovascular techniques improved, so did interest in REBOA. Case reports demonstrated effectiveness in patients with hemorrhagic shock from ruptured abdominal aortic aneurysms, aortic-enteric fistulas, postpartum, or abdominal/pelvic surgery hemorrhage, hemoperitoneum after splenic artery aneurysm, gastrointestinal hemorrhage, and vascular injuries [9–12]. Despite emerging indications and greater potential as an additional tool for improving resuscitation, the true efficacy of REBOA as a bridging hemostatic measure in civilian injury patterns is not yet established, and the hemostatic effect may not be as profound as previously theorized [13]. Although the use of REBOA to temporize hemorrhage has increased in civilian trauma care over the past fifteen years, there is no high-grade empirical evidence demonstrating improvement in survival when REBOA is utilized in comparison to the standard of care for severe hemorrhage [14, 15]. The risk-benefit ratio of this technology is still being investigated in different patient populations. Before widespread adoption, a rational and evidence-based evaluation of this tool is needed to identify its correct indications.

Search Strategy

PUBMED and Google Scholar (first ten pages) were searched using the terms REBOA and resuscitative thoracotomy (RT). All resulting citations were screened for relevance. Two reviewers (SA and TA) performed an iterative process starting with titles, then abstracts and full text as necessary for inclusion or exclusion. The research team excluded references including only pediatric patients, patients without blood loss, those that described occlusion of vessels other than the aorta, reviews, letters to the editor, opinion pieces and those without primary data. Articles that controlled aortic flow using extravascular methods like clamps and extracorporeal circuits were also included. Reviews were screened for relevant citations, and those with REBOA and/or RT patients or groups were included in this chapter. Disagreements about study eligibility were discussed, and the consensus was reached regarding inclusion. Once studies for inclusion were identified, the full text was reviewed, and key data extracted. For animal studies, data included comparator groups, hemorrhage protocol, duration of occlusion, devices used, comorbidities, and primary study aims. For clinical studies and case reports, data included patient type and number, device used, comparator group, major findings, and method of achieving aortic occlusion.

PICO

Patients	Intervention	Comparator	Outcomes
Exsanguinating trauma patients	REBOA	Resuscitative thoracotomy (RT)	Complications, morbidity, and mortality

Procedural Complexity: Who Can Perform What?

Only surgeons with experience in the management of cardiac and thoracic injuries should perform RT (e.g., trauma, cardiothoracic, vascular surgeons) [16]. In the civilian setting, the American College of Surgeons—Committee on Trauma (ACS-COT) and the American College of Emergency Physicians (ACEP) emphasized that REBOA should be performed by an acute care surgeon or an interventionalist (vascular surgeon or interventional radiologist) trained in REBOA, with the implication that this individual has the capabilities to surgically intervene. Emergency medicine (EM) physicians with added certification in critical care (EMCC) trained in REBOA may train and perform REBOA in conjunction with an acute care surgeon or vascular surgeon trained in REBOA, as long as the surgeon(s) is/are immediately available to control the focused source of bleeding definitively [13]. EMCC-certified physicians, especially those with no critical care training, must not perform REBOA unless a surgeon is immediately available [13].

RT used in the military setting is restricted to forward military treatment facilities with surgical and resuscitation capability (typically Role-2 or higher) and by surgeons familiar with and trained in this procedure [17]. REBOA use in the military setting is considered an exceptional circumstance in which it may be used, as long as those deploying the device have formal training in Basic Endovascular Skills for Trauma (BEST course®). Femoral access in this hemodynamically unstable patient population is difficult and is the rate-limiting step in placing a REBOA. If placement is unsuccessful, then the individual must have the skills to perform an open femoral cutdown. Besides, once access is achieved, monitoring the patient for complications associated with access or balloon inflation is important. Thus training for this device must be comprehensive and multifaceted; The BEST course® achieves these goals [18].

The Ideal Setting: Where and When Should the Intervention Occur?

The Western Trauma Association published its guidelines for RT in 2012. Their recommendation for undergoing ED RT is based on the type of trauma (blunt vs. penetrating), pre-hospital transport time with ongoing CPR, and signs of life. Patients with penetrating trauma with absent signs of life and transport time with ongoing CPR exceeding 15 min are pronounced dead. Patients presenting with

blunt trauma with pre-hospital CPR exceeding 10 min and no signs of life are pronounced dead. All other blunt or penetrating trauma patients in extremis, who are not pronounced dead as per the aforementioned criteria, should undergo ED RT. [7] The Eastern Association for the Surgery of Trauma (EAST) guidelines conditionally recommend against ED RT in patients with cardiac arrest in blunt trauma patients and no signs of life on arrival. These guidelines are based on a meta-analysis of 72 studies including 10,238 patients. All patients with penetrating thoracic or extra-thoracic injuries, regardless of signs of life, should undergo ED RT; While only patients with blunt trauma and signs of life should undergo ED RT. [19] Patients deemed salvageable after ED RT should be transported to the OR for further management [20].

Some EMS teams outside of the USA, using REBOA are staffed with physician providers and are equipped to perform RT in this setting [21]. However, any attempt to transfer patients with an aortic clamp is predestined to fail [22]. In the USA, this is not the case; thus the recommendation remains to resuscitate and transport the patient to a nearby trauma center, as quickly as possible [18]. The ACS-COT's joint statement addressed the use of REBOA in the pre-hospital environment [15, 18]. They indicate an allowance for REBOA placement in the specific instance that a physician with REBOA experience is placing it, and that definitive control is within 15 and 30 min, for balloons inflated in Zone I and III, respectively [18].

The consensus among experts is that REBOA can be used in austere military settings, EDs, ORs, and intensive care units, but disagrees with the statement that REBOA is feasible in the pre-hospital setting [23]. The rationale is that one must also consider the experience and training of the providers performing this procedure in this setting. Outside of the USA, much of the literature regarding REBOA in the pre-hospital setting is with physician providers as part of the EMS team.

The UK-REBOA trial, which explores this question, began enrollment in 2017 and is set to publish its findings in March 2021. However, this trial's enrollment process is proving to be prolonged, which may delay its ability to provide a definitive answer anytime soon. In light of the current evidence, the issue of pre-hospital insertion of REBOA should be approached with caution. Although the UK experience is encouraging with reported improved survival, the modality and results are not easily reproducible [24]. More research must be performed before a positive recommendation can be made for this procedure in the pre-hospital setting. Until these studies are performed, REBOA should be reserved for select cases in advanced centers with high expertise and a clear post-insertion protocol.

Hemorrhage Control in Austere Environments

In austere environments, non-compressible torso hemorrhage (NCTH) was found to be the most common cause of potentially survivable deaths for wounded soldiers [25]. The inability to control bleeding from NCTH is addressed in the Tactical Combat Casualty Care Guidelines as well as the 2020 Clinical Practice Guidelines (CPG). [26] NCTH hemorrhage is lethal and can lead to prohibitively high mortality

rates in the first few minutes after injury. The estimated peak time of death or irreversible metabolic derangements after truncal injury may occur well before 30 min and likely before reaching definitive care [26]. Even in the civilian population, patients with gunshot wounds (GSW) or with high torso AIS (Abbreviated Injury Scale) scores had higher mortality rates within the first fifteen minutes [27]. As a field, or on-scene RT is not a meaningful option given the complexity of post-thoracotomy management and disappointing results [28, 29]. REBOA is an attractive tool when combined with whole blood resuscitation, to temporize hemorrhage and extend the "golden hour" or half-hour as one may call it. It can be deployed in an austere environment en route to reaching definitive care [27]. Its role is important to consider given the percentage of patients who die of their wounds in the field, as well as the dearth of additional temporizing techniques in combatants sustaining NCTH.

One arena in which REBOA is potentially useful is in the austere setting. However, the perceived benefit of REBOA in NCTH is present with the caveat that definitive hemorrhage control occurs within 30 min of balloon inflation [30]. Morbidity and mortality from REBOA remain high even within fifteen minutes of balloon inflation, negating the benefits of hemorrhage control; Thus, timely transport must be present [31]. As the catheter technology and occlusion practices continue to evolve, hopefully so will the quality and quantity of data guiding its use [32]. Despite a well-organized and structured trauma system, with improved transport times, hemorrhage control in the setting of NCTH remains a considerable challenge.

In-Hospital Management: When to Inflate or Directly Operate?

As opposed to the comparatively austere pre-hospital setting, the hospital is a backdrop in which definitive control may be achieved via its trauma team and the OR. Potential indications for RT or REBOA in trauma are primarily based on the patient's injury pattern and physiological status at the presentation in the trauma bay. In patients who present without a pulse, the decision to intervene is based on the mechanism and pattern of injury, duration of CPR, presence of a narrow organized complex cardiac rhythm, and/or organized cardiac activity by an ultrasound exam. For trauma patients presenting with signs of life on admission in profound shock, the use of RT vs. REBOA is determined by vital signs, response to resuscitation, the likely pattern of injury, and the source of hemorrhage. All of these parameters are equally important in determining the intervention required [33]. The updated CPG of the Joint Trauma System (JTS) are descriptive in the indications for REBOA use in patients with either traumatic cardiac arrest or profound shock and acknowledge the limitations and danger of this technology as well [30]. This section will guide the use of REBOA vs. RT in trauma. The indications presented henceforth are derived from the JTS CPG. [34] Modified algorithms, derived from expert opinions regarding intervention with REBOA or RT, for the management of traumatic arrest and the management of hemorrhagic trauma with concomitant shock, are depicted in Figs. 5.1 and 5.2.

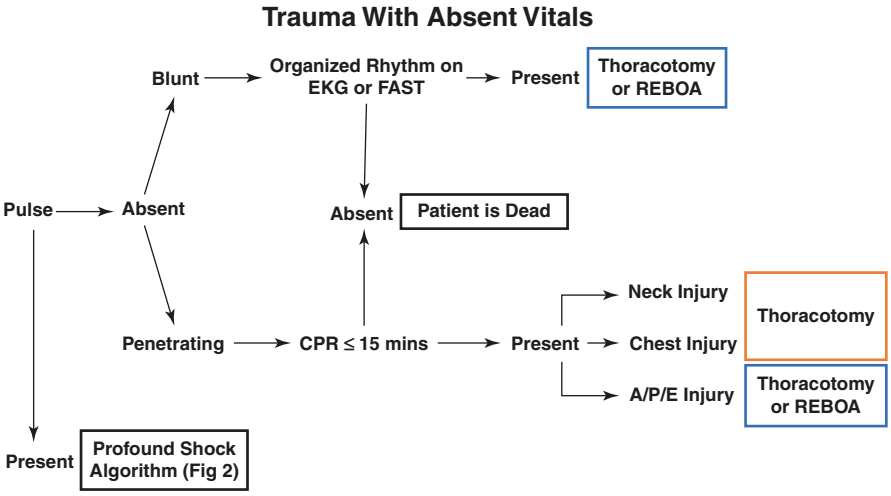

Fig. 5.1 Traumatic arrest algorithm for RT or REBOA for hemorrhagic shock

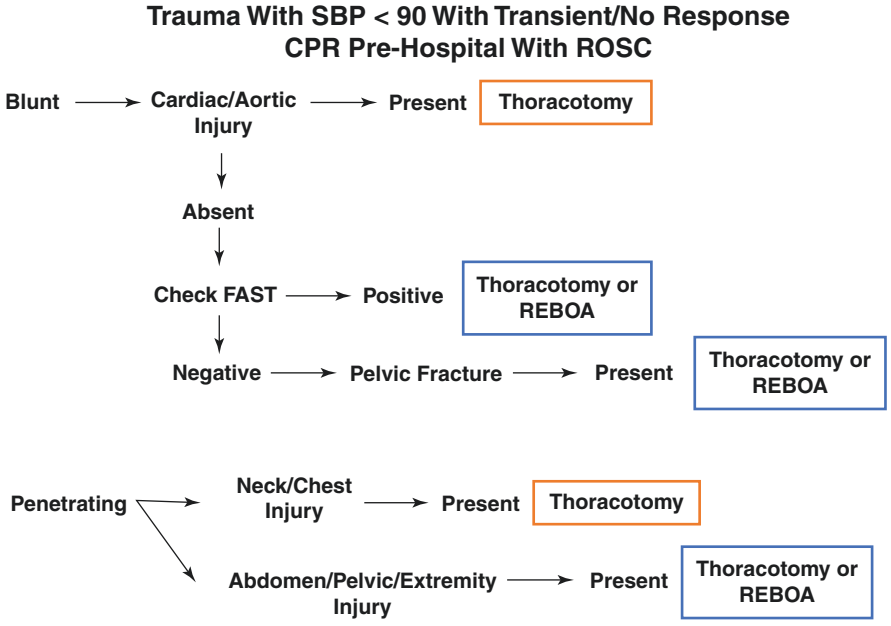

Fig. 5.2 Profound hemorrhagic shock algorithm for RT or REBOA

1. **Operate, Never Inflate:**
   - Patients with penetrating thoracic trauma who present in profound shock should undergo prompt RT. Upon accessing the thoracic cavity, definitive hemorrhage control can be directly performed, and the descending thoracic

aorta can be clamped above the diaphragm to augment myocardial and brain perfusion. The deployment of REBOA in the setting of thoracic hemorrhage is contraindicated given its potential to exacerbate hemorrhage from great vessel injury [35].

- Patients with blunt cardiac injury or traumatic aortic injury who present in profound shock should undergo prompt RT. In this setting, deploying REBOA is contraindicated, and RT remains the standard of care.
- Patients with hemorrhage proximal to zones of REBOA occlusion, including areas of the neck, axilla, and superior mediastinum, should strictly undergo RT if surgical intervention is deemed necessary [7].

2. **Operate or Inflate:**
   - Patients arriving with cardiopulmonary resuscitation (CPR) in progress should strictly undergo RT given that the patient is in extremis [36]. However, some emerging reports highlight the potential role of REBOA in this population [37].
   - Patients with blunt trauma arriving with loss of vitals, but with organized rhythm detected on an EKG or FAST, with low/no suspicion for supradiaphragmatic trauma, intervention with either zone I REBOA or RT is feasible.
   - Patients with penetrating abdominal, pelvic, or lower extremity trauma receiving CPR for less than 15 min, without a devastating head injury, may also be candidates for either REBOA or RT.
   - Patients with penetrating injuries having a thoracoabdominal trajectory can undergo REBOA, as opposed to RT, only after ascertaining that the source of hemorrhage is sub-diaphragmatic and ruling out thoracic hemorrhage using a chest X-ray and a FAST exam [38].
   - In all these patients, the decision to place a REBOA as opposed to RT is still subject to conjecture and risk and must be performed within minutes of presentation, without contributing to a delay in definitive hemorrhage control.
3. **Do Not Operate or Inflate:**
   - Relative contraindications to both procedures include elderly age (age > 70 years), pulseless cardiac electric activity arrest exceeding 10 min, presence of terminal illness, and/or profound comorbidities [39].

Catch-22: Anatomic Indication Does Not Necessarily Imply Physiologic Indication!

In a recent study, it was reported that 55% of patients with potential anatomic indications for REBOA ultimately did not have physiologic indications once a response to resuscitation was reached [40]. Such information is readily obtained from the patient's primary survey, clinical assessment, and imaging modalities such as focused abdominal sonographic examination for trauma (FAST), chest, and pelvic X-ray. In those patients, REBOA, as opposed to RT, may be inserted for transient responders or non-responders to resuscitation upon verification of the sub-diaphragmatic source of the hemorrhage [41].

In-Hospital Outcomes: What the Evidence Suggests?

- At present, we do not have high-quality Level I evidence for REBOA efficacy in the treatment of traumatic hemorrhagic shock, and additional research is warranted.

Current guidelines or algorithms adopted by trauma centers are not backed by empirical evidence demonstrating a clear survival benefit of REBOA when compared to RT, which is the standard of care.

- Studies ensuring REBOA's safety and demonstrating an acceptable risk-benefit ratio are also lacking. The current indications for REBOA are based on low-quality evidence and expert opinion with little consensus.

A recent systematic review and meta-analysis compared REBOA to RT to determine outcomes in patients with NCTH. The constituent three studies included data from the following databases: Japanese Trauma Data Bank, Japanese Diagnosis Procedure Combination Data Bank, and The American Association for the Surgery of Trauma Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery Registry [42–44]. This meta-analysis, reflecting mainly observational data, concluded that REBOA had a positive effect on mortality among NCTH patients compared to RT. [45] However, these results may have significant indications and survival bias, making the comparison between the two methods difficult in each of these three studies [46, 47]. When REBOA is compared to RT, the patients undergoing an RT are almost uniformly in cardiac arrest and dire straits; thus, the outcome from this comparison tends to favor REBOA and jeopardizes the internal and external validity of the studies [48]. Though difficult, standardization of comparison groups, with randomization is needed to provide more definitive answers.

Complications and Limitations

Despite the comparative morbidity of undergoing a large chest wall incision, experience with REBOA has shown us that this device is not without its own risk. In the past three decades, there has been a significant clinical shift in the performance of RT from a nearly obligatory procedure to a more selective undertaking [7]. Enduring the test of time, the complications and success rates of RT are primarily dependent on the patient selection that relies on injury patterns that dictate where RT is performed (ED vs. OR), that in and by itself may influence patient outcomes [49]. The optimal application of RT requires a thorough understanding of its physiologic goals, technical skills, and subsequent cardiovascular and metabolic derangements. Technical complications of RT involve virtually every intrathoracic structure, predisposing to lacerations of the heart, coronaries, aorta, phrenic nerves, esophagus,

and/or lungs, as well as avulsion of aortic branches to components of the mediastinum. In those who survive RT, recurrent chest bleeding, pericarditis, pleuritis, and infections to the sternum and chest wall may occur, and post-pericardiotomy syndrome [50]. The complications associated with the use of REBOA are partially attributed to the limitations of currently available devices. These limitations include the size of the catheter and the introducer sheath and catheter stability. Technical complications are divided into several categories: issues associated with arterial access, challenges associated with balloon positioning, inflation, and deflation, as well as with sheath removal [51, 52]. Reported femoral access complications to include arterial disruption, dissection, pseudoaneurysms, hematoma, thromboembolism, extremity ischemia, and the problem of prolonged occlusion time and delayed definitive control. Aortoiliac injuries have also occurred; these include intimal tear, dissection, thrombosis, and rupture, which may be fatal or cause limb loss. Balloon rupture may occur with over-inflation of the balloon relative to the aortic diameter. Unintended inflation of the balloon in the iliac vessels may lead to rupture or thrombosis [51–53].

Other limitations common to open or endovascular occlusion of the aorta include occlusion time and physiology post-release. Even if one's technique is impeccable, prolonged occlusion results in significant distal ischemic reperfusion injury, predisposing the patient to organ dysfunction, cardiovascular collapse, and spinal cord ischemia [51, 54, 55]. In as little as fifteen minutes, the metabolic derangements can be irreversible, thus emphasizing the importance of proximity to definitive hemorrhage control, which is feasible with RT.

Recently, to mitigate the risk associated with occlusion times, partial occlusion or intermittent deflation/inflation of the balloon has been introduced [56]. Partial REBOA (pREBOA) or intermittent occlusion REBOA (iREBOA) practices were utilizing the same catheter to allow limited blood flow past the balloon. Theoretically, allowing some flow may limit complications of ischemic reperfusion injury. Currently, REBOA is primarily utilized as an all-or-none flow occlusive device. Several animal studies indicate this is potentially feasible in limiting ischemic burden; however, partial occlusion is difficult to achieve without continuous monitoring of the blood pressure both above and below the balloon along with a clinical assessment of the rate of bleeding. Besides, determining and maintaining a consistent degree of partial inflation is difficult to achieve, given the complex physiologic environment [56]. Thus at this point, there is presently insufficient data to guide this practice [32, 57–59].

In summary, limitations of REBOA range from technical aspects of placement and maintenance to the metabolic derangements from prolonged ischemia. Even if the catheter or balloon profile evolves such that placement is more facile, the ultimate limitation, whether the patient is undergoing an RT or REBOA placement, is proximity to definitive hemorrhage control. Unlike an RT, which is usually performed in patients in extremis and does not possess the same technical limitations, REBOA placement in a hypotensive patient nearing extremis may result in a prolonged time to achieving this control because of the above-noted limitations.

Table 5.1 Summary of RT vs. REBOA

Variables	RT	REBOA
Procedural Complexity	High	Low
Personnel	Surgeon Only	Surgeon/Interventionalist/EM+Critical Care Certification
Location	ED/OR	Prehospital + Inhospital
Temporizing Hemorrhage Ability	Complete Occlusion	Complete Occlusion
Definitive Hemorrhage Control	Yes	No
Indications	More + Better Evidence	Few + Lower Evidence
In-Hospital Outcomes	Standardized Studies With Randomization Are Needed For A Definitive Answer	
Complications & Limitations	Low	High
Overall Verdict	Currently, RT Takes Precedence Over REBOA	

Recommendations Based on the Data

- In its current state and indications, it is not time for REBOA to replace RT in patients with severe NCTH (Table 5.1).

The indications for RT are derived from evidence-based algorithms that establish the feasibility of intervention based on clear inclusion and exclusion criteria. RT has endured the test of time, subjecting it to decades of procedural and patient selection refinement. RT is not without its complications, but physicians have had ample time to learn from these complications, further contributing to an improvement in post-operative management. On the other hand, REBOA is novel. The catheter continues to evolve, and balloon sizes are not final, device application (pREBOA vs. iREBOA vs. complete occlusion) is still under investigation. The ease of safely performing this procedure is a concern as well. Even the complications associated with this device have not been adequately recognized. REBOA's utilization currently surpasses its indications and requires certification before use [60]. Its utilization must be adapted to the individual institution's available resources, and logistical familiarity is needed, as is greater practice with this procedure [61]. Besides, just like RT, there needs to be a well-defined population delineated before providing any strong recommendations for its use. This, too, will require time, and controlled prospective studies.

Summary of Recommendations

- In its current state and indications, it is not time for REBOA to replace RT in patients with severe NCTH (evidence quality high; strong recommendation).

- Its utilization must be adapted to the individual institution's available resources, and logistical familiarity is needed, as is greater practice with this procedure (evidence quality low; moderate recommendation).

Personal View of the Data

However, there might be a future for REBOA, but it is with a specific patient population and a specific set of indications that will allow this procedure to succeed. While there are several animal models and cadaver studies in the literature, these results have yet to be translated into the hemorrhaging trauma patient. The goal of this research is to ultimately make this technique user-friendly, efficient, and safe for the hemorrhaging patient [62, 63]. With more level I and level II evidence, standardization of technique, and widespread availability, we can eventually outline recommendations to make this group of patients less vulnerable to injury. Moving forward, increased efforts should focus on integrating REBOA to RT instead of attempting to replace it.

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