Early appropriate care and opportunities for integrated care pathways in orthopaedic trauma

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Abstract

Early appropriate care (EAC) is a treatment protocol for trauma patients with unstable fractures of the thoracolumbar spine, pelvis, acetabulum, and/or femur. The protocol was designed to expedite treatment based on patient physiologic readiness for definitive fracture surgery. In the EAC protocol, patients are aggressively resuscitated and managed by a multidisciplinary team. Upon achieving predefined thresholds for adequate resuscitation, patients undergo definitive stabilization of their fractures with the goal of performing surgery within 36 hours of injury. As an integrated care pathway, the EAC protocol defines a time dependent strategy to trauma care and minimizes complications and reduces cost through a multidisciplinary approach. Adoption of the EAC protocol was achieved through buy-in from all involved parties in the development phase and contributed to subsequent adherence to the protocol. As such, lessons learned from the development, institution and study of the EAC protocol may be applied to other clinical challenges in orthopaedic trauma, including fracture management in high-energy geriatric injuries as well as head injury.

Keywords: pathway, early appropriate care, timing fixation, multiply-injured

1. Introduction

Trauma care is provided in a multidisciplinary fashion and is most effective and efficient in regionalized trauma centers (1). In particular, the multiply-injured patient requires immediate care from several specialists and availability of intensive care units and operating rooms. As a result, the care of the trauma patient is resource intensive but cost effective due to improved clinical outcomes achieved in trauma centers (2). Nevertheless, trauma centers face challenges in financial viability, and continuous efforts are required to establish practice patterns that result in optimal patient outcomes and are also cost-efficient (3, 4).

One avenue for achieving excellent clinical outcomes in a cost-efficient manner in trauma care is the integrated care pathway (ICP) (5). ICPs are time-dependent treatment protocols utilizing a multidisciplinary approach. With respect to orthopaedic practice, ICPs have been studied extensively in the total joint arthroplasty literature and are associated with decreased complications and cost in this population (6, 7). They have also been utilized with success in geriatric patients with hip fracture (8, 9). However, their use is not as well-established in the management of the multiply-injured patient requiring fracture care.

The Early Appropriate Care (EAC) protocol is a type of ICP developed to address the timing of definitive surgery in unstable fractures of the spine, pelvis, acetabulum, and femur (10). In the trauma patient, these fractures are similar injuries because they predispose to systemic inflammation and require patients to maintain bed rest prior to fixation (11). Prolonged bed rest is associated with poor pulmonary compromise and thromboembolic disease (12). For these reasons, many authors advocate early definitive fracture fixation in order to promote mobility, reducing complications and length of stay (LOS) (13-15). However, the balance between early fracture fixation and patient’s ability to tolerate surgery has been debated within the literature (16, 17). The EAC protocol addresses these issues by defining specific resuscitation thresholds for fracture fixation with the goal of definitive fracture surgery within 36 hours of injury. In this review, we provide an overview of the factors leading to the development of the EAC protocol, discuss outcomes associated with the EAC protocol, and define the use of and opportunities available for ICPs in orthopaedic trauma.

2. Regionalization of trauma care: background for Early Appropriate Care

The trauma patient is frequently associated with injuries that span the domain of many specialties and therefore requires a multidisciplinary approach for treatment (18). Substantial investment in resources is required to maintain readiness for trauma care, and, as a result, the care of the trauma patient is regionalized (19). The American College of Surgeons (ACS) formalized this regionalization in 1976 by categorizing hospitals based on resources needed to provide different levels of care for trauma (20).

Subsequent to the development of trauma center status, multiple studies demonstrated the benefit of Level I trauma centers on clinical outcomes and cost. Nathens et al showed that states with trauma system implementation had an 8% reduction in motor vehicle crash mortality compared to states without an organized system of trauma care, after adjusting for restraint laws, laws that deter drunk driving, and laws that allow for highway speeds greater than 55 mph (21). The findings of this study were verified in the National Study on the Costs and Outcomes of Trauma (NSCOT), a large multi-center study examining mortality from all mechanisms of injury. In this study, MacKenzie et al showed that both in-hospital mortality (relative risk of 0.80) as well as one year mortality (relative risk of 0.75) were significantly lower in level I trauma centers compared to hospitals without trauma center designation (22).

In addition to improved clinical outcomes, care provided by trauma centers has been shown to be cost-effective. In an analysis of the NSCOT data, Mackenzie et al showed that the added cost of treatment at a trauma center was $36,319 per life year gained compared to hospitals without trauma center designation (2). Although the economic value of a statistical year of life has been debated, a commonly cited benchmark is $50,000 to $200,000 (23). Based on this estimate, the authors concluded that the more expensive care provided at trauma centers is more cost-effective. Furthermore, trauma care has been shown to positively impact the financial characteristics of a trauma center (24, 25). In a retrospective study of a single Level I trauma center, Breedlove et al showed that Level I trauma care had favorable contribution margins (40.2%) relative to other service lines at their hospital, including orthopaedics (29.8%), oncology (26.3%), and cardiac care (15.6%) (24). The authors concluded that the investment necessary to maintain trauma center status is sustained by favorable contributions to hospital net revenue.

Despite improved and cost-effective care provided by trauma centers, trauma centers face significant challenges to financial viability, particularly due to issues surrounding patient transfer. In an analysis of the National Trauma Data Bank, Koval et al studied patients with low Injury Severity Scores (ISS $\leq$ 9) (26). They found that 21% of patients with low severity injuries were transferred to a Level I trauma center. Compared to patients who were not transferred, transferred patients with low severity injuries were more likely to have Medicaid insurance versus other types of insurance (OR 2.02, 99% CI 1.89-2.15), were more likely to present during evenings or nights compared to mornings or afternoons (OR 2.25, 99% CI 2.15-2.35), and be African American versus Caucasian race (OR 1.28, 99% CI 1.21-1.36), after controlling for confounding factors. The authors concluded that transfer of injured patients occurs for reasons other than medical necessity, as outlined by the Emergency Medical Treatment and Active Labor Act. In another study of patients treated at a Level I trauma center, transfer patients were found to have lower ISS compared to patients who were not transferred (27). Furthermore, the authors found that a higher proportion of patients with low severity injury (ISS < 18) had no insurance versus patients with ISS $\geq$ 18. Transferred patients were also more likely to undergo delayed definitive fixation of their fractures, which is associated with higher complications in medically stable patients. These studies suggest that initial triage and transfer processes require optimization so that trauma centers can continue to maintain financial viability and provide expeditious fracture care. In this setting of financial challenges, trauma centers must seek patient care strategies that produce excellent clinical outcomes but are also cost-effective.

3. Development of the Early Appropriate Care protocol

Trauma centers are able to provide better patient outcomes in part due to patient care algorithms that continuously evolve based on research efforts. The management of unstable axial fractures (spine, pelvis, acetabulum, and femur) in the multiply-injured patients remains an area of active investigation. Based on this investigation, fracture care in these patients has changed dramatically with respect to timing of definitive surgery. Early Appropriate Care (EAC) is a protocol driven pathway for fracture care in multiply-injured patients that emerged from this investigation (10). Based on measures of resuscitation, including lactate, arterial pH, and base excess, patients with unstable fractures of the axial skeleton undergo definitive treatment of their fractures within 36 hours of injury. Efforts are made in patients who do not meet these thresholds to continue resuscitation so that fracture care may be undertaken in an expeditious manner.

The EAC protocol was developed in the background of a significant volume of work in the area of fracture care in multiply-injured patients. In a landmark paper, Bone et al performed a prospective, randomized study evaluating early (≤ 24 hours after injury) versus delayed (> 48 hours after injury) treatment of femoral shaft fractures (28). They reported more pulmonary complications (acute respiratory distress syndrome (ARDS), pneumonia, and fat embolism), greater hospital costs, and longer LOS in multiply-injured patients treated on a delayed basis. This study was foundational for the philosophy of early total care in which all fractures are treated on an early basis. The authors suggested that early total care allows patients to avoid bed rest and recumbent positioning, which are associated with poor pulmonary toilet and thromboembolic complications (12).

The paradigm of early total care shifted with the introduction of damage control orthopaedics (DCO) (29). In this treatment approach, the initial injury event is described as a "first hit," which primes an inflammatory response (30). Fracture surgery is the "second hit" that aggravates the inflammatory response and predisposes the trauma patient to immune-mediated complications, including systemic inflammatory response syndrome, ARDS, and multiple organ dysfunction syndrome. In order to minimize the "second hit," many authors suggested that definitive fracture surgery should be delayed in favor of temporizing stabilization, such as external fixation (31-33). In particular, subgroups of "borderline" and unstable patients were thought to be vulnerable to the "second hit" phenomenon, and DCO was recommended in these patients (34). In a randomized controlled trial, the European Polytrauma Study on the Management of Femur Fractures study group compared DCO to early definitive treatment of femoral shaft fractures (16).

Among stable patients, DCO was associated with increased time on ventilation but no differences in pulmonary complications. However, in borderline patients, early definitive treatment was associated with higher rate of acute lung injury, with no difference in other pulmonary complications.

The DCO strategy set the stage for EAC. DCO studies emphasized that subgroups of patients require further resuscitation prior to definitive fracture surgery. The main question was which patients require further resuscitation or should be delayed for other reasons. In developing the EAC protocol, multivariable regression analysis was undertaken in a large cohort of patients (n=1,443) with unstable injuries of the thoracolumbar spine, pelvis, acetabulum, and/or femur in order to identify injuries, physiology, or laboratory parameters associated with complications (10). This set of injuries was selected for review due to bed rest and recumbent positioning required prior to fixation, as these activity restrictions portend a common pathway of poor pulmonary toilet and thromboembolic disorders (12). Definitive fracture fixation within 36 hours of injury was recommended in patients with lactate < 4.0 mmol/L, pH ≥ 7.25, or base excess ≥ -5.5 mmol/L (Table 1).

Table 1. Early Appropriate Care protocol

	Timing of fracture fixation	
Parameter*	≤36 hours	>36 hours
pH	≥7.25	<7.25
Base excess (mmol/L)	≥-5.5	<-5.5
Lactate (mmol/L)	<4.0	≥4.0

*Definitive fracture fixation recommended when a patient has responded to resuscitation and any one parameter is met

In the EAC protocol, resuscitation is ongoing and continuously monitored in order to expedite definitive fracture surgery. In a prospective evaluation of the EAC protocol, Vallier et al found that all patients (n=335) achieved adequate resuscitation within 36 hours of injury (11). Definitive fracture fixation was delayed most commonly due to surgeon preference. Patients treated on an early basis experienced fewer complications and shorter length of stay. These findings are similar to the results of other investigators who found that diligent resuscitation after injury promotes early fracture care and limits the use of DCO (35), preventing additional hospital stay and costs associated with a secondary surgery.

4. Cost and outcomes associated with Early Appropriate Care

The EAC protocol was developed in the context of increasing challenges to the viability of trauma care. Specifically, disproportionately frequent care for the underinsured, declining reimbursement from payers, and fewer available subspecialists, represent threats to high quality care provided by Level I trauma centers (4, 27, 36). The EAC protocol not only addresses clinical outcomes but also optimizes efficiency and cost associated with trauma care.

Because the EAC protocol emphasizes the resuscitation process, patients are continuously monitored for adequacy of resuscitation and undergo fracture fixation in an expeditious manner when thresholds for surgery are met. As a result, patients recover and participate with physical therapy after surgery and are on their way to hospital discharge in a time-efficient manner. Indeed, prospective review of the EAC protocol at a Level I trauma center demonstrated that patients undergoing early fixation (≤ 36 hours after injury) had shorter mean intensive care unit (ICU) stays (4.5 vs 9.4 days, $p < 0.0001$) and hospital LOS (9.4 vs 15.3 days, $p < 0.0001$) compared to delayed fixation (>36 hours after injury) (37). The increased LOS for patients treated on a delayed basis translated to a mean loss of revenue of US $6,380 per patient. Furthermore, the authors estimated that the facility revenue loss associated with a hospital bed that could not be used for an additional trauma patient was US $35,330.

Furthermore, the reduction in complications associated with the EAC protocol translates to more cost-effective care. In another study analyzing the financial impact of the EAC protocol, Childs and Vallier found that a complication increased the cost of care by US $4,368 for patients with femur fractures and US $4,304 for patients with pelvis or acetabulum fractures (38). The authors estimated that the reduction in complications associated with implementation of the EAC protocol resulted in annual cost savings of US $2,227,151 to their trauma center. In sum, these data represent compelling support for the use of the EAC protocol, both with regard to improved patient outcomes as well as systems based processes and cost savings.

5. Integrated care pathways in orthopaedic trauma

The EAC protocol represents one example of the increasing trend toward the use of integrated care pathways (ICPs) in orthopaedics and medicine as a whole (5). An ICP standardizes care at specific time points during a treatment course (39). ICPs are dependent on a multidisciplinary approach to achieve predefined outcomes (40). ICPs in trauma, as well as other subspecialties, including total joint arthroplasty and pediatric orthopaedics, have also demonstrated success by reducing complications, hospital LOS, and cost (6, 41-43). As an ICP, the EAC protocol has an established track record for fewer complications, shorter hospital LOS, and lower costs of care (11, 37, 38, 44).

Because multidisciplinary care is necessary for the care of the orthopaedic trauma patient, the opportunities for ICPs in orthopaedic trauma are substantial. Geriatric fracture cares for both low-energy and a high-energy injury is an area of particular interest, given the aging population (45). ICPs have been studied extensively in geriatric hip fracture literature. In a study evaluating co-management of geriatric patients with hip fracture by orthopaedic surgeons and geriatricians, Friedman et al found lower complication rates (30.6% versus 46.3%), shorter LOS (4.6 versus 8.3 days), and shorter time to surgery (24.1 versus 37.4 hours) for co-managed patients compared to standard care (46). In another study, the authors found that this co-managed protocol driven program resulted in significant cost savings, 66.7% of the expected costs nationally (47). Co-management services and treatment protocols optimize the treatment of this fragile population and reduce expenses.

The study of ICPs in high-energy geriatric trauma is more limited. The high-energy geriatric trauma patient represents unique challenges. Due to the physiology and comorbidities specific to the geriatric population (48), this subgroup of trauma patients may benefit significantly from a multidisciplinary approach available through an ICP. Of note, trauma centers that provide effective care for younger adult trauma patients do not necessarily provide the same level of care for geriatric patients. In a retrospective review of the Quebec Trauma Registry, Moore et al showed that risk-adjusted mortality rate for younger adult trauma patients did not necessarily correlate with risk-adjusted mortality rate for geriatric patients (49). These findings suggest that trauma principles utilized for young adult patients may not necessarily apply to geriatric patients.

Furthermore, geriatric trauma patients often present with normal vital signs but are under-resuscitated. In a retrospective study, elderly patients (≥ 65 years old) presenting with normal vital signs were found to have a higher mortality rate compared to other adult patients (17 to 35 years old) presenting with normal vital signs (50). The authors found that mortality associated with a heart rate greater than 90 in elderly patients did not equal mortality in a younger cohort until heart rate was greater than 130. The authors concluded that increased caution is required in geriatric trauma patients and new triage set points of HR > 90 and SBP < 110 mmHg should be considered. Another study examined the impact of increased vigilance in geriatric trauma patients by initiating trauma team activation for all patients age 70 years or more with early aggressive monitoring and resuscitation (51). The authors found significantly reduced mortality after the initiation of this ICP (34.2% versus 53.8%, p=0.003). The importance of recognizing occult shock was emphasized by another study examining the impact of aggressive monitoring and resuscitation in the geriatric population who presented with pedestrian versus motor vehicle mechanism of injury, having multiple fractures, head injury, initial blood pressure less than 150 mmHg, or acidosis (52). In this study, Scalea et al found that early invasive monitoring improved survival in patients older than 65 years-old from 7% to 53%. These studies suggest that recognizing occult shock with early invasive monitoring and providing aggressive resuscitation are key elements of an ICP for high-energy geriatric trauma.

In an example of applying these principles to practice, Bradburn et al established an ICP for geriatric trauma patients (53). Their ICP consisted of identifying high-risk geriatric patients based on injury profile, medical history indicators, and physiologic parameters. After identifying a high-risk patient, markers of resuscitation, including ABG and base excess, as well as ICU admission and geriatric consultation were obtained. Compared to a time period prior to the initiation of this high-risk geriatric protocol, the authors found a significant decrease in mortality after adjusting for confounding variables (OR 0.63, p=0.046). In another study examining the use of the EAC protocol in elderly trauma patients, Reich et al found no difference in complications for patients ≤ 30 years-old (16%) compared to patients ≥ 60 years-old (16%, p=0.84). The authors concluded that the EAC protocol was a viable treatment algorithm for elderly patients but that further study was required to evaluate pre-existing medical conditions. Future study examining the impact of these measures on hospital course and costs of care will further delineate the effect of an ICP in elderly high-energy trauma patients.

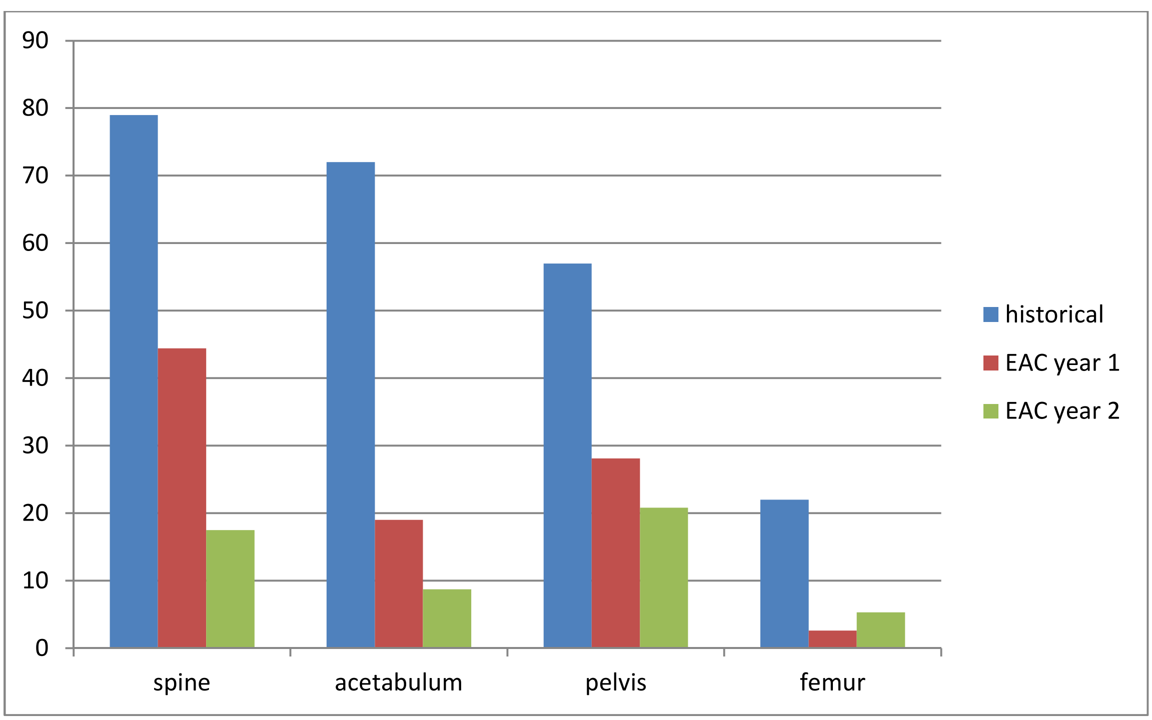
The presence of a head injury in the patient requiring fracture fixation presents a unique challenge for which ICPs could play an important role. Specifically, the timing of definitive fracture fixation in the setting of head injury has been evaluated multiple times in prior literature, but evidence regarding timing of fracture surgery is still unclear (54). The primary concern for early fracture fixation in this cohort of patients is intra-operative hypotension and hypoxia with the potential to cause secondary brain injury (55, 56). Jaicks et al found a trend toward increased hypotension and hypoxia in patients with head injury receiving early fracture fixation (< 24 hours) versus patients receiving delayed fixation (> 24 hours) (57). The implications of these findings were unclear as the study found no difference in mortality or LOS. In another study examining early femur fracture fixation in patients with head injury, Scalea et al found no difference in discharge GCS, mortality, and CNS complications between patients treated on an early basis (≤ 24 hours) and patients treated on a delayed basis (> 24 hours) (58). To our knowledge, high quality prospective evaluation has not been performed.

An ICP in this subgroup of patients with head injury requiring fracture fixation would necessarily involve a multidisciplinary team of neurosurgeons, intensivists, anesthesiologists, and orthopaedic surgeons to determine preoperative monitoring and resuscitation as well as appropriate anesthesia and intraoperative monitoring. Intracranial pressure monitoring in these patients appears warranted in many situations (58). Furthermore, fluid resuscitation supplemented by vasopressors as necessary is required to avoid central nervous system hypoperfusion (59). Future study examining thresholds for surgery and the impact of these thresholds on complications and costs is required for the development of an ICP.

Despite improved clinical outcomes and cost of care associated with ICP, the adoption and use of ICPs may represent a significant barrier (5). Manning et al suggested that adoption of ICP may be limited by a culture of physician autonomy, scarce resources, and conflicting financial incentives between physicians and hospital management. Specifically, in the culture of orthopaedics, independence is highly-valued so with the implementation of an ICP, the surgeon may be reluctant to participate (60). Furthermore, implementing an ICP represents a major undertaking requiring substantial investments of time and money. The lack of resources and time was identified as one of the greatest barriers to collaboration among providers (61). Finally, cooperation between hospital management and physicians required for instituting an ICP may be limited by reimbursement. Hospitals often receive one predefined payment for a patient's hospital stay based on a diagnosis, but the physician may be reimbursed on a per procedure basis, which creates a conflicting financial reimbursement structure (62). These barriers to ICP adoption can be addressed by involving the orthopaedic surgeon in the development and implementation of the ICP (63). This process ensures ownership and buy-in from the orthopaedic surgeon. Furthermore, incentives for participation in the ICP, including financial bonuses and better operative room availability, may also improve physician adoption of an ICP (64). Finally, penalties for non-adherence are viewed as a final resort and may have implications on hospital credentialing and financial reimbursement (65).

Implementation of the EAC protocol was noted to be successful almost at the start and adherence improved steadily over a two-year period (Figure 1) (66).

Figure 1. Delayed fixation by fracture type (66). Comparison of percentage (y axis) of patients treated on a delayed basis depending on the type of fracture: spine, pelvis, acetabulum, or femur. Comparisons are made with a historical group of patients treated for 3 years prior to the EAC protocol implementation and with the first and second years after the implementation of EAC.



In the first three months after implanting the EAC protocol, 22% of fractures were treated on a delayed basis compared to 76% of similar fractures treated historically (Table 2).

Table 2. Fractures treated more than 36 hours after injury in the Early Appropriate Care protocol. 59 fractures in 54 patients were treated on a delayed basis.

Quarter*	Fractures treated with definitive fixation more than 36 hours after injury (%)	Surgeon choice to treat fractures more than 36 hours after injury (%)
1	22.0	16.2
2	27.0	16.2
3	23.0	8.8
4	17.0	11.3
5	10.2	10.2
6	11.8	8.8
7	15.3	5.1
8	10.0	10.0

*Each quarter is defined by a sequential 3 month period
Data are used with permission from the work of Vallier et al (66)

Furthermore, in the last three months of the study period, <10% of fractures were treated on a delayed basis. Of note, all patients met thresholds for resuscitation within 36 hours of injury, but 54 patients were treated on a delayed basis. The most common reason for delayed treatment was surgeon preference (67%). The authors concluded that teamwork from providers as well as institutional support in the form of operating room and equipment accessibility contributed to the rapid adoption of the EAC protocol. The authors also reported that protocol development involved subspecialists from general surgery, critical care, anesthesiology, neurosurgery, and orthopaedic trauma. All involved parties took part in developing details of the protocol and timeline for implementation. This process ensured ownership from all involved physicians. Finally, the authors noted that the EAC protocol contains a simple set of parameters, which assisted in adherence. Although implementation of the EAC protocol was found to be successful, continued study of processes relevant to ICP implementation is needed to optimize care and reduce cost.

6. Conclusion

The regionalization of trauma care centralizes specialists and resources necessary for the optimal care of the trauma patient. In the setting of trauma centers, ICPs show promise in optimizing patient outcomes and improving the efficiency and cost of care. As an example of an ICP, the EAC protocol decreases complications and reduces costs among patients with unstable fractures of the thoracolumbar spine, pelvis, acetabulum, and femur. Certainly, ICPs have been used with success for patient populations within orthopaedics with opportunities available for optimization of these pathways in geriatric trauma and head injury. Further examination of methods for instituting and adopting ICPs represents another avenue for investigation.

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