Novel Central Line Securement Vest to Prevent Mechanical Complications of Tunneled Central Lines: Experience from a Cohort of Pediatric Patients with Intestinal Failure

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Highlights

- The Central Line Securement Vest is a novel medical device for pediatric patients.
- This study presents a cohort of patients with intestinal failure who use the vest.
- We compare rates of multiple adverse events 12 months before and after vest usage.
- The rate of line infections and trauma were lower after vest usage.
- The remaining outcomes were comparable before and after vest usage.

Abstract

Background: Tunneled central lines are used to deliver medications, hydration, and total parenteral nutrition. The current modality for their securement is by a transparent sterile adhesive. Mechanical line traumas, including line fissures, breaks and dislodgements, occur frequently in children. A novel device, the Central Line Securement Vest, was created to protect central lines from mechanical trauma.

Objective: We present here our experience with the device and report its use in patients with intestinal failure treated at our institution.

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Methods: All patients who have used the Central Line Securement Vest at our institution during the last decade were identified. We reviewed the patients' electronic records and compared the rate of line mechanical trauma, line infections, line replacements, Emergency Department (ED) visits, and hospital admissions for a period of 12 months before and after the use of the device.
Results: Ten patients were identified. Four patients had purchased the device at the time of line insertion. Six patients had a period of time of line use before beginning use of the device. The rate of line traumas and infections decreased after using the device: 0.19 ± 0.15 vs 0.05 ± 0.04 trauma/month, pre– vs post–device use, $P < 0.05$. Similarly, the rate of line infections decreased post–device use: 0.18 ± 0.13 vs 0.09 ± 0.06 infections/month, pre– vs post–device use, $P < 0.05$. The rate of line replacements, ED visits, and hospital admissions were similar pre– and post–device use.
Conclusion: We report here our institution's experience with a novel central line securement device designed to protect the line from mechanical trauma.

Keywords: pediatrics, neonatal, infection prevention, nutrition, community/home health

Introduction

Tunneled central lines are used to deliver medications, hydration, and total parenteral nutrition (TPN) to patients with various medical conditions. Tunneled central lines are catheters that are placed into a central vein via a subcutaneous tunnel between the insertion site and the targeted vasculature. Preferred sites for delivery of TPN are the internal jugular vein and subclavian vein, although the femoral veins can be employed as well. These lines terminate in the superior or inferior vena cava depending on the insertion site.[1] In the pediatric population, some of the most common uses include long-term vascular access and pathologies such as states of malabsorption or malnutrition and oncologic or infectious conditions.[2]

The current modality for securement of tunneled central lines, supported by the Centers for Disease Control and Prevention (CDC) guidelines, is by a transparent sterile adhesive[3] (Figure 1).

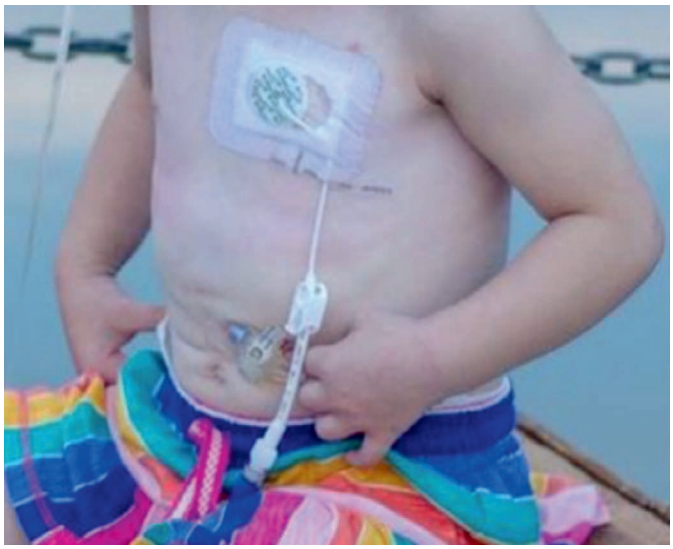

Figure 1. **The current method for the securement of central lines. The central line is protected solely by a clear adhesive dressing. Note that most of the central line is not protected and is subjected to mechanical trauma—friction, torsion, bending, or traction—and to various bodily fluids or environmental agents.**

As a result, a large part of the central line is freely movable and exposed to twisting, flexion, or traction. Mechanical line traumas (including line fissures, breaks, or dislodgements) occur frequently in the pediatric population; young children are generally very mobile, may view the line as a foreign body, and may not understand the importance of protecting the central line.[4] Currently, pediatric tunneled central lines have a failure rate of 29% prior to completion of therapy.[5] Line repair is reported in up to 33% of pediatric tunneled central lines, with a 3-fold increase in sepsis in the 30 days following line repair.[6] Significant mechanical line traumas may necessitate admission to the hospital for the placement of a new line, cause lost treatment or nutrition time, and be responsible for potential loss of access sites, with only 6 vessels generally available for the insertion of tunneled central lines.[7,8] In addition to the risk of bleeding and infections, line traumas place a significant financial burden on our health care system, with an approximate cost of $5000 for a simple repair, $18,000 for a complete line replacement, and $39,000 per episode of sepsis.[9]

To protect tunneled central lines from mechanical trauma, a novel device was manufactured and has been commercially available since 2012 (Central Line Securement Vest, Gus Gear Inc., Valencia, PA). The Central Line Securement Vest was designed by a parent of a child, is manufactured by Gus Gear Inc. and is recommended by gastroenterologists at our hospital. Numerous families in the United States have purchased the device and have been using it over the last decade. However, many more hospitals, medical personnel, and families in the United States and worldwide are not aware of its existence. Moreover, to our knowledge, there have been no published data of its use in patients.

The goal of this report is to describe the Central Line Securement Vest and report its use in patients with intestinal failure treated at our institution. With the inherent biases of a retrospective design, we also present the rates of central tunneled line complications in a small group of patients before and after the use of the device.

Methods

The study was approved by the Institutional Review Board of the University of Pittsburgh and was performed at the Children's Hospital of Pittsburgh, a pediatric quaternary care hospital.

Figure 2. **Central Line Securement Vest. (a) The central line is extruded through one of the four horizontal openings and is secured using one fastener. If the line is connected to an infusion line, the second fastener is placed on the infusion line. The force applied to the infusion line is transmitted to the fasteners and does not exert tension on the central line. (b, white arrow) The protecting layer of the vest is closed using hook and loop tape and protects the entire central line from external contact. (c) The infusion line is seen exiting the vest.**

Description of the Device

The Central Line Securement Vest consists of a textile vest with a series of securement and locking mechanisms (Figure 2). After the central line is secured with the transparent adhesive, as recommended by the CDC,[3] the device is positioned on the chest. The distal portion of the central line is placed through 1 of 4 access orifices of the vest, closest to the location of the line. One locking fastener is attached to the central line. When the central line is attached to the infusion catheter, the other locking fastener is attached to the infusion line. The front flap is then secured with the circumferential hook and loop adhesives, completely enclosing the central line. The infusion line exits through the lateral aspect of the vest. With the 2 locking fasteners in place, any force applied to the infusion line is absorbed by the fasteners and does not reach the central line. With the front flap secured, the central line is protected from mechanical trauma and from various external contaminants. The locking fasteners are removable, allowing for imaging studies to be performed while the vest remains on the patient. The device is intended to be worn at all times and allows TPN infusions during wear. It is machine washable and reusable. The vest can be used in conjunction with existing methods of central line stabilization at the exit site including, but not limited to, subcutaneous and suture-free devices. These devices stabilize the catheter at the exit site but do not provide any securement of the external portion of the catheter, which is frequently damaged in the course of daily activities. The Central Line Securement Vest gives extra securement of the proximal catheter and provides external line securement when used with the previously mentioned devices or those included in commonly used care bundles.

This Central Line Securement Vest has been commercially available since 2012. The manufacturer reports that more than 3000 devices have been sold to families in over 50 different hospital systems since its development.

Patient Population and Data Extraction

All patients who have been using the Central Line Securement Vest at our institution were identified from the Intestinal Failure Clinic's patient population by the nurse practitioner (KA) and the nurse (JAY), who are responsible for the care of these patients. Our Intestinal Failure Clinic prescribes TPN yearly to approximately 60 patients. Of these patients, a total of 10 used the Central Line Securement Vest, and all of these patients were included in our analysis. These patients all had long-standing central lines that were cuffed silicone catheters. One researcher (RSH) reviewed the electronic records of these 10 patients and recorded the following demographic information: patient's date of birth, the age of the patient at the time of central line insertion, the underlying diagnosis, and the date the patient started using the device. The reviewer also recorded all incidents of line-related complications before and after starting use of the device for a maximum period of 12 months. The specific complications included episodes of line mechanical trauma, line infections, line replacements, the number of Emergency Department (ED) visits, and number of hospital admissions. Line mechanical trauma was defined as any mechanical trauma to the central line that necessitated line repair or repositioning, such as fissure in the line, leakage of the line, or dislodgement needing repositioning of the line. These were extracted from the clinical notes and were identified in the medical documentation by either chief complaint or consultation of the venous access team, which at our institution is recorded in the ED note. Line-related infections were identified in the medical records from the ED and inpatient clinical notes and were confirmed by a positive blood culture present during the same time. Line replacements were identified by the specific procedural notes present in the electronic medical record. All the line replacements were recorded, irrespective of the reason for replacement. Some of the identified catalysts for line replacement were as follows: line infections that could not be managed medically, poor blood return of the line, line trauma that could not be repaired either conservatively or with line rewiring, and line dysfunction, including the inability to infuse medications and nutrition. The data could not be discretely recorded because many cases were multifactorial with a multidisciplinary team guiding decision-making. ED visits and hospital admissions were identified in the medical record by note type. All ED visits and hospital admissions during the study period were recorded. The date of initiation of Central Line Securement Vest usage was obtained from the clinical documentation. Our goal was to record line complications for 12 months before

Table 1. **Patient Demographics**

Age at time of data collection	Diagnosis	Age at central line insertion	Age at device use	Length of device use (months to study date)
4 years	Megacystitis, microcolon, hypoperistalsis syndrome	1 month	7 months	>12
5 years	Jejunal atresia	1 month	17 months	>12
15 years	Intestinal aganglionosis	1 year	5 years	>12
3 years	Necrotizing enterocolitis	6 months	9 months	>12
2 years	Gastroschisis	1 months	9 months	>12
3 years	Gastroschisis	2 months	13 months	>12
12 months*	Intestinal atresia	2 months	2 months	10
10 months*	Necrotizing enterocolitis	3 months	3 months	7
4 years*	Intestinal malrotation	3 months	3 months	>12
8 years*	Intestinal aganglionosis	1 month	1 month	>12

*These patients started using the device at the time of central line insertion.

and 12 months after the use of the central line vest. However, in many patients there was a period of less than 12 months between the tunneled central line insertion and onset of Central Line Securement Vest use or from the onset of the Central Line Securement Vest use and data extraction. To account for this, the rate of events per month was obtained by dividing the number of events to the number of months before or after device use. The event rate per month was compared for the period before (pre–device) and after (post–device) use of the device.

Statistical Analysis

Reported data represents the calculated event rate per month. Data are presented as mean ± standard deviation. Data were analyzed using the statistical software SigmaPlot version 14.0 (SyStat Software Inc, Chicago, IL). Normality was assessed using the Shapiro-Wilk test; $P < 0.05$ was considered significant. We compared the event rate per month for line trauma, line infections, line replacements, ED visits, and line-related admissions for pre– vs post–device use by using the one-sided paired *t*-test.

Results

We identified 10 patients from our institution who had been using the device. The characteristics of these patients are presented in Table 1. Four of these patients had purchased the device at the time of tunneled central line insertion. Six patients started using the device after the central line was in place for a period of time, ranging from 3 months to 4 years (Table 1).

We compared the rate of events pre– and post–device use for the 6 patients who had the line for a period of time before wearing the device. The rate of line trauma was lower after the use of the device: 0.19 ± 0.15 vs 0.05 ± 0.04 traumas/month, $P < 0.05$. The rate of line infections was lower after the use of the

Table 2. **Rate of Events per Month Pre– and Post–Device Use in the 6 Patients Who Had a Period of Time with a Central Line in Place Prior to Vest Usage**

	Pre–device use (events/mo), mean ± SD	Post–device use (events/mo), mean ± SD	*P*
Line traumas	0.19 ± 0.15	0.05 ± 0.04	0.02
Line infections	0.18 ± 0.13	0.09 ± 0.06	0.04
Line replacements	0.2 ± 0.3	0.08 ± 0.05	0.09
ER visits	0.6 ± 0.3	0.3 ± 0.2	0.08
Admissions	0.5 ± 0.4	0.2 ± 0.2	0.1

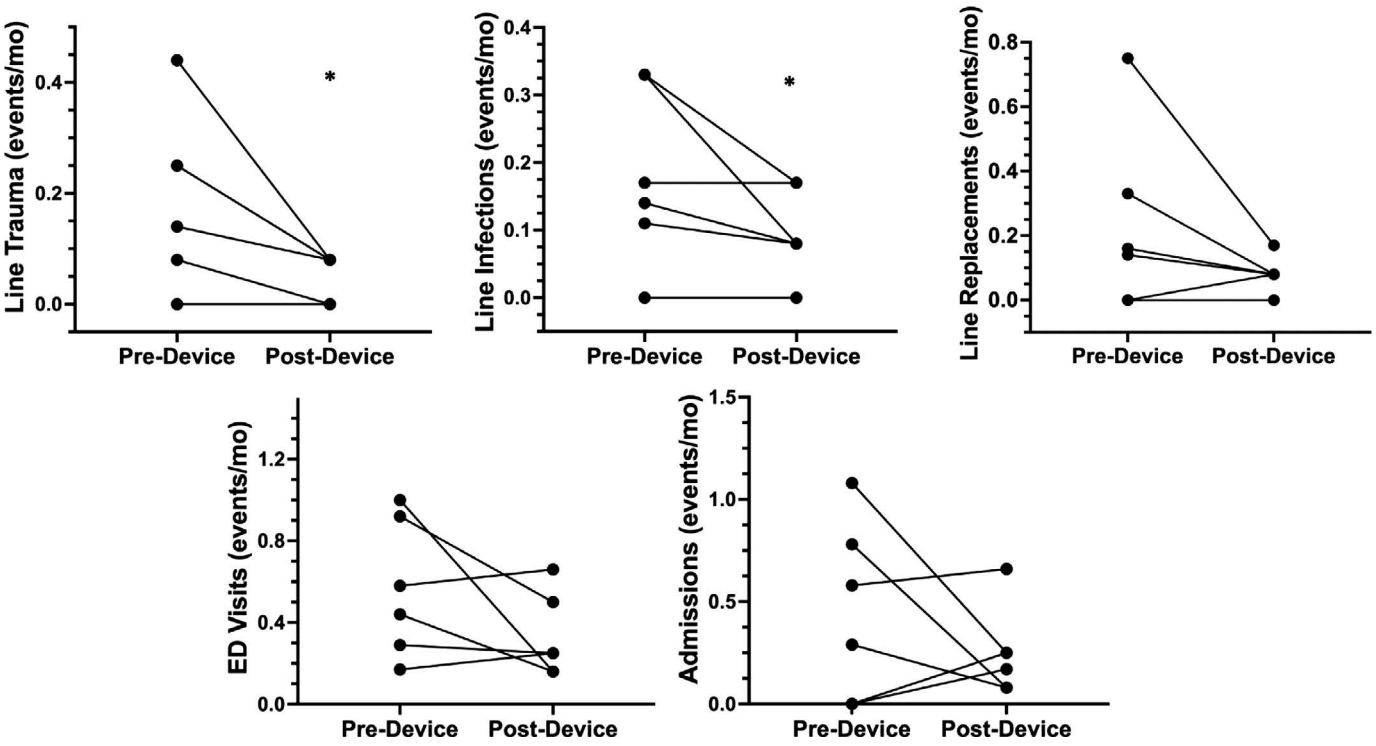

Figure 3. **Events pre– and post–device use: mechanical line traumas, line infections, line replacements, ED visits, and hospital admissions. *$P < 0.05$.**

device: 0.18 ± 0.13 vs 0.09 ± 0.06, $P < 0.05$. The rate of line replacements, ED visits, and hospital admissions was similar pre– and post–device use (Table 2). Figure 3 illustrates the rate of line traumas, line infections, line replacements, ED visits, and hospital admissions for each patient pre– and post–device use (Figure 3).

Table 3 presents the rate of line-related complications, ED visits, and hospital admissions for the 4 patients who started wearing the vest at the time of placement of the tunneled central line. The rate of line traumas in this population was 0.05 ± 0.1 line traumas/month.

Discussion

Central line care and maintenance is a great burden for medical professionals. When patients transition to home TPN, this incredible burden is placed on families with no guarantee of adequate home care. Many pediatric patients with intestinal failure require TPN much of the day. The average TPN patient requires a continuous infusion between 12 and 18 hours for every feed. Depending on severity of illness, patients can require TPN from 2 to 7 times per week.[10] Due to the long periods of time undergoing TPN, there is an increased risk of dislodgement and trauma, as the line is attached to a voluminous bag. To protect the line from mechanical trauma, providers frequently recommend a restriction of activity during infusions. With evidence that children with intestinal failure have gross motor delays,[11] families are faced with the decision to restrict activity and contribute to this potential source of developmental delay or allow some play with the risk of line trauma. Thus, families and clinicians have been seeking a safe, comfortable securement device that would improve long-term patient quality of life by preventing line trauma and preserving central access.

Table 3. **Events per Month Post–Device Use in the 4 Patients Who Started Using the Vest at Time of Central Line Placement**

Events	Post–device use, mean ± SD
Line traumas	0.05 ± 0.1
Line infections	0.8 ± 0.9
Line replacements	0.04 ± 0.09
ER visits	0.4 ± 0.2
Admissions	0.5 ± 0.8

The Central Line Securement Vest was manufactured with the goal of protecting the entire line, from exit to hub, from mechanical trauma without causing pain. To our knowledge, it currently is the only wearable technology designed to protect and secure the central line and to absorb the energy exerted on the infusion line. It is a registered FDA Class I Exempt device and is designed to be used in addition to the adhesive sterile dressing, the currently recommended CDC standard of care.[3] The few other available devices for the protection of tunneled central catheters are either invasive devices attached to the skin, adhesives that can cause medical adhesive–related skin injury, or simple fabric covers that do not secure the line.[12]

We reported our experience with Central Line Securement Vest for a cohort of 10 patients with intestinal failure who are

followed by our Intestinal Care team, 6 of whom have data both before and after use of the device. Our results suggest that the rate of mechanical line trauma decreased after the use of the Central Line Securement Vest compared with the rate of line trauma before the use of the device. Our data also show a decrease in line-related infections after the use of the device. Previous studies report that line trauma requiring repair increases the risk of line infections.[6] The decreased rate of infections observed in patients after wearing the device may be secondary to the decreased rate of line traumas, preventing need for repair. The decrease in line infection may also reflect a decrease in exposure to external contaminants. However, whether this improvement in mechanical trauma and infections is due to the device versus increasing familiarity with the care of the line cannot be answered by our retrospective study. A prospective study assessing mechanical line trauma and infections in patients randomized to wearing the Central Line Securement Vest versus standard of care (the adhesive dressing) is underway and is expected to be completed in August 2022.

The Central Line Securement Vest has been adopted by our gastroenterology specialists and is universally recommended to patients who are discharged from our center after central line placement. However, only some of our patients have purchased the device, many citing financial reasons for not acquiring it. The cost of $149 for smaller vests and $159 for larger vests remains a barrier to improving access to this piece of medical equipment. The financial burden of this device is not insignificant or overlooked by our team. The data generated by studies like this, as well as our ongoing prospective trial, will provide the vital cost-savings information required to work toward insurance coverage for patients and families. Currently, families can purchase the vest directly from the manufacturer and apply for discounts as well as employ benefits such as health savings accounts or flexible spending accounts. Additionally, some hospital systems have seen benefits for their central line patients who use the vest and have started to provide vests to all their patients. These remain temporary and imperfect solutions while we work toward equitable access by generating data that will support future families in obtaining Central Line Securements Vests as a part of their child's care.

Our institution's experience with the device during the last 10 years has been positive. Families who use the device reported that their children experienced fewer line-related complications and a better quality of life outside of the hospital. This first analysis of the use of the Central Line Securement Vest suggests that the use of the device is associated with decreased rates of mechanical line trauma and line-related infections. Of note, during the last year, the device has been slightly modified to be fully MRI compatible and has an anterior closure. All patients in this study have been wearing the original device.

Limitations

This study has several limitations that stem from the inherent biases of the retrospective design. First, the results of our chart review rely on accurate and detailed medical record documentation. We performed a detailed chart review, and it is unlikely, albeit possible, that we have missed data related to line repairs as we thoroughly reviewed the ED and hospital notes for these patients. Second, it is possible that some patients might have sought care elsewhere for some instances of mechanical trauma. This is, however, less likely because our center is the only tertiary care center that covers western Pennsylvania, and our patients usually present to our hospital for care. Third, families that invested in the device may represent a distinct population for the level of care they provide their child in several ways. This could reflect a higher level of health care literacy, a greater allowance of resources for health care expenses, and an overall more attentive level of care. As such, these families may experience fewer central line–related complications regardless of the presence of a wearable central line securement device. Our pre– and post–device use data might have controlled for some of these factors.

In conclusion, we report the use of a novel device designed to protect tunneled central catheters from mechanical trauma. The device is used by numerous families worldwide. In our patient population, the use of the device was associated with a decrease in the rate of mechanical trauma when compared with the rate of mechanical trauma prior to using the Central Line Securement Vest.

Disclosure

The authors have no conflict of interest to disclose.

Acknowledgments

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Editor note

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References

1. Dibb M, Lal S. Home parenteral nutrition: vascular access and related complications. *Nutr Clin Pract*. 2017;32(6):769–776. doi:10.1177/0884533617734788.
2. DiMaria-Ghalili, RA Winlker, MF. Characteristics of a cohort of home parenteral nutrition patients at the time of enrollment in the Sustain Registry. *JPEN J Parenter Enteral Nutr*. 2015;40(8):1140–1149.
3. Alexander, Mary O'Grady, Naomi B Lillian. Guidelines for the prevention of intravascular catheter-related infections. 2011. https://www.cdc.gov/infectioncontrol/pdf/guidelines/bsi-guidelines-H.pdf. Published online July 2011. Accessed May 12, 2021.
4. Cesaro S, Corrò R, Pelosin A, et al. A prospective survey on incidence and outcome of Broviac/Hickman catheter-related complications in pediatric patients affected by hematological and oncological diseases. *Ann Hematol*. 2004;83(3):183–188. doi:10.1007/s00277-003-0796-9.

5. Ullman AJ, Marsh N, Mihala G, Cooke M, Rickard CM. Complications of central venous access devices: a systematic review. *Pediatrics*. 2015;136(5):e1331–1344. doi:10.1542/peds.2015-1507.
6. Hwang FR, Stavropoulos SW, Shlansky-Goldberg RD, et al. Tunneled infusion catheter breakage: frequency and repair kit outcomes. *J Vasc Interv Radiol*. 2008;19(2 Pt 1):201–206. doi:10.1016/j.jvir.2007.08.030.
7. Rey C, Alvarez F, De La Rua V, et al. Mechanical complications during central venous cannulations in pediatric patients. *Intensive Care Med*. 2009;35(8):1438–1443. doi:10.1007/s00134-009-1534-0.
8. Peng C, Monagle P, Newall F. Clinical outcomes of management of CVAD occlusions. *Arch Dis Child*. 2011;96(9):885–887. doi:10.1136/adc.2010.194969.
9. *MySurePayHealth*. Recondo Price Transparency. (n.d.). 2018. https://upmc.msph.recondohealth.net/?legal_name=UPMC+East#/. Accessed February 6, 2022.
10. Bielawska B, Allard J. Parenteral nutrition and intestinal failure. *Nutrients*. 2017;9(5):466. doi:10.3390/nu9050466.
11. So S, Patterson C, Gold A, et al. Neurodevelopmental outcomes of infants with intestinal failure at 12 and 26 months corrected age. *Early Hum Dev*. 2019;130:38–43. doi:10.1016/j.earlhumdev.2018.12.020.
12. Ullman AJ, Cooke M, Rickard CM. Examining the role of securement and dressing products to prevent central venous access device failure: a narrative review. *JVA*. 2015;20(2):99–110. doi:10.1016/j.java.2015.03.001.

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