Evolution of Process and Outcome Measures during an Enhanced Recovery after Thoracic Surgery Program

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Background: A time course analysis was undertaken to evaluate how perioperative process-of-care and outcome measures evolved after implementation of an enhanced recovery after thoracic surgery (ERATS) program.

Methods: Outcome and process-of-care measures were compared between patients undergoing major elective thoracic surgery during a 9-month pre-ERATS implementation period to those at 1–3, 4–6, and 7–9 months post-ERATS implementation. Outcome measures included length of stay, the 30-day readmission rate, 30-day emergency department visits, and minor and major adverse events. Process measures included first time to activity, out-of-bed, ambulation, fluid diet, diet as tolerated, as well as removal of the first and last chest tube, epidural, patient-controlled analgesia, and Foley and intravenous catheters.

Results: In total, 704 patients (352 pre-ERATS, 352 post-ERATS) were included. Mobilization-related process measures, including time to first activity (16.5 vs. 6.8 hours, p<0.001), out-of-bed (17.6 vs. 8.9 hours, p<0.001), and ambulation (32.4 vs. 25.4 hours, p=0.04) saw statistically significant improvements by 1–3 months post-ERATS implementation compared to pre-ERATS. Time to Foley removal improved by 4–6 months post-ERATS (19.5 vs. 18.2 hours, p=0.003). Outcome measures, including the 30-day readmission rate and emergency department visits, steadily decreased post-ERATS. By 7–9 months post-ERATS, both minor (18.2% vs. 7.9%, p=0.009) and major (13.6% vs. 4.4%, p=0.007) adverse events demonstrated statistically significant improvements. Length of stay trended towards improvement from 6.2 days pre-ERATS to 4.8 days by 7–9 months post-ERATS (p=0.06).

Conclusion: The adoption of ERATS led to improvements in multiple process-of-care measures, which may collectively and gradually achieve optimization of clinical outcomes.

Keywords: Enhanced recovery after surgery, Postoperative care, Outcome and process assessment, Interrupted time series analysis, Thoracic surgery

Introduction
Enhanced recovery after surgery (ERAS) has been successfully implemented in multiple surgical domains, including colorectal, cardiac, and pediatric surgery, to optimize surgical outcomes through evidence-based protocols in perioperative care [1-3]. This has led to improvements in postoperative recovery for patients [4]. However, enhanced recovery after thoracic surgery (ERATS) pathways have not been extensively studied. Limited evidence suggests that strategies for preoperative optimization, minimization of fasting time, prophylactic thromboprophylaxis, optimized anesthetic and analgesic techniques, and postoperative early mobilization and chest drain removal can decrease morbidity and length of stay (LOS) in thoracic surgery patients [5].

Identifying how standardization of interventions can influence clinical outcomes can help to understand the elements that lead to a successful enhanced recovery program [6]. In the Donabedian model of healthcare quality assess-
ment, processes are described as components of care that work to deliver the desired outcome [7]. The impact of different perioperative processes of care on patient outcomes, such as postoperative morbidity and LOS, remains unclear. Studies have demonstrated that benefits from enhanced recovery protocols occur in proportion to adherence to processes by patients and providers [8,9], suggesting that effective ERATS implementation requires a change in behaviors among key stakeholders towards optimizing perioperative processes and ultimately clinical outcomes.

Improvements in process-of-care and clinical outcome measures may not occur immediately as individual and organizational barriers to change-management first need to be overcome [10,11]. Understanding how these measures evolve individually and/or concurrently during implementation of ERATS pathways can help identify areas that require further improvement. Awareness of these patterns can also inform how to monitor progress and performance in ERATS and adjust practices accordingly. In this study, a time course analysis was undertaken to evaluate how postoperative process-of-care measures and clinical outcome measures evolved over time following division-wide implementation of ERATS at a high-volume thoracic surgical center in Ontario, Canada.

Methods

ERATS program

The ERATS program at The Ottawa Hospital was approved by the Ottawa Health Science Network Research Ethics Board (OHSN-REB approval no., 20170687) as a quality improvement initiative designed to advance patient outcomes, satisfaction, and reduction in cost of care. The Division of Thoracic Surgery incorporated ERATS elements into existing clinical pathways over an implementation period of 3 months. These updated pathways were developed through multiple literature reviews and group consensus by a multidisciplinary team involving surgeons, anesthesiologists, nurses, research staff, pharmacists, educators, nutritionists, and administrative staff during regularly scheduled meetings. Multiple educational sessions were held for allied healthcare staff during the implementation period to ensure that they could effectively adopt these protocols.

Patient education material was created as an integral part of the program to engage patients more actively in enhanced recovery pathways. Among other information, this material consisted of an overview of expectations for shorter LOS, patient diary for daily goals, smoking cessation, exercise prior to surgery, and education on the benefits of early mobilization and enteral feeding.

The ERATS pathways spanned the continuum of pre-admission unit care to discharge day care and included components such as a chronic obstructive pulmonary disease treatment algorithm, standardized anesthetic protocols, early ambulation and oral feeding, and automatic thoracic physiotherapy referrals. For example, the postoperative day 1/discharge day pathways for video-assisted thoracoscopic surgery (VATS) simple wedge resection included intake and output assessments every 12 hours, monitoring of chest tube/drainage system every hour, deep breathing and coughing exercises every hour, patient teaching, and discharge planning. Full pathways for various thoracic procedures can be found online [12].

Study population

The aim of this 21-month prospective, longitudinal study spanning from September 2017 to May 2019 was to evaluate process and outcome measures related to ERATS. The requirement for informed consent was waived by the Ottawa Health Science Network Research Ethics Board for this study as it used data collected as part of a quality improvement initiative. The study period consisted of a 9-month pre-ERATS implementation period (control group), followed by a 3-month implementation period, and a 9-month post-implementation period, which was divided into 3 tri-monthly cohorts (1–3 months, 4–6 months, and 7–9 months post-ERATS implementation) and formed the experimental group. The 3-month implementation period consisted of training and adoption of ERATS protocols for all staff within the division, and was thus excluded from the analysis to facilitate a comparison of pre- and post-implementation.

During the pre- and post-implementation periods, all adult patients (age >18 years) undergoing a major elective thoracic procedure including VATS or open lung resection (wedge resection, segmental resection, lobectomy, pneumonectomy), laparoscopic or open esophagectomy, gastrectomy, or paraesophageal hernia repair, met the study inclusion criteria. Patients were excluded if their procedure was aborted, incomplete, or an emergency surgery, if they were not admitted at least overnight, or if they were unable to speak English or French.
Data collection

Process-of-care data were recorded prospectively by nursing staff trained in ERATS protocols and were tracked on an ongoing monthly basis. Using preformatted medical record forms, documentation of process-of-care measures spanned the recovery unit, observation unit, and the ward. Outcome measures were documented by the Ottawa Thoracic Morbidity and Mortality system, which represents a standardized approach to identify mortality and both the presence and severity of all adverse events (AEs) after surgery [13].

The outcome measures collected for this study included hospital LOS measured in days, minor (Clavien-Dindo grade I–II) and major (Clavien-Dindo grade III–IV) AEs as defined by the Thoracic Morbidity and Mortality system [13], readmission within 30 days, and post-discharge visits to the emergency department (ED) within 30 days. Process-of-care measures, which represent components of care that work to deliver the desired outcome, were measured in time to describe how they changed with ERATS implementation beyond the traditional measurement of adherence. These included time to first activity, time to out-of-bed, time to ambulation, time to first fluids, time to first diet, time to discontinuation of Foley catheter, time to discontinuation of the intravenous (IV) line, time to discontinuation of the IV saline lock, time to epidural removal, time to patient-controlled analgesia (PCA) removal, time to first chest tube removal, and time to last chest tube removal. The 12 process-of-care measures are defined in Table 1.

Statistical analysis

To assess how outcome and process measures changed over time after introducing ERATS, data from the pre-ERATS group were compared to the 3 trimonthly post-ERATS implementation groups. Continuous variables were compared using the Kruskal-Wallis rank sum test for multiple comparisons with Dunn post-hoc analysis. Categorical data were compared using the Pearson chi-square test. All p-values for multiple comparisons were corrected using the Holm-Bonferroni method.

Results

A total of 352 patients were enrolled in each of the pre- and post-ERATS implementation periods and were included in this study (Table 2). The mean age of participants was 65.5 years in the pre-implementation group and 64.5 years in the post-implementation group. The most frequently performed surgical procedures throughout the 2 periods were VATS lobectomy (n=237), sublobar resection (n=223), and laparoscopic hiatal hernia repair (n=64).

In the evaluation of the 12 postoperative process-of-care measures, statistically significant differences in time to first activity, time to ambulation, and time to out-of-bed were seen in the first three months post-ERATS implementation compared to the control group (Table 3). Median time to first activity decreased from 16.5 to 6.8 hours (p<0.001) while time to ambulation decreased from 32.4 to 25.4 hours (p=0.04). Time to out-of-bed decreased from 17.6 to 8.9 hours (p<0.001). Statistical significance for all 3 variables was maintained throughout the subsequent post-ERATS groups. Time to discontinuation of Foley catheter

Table 1. Definition of different postoperative process-of-care measures in enhanced recovery after thoracic surgery

| Process-of-care measure                  | Description                                                                 |
|-----------------------------------------|-----------------------------------------------------------------------------|
| Time to first-activity                  | Time when the patient was first able to “dangle”, that is to sit on edge of the bed for >5 minutes |
| Time to out-of-bed                      | Time when the patient was first able to get out of bed into a chair (with or without assistance) |
| Time to ambulation                      | Time when the patient was able to get in and out of bed without assistance   |
| Time to first fluids                    | Time when the patient first drank clear fluids or water (not when it was ordered) |
| Time to first diet                      | Time when the patient first ate a diet as tolerated (not when it was ordered) |
| Time to first chest tube removal        | Time when the first chest tube was physically removed                       |
| Time to last chest tube removal         | Time when the last chest tube was physically removed (recorded if >1 chest tube present) |
| Time to PCA removal                     | Time when IV PCA was no longer running                                      |
| Time to epidural removal                | Time when the epidural was physically removed                               |
| Time to discontinuation of Foley        | Time when the catheter was first physically removed                         |
| Time to discontinuation of IV           | Time when the last IV was physically removed                                |
| Time to discontinuation of IV saline lock| Time when IV was no longer running                                          |

PCA, patient-controlled analgesia; IV, intravenous.
decreased from 19.5 hours pre-ERATS implementation to 18.2 hours (p=0.003) by 4–6 months post-ERATS and 18.3 hours in 7–9 months post-ERATS (p=0.003). No other statistically significant differences were identified, but all other process-of-care measures except for time to epidural removal trended toward improvement by the end of the post-ERATS period.

The median hospital LOS was 3 days across all groups and did not change throughout ERATS adoption. The mean values were also calculated. The mean overall LOS for all procedures demonstrated borderline statistically significant differences between groups (p=0.06), having declined from 6.2 to 4.8 days by 7–9 months post-ERATS implementation (Table 4). Likewise, in patients who underwent VATS lobectomy and sublobar resection, LOS steadily decreased from 4.3 to 3.3 days (p=0.34) and from 3.4 to 2.2 days (p=0.13), respectively, by the end of the post-ERATS period.

Thirty-day ED visits and readmissions did not demonstrate statistical significance (Table 4). However, both showed a decreasing trend from 11.6% to 7.9% (p=0.26) and 5.1% to 2.6% (p=0.27), respectively, by 7–9 months post-ERATS compared to control. Significant differences in the number of minor and major AEs were seen between pre-ERATS and 7–9 months post-ERATS, with minor AEs decreasing from 18.2% to 7.9% (p=0.009) and major AEs decreasing from 13.6% to 4.4% (p=0.007). Prior to this, the number of minor AEs was higher 1–3 months post-ERATS than pre-ERATS (31.7% versus 18.2%, p=0.002).

### Discussion

To date, most papers evaluating enhanced recovery in thoracic surgery have been limited to a small number of procedures [14]. Given that only a small proportion have additionally been comparative, the current study is an important addition to the literature that describes a division-wide adoption of ERATS spanning a diverse number of procedures through comparing processes and outcomes before and after adoption of the program. We observed immediate and progressive change to process-of-care measures following ERATS implementation and a delayed improvement in clinical outcome measures. Process changes appeared safe without eventual worsening of AEs or readmissions, while leading to gradual reduction in LOS. These findings are consistent with others demonstrating that adherence to ERAS protocols cumulatively increases over time [15,16], and optimization of patient outcomes in ERATS is likely a sum of multiple alterations in perioperative processes.

Among the 12 process-of-care measures, those related to mobilization including time to first activity, ambulation, and out-of-bed showed immediate changes in the first 3 months post-ERATS implementation and were sustained in the following 6 months. Active prevention of physical decline through early mobilization is known to effectively shorten the hospital stay and reduce postoperative morbidity [17,18]. Due to its benefits in preventing thromboembolic events, muscular and cardiorespiratory deconditioning,
Table 3. Comparison of process-of-care measures in hours between the pre-ERATS implementation period and post-ERATS implementation periods\(^{a,b}\)

| Process measures | Pre-ERATS | 1–3 mo post-ERATS | 4–6 mo post-ERATS | 7–9 mo post-ERATS | Kruskal-Wallis |
|-----------------|-----------|-------------------|-------------------|-------------------|---------------|
|                 | No.   | Median (IQR)      | No.   | Median (IQR)      | No.   | Median (IQR)      | No.   | Median (IQR)      | χ\(^2\) | p-value |
| First activity  | 341   | 16.5 (13.8)       | 120   | 6.8 (13.1)        | <0.001 | 100   | 7.2 (13.0)        | <0.001 | 91     | 6.8 (12.2)       | <0.001 | 45.2 | <0.001 |
| Ambulation      | 327   | 32.4 (43.7)       | 116   | 25.4 (24.4)       | 0.04   | 105   | 25.8 (23.8)       | 0.01   | 95     | 25.7 (26.5)      | 0.03   | 12.3 | 0.007  |
| Out-of-bed      | 344   | 17.6 (13.1)       | 119   | 8.9 (14.3)        | <0.001 | 102   | 8.4 (13.8)        | <0.001 | 95     | 9.5 (12.6)       | <0.001 | 39.5 | <0.001 |
| D/C Foley       | 276   | 15.5 (50.0)       | 98    | 18.8 (9.2)        | 0.08   | 80    | 18.2 (3.7)        | 0.003  | 71     | 18.3 (3.7)       | 0.05   | 13.9 | 0.003  |
| First diet      | 330   | 20.8 (12.4)       | 111   | 20.3 (6.6)        | 0.12   | 102   | 20.2 (6.9)        | 0.11   | 95     | 20.0 (6.3)       | 0.05   | 8.4  | 0.04   |
| First fluids    | 328   | 5.7 (10.7)        | 118   | 4.5 (4.8)         | 0.12   | 99    | 5.1 (5.7)         | 0.12   | 93     | 5.6 (6.3)        | 0.08   | 6.8  | 0.08   |
| D/C first chest tube | 243 | 45.0 (47.5)       | 99    | 44.0 (27.8)       | 0.08   | 86    | 25.8 (26.5)       | 0.08   | 78     | 34.1 (26.4)      | 0.03   | 6.6  | 0.09   |
| D/C last chest tube | 155 | 70.1 (71.5)       | 32    | 65.8 (34.3)       | 0.08   | 42    | 47.7 (29.1)       | 0.08   | 33     | 67.2 (25.5)      | 0.03   | 5.3  | 0.15   |
| Epidural-removal | 96    | 77.7 (52.7)       | 17    | 52.3 (46.7)       | 0.08   | 7     | 51.0 (12.0)       | 0.08   | 13     | 85.2 (28.2)      | 0.54   | 8.3  | 0.04   |
| PCA removal     | 188   | 41.5 (24.3)       | 46    | 43.6 (26.0)       | 0.08   | 47    | 43.1 (26.0)       | 0.08   | 38     | 40.5 (29.4)      | 0.11   | 1.1  | 0.78   |
| D/C IV          | 312   | 70.8 (81.7)       | 112   | 67.5 (72.7)       | 0.08   | 104   | 69.7 (71.9)       | 0.08   | 94     | 68.0 (64.5)      | 0.08   | 1.8  | 0.62   |
| DC IV saline lock | 329 | 29.1 (29.2)       | 115   | 24.9 (23.5)       | 0.08   | 105   | 24.6 (28.3)       | 0.08   | 91     | 28.3 (28.3)      | 0.08   | 6.4  | 0.09   |

ERATS, enhanced recovery after thoracic surgery; IQR, interquartile range; D/C, discontinuation; PCA, patient-controlled analgesia; IV, intravenous.
\(^{a}\)Dunn post-hoc analysis was used to compare each trimonthly post-ERATS group to the pre-ERATS group if the Kruskal-Wallis test was significant. Post-hoc p-values were adjusted according to the Holm-Bonferroni method. \(^{b}\)Significant values \((p<0.05)\) are bolded.

Table 4. Comparison of outcome measures between the pre-ERATS implementation period and trimonthly post-ERATS implementation periods\(^{a,b}\)

| Variable          | Pre-ERATS | 1–3 mo post-ERATS | 4–6 mo post-ERATS | 7–9 mo post-ERATS | Kruskal-Wallis |
|-------------------|-----------|-------------------|-------------------|-------------------|---------------|
|                   | No.   | Value             | No.   | Value             | No.   | Value             | No.   | Value             | χ\(^2\) | p-value |
| LOS (day)         |        |                   |                   |                   |               |                   |                   |                   |               |           |
| Overall           | 352    | 6.2±9.6           | 126   | 5.7±10.1          | 112   | 4.5±4.3           | 114   | 4.8±10.4          | 7.5    | 0.06    |
| VATS lobectomy    | 107    | 4.3±3.4           | 53    | 4.2±2.9           | 45    | 5.2±4.2           | 32    | 3.3±1.6           | 3.4    | 0.34    |
| Sublobar resection| 118    | 3.4±3.3           | 40    | 2.7±2.3           | 35    | 2.7±3.3           | 30    | 2.2±1.5           | 5.6    | 0.13    |
| 30-day ED visits  | 11.6   | (41/352)          | 12.7  | (16/126)          | 0.75  | 6.2 (7/112)       | 0.10  | 7.9 (9/114)       | 0.26   |           |
| 30-day readmission| 5.1    | (18/352)          | 3.2   | (4/126)           | 0.37  | 3.6 (4/112)       | 0.50  | 2.6 (3/114)       | 0.27   |           |
| Any AEs           | 31.8   | (112/352)         | 45.2  | (57/126)          | 0.007 | 37.5 (42/112)     | 0.27  | 12.3 (14/114)     | <0.001 |           |
| Minor AEs         | 18.2   | (64/352)          | 31.7  | (40/126)          | 0.002 | 23.2 (26/112)     | 0.24  | 7.9 (9/114)       | 0.009  |           |
| Major AEs         | 13.6   | (48/352)          | 13.5  | (17/126)          | 0.97  | 14.3 (16/112)     | 0.86  | 4.4 (5/114)       | 0.007  |           |

Values are presented as mean±standard deviation or % (number). Values are presented as mean±standard deviation or % (number), unless otherwise stated.

ERATS, enhanced recovery after thoracic surgery; LOS, length of stay; VATS, video-assisted thoracoscopic surgery; ED, emergency department; AE, adverse event.

\(^{a}\)The Kruskal-Wallis test was used to compare LOS, which was a continuous variable. The p-values for proportional variables represent comparisons to the pre-ERATS group. \(^{b}\)Significant values \((p<0.05)\) are bolded.
while stimulating gastrointestinal recovery, adherence to early mobilization has been a strongly enforced element of most enhanced recovery programs and may explain why changes in mobilization occurred early [19-23]. Moreover, care coordination around mobilization in particular requires multidisciplinary collaboration among allied health providers regarding the patient’s functional status, thereby facilitating more timely physiotherapy consultations and coordinated task management [17]. In our institution, for example, a continuum of providers is involved in facilitating activity in patients who undergo simple wedge resections beginning from the post-anesthesia care unit to discharge day [12]. During transport to their rooms after surgery, patients are required to ambulate to the chair, and later helped to bed if possible. Despite initial concerns over possible falls or injuries, time to ambulation also improved immediately following ERATS implementation. A previous 6-year study of a dedicated early ambulation protocol in thoracic surgery also reported improvements in patient outcomes with no related injuries or falls, demonstrating the feasibility of early mobilization without loss of safety [24].

Improvements in process-of-care measures may be interdependent with each other. In our study, changes in the time to discontinuation of Foley catheterization were seen by 4–6 months post-ERATS implementation. Limiting Foley catheter use in ERAS is a major goal in reducing AEs such as urinary tract infections and bladder damage. Early discontinuation has been found to facilitate ease of patient mobility and ambulation [25], whereas reducing bed rest can decrease the risk of postoperative urinary retention, and as a result, the duration of Foley catheter use [26]. Concerns regarding urinary retention at our institution eventually diminished over time as this interdependency was emphasized. Provider education in ERATS may benefit from describing the interactions between different process-of-care measures and reinforcing the importance of adhering to not just one but multiple processes.

Other process-of-care measures that did not significantly change throughout the post-ERATS implementation period included timing of chest tube, PCA, and epidural removal. Despite the push for standardized pathways for chest tube management, there remains insufficient evidence to make strong recommendations regarding the timing of removal [27]. Consequently, some variations may exist between providers based on individual considerations such as the adopted volume and air leak thresholds [28]. Decisions around PCA and epidural removal are also challenging to standardize due to differences in surgical indication, type of anesthesia, and the risk of suboptimal pain control. The goal should be to optimize pain control earlier in the postoperative period to enable mobilization, promote better recovery, and decrease the risk of chronic persistent postoperative pain. Although there is limited evidence for optimal analgesic techniques under fast-tracking for thoracic patients [29], implementing a standardized, multimodal approach to shorten analgesia duration and enhancing oral rather than IV administration without significantly compromising pain control may be most beneficial in ERATS.

Despite an increase in minor AEs immediately after ERATS implementation, there was a significant reduction in all AEs by 7–9 months post-ERATS, demonstrating that perioperative processes in ERATS can be safely optimized without increasing eventual harm to patients. Temporary worsening of minor AEs after introducing ERATS may indicate initial learning curve effects or adjustments to existing processes, as has been previously noted [16].

Since LOS was measured in days, changes in scales of less than 1 day may not have been demonstrated using median values. The mean LOS for all procedures and for pulmonary resection steadily decreased throughout the 9-month post-implementation period compared to the control group. Other ERATS studies have shown variable changes in the duration of hospital stay, usually with a magnitude of 1 day [6,24,30]. In a prior study of enhanced recovery with early ambulation in thoracic surgery, Khaidhar et al. [24] demonstrated no statistically significant differences in LOS between early and late post-ERAS implementation despite notable improvements in ambulation speed and performance. LOS also significantly decreased when comparing the overall post-implementation period to pre-implementation. Thus, while significant improvements in the duration of hospital stay should not be expected as an immediate occurrence after ERATS adoption, it can occur and be maintained once changes in process measures mature and progress.

This study has several limitations. First, heterogeneity in the case mix for gastrectomy and open lobectomy was apparent, which may have contributed to some differences in process and outcome measures. However, the difference in case mix was relatively small, with these 2 procedures accounting for less than 8% of patients. Importantly, this is a consequence of a division-wide implementation of enhanced recovery protocols spanning multiple procedures and hundreds of patients, which itself is a considerable achievement that allowed for a description of the overall evolution of processes and outcomes. Second, secular
trends in the data, such as natural improvements in outcomes over time, are a limitation inherent to the study design. This limitation is likely minimal given that the study period was relatively short. Moreover, secular trends may reflect gradual behavioral changes in providers and patients with ERATS adoption, which do not necessarily need to be mitigated for the purpose of this study. Third, multiple linear regression analysis was not conducted in this study as its primary focus was on the trends in process and outcome measures over time. Future studies may include such an analysis to control for possible confounders and determine the direct relationship between individual processes and outcomes while keeping in mind limitations such as multicollinearity. Lastly, missing data was a limitation that partially reflected the variable N numbers for different process measure items. However, the ability to capture data for multiple procedures was a considerable achievement that was made possible by excellent commitment from numerous providers, especially nursing staff who were not part of the research team. Although some missing data were inevitable, this study was able to describe overall trends in processes and outcomes upon a large-scale, divisional adoption of ERATS.

In conclusion, this study demonstrated that ERATS implementation leads to immediate and progressive evolution of process-of-care outcomes, which preceded improvements in clinical outcomes such as LOS without eventual worsening of AEs. Providers can be reassured when improvements in patient outcomes in ERATS are initially slow and should monitor alterations in process measures to inform and further improve ERATS adoption.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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