Randomized clinical trial comparing double-lumen tube and EZ-Blocker® for single-lung ventilation

K. Ruetzler1*, G. Grubhofer1, W. Schmid1, D. Papp1, S. Nabecker1, D. Hutschala1, G. Lang2 and H. Hager1
1 Department of Cardiothoracic and Vascular Anesthesia and Intensive Care Medicine and 2 Department of Thoracic Surgery, Medical University of Vienna, Waehringer Guertel 18-20, 1090 Vienna, Austria; received from the Outcomes Research Consortium
* Corresponding author. E-mail: kurt.ruetzler@meduniwien.ac.at

Editor’s key points
- A new EZ bronchial blocker was compared with double-lumen tube (DLT) for providing single-lung ventilation (SLV).
- Forty patients undergoing thoracic surgery were randomized to one of two groups.
- EZ-Blocker® (EZ) provided comparable quality of lung collapse to DLT, but took longer for its placement.
- EZ will be an efficient alternative for SLV where DLT cannot be used.

Background. In several clinical situations, lung separation and single-lung ventilation (SLV) is essential. In these cases, the double-lumen tube (DLT) is the most widely used device. Bronchial blocker such as Univent or Arndt Blocker serves as an alternative. The EZ-Blocker® (EZ; AnaesthetIQ B.V., Rotterdam, The Netherlands) is a new device promising to exceed clinical performance of DLT. The aim of this study was to assess the clinical performance of EZ in comparison with conventional left-sided DLT.

Methods. Forty adult patients undergoing elective thoracic surgery requiring thoracotomy and SLV were included in this study. The patients were randomly assigned to one of two groups: EZ (combined with conventional 7.5 or 8.5 mm single-lumen tube) or DLT (37 or 39 Fr left-sided DLT). Time for intubation procedure and time to verification of the correct position of EZ or DLT using fibreoptic bronchoscopy (FOB) were recorded. After surgery, a thoracic surgeon rated the quality of collapse of the lung (1–3 on a three-level scale).

Results. Time for intubation using DLT 85.5 (54.8) s was significantly faster (P=0.001) than using EZ 192 (89.7) s, whereas time for bronchoscopy was not significantly different (P=0.556). Conditions of surgery were rated equally [DLT 1.3 (0.6) vs EZ 1.4 (0.6), P=0.681].

Conclusions. Although time for intubation was longer with the EZ, the device proved to be an efficient and easy-to-use device. The EZ is a valuable alternative device to conventional DLT. Verification of the correct position of the EZ by FOB seems to be obligatory. This study was registered at http://www.clinicaltrials.gov (identifier: NCT01171560).

Keywords: airway; intubation, tracheal; surgery, thoracic

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Several clinical situations and procedures, such as pulmonary, thoracic, and cardiac surgery, require single-lung ventilation (SLV). The most commonly used device for this is the double-lumen tube (DLT).1 2 Bronchial blockers (BBs), such as Univent torque control blocker,3 wire-guided endobronchial Arndt Blocker,4 5 and the Cohen Flex-tip Blocker,6 commonly serve as an alternative to DLT. The efficiency to achieve lung isolation for elective thoracic surgery is comparable between the DLT and BB.2 7

When comparing DLT and BB, positioning of DLT is faster and dislocation during surgery is rare, but introducing can be impossible in some cases.8 DLT is more rigid compared with a single-lumen tube (SLT), making it more difficult to place and increasing the risk for potential traumatic injury.9 10 In situations when DLT cannot be placed or positioned, BB can be the favourable alternative.11 BB causes less postoperative sore throat (ST) and hoarseness12 13 compared with DLT; however, BB requires more time for placement and added suction due to its smaller lumen to achieve collapse of the non-ventilated side of the lung.7 Both DLT and BB require the use of fibreoptic bronchoscopy (FOB),14–16 and consequently, a certain level of experience is a prerequisite.17

The EZ-Blocker® (EZ; AnaesthetIQ B.V. and IQ Medical Ventures B.V., Rotterdam, The Netherlands) is a new BB promising to exceed the clinical performance of DLT.18 The EZ is manufactured with a Y-shaped distal end. Both distal ends are fitted with an inflatable cuff and a patent central lumen. The EZ is inserted through the designated port on the enclosed multiport adapter attached to a conventional SLT of adequate size (7 mm inner diameter minimum). The multiport adapter is designed to connect to a ventilation device and contains two additional upper ports, one for the blocker itself and the other for the bronchoscope. The EZ is brought into position in the trachea, with the one distal end introduced into the left bronchus and the other distal end in the right mainstem bronchus. The cuffs are inflated.

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separately, allowing each side of the lung to be ventilated independently of the other.

To our knowledge, no prospective randomized clinical trial has assessed the performance of this new device in a clinical setting. The aim of this study was to compare the performance of EZ with DLT as follows.

We recorded time to intubation, time required for bronchoscopy, and the effect on oxygenation during SLV to evaluate the functionality of the device. Furthermore, we recorded the incidence of side-effects, such as ST and hoarseness.

Methods

The study was approved by the Ethics Committee of the Medical University Vienna (Ref. 096/2010) and registered at clinicaltrials.gov (identifier: NCT01171560). After informed written consent, 40 adult patients undergoing elective thoracic surgery requiring thoracotomy and SLV were included in this study.

Exclusion criteria were as follows: age <18 or >90 yr; ASA >III; BMI >45; any contraindications against placing a DLT; thoracic surgery within the last 4 weeks; systemic infection or suspected tuberculosis; and patients with a previous diagnosed or suspected difficult airway.

The patients were randomly allocated to one of two groups: EZ or DLT. Randomization (1:1) was based on computer-generated codes that were kept in sequentially numbered opaque envelopes.

Patients in both groups were premedicated with 7.5 mg midazolam p.o. In the operating theatre, all patients received standard monitoring including invasive arterial blood pressure monitoring with an invasive arterial cannula, heart rate and ECG, peripheral oxygen saturation (SpO2), end-tidal capnography, ventilation peak and plateau pressures, and continuous spirometry.

All patients were preoxygenated for at least 2 min. For induction, all patients in both groups received midazolam 0.04 mg kg$^{-1}$, fentanyl 2 μg kg$^{-1}$, propofol 1.5 mg kg$^{-1}$, and rocuronium 0.6 mg kg$^{-1}$.

All patients were placed in a supine position and intubated by an experienced anaesthesiologist exactly 2 min after receiving neuromuscular block.

Patients assigned to the DLT group were intubated using a left-sided DLT (Bronchocath, left-sided; Rüsch, Kernen, Germany) of an adequate size (37 Fr for women and 39 Fr for men). DLT was introduced into the trachea using conventional direct laryngoscopy. After passing the vocal cords, the DLT was rotated 90° towards the left and advanced until slight resistance was met.

Patients assigned to the EZ group were intubated using a conventional SLT (Mallinckrodt, Athlone, Ireland) of an adequate size [7.5 mm intraluminar diameter (ID) for women and 8.5 mm ID for men] using conventional direct laryngoscopy. The multiport adapter was placed on the SLT, and the EZ was inserted through one of the two upper ports on the multiport adapter with completely deflated cuffs. The EZ was advanced until slight resistance was met, suggesting the position between the end of the tracheal tube and the main carina has been reached, with the two distal ends of the EZ protruding into the left and right main bronchi (Fig. 1).

Time to initial tube placement (ITP) was defined as the time from passing of the tube (DLT or SLT) past the vocal cords to satisfactory placement in the endobronchial lumen has been achieved (DLT or EZ).

After completing the intubation procedure, the correct position in the trachea or mainstem bronchus (as applicable) was verified and signs of bronchial injuries were recorded using FOB in all cases. For patients undergoing SLV using the EZ, fiberoptic bronchoscope was inserted in the free port of the multiport adapter. The cuffs on the distal extensions of the EZ were inflated under direct visual guidance to ensure functionality of the device. The volume of air required to inflate the relevant cuff was documented.

The head of the patient was then carefully held in position and the body of the patient was brought into a lateral position to the side where the lung is ventilated. For this change of position, the EZ balloon or the bronchial cuff of DLT was deflated to reduce the risks of traumatic complications. After positioning, the correct position of DLT or EZ was reassessed using FOB.

During SLV, pressure-controlled ventilation with a peak pressure of 20–25 cm H2O and a PEEP of 5 cm H2O was used on the dependent lung. Initially, 100% oxygen was used. As early as possible, oxygen in air (FIO2) was gradually reduced by 10%, while aiming to keep the partial pressure of oxygen in arterial blood (PaO2) above 13.3 kPa.
possible, end-tidal carbon dioxide ($\text{EtCO}_2$) was stabilized at 4.6–5.3 kPa and sevoflurane was used to maintain anaesthesia (mean alveolar concentration = 1.0). During surgery, the sevoflurane dose was adjusted to keep the depth of anaesthesia, assessed by bispectral index, between 40 and 50 (A-2000 Monitor, Aspect Medical Systems, Leiden, The Netherlands).

As SLV became required during the operation, the EZ balloon or bronchial cuff of DLT was inflated. After opening of the pleura and direct examination of the lungs, the thoracic surgeons rated the extent of collapse of the lung, which is relevant for performing atraumatic surgery as follows:

1. excellent (complete collapse with perfect surgical exposure),
2. fair (total collapse, but still some residual air in the lung), and
3. poor (no collapse, or partial collapse with interference in surgical procedure).

The use of this straightforward classification was based on a previous study by Campos and Kernstine.7

The anaesthetist performing the intubation evaluated their subjective feeling of difficulty in the use of the respective devices (1, very easy; 2, easy; 3, medium; 4, worse; 5, impossible).

Twenty minutes before the end of surgery, all patients received paracetamol 1 g i.v. After the end of surgery, all patients were extubated carefully in the operating theatre when they met the extubation criteria. For postoperative pain therapy, all patients received fractional piritramide 3 mg i.v.

Decline in oxygen saturation during surgery, defined as a decrease in peripheral oxygen saturation ($SpO_2$) below 90%, and sex, age, weight, height, ASA score, and Mallampati score were documented.

An independent investigator, blinded to the group assignment of the patients, asked the patients 24 h after surgery about the incidence and subjective intensity of ST and hoarseness.

ST was defined as continuous throat pain22 and was classified in two categories (yes or no). If the answer was yes, the intensity of ST was graded 1–3 as follows13 23:

1. mild (pain with deglutition),
2. moderate (pain present constantly and increasing with deglutition), and
3. severe (pain interfering with eating and requiring analgesic medication).

Postoperative hoarseness was defined as an acoustic quality that was different from the previous voice quality of the patients13 and was classified into two categories (yes or no). If the answer was yes, the intensity of hoarseness was graded 1–3 as follows:

1. noticed by patient
2. obvious to observer
3. aphonia.

### Statistical analysis

The data were anonymized for statistical analysis. For descriptive statistics, we used Sigmaplot, Version 11.0, Systat Software Inc. Analysis of time for intubation was done using Student’s t-test. We used the Mann–Whitney rank-sum test to analyse ratings, ST, and hoarseness.

Differences in the incidence of ‘successful blind insertion’ and ‘malposition after repositioning’ were analysed using Fisher’s exact test.

The power was calculated according to the assumption that in the time frame of 5 min, we will need 300 s to place a DLT with a standard deviation (SD) of 60 s and assuming a gain of a minute being clinically relevant. Thus, based on the power of 0.95 and an $\alpha$ error of 5%, we would find a statistically significant difference with 26 patients. Owing to the difficult setting and the potential risk of failure to intubate despite careful preparation, we decided to enroll 40 patients into the trial.

### Results

Forty patients, 20 patients in each group, were enrolled in this study. One of the patients (in the EZ group) had to be excluded from the analysis due to a protocol violation. Of the remaining participants, no significant differences between the two groups with respect to patient characteristic data were detected (Table 1).

The placement of DLT took mean (so) (range) 85 (55) (22–188) s and was significantly faster than using EZ [192 (90) (51–430), $P < 0.001$].

Time for FOB took 155 (92) (90–220) s for DLT and 127 (60) (41–278) s for EZ. The difference was not statistically significant ($P=0.556$), nor clinically relevant.

Tracheal intubation was successful in all patients of both groups. Successful blind insertion, defined as successful placement of an airway device in the correct position in the

### Table 1. Patient characteristics and surgical procedure. Data are number of patients or mean (so). DLT, double-lumen tube; EZ, EZ-Blocker

<table>
<thead>
<tr>
<th></th>
<th>DLT (n=20)</th>
<th>EZ (n=19)</th>
<th>$P$-value</th>
</tr>
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<tbody>
<tr>
<td>Included</td>
<td>20</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Drop out</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Age (yr)</td>
<td>61.9 (14.4)</td>
<td>54.4 (20.2)</td>
<td>0.339</td>
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<tr>
<td>Weight (kg)</td>
<td>79.4 (19.4)</td>
<td>74.0 (13.4)</td>
<td>0.407</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>172.9 (11.4)</td>
<td>170.2 (8.9)</td>
<td>0.409</td>
</tr>
<tr>
<td>ASA (1–5)</td>
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<td>2.0 (0.7)</td>
<td>0.125</td>
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<tr>
<td>Mallampati (1–4)</td>
<td>2.1 (0.6)</td>
<td>1.9 (0.6)</td>
<td>0.306</td>
</tr>
<tr>
<td>Lung biopsy</td>
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<td>1</td>
<td></td>
</tr>
<tr>
<td>Lobectomy</td>
<td>8</td>
<td>5</td>
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<tr>
<td>Segmentectomy</td>
<td>6</td>
<td>7</td>
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<tr>
<td>Pleural decortication</td>
<td>4</td>
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trachea/mainstem bronchus without help of FOB, was successfully performed in 18 of 20 cases (success rate 90%) in the DLT group and in four of 19 cases (success rate 21%) in the EZ group. Difference between the two devices in the frequency of successful blind insertion was significant to the advantage of DLT \((P<0.001)\).

In the EZ group, 9.3 (2.8) ml air was necessary for blocking the mainstem bronchus without any remaining air leak.

After moving patients from a supine position to a lateral position, the correct position of DLT or EZ was verified using FOB. In three cases using DLT and seven cases using EZ, malposition was found and corrected. Difference in malposition after repositioning between the two devices was not significant \((P=0.155)\).

There was no significant difference \((P=0.244)\) in the decline of oxygenation \([2.9 (5.8) \text{ min in the DLT group and } 2.1 (8.0) \text{ min in the EZ group}]\) during SLV, defined as \(Sp_{90}\), \(<90\%\).

After surgery, thoracic surgeons rated lung collapse (Table 2). Conditions of surgery and lung collapse using DLT were rated 1.3 (0.6) and EZ was rated 1.4 (0.6) \((P=0.681)\). The subjective feeling of the anaesthetists about the difficulty of intubation was rated 1.5 (1.1) (DLT) and 1.8 (1.0) (EZ, \(P=0.163\)) (Table 3).

On the day after surgery, the incidence of ST was 45% in DLT (nine out of 20 cases) and 47% (nine out of 19 cases) in the EZ group. Subjective intensity of ST was not significantly different \([DLT 1.3 (0.5) \text{ vs } EZ 1.2 (0.4), P=0.649]\) (Table 4).

### Table 2 Quality of lung collapse rated by thoracic surgeons. DLT, double-lumen tube; EZ, EZ-Blocker®; 1, excellent (complete collapse with perfect surgical exposure); 2, fair (total collapse, but the lung still has residual air); 3, poor (no collapse, or if there is partial collapse with interference in surgical procedure).

<table>
<thead>
<tr>
<th></th>
<th>DLT (n = 20)</th>
<th>EZ (n = 19)</th>
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<tbody>
<tr>
<td>1</td>
<td>15</td>
<td>13</td>
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<tr>
<td>2</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mean ((\omega))</td>
<td>1.3 (0.6)</td>
<td>1.4 (0.6)</td>
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<tr>
<td>Median</td>
<td>1</td>
<td>1</td>
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</table>

### Table 3 Subjective rating for using the respective device by anaesthetists. DLT, double-lumen tube; EZ, EZ-Blocker®; 1, very easy; 2, easy; 3, medium; 4, worse; 5, impossible.

<table>
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<th></th>
<th>DLT (n = 20)</th>
<th>EZ (n = 19)</th>
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<tr>
<td>1</td>
<td>15</td>
<td>10</td>
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<td>2</td>
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<td>3</td>
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<tr>
<td>3</td>
<td>0</td>
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<tr>
<td>4</td>
<td>1</td>
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<tr>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Mean ((\omega))</td>
<td>1.5 (1.1)</td>
<td>1.84 (1.0)</td>
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<tr>
<td>Median</td>
<td>1</td>
<td>1</td>
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</table>

The incidence of hoarseness was 35% in DLT (seven out of 20 cases) and 42% (eight out of 19 cases) in the EZ group. Subjective intensity was not significantly different \([DLT 1.3 (0.5) \text{ vs } 1.1 (0.4), P=0.613]\) (Fig. 2).

There were no serious complications resulting from the placement of the device or FOB in either group. No patient required re-intubation and we did not encounter any anatomical features that could interfere with the results of this trial.

### Discussion

The results of our study are consistent with results obtained in similar studies assessing BB: initial time to intubation takes longer with EZ than with DLT, and malpositioning of EZ during intraoperative repositioning of the patient is more likely than with DLT.

The first application of a BB was reported in 1936 by Magill \cite{24} and consisted of a rubber tube with an inflatable cuff at the distal end. Alternatively, a vascular embolectomy catheter like Fogarty was frequently used. \cite{25} The first modern BB was reported by Inoue and colleagues \cite{3} in 1982 and is called the ‘Univent tube’. The Univent tube was modified in 2001 and is currently available as ‘Torque Control Blocker Univent’. In 1999, Arndt and colleagues \cite{5} reported the first clinical application of a new BB called an ‘Arndt wire-guided blocker’. Nowadays, the Arndt BB is also used increasingly in paediatric anesthesia, also in combination with a laryngeal mask instead of an SLT. \cite{26,27} In 2005, Cohen \cite{6} described a new BB called the ‘Cohen Flex-tip Endobronchial Blocker’. The most recent BB has only been available for the past few months and is called the Coopdech. \cite{28} In a recent study by Narayanaswamy and colleagues, \cite{29} three BBS provided equivalent performance compared with left-sided DLT.
during left-sided open or video-assisted thoracoscopic surgical (VATS) procedures. Narayanaswamy and colleagues found that placing a BB was more time-consuming and intraoperative repositioning was required more often compared with DLT, which matches our findings.

In a previous study by Campos and Kernstine,7 ITP of DLT took 128 s, Univent BB took 158 s, and Arndt BB took 214 s. In our study, ITP of DLT took 85 s and EZ took 192 s. Consequently, EZ tube placement seems to take similarly as long as for Arndt and Univent BB, the difference seems to be clinically not relevant. Mungroop and colleagues18 reported a mean time for EZ of 70 s. The reason for this difference is most likely due to experience of the individual anaesthetists, a conclusion also drawn by Campos and colleagues17 in another study.

The results of our study demonstrate that the placement of the device without the aid of FOB (blind insertion) is less successful for BB than for DLT. Malposition of airway devices after turning to the lateral position is a familiar problem and may result in a failure to sufficiently collapse the lung and an increased risk of hypoxia during SLV.30 In the study by Campos and Kernstine, malposition after turning patients to a lateral position occurred in one of 16 cases using Univent BB, in five of 32 when using Arndt BB, and never in the application of DLT (0/16). In our study, malposition of DLT occurred in three of 20 and seven of 20 when using EZ. In summary, dislocation of EZ after repositioning occurs more frequently, but if recognized early, the position can easily be corrected by using FOB, even in lateral positions.7 As a consequence, we support the recommendations of Cohen,11 Campos,16 Brodsky and Lemmens,15 Slinger,14 and Benumof12 of the obligatory use of an FOB in the placement of SLV devices to ensure correct positioning and functionality of these devices.

In a study by Campos and colleagues,17 surgeons rated the lung collapse from excellent to poor. Although Campos described better results for DLT than the tested BB, lung collapse in our study was achieved equally well using DLT and EZ. The difference in these findings may be due to our study assessing lung collapse only in open thoracotomies, whereas Campos and colleagues also used VATS.

The anaesthesiologists in our study rated their subjective feeling of how complicated the use of the respective devices was, suggesting comparable ease of use for DLT and EZ.
ST and hoarseness are well-known postoperative complaints, especially after tracheal intubation.\textsuperscript{33}

The incidence of hoarseness after tracheal intubation is about 50%.\textsuperscript{13, 34} It was demonstrated that the tracheal tube size is a common risk factor for higher incidence of ST and hoarseness.\textsuperscript{22, 23, 35} The incidence of an ST after conventional tracheal intubation varies from 14.4\% to 60%.\textsuperscript{12, 13, 22, 34} The wide range of incidence may be due to different skill and experience levels of the performing physician. In a recent study by Zhong and colleagues,\textsuperscript{12} the incidence of ST of different BB was assessed (Coopdech 13\%, Arndt 20\%, and Univent 30\%). Interestingly, we did not find any significant differences in the incidence of ST and hoarseness in our study. An explanation for this may be that in our study, all intubations were performed by the same experienced anaesthetist.

In several clinical situations, intubation using DLT appears difficult and sometimes impossible.\textsuperscript{26, 27} In these situations, we agree with Campos\textsuperscript{38} that the safest alternative to enable SLV in an anticipated or known difficult airway is the combination of SLT and any of the independent BBs.

We also agree with Campos and colleagues\textsuperscript{17} that regardless of whether a DLT or BB was chosen, it is important that the practitioner is familiar with the device.

In some clinical situations, postoperative ventilation may be required and if using a DLT, exchange to SLT is indicated. The exchange from DLT to SLT may be compounded by swelling caused by the DLT. Even the use of a tube exchanger does not guarantee success in the exchange of a DLT to an SLT.\textsuperscript{39} In such a clinical setting, the application of a BB is indicated.

In conclusion, the EZ is an efficient, successful, and easy-to-use airway device to provide SLV to enable thoracic ventilation when the practitioner is familiar with the device.

Conflict of interest
None declared.

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