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Transition of Extremely Preterm Infants from Birth to Stable Breathing: A Secondary Analysis of the CORSAD Trial

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Keywords
Extremely preterm infants · Stabilization · Respiratory support · Positive pressure ventilation

Abstract
Objective: Exploratory secondary analysis of the CORSAD trial compared a new resuscitation system (rPAP) to the standard T-piece system. This analysis focused on the subgroup of infants who were not intubated in the delivery room. The aim was to compare the use of noninvasive positive pressure ventilation (PPV), oxygen saturation, and Apgar scores for the two resuscitation systems during the 30-min intervention period. ***Methods:*** This is secondary analysis of CORSAD trial using data from the intervention period in the delivery room. Infants in the original randomized system groups were divided into intubated and nonintubated groups. For nonintubated breathing infants, we compared demographics, the use of PPV, Apgar scores, and oxygen saturation at 5 and 10 min after birth. Generalized linear models were applied to calculate the risk difference and odds ratio with 95% CI between the two groups. ***Results:*** Among nonintubated infants, the use of PPV repeatedly (defined as PPV with at least 1 min of spontaneous breathing between PPV cycles) was less frequent in the rPAP group (26.8% vs. 43.3%, %RD −16.5, 95% CI [−31.7 to −1.1], *p* 0.04). The use of PPV after 5 min of age was also less common in the rPAP group (23.2% vs. 38.8%, %RD −15.6, 95% CI [−30.7 to −0.8], *p* 0.04). There were no statistically significant differences in Apgar scores or oxygen saturation levels between the groups. ***Conclusion:*** In the CORSAD trial, less PPV was needed to establish stable breathing in extremely preterm infants using the rPAP compared to using the standard T-piece without significant difference in Apgar scores or oxygenation.

Introduction

It has been established that avoiding intubation and mechanical ventilation of extremely preterm infants after birth decreases the risk of BPD and death in this group of vulnerable infants [1]. CPAP and noninvasive ventilation in the delivery room (DR) are therefore recommended for extremely preterm born infants [2–4].

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In recent years, focus has shifted from an aggressive resuscitation approach to a more gentle, physiological approach when stabilizing preterm infants in the DR. Delivering CPAP from start, avoiding positive pressure ventilation (PPV) if possible, physiological cord clamping, and tactile stimuli are now becoming the gold standard and are appearing in the newest international guidelines [3, 4]. There has also been an increasing interest in improving interfaces and devices used in the DR. The recently completed CORSAD trial showed that using a new resuscitation system, now marketed as the rPAP (Inspiration Healthcare, UK), for respiratory support for extremely preterm infants after birth, decreased DR intubations compared with using the standard T-piece system that has been used for decades [5]. The rPAP is a variable flow resuscitator and differs from the T-piece in two important aspects. First, it is pressure stable and has substantially lower imposed work of breathing (iWOB) compared to the T-piece [6]. Second, it can be used with a nasal interface instead of a face mask.

Based on the results of the CORSAD trial, clear conclusions cannot be made if the reduced intubation rate was related to the rPAP pressure stability and lower iWOB, the nasal interface, or the combination. The clinical importance of iWOB during stabilization is not known and further clinical studies are needed to resolve the issue. Using a face mask as an interface has been debated in recent years due to problems related to mask leakage and airway obstruction [7–9]. Furthermore, concerns have been raised that pressure on the face can trigger the trigeminocardiac reflex leading to apnea and glottic closure [10, 11]. Meta-analyses comparing use of face mask to nasal interface have concluded that the nasal interface may be beneficial but that more studies are needed [12, 13].

In this exploratory secondary analysis of the CORSAD trial, we focused on the subgroup of infants that were not intubated in the DR. The aim was to compare the use of noninvasive PPV and vital parameters for the two resuscitation systems during the 30-min intervention period.

Methods

Study Design

This is exploratory secondary analysis of the CORSAD trial, using data from the 30-min intervention period in the DR. The infants in the randomized system groups were further divided into intubated and nonintubated groups at the end of the intervention period.

We focused on the nonintubated infants divided according to the randomized system groups. The aim was to compare all the variables related to the stabilization in the DR during the 30-min intervention period for the two resuscitation systems.

Infants were randomized when vaginal birth or C-section was imminent. The intervention followed international resuscitation guidelines and a clinical management protocol [2]. The resuscitation strategy was identical for the groups except that a nasal interface was used in the rPAP group and a face mask in the T-piece group. If the infant reached stable breathing with no further need for PPV, the intervention with the randomized system ended after 10 min and further respiratory support provided according to local protocol. Randomization and collection of data was in a secure electronic case report form. A dedicated study sheet was used during the intervention by a nurse and data at 72 h of age were collected from patient records by local PI or study nurse. Further details on the intervention and investigation plan can be found in the primary analysis of the CORSAD trial [5]. The CORSAD trial was approved by the Swedish regional Ethical Committee (Dnr. 2015/927-31/4). Parents to included patients received both oral and written information about the study prior to signing an informed consent.

Variables of Interest

The use of PPV was divided in 3 categories and compared: use of PPV at all, use of PPV repeatedly, and use of PPV after 5 min of age. All three were prespecified variables and were collected during the intervention directly to a data collection sheet.

Use of PPV at all was defined as any PPV given during the intervention period. Use of PPV repeatedly was defined as use of noninvasive PPV with at least 1 min of spontaneous breathing between PPV cycles. Use of PPV after 5 min was defined as any PPV given after 5 min of age. Starting and adjusted peak inspiratory pressures (PIPs), Apgar scores, SpO2, and FiO2 at 5 and 10 min after birth were also compared.

Statistical Analysis

Analysis was performed using the intention-to-treat principle. This post hoc analysis was not included in the CORSAD trial statistical analysis plan and no power analysis was performed. As first step, all variables related to DR stabilization were compared. *t* test or nonparametric test was used when appropriate for continuous variables after normality test. Binary variables and demographic variables were compared by χ^2 or Fisher's exact test, as appropriate.

Generalized linear model with identity link was applied to estimate the risk difference (RD) with 95% confidence intervals. To calculate odds ratio (OR) with 95% confidence intervals, generalized linear model with logit link was applied. Confounders included in the multivariate analysis were the same chosen in the original CORSAD trial for the stratified randomization (gestational age, antenatal steroid, and site). All analysis were 2-sided and *p* value was considered significant when less than 0.05. We used the statistical program STATA version 14.2 (StataCorp, College Station, TX, USA) to perform the analyses.

Results

In total, 250 infants were randomized before birth and four infants were stillborn. One patient had treatment limitations before 5 min, no further PPV, not intubated, died after the end of intervention. This infant was removed from the post hoc analysis giving a total of 123

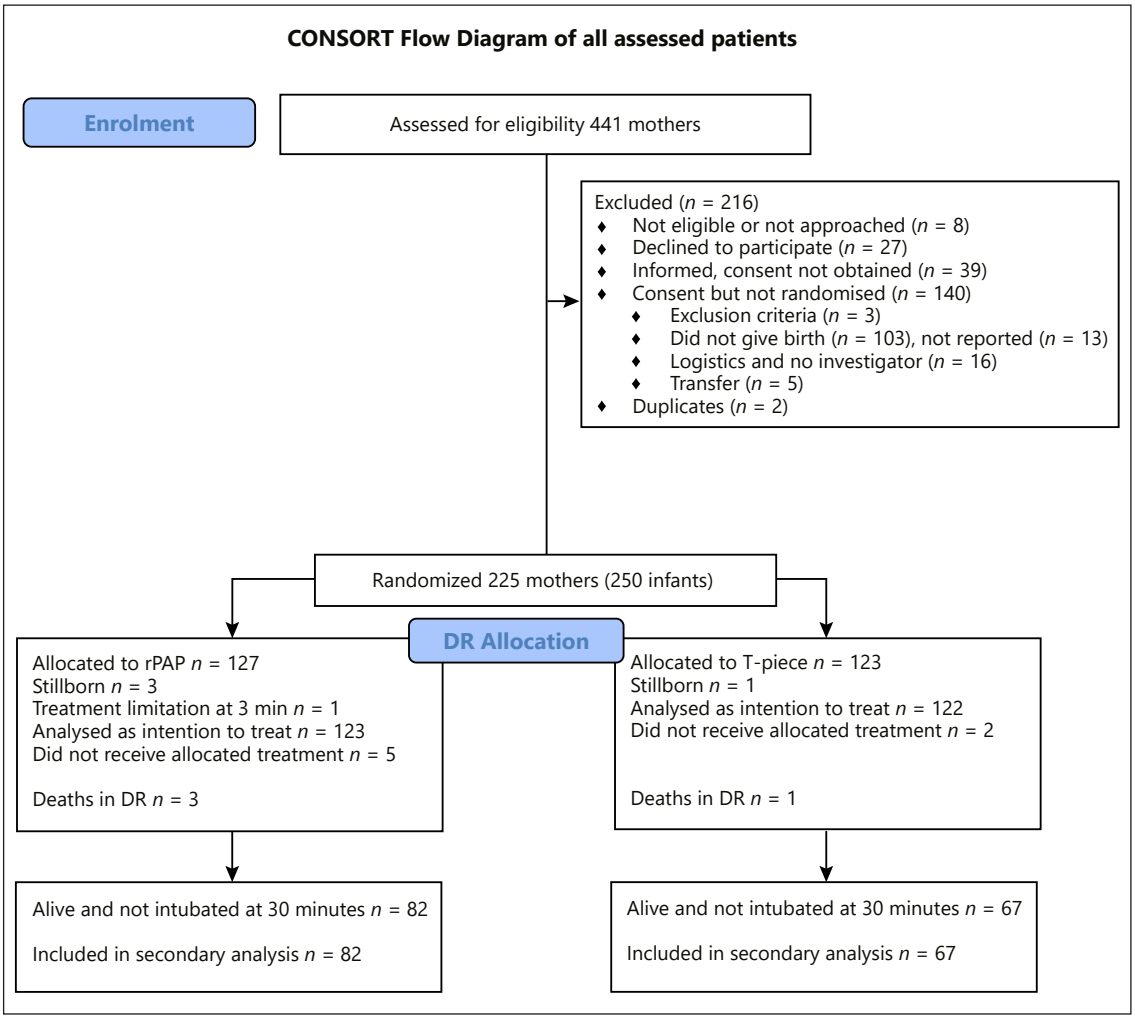

Fig. 1. CONSORT diagram of patient recruitment, randomization, retention, and inclusion for secondary analysis.

infants in the rPAP group and 122 in the T-piece group. At 30 minutes, 82/123 in the rPAP group and 67/122 in the T-piece group were not intubated or dead (Fig. 1).

Baseline characteristics for the nonintubated infants compared for the two systems are shown in Table 1 and comparisons for intubated versus nonintubated can be found in online supplement 1 (for all online suppl. material, see www.karger.com/doi/10.1159/000528754). There were no significant differences in demographics or maternal characteristics between the 2 groups. All variables related to DR stabilization such as number of infants breathing at birth, PPV use, PIP and positive end-expiratory pressure levels, Apgar scores, and saturation at 5 and 10 min are presented in Table 2. RDs were calculated and shown in Table 3.

PPV used repeatedly was less in the rPAP group (26.8% vs. 43.3%, RD in % −16.5, 95% CI [−31.7 to −1.1], p 0.04). PPV after 5 min of age was also less common in the rPAP group (23.2% vs. 38.8%, RD in % −15.6, 95% CI [−30.7 to −0.8], p 0.04). At 5 min of age, 48.8% of the infants in the rPAP group and 34.3% in the T-piece group had reached SpO2 >80%. At 10 min of age, 89.0% in the rPAP group and 86.6% in the T-piece group had reached >85%. The differences in saturation between the groups were not statistically significant.

Table 4 shows crude ORs and adjusted ORs; T-piece was used as reference group. Even after adjusting for gestational age, antenatal steroid, and site, the odds of requiring repeatedly PPV or PPV after 5 min were significantly lower in the rPAP group.

Table 1. Background information

	Nonintubated ($n = 149$)		p value
	rPAP ($n = 82$)	T-piece ($n = 67$)	
Gestational age, mean (SD), weeks	26.14 (1.2)	26.10 (1.3)	0.88
Multiple pregnancy			
Twins, *n* (%)	16 (19.5)	12 (17.9)	0.74
Triplets, *n* (%)	0 (0)	1 (1.5)	
Female, *n* (%)	40 (48.8)	35 (52.2)	0.67
Birthweight, mean (SD), g	846.1 (192.9)	863.0 (195.8)	0.60
Antenatal steroids			1.00
Complete, *n* (%)	69 (84.2)	57 (85.1)	
Incomplete, *n* (%)	13 (15.9)	10 (14.9)	
Caesarean delivery, *n* (%)	60 (73.2)	45 (67.2)	0.42
General anesthesia, *n* (%)	4 (4.9)	1 (1.5)	0.38
Caesarean section for fetal concern, *n* (%)	36 (43.9)	30 (44.8)	0.92
Clinical chorioamnionitis, *n* (%)	22 (26.8)	16 (23.9)	0.68
Pre-eclampsia/eclampsia, *n* (%)	19 (23.2)	16 (23.9)	0.92
Premature rupture of membranes, *n* (%)	26 (31.7)	22 (32.8)	0.88
Ablatio, *n* (%)	12 (14.6)	7 (10.5)	0.45

Table 2. Explanatory variables, analysis with all infants alive and breathing spontaneously at 30 min

	rPAP (82)	T-piece (67)	p value
Breathing upon arrival, *n* (%)	61 (74.4)	52 (77.6)	0.65
Time to heart rate >100 bpm, mean (SD)[2], min	1.36 (1.8)	1.22 (1.4)	0.60
Time to stable breathing, mean (SD)[1], min	4.2 (3.3)	3.7 (3.2)	0.35
Apgar 5 min, median (IQR)	8 (7–9)	8 (7–9)	0.51
Apgar 10 min, median (IQR)	9 (8–10)	9 (8–10)	0.31
PPV used at all, yes, *n* (%)	61 (74.4)	48 (71.6)	0.72
PPV repeatedly, yes, *n* (%)	22 (26.8)	29 (43.2)	**0.04**
PPV used after 5 min, yes, *n* (%)	19 (23.2)	26 (38.8)	**0.05**
PIP at start, median (IQR)	20 (20–20)	20 (20–20)	0.90
Need to increase PIP, *n* (%)	10 (12.2)	11 (16.4)	0.46
PEEP level at start in cmH_2O, median (IQR)	5 (5–5)	5 (5–5)	0.43
PEEP level at 5 min in cmH_2O, median (IQR)	5 (5–6)	5 (5–7)	0.27
PEEP level at 10 min in cmH_2O, median (IQR)	5 (5–6)	5 (5–7)	0.49
SpO2 at 5 min, median (IQR)	80 (68–90)	75 (60–88)	0.22
Missing data, *n* (%)	4 (5)	3 (4)	
Ratio SpO2/FiO2 at 5 min, median (IQR)	210 (150–283)	188 (146–266)	0.18
Missing data, *n* (%)	4 (5)	2 (3)	
SpO2 at 10 min, median (IQR)	93 (91–95)	93 (90–94)	0.09
Missing data, *n* (%)	3 (3.6)	2 (2.9)	
Ratio SpO2/FiO2, median (IQR)	307 (225–380)	300 (190–317)	0.16
Missing data, *n* (%)	3 (3.6)	2 (3)	

PIP, peak inspiratory pressure; PPV, positive pressure ventilation; PEEP, positive end-expiratory pressure. [1]No PPV given after that time. [2]Confirmed with either ECG or pulse oximeter.

Discussion

This secondary analysis of the CORSAD trial data investigated the effect of the intervention in the DR and outcomes that reflect on the infants cardiac and respiratory stability during resuscitation. We focused the analysis on the infants who established stable spontaneous breathing after stabilization with either the rPAP or the T-piece and were not intubated/died in the DR. Infants who were stabilized with the rPAP received less PPV after 5 min compared to the infants stabilized with the T-piece. The need for repeated PPV was also less frequent in the

Table 3. RD of nonintubated infants at 30 min in the DR

	rPAP (82)	T-piece (67)	%RD (95% CI)	*p* value
PPV at all, *n* (%)	61 (74.4)	48 (71.6)	2.7 (−11.6 to 17.1)	0.71
PPV after 5 min, *n* (%)	19 (23.2)	26 (38.8)	−15.6 (−30.7 to −0.8)	**0.04**
PPV repeatedly, *n* (%)	22 (26.8)	29 (43.3)	−16.5 (−31.7 to −1.1)	**0.04**
SpO2 >80% at 5 min, *n* (%)	40 (48.8)	23 (34.3)	14.5 (−1.2 to 30.1)	0.07
SpO2 >85% at 10 min, *n* (%)	73 (89.0)	58 (86.6)	2.45 (−8.1 to 13.1)	0.65

Table 4. OR and adjusted OR for nonintubated infants

	OR, crude	aOR[1]	*p* value of aOR
PPV at all	1.15 (0.56–2.37)	1.10 (0.52–2.33)	0.80
PPV after 5 min	0.48 (0.23–0.97)	0.45 (0.22–0.94)	**0.03**
PPV repeatedly	0.48 (0.24–0.96)	0.48 (0.24–0.94)	**0.03**
SpO2 >80% at 5 min, *n* (%)	1.82 (0.94–3.54)	1.94 (0.97–3.88)	0.06
SpO2 >85% at 10 min, *n* (%)	1.26 (0.47–3.37)	1.29 (0.48–3.47)	0.62

PPV as independent variable. T-piece group used as reference. [1]Adjusted for gestational age, antenatal steroid, and site.

rPAP group. There was no statistically significant difference between the groups with regard to any PPV used or PIP pressures. More infants had SpO2 over 80% at 5 min of age in the rPAP group compared to the T-piece group, although the difference was not statistically significant. Adding these new results to the primary outcome of the CORSAD trial, with fewer infants intubated, speaks in favor of the rPAP when stabilizing extremely preterm infants after birth [5].

In all trials that are not blinded, there is a risk of user bias and the CORSAD trial is no exception. Two of the criteria for DR intubation (e.g., primary outcome) were subjective and left to the treating clinician's discretion. If there was a user preference for rPAP leading to less intubations (primary outcome), we would expect that more infants in the rPAP group needed extended stabilization. This should result in repeated PPV for longer duration, lower SpO2, and higher FiO2. In our secondary analysis, this was not the case (Tables 3, 4) with lower need for PPV in the rPAP group and no significant difference in SpO2. This speaks in favor of the rPAP device and shows that user bias was as least limited.

The rPAP differs from the traditional T-piece in two fundamental ways. It uses nasal prongs as an interface and it is a variable flow device which is more pressure stable and has less iWOB than the T-piece [6]. We cannot conclude which of these differences contribute most to the lower intubation rate and less need for PPV in the rPAP group. It has been shown that most extremely preterm infants breathe at birth [14]. However, in resuscitation trials, a majority of preterm infants receive PPV after birth. This was also the case in the CORSAD trial with over 70% of infants showing signs of spontaneous breathing before start of stabilization and approximately 90% of the infants receiving PPV in both groups [5]. This could, in part, be explained by physicians' belief that infants need PPV to open the lungs or be related to the practice of placing a mask interface onto the infant's face. It has been shown repeatedly that mask ventilation is difficult in newborn infants with frequent mask leakage and airway obstruction concerns. In 2018, Hooper et al. [15] showed in animal models that placement of a face mask on preterm rabbits leads to apnea and glottic closure. This phenomenon earlier referred to as the diving reflex seemed to trigger the trigeminocardic reflex leading to airway closure and absent or inefficient ventilation. In newborn infants, Kuypers et al. [10] showed in a retrospective study that placing a face mask on preterm infants that were breathing from start leads to apnea in over 50% of the infants. Gaertner et al. [16] showed the same result in over 10% of term and late preterm infants. Recently, meta-analyses have looked at the comparison between face mask and nasal interface during the stabilization of

preterm infants and concluded that a nasal interface might be preferable [12, 13].

The importance of the iWOB of respiratory support devices has never been investigated in clinical settings for infants. The T-piece is a simple resistor system, providing CPAP in a similar way as the first CPAP system introduced by Gregory in the seventies. The rPAP is a variable flow resuscitator and provides CPAP in the same way as, for example, the infant flow which has been widely used for CPAP treatment in infants for decades. Earlier bench studies showed that the T-piece is pressure unstable and has high iWOB compared to the rPAP [6]. In the light of the results of this analysis, increased need for repeated PPV and late PPV could indicate that iWOB plays a role when stabilizing preterm infants at birth. Providing pressure-stable CPAP with the rPAP could promote more consistent spontaneous breathing compared to using the pressure-unstable T-piece.

Using DR intubation as a primary outcome in the extremely preterm population has been debated. However, the recent update of the ILCOR guidelines has classified this outcome as important [17]. It has earlier been shown that avoiding intubation and mechanical ventilation in extremely preterm infants after birth leads to less BPD and death at 36 weeks of age [1]. Using the rPAP led to less intubation and less need for prolonged or repeated noninvasive PPV. This creates a window of opportunity to avoid initial mechanical ventilation and deliver early rescue surfactant in a less invasive way (INSURE, MIST, or LISA). Composite outcomes reflecting the success of transition have gained more interest in recent years. That parameters, such as not reaching Sp02 of 80% or bradycardia at 5 min of age, are associated with adverse outcomes shows the importance of including multiple factors as outcomes in clinical trials [18]. The European resuscitation counsel guidelines have now included that extremely preterm infants should have at least 80% in SpO2 at 5 min of age [4]. It is of concern that a minority of infants in both groups in the CORSAD trial reached the recommended saturation of 80% at 5 min of age, but that could be explained, to some extent, by lower oxygen recommendations from start in earlier guidelines. Combining heart rate, SpO2, Apgar scores, the need for PPV, and the need for intubation could be used to describe effective and safe transition. A simple composite outcome could be infants breathing on their own with noninvasive respiratory support and SpO2 within targets at 5 and 10 min.

Limitations

Post hoc analysis carries an inherent bias as researchers can fit a hypothesis to the observed result. In this exploratory analysis, we were able to show a pattern in our data even if this was not the primary objective of the RCT.

In this subgroup analysis of infants who established breathing, there is a loss of randomization, with the consequent risk of selection bias. Aware of that, we tried to compensate, adjusting for important confounders, such as gestational age, site, and antenatal steroid, that we used for the stratified randomization of CORSAD trial.

The relatively small number of patients was a limitation, increasing the probability of failing to reject our null hypothesis when false. For purpose of transparency, we also compared PPV data for the original CORSAD cohort (online suppl 1) to ensure that our results were consistent.

Conclusion

In the CORSAD trial, less PPV was needed to establish stable breathing in extremely preterm infants using the rPAP compared to using the standard T-piece. Using the rPAP for stabilization facilitated the transition to spontaneous breathing with less need for PPV without significant difference in Apgar scores or oxygenation.

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Statement of Ethics

The CORSAD trial was approved by the Swedish regional Ethical Committee (Dnr. 2015/927-31/4). Parents to included patients received both oral and written information about the study prior to signing an informed consent.

Conflict of Interest Statement

Dr. Drevhammar has received royalties from Inspiration Healthcare as one of the inventors of the new respiratory support system. Inspiration Healthcare, the manufacturer of the device, had no input into the content of the manuscript.

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Author Contributions

All authors have made substantial contributions to all of the following: Snorri Donaldsson: conception and design of the study, data collection, original draft preparation, writing, reviewing, and editing. Elena Palleri: conception and design of the analysis, methodology, data curation, and writing. Thomas Drevhammar: conception and design, data collection, validation, and writing. Baldvin Jonsson: conception and design, writing, editing, and supervision.

Data Availability Statement

Access to deidentified CORSAD data requires an association with the study and agreement to abide by study policies and procedures. Data can be requested for ancillary analyses, but a CORSAD investigator must be directly involved as co-investigator. Data access is provided to investigators, collaborators, or ancillary study investigators for research on completion of the following procedure: a paper proposal must be approved for each paper, prior to request for data. It should describe the research question, main goals, and initial analytical approach. The proposal is reviewed for consistency with the goals of the CORSAD study, lack of overlap with other work, and scientific integrity. All persons who will have access to study data need to be named on the proposal. If there is a change of analyst (someone new who will access the data), the name of the new analyst needs to be communicated to CORSAD investigators. Proposals can be emailed to Snorri Donaldsson at snorri.donaldsson@ki.se.

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