ORIGINAL ARTICLE

WILEY

Dwell time and bloodstream infection incidence of umbilical venous catheterization in China

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Funding source
Capital's Funds for Health Improvement and Research, Grant/Award Number: 2022-2-2095

Received: 21 February 2023
Accepted: 21 September 2023

ABSTRACT

Importance: Central line-associated bloodstream infection (CLABSI) is one of the most serious complications of central venous access devices. Reducing the risk of CLABSI is of utmost significance in efforts to improve neonatal mortality rates and enhance long-term prognosis.

Objective: To determine the dwell time and incidence of CLABSI of umbilical venous catheterization (UVC) for preterm infants in China.

Methods: Preterm infants with UVC admitted to 44 tertiary neonatal intensive care units in 24 provinces in China were enrolled. Study period was from November 2019 to August 2021. The end point of observations was 48 h after umbilical venous (UV) catheter removal. The primary outcomes were dwell time of UV catheter and UVC-associated CLABSI. Data between infants with UV catheter dwell time ≤7 days and >7 days, and with birth weight (BW) ≤1000 g and >1000 g were compared.

Results: In total, 2172 neonates were enrolled (gestational age 30.0 ± 2.4 weeks, BW 1258.5 ± 392.8 g). The median UV catheter dwell time was 7 (6–10) days. The incidence of UVC-associated CLABSI was 3.03/1000 UV catheter days. For infants with UV catheter dwell time ≤7 days and >7 days, the UVC-associated CLABSI incidence was 3.71 and 2.65 per 1000 UV catheter days, respectively, $P = 0.23$. For infants with UVC dwell times of 3–6, 7–12, and 13–15 days, the UVC-associated CLABSI rates were 0.14%, 0.68%, and 2.48% ($P < 0.01$). The Kaplan–Meier plot of UV catheter dwell time to CLABSI showed no difference between infants with BW ≤1000 g and >1000 g ($P = 0.60$).

Interpretation: The median dwell time of UV catheter was 7 days, and the incidence of UVC-associated CLABSI was 3.03/1000 catheter days in China. The daily risk of UVC-associated CLABSI and other complications increased with the dwell time.

KEYWORDS
Central line, Dwell time, Infection, Newborn, Umbilical

DOI: 10.1002/ped4.12403

INTRODUCTION

Umbilical venous catheterization (UVC) is a common traumatic procedure in neonatal intensive care units (NICUs). The purpose of UVC is to establish a better intravenous access than peripheral cannulas for newborn infants.[1] The correct tip position of an umbilical catheter is the junction of the inferior vena cava and right atrium.[2] Complications of UVC include catheter-associated infections.[3,4] Several terms have been used to describe bloodstream infections associated with catheters, in which central line–associated bloodstream infection (CLABSI) has been widely used in relevant guidelines, both in English and in Chinese.[5–7] The incidence of UVC-associated CLABSI varies from 1 to 16.9 per 1000 catheter days[4,8–10] and increases as the dwelling-time of UVC increases.[9–11] The optimal dwelling-time for UVC remains undetermined. It was reported that early planned removal of umbilical venous (UV) catheter before day 4, then followed by replacement with peripherally inserted central-line catheter (PICC) helped reduce the risk of CLABSI.[9] However, currently available trial data were insufficient to make any conclusion whether the early planned removal of UV catheters reduced the risk of infection in newborns.[10] In 2022, the Centers for Disease Control and Prevention of the United States recommended that the umbilical catheter shall be removed within or before 7 days of dwell time if the newborn requires a central line for longer period in order to reduce the UVC-associated CLABSI.[11] However, the confidence level in this evidence was low because most studies enrolled were imprecise and inconsistent,[11] with only one conducted in the current standard of care.[12] Chinese guideline for the management of UVC also recommended that an UV catheter shall not be kept for more than 7 days.[7] However, this view is primarily based on current practice and experience in China, rather than on any national-level study with a calculated sample size.[7]

In China, survival rate of preterm infants has improved significantly in recent years.[13,14] The average dwell time of umbilical catheters in various NICUs in China varied from 4.9 to 7.2 days.[15,16] However, most of the studies were single-center studies. Currently, there is a lack of national-level studies on dwell time of UV catheters, or the incidence of UVC-associated CLABSI in China. Therefore, the objective of this study was to determine the dwell time and incidence of UVC-associated CLABSI in China at a national level.

METHODS

Ethical approval

This study was approved by the Institutional Review Board of Beijing Children's Hospital (#2019-k-337) and was registered in the Chinese Clinical Trial Registry (registration number: ChinCTR1900027467) (http://www.chictr.org.cn). Informed consent was waived and all data were de-identified and no extra blood/tissue samples were required for this study.

Study design and participants

This was a prospective cohort study. Infants were admitted to 44 tertiary hospitals in 24 provinces in China. A full list of participating hospitals and site investigators was provided in File S1. All NICUs were located in tertiary hospitals, and the median number of beds was 45 (interquartile range: 30–69). No hospitals in Hong Kong, Macau, Taiwan, Jilin, Heilongjiang, or Tibet were included in this study. The study period was from November 1, 2019 to August 31, 2021. The inclusion criteria for infants were for (1) gestational age (GA) <37 weeks; and (2) an UV catheter was inserted after admission. The exclusion criteria were for (1) infants with low-lying UVCs; or (2) data required were in-complete; or (3) need for palliative care. The end point of observation was at 48 h of the UVC being taken out. All UVC tips were sent for culture assessments after being removed. UVC infection control followed the recommendations of the Chinese guidelines.[7]

Study variables and data collecting

The study variables were as follows: (1) patient demographics and general information: gender, GA, birth weight (BW), Apgar score at 5 min, C-section birth, prolonged premature rupture of membrane (PPROM) >18 h, antibiotic exposure rate, and chorioamnionitis; (2) UV catheter dwell time and UVC-associated complications (occlusion, migration of UVC tip, oozing at the UVC insertion site, pericardial/pleural effusion, cardiac arrhythmia). Case report forms were used for data collection. Real-time safety monitoring was performed at each site by patient safety and quality control department of each hospital. The UVC-associated CLABSIs were described as the incidence of CLABSI per 1000 NICU days and the daily rate of UVC-associated CLABSI.

Definitions

Low-lying UVC was defined as the tip of UV catheter located not at the junction of the inferior vena cava and right atrium (ranged from 9th to 10th vertebrae on anterial posterial X-ray).[2,17–19] Extremely low birth weight (ELBW) infant was defined as infants born with BW <1000 g. UVC-associated CLABSI was defined as a primary bloodstream infection occurring within 48 h after the UV catheter insertion or within 48 h period following the catheter removal.[7,11] According to the guideline by Chinese Society of Critical Care Medicine,[20] a primary bloodstream infection associated to a central line was diagnosed when any one of the following four criteria were met: (1) at least

one time of semiquantitative catheter culture result [the quantity of organisms isolated from the tip ≥15 colony-forming units (CFUs) per catheter segment] or quantitative catheter culture results that is positive (i.e., ≥1000 CFUs per catheter segment), and meanwhile the peripheral blood culture is positive with the same pathogen as in the catheter culture; (2) simultaneous quantitative blood cultures with a ratio of ≥5:1 (catheter *vs*. peripheral); (3) growth in a catheter lumen blood culture, such that growth is detected 2 h sooner in the sample drawn from the catheter; (4) and/or the same organism is isolated from a peripheral vein blood culture and a catheter outlet culture. Incidence of UVC-associated CLABSI per 1000 UV catheter days was calculated as the number of CLABSIs divided by total dwell days of umbilical catheters × 1000. Daily rate of UVC-associated CLABSI was defined as the number of CLABSI newly developed on a certain day/number of patients who still had umbilical catheters in situ on that day (%).[21] Occlusion of the catheter was defined as the inability of drawing back blood or pushing fluid in via the catheter. UV catheter tip migration was defined as the UV catheter tip migrated to an in-appropriate position when it was reexamined by X-ray or ultrasound after one to several days of insertion. Antibiotic exposure was calculated as number of UVC patients on antibiotics/number of patients who still had umbilical catheters.

Sample size calculation and statistical analyses

The primary outcome was the incidence of CLABSI per 1000 UV catheter days. The sample size calculation was based on UVC-associated CLABSI incidence reported previously (5/1000 UV catheter days).[15,22] It was considered clinically significant if the UVC-associated CLABSI incidence in patients with 7–15 days of UV catheter dwell time was two times of that in patients with less than 7 days of UV catheter dwell time. A sample size of 10 351 UV catheter days would achieve 80% power, assuming a one-sided significance level of 0.05% and a 20% dropout rate.

Statistical analysis was performed using the SPSS statistical software (version 25.0). Data were compared between infants with UV catheter dwell time ≤7 days and >7 days, and between ELBW and non-ELBW infants. A two-sided *P*-value of 0.05 was considered to be statistical significance. Data with a normal distribution were expressed as mean ± standard deviation, and compared using *t* test. Data with a non-normal distribution were expressed as median (interquartile range), and compared using nonparametric Mann–Whitney *U* test. Enumeration data were expressed as rate (%). The chi-squared test (χ^2 test) was used to compare two sets of independent samples, and the likelihood χ^2 test was used for multiple sets of independent samples. The daily rate of UVC-associated CLABSI was analyzed according to the stratification principle (based on similar data) if the expected count was less than 5. The Kaplan–Meier plot of UV catheter dwell time to the emergence of UVC-associated CLABSI was used to compare ELBW versus non-ELBW infants. Cox proportional hazards regression analysis was employed to identify risk factors for UVC-associated CLABSI.

RESULTS

Demographic data

Among 4110 infants approached for eligibility assessment, 3124 (76%) infants met the inclusion criteria, and 2172 infants were finally enrolled (Figure 1). The average GA was 30.0 ± 2.4 weeks and BW was 1258.5 ± 392.8 g. There were 1128 infants (51.9%) with the umbilical catheter dwell time of ≤7 days, and 458 infants (14.7%) with BW ≤1000 g. The demographic characteristics are illustrated in Table 1. Between infants who had UV catheter dwell time ≤7 days and >7 days, there were no significant differences in male gender, GA, BW, Apgar score at 5 min, born via caesarean section, PPROM >18 h, antenatal antibiotic exposure, and chorioamnionitis (all $P > 0.05$); there were significant differences in the rate of PICC replacement after the UV catheter was taken out ($P < 0.01$). Between infants with BW ≤1000 g and >1000 g, there were significant differences in male gender, GA, BW, Apgar score at 5 min, born via caesarean section, PPROM >18 h, chorioamnionitis, and rate of PICC replacement (all $P < 0.05$).

Dwell time of UV catheter

A total of 17 168 UV catheter days were recorded, and the median UV catheter dwell time was 7 (6–10) days. For patients with UV catheter dwell time ≤7 and >7 days, total UV catheter days were 6207 and 10 961 days, respectively. For infants with BW ≤1000 g and >1000 g, the total UV catheter days were 3575 and 13 593 days, respectively. The UV catheter dwell time for infants with BW ≤1000 g and BW >1000 g were 7 (6–10) days and 7 (6–10) days, respectively, ($P = 0.52$). There were 1406 infants (64.7%) who had UV catheters being replaced by PICC, among them 839 (74.4%) infants had the UV catheter dwell time ≤7 days.

CLABSI and other complications of UVC

There were 390 infants (18.0%) had the UV catheters being removed due to UVC-associated complications (Table 2). The overall incidence of UVC-associated complications was 16.9/1000 UV catheter days. The daily risk of UVC-associated complications, including UVC-associated CLABSI showed increasing trends with the increase of dwell time (Figure 2A,B). UVC-associated

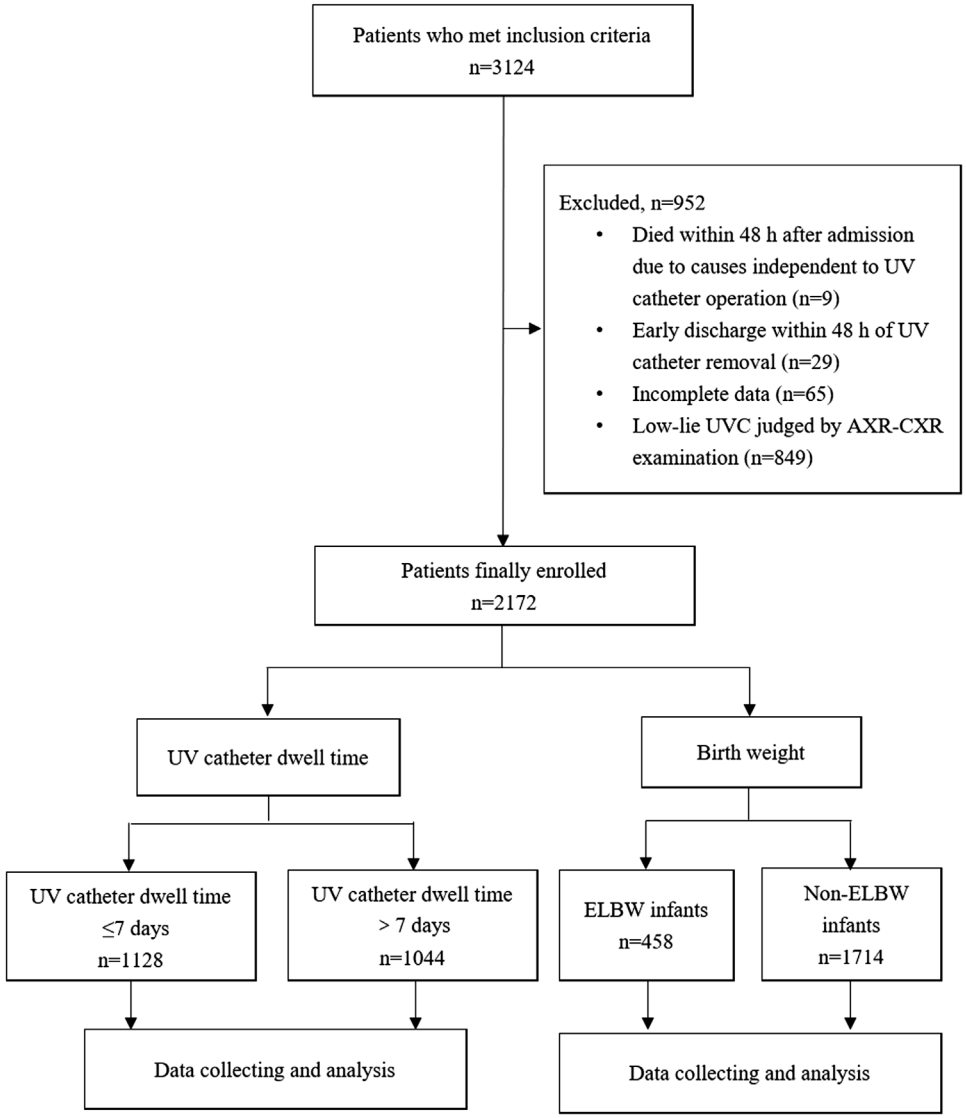


FIGURE 1 Flow chart of enrollment. In total, 2172 out of 3124 eligible neonates were enrolled in this study. UV, umbilical venous; UVC, umbilical venous catheterization; ELBW, extremely low birth weight; AXR, abdomen X ray; CXR, chest X ray.

CLABSI occurred at the day of 8 (7–11), UV catheter occlusion at the day of 6 (4–9), UV catheter tip migration at the day of 5 (3–6), oozing at UV catheter insertion site at the day of 6 (3–9), and UVC-associated pericardial effusion at the day of 3 (1–6).

In total, 52 infants developed UVC-associated CLABSI (3.03/1000 UV catheter days). For infants with UV catheter dwell time ≤7 days and >7 days, the incidences of UVC-associated CLABSI were 3.71/1000 and 2.65/1000 UV catheter days, respectively ($\chi^2 = 1.474$, $P = 0.23$). For infants with UV catheter dwell time of 3–6, 7–12, and 13–15 days, the rate of UVC-associated CLABSI over number of UVC left were 0.14% (11/7698), 0.68% (32/4697), and 2.48% (10/404), respectively. The differences among the three groups were statistically significant (likelihood ratio $\chi^2 = 44.481$, $P < 0.01$), but the difference between UV catheter dwell time of 3–6 days and 7–12 days was not statistically significant (likelihood ratio $\chi^2 = 1.604$, $P = 0.90$). The difference between UV catheter dwell time of 3–6 days and 13–15 days was statistically significant ($\chi^2 = 24.459$, $P < 0.01$). The difference between UV catheter dwell time of 7–12 days and 13–15 days was statistically significant ($\chi^2 = 12.547$, $P < 0.01$). The rate of antibiotic exposure in infants with UV catheters from days 3–6 was 91%, which was significantly higher than that on days 7–12 (47.9%) ($\chi^2 = 311.571$, $P < 0.01$) and days 13–15 (55.6%) ($\chi^2 = 129.377$, $P < 0.01$).

The Kaplan–Meier plot of UV catheter dwell time to UVC-associated CLABSI showed no difference between ELBW infants and non-ELBW infants groups ($\chi^2 = 0.269$,

TABLE 1 Demographic and baseline data

Characteristics	All patients (n = 2172)	Subgrouping by UV catheter dwell time				Subgrouping by BW			
		Dwell time ≤7 days (n = 1128)	Dwell time >7 days (n = 1044)	Statistics	P	BW ≤1000 g (n = 458)	BW >1000 g (n = 1714)	Statistics	P
Male	1162 (53.5)	608 (53.9)	554 (53.1)	0.152	0.70	217 (47.4)	945 (55.1)	8.736	<0.01
GA (weeks)	30.0 ± 2.4	30.1 ± 2.4	29.9 ± 2.4	0.195	0.66	27.9 ± 2.0	30.6 ± 2.2	23.825	<0.01
BW (g)	1258 ± 393	1265 ± 312	1251 ± 464	0.045	0.83	885 (800–950)	1300 (1160–1500)	63.735	<0.01
C-section born	1508 (69.4)	793 (70.3)	715 (68.6)	1.833	0.40	279 (60.9)	1229 (71.7)	24.236	<0.01
PPROM >18 h	346 (15.9)	178 (15.8)	168 (16.1)	0.039	0.84	47 (10.3)	299 (17.4)	13.923	<0.01
Apgar score at 5 min	9 (8–10)	9 (8–10)	9 (8–10)	−0.216	0.83	9 (8–9)	9 (8–10)	8.606	<0.01
Antenatal antibiotics exposure	839 (38.6)	428 (37.9)	411 (39.4)	0.464	0.50	163 (35.6)	676 (39.4)	2.260	0.13
Chorioamnionitis	245 (11.3)	131 (11.6)	114 (10.9)	0.261	0.61	37 (8.1)	208 (12.1)	5.944	0.02
PICC after UVC	1406 (64.7)	839 (74.4)	567 (54.3)	95.660	<0.01	393 (85.8)	1013 (59.1)	112.915	<0.01

Note: Data are expressed as n (%) or mean ± standard deviation or median (interquartile range).
Abbreviations: BW, birth weight; GA, gestational age; PICC, peripheral inserted central catheter; PPROM, prolonged premature rupture of membrane; UV, umbilical venous; UVC, umbilical venous catheterization.

TABLE 2 Incidence of UVC-associated complications

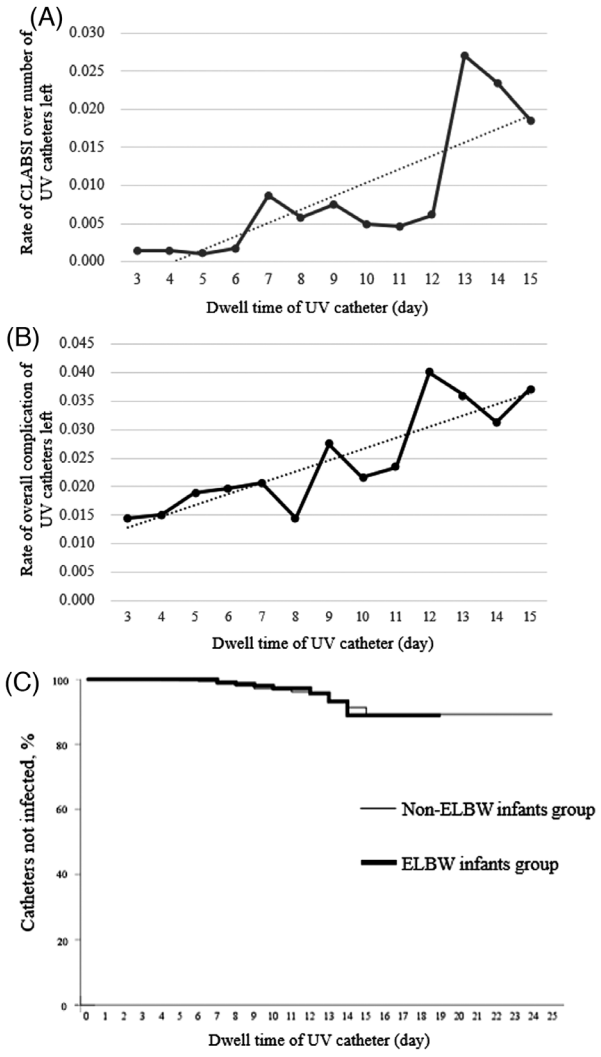
UVC-associated complications	All patients (n = 2172)	Subgrouping by UV catheter dwell time				Subgrouping by BW			
		Dwell time ≤7 days (n = 1128)	Dwell time >7 days (n = 1044)	Statistics	P	BW ≤ 1000 g (n = 458)	BW > 1000 g (n = 1714)	Statistics	P
CLABSI	3.03	3.71	2.65	1.474	0.23	2.52	3.16	0.391	0.63
UV catheter occlusion	9.26	17.20	4.74	67.424	<0.01	11.75	8.24	3.920	0.05
UV catheter tip migration	3.49	8.86	0.46	80.381	<0.01	5.59	2.94	5.715	0.02
Oozing at UV catheter insertion site	0.64	1.29	0.27	4.891	0.03	0.28	0.74	0.345	0.56
Pericardial effusion	0.47	1.13	0.09	7.051	0.01	0.84	0.37	0.528	0.47
Pleural effusion	0.06	0.16	0	–	0.36	0	0.07	–	1.00
Cardiac arrhythmia	0.06	0	0.09	–	1.00	0	0.07	–	1.00

Note: Data expressed as n/1000 catheter days.
Abbreviations: BW, birth weight; CLABSI, central line-associated bloodstream infection; UVC, umbilical venous catheterization; UV, umbilical venous.

P = 0.60) (Figure 2C). Male gender (P = 0.08), GA (P = 0.92), BW (P = 0.61), maternal chorioamnionitis (P = 0.08), antenatal (P = 0.42), and postnatal maternal antibiotics exposure (P = 0.07) were not significantly associated with an increased risk for the CLABSI event in Cox proportional hazards regression analysis.

DISCUSSION

To our knowledge, this multicenter study of 2172 neonates (with a total of 17 168 UV catheter days) is the first national-level cohort study of UV catheter dwell time and CLABSI in China. The average GA (30.0 weeks) and BW (1258.5 g) were similar to those of a cross-sectional survey from 25 tertiary NICUs in China from 2015 to 2018 (GA 30.3 weeks and BW 1350 g),[23] and a recent report of outcomes among preterm infants in China (GA 29.5 weeks and BW 1321 g).[24] The percentage of ELBW in our study was higher than the above studies.[23,24] Our study found that the median dwell time of UV catheter in China was 7 days currently. The incidence of CLABSI in our study was 3.03/1000 UV catheter days, which was similar to the report in Australia (3.3/1000 UV catheter days).[9] In our study, the incidence of UVC-associated CLABSI between



No. at risk	n	D3	D6	D9	D12	≥D15
ELBW infants group	458	438	355	179	62	11
non-ELBW infants group	1714	1639	1372	621	265	49

FIGURE 2 CLABSI and complications of UVC. (A) Daily CLABSI risk after UVC insertion. The daily risk of CLABSI was in general trending up when UV catheter dwell time increased (calculated by "the number of newly diagnosed CLABSI divided by the UVC left at the same day"). (B) The daily risk of complications after UVC insertion was trending up. (C) Kaplan–Meier estimator curve of CLABSI to dwell time of UVC. Numbers of catheters remaining at every 3 days are listed below the graph. The distribution of time to catheter infection had no differences between ELBW infants (thick line) and non-ELBW infants (thin line) ($P = 0.60$). CLABSI, catheter-associated bloodstream infection; UVC, umbilical venous catheterization; UV, umbilical venous; ELBW, extremely low birth weight.

0–7 days and 7–15 days of UV catheter dwell time did not show significantly difference, which was not in consistence with the study by Butler–O'Hara in 2012.[25] Butler–O'Hara et al.[25] reported that the incidence of UVC-associated CLABSI was 1.0/1000 and 4.0/1000 UV catheter days for UV catheter dwell time between ≤7 days and >7 days ($P < 0.05$), and concluded that dwell time was an independent risk factor for UVC-associated CLABSI. The possible reasons for the difference between our study and Butler–O'Hara's study were as follows: (1) the percentage of PICC replacement in infants with UV catheter dwell time 0–7 days in our study was much higher than that in Butler–O'Hara's study, and the influence of the replacement on UVC-associated CLABSI has not been counted in both studies; and (2) the overall hand hygiene in NICUs in China was not as good as in Australia. A systemic review by Gordon et al.,[10] concluded that there was insufficient evidence to prove that an early planned removal of UVC at 7–10 days and then the replacement of UVCs with either a short or longline intravenous catheter was beneficial to reduce CLABSI for newborns with BW <1251 g.[10]

It needs to pay attention that in our study, the antibiotic exposure rate was very high (91%) in infants with UV catheter dwell time of 3–6 days. Though this 91% of antibiotic exposure rate was significantly higher than that in 13–15 days of UV catheter dwell time (55.6%), the rate of CLABSI between these two time periods was not statistically different. This indicated that antibiotic exposure might not contribute to reducing CLABSI. Though various antibiotics stewardships have been developed to reduce antibiotics usage in neonates, it is still quite common in China to cover preterm neonates by empiric antibiotics in the first week of life.[26,27] The recent epidemiology study of antibiotics exposure in China showed that 88.4% of preterm infants with GA less than 34 weeks received antibiotics at the early stage of life, and the median duration of each antibiotic course was 9 days (interquartile range, 6–14 days).[28] So far, no national-level study has been done to reveal the empirical status of antibiotics exposure in China.

The percentage of ELBW in our study was not low (21.1%). It was well-known that ELBW is more vulnerable to infection[29]; hence, theoretically ELBW should have a higher risk of CLABSI. Our study did no find a significant difference between ELBW and non-ELBW in UVC-associated CLABSI. We are suspecting that the high exposure of antibiotics might have influenced the result of CLABSI in ELBW infants. In our study, most ELBW infants were covered by antibiotics from the day of birth to at least postnatal day 7. In this vulnerable preterm population, we need to carefully think it over that, antibiotics might have truly provided prophylaxis against CLABSI, or that the antibiotics were in fact treating sepsis (and usage of antibiotics in this time frame is not prophylaxis but therapeutic), or that the UVC maintenance bundle was highly effective even for UVCs >7 days dwell time, hence why the rate of infection was low in this population (2.52 per 1000 UV catheter days). Unfortunately, the sample size of this study was estimated based on previously reported CLABSI incidents for all preterm infants but not

for ELBW. Therefore, the sample size of 458 ELBW in our study was likely to be inadequate to draw any conclusion.

Our study found that the incidence of CLABSI ranked third in terms of UVC complications, causing the UVC to be removed. The top two complications were catheter occlusion, and migration of UV catheter tip. This was slightly different from the systematic review and meta-analysis by Gibson et al.[30] which reported that migration was the most common complication of UVC. The mild variance could be explained by the following: In our study, the cause of catheter occlusion was not recorded and the UV catheter tip was not monitored daily. Considering that migration of the UV catheter tip was also one of the reasons for catheter occlusion,[31] we did not consider our results to be conflicting. The incidences of oozing, pericardial/pleural effusion, and cardiac arrhythmia were very low. The literature on these complications has mostly been in the form of case reports.[32]

The dwell time of UV catheter is largely based on comprehensive judgment involving patient's condition, physician's experiences, NICU environment, and care bundles of central lines.[33] The limitations of this study were as follows: (1) the observational nature of this cohort study; (2) data of dwell time and CLABSI of the PICC following UV catheter removal were not available. Because the end point of our study was at 48 h after pulling out the UV catheter, we did not take any data after that time point. (3) This was not a population-based study. (4) Patients with GA >37 weeks were excluded from the study.

The median dwell time of UV catheter was 7 days in China, and the incidence of UVC-associated CLABSI was 3.03/1000 UV catheter days for preterm infants in NICUs. The daily risk of UVC-associated complications increased with the dwell time. Our study revealed the current status of UVC in China, but the data are insufficient to reach a conclusion for the optimal dwell time of UVC. It is still suggested to follow the recommendations of the current guidelines that UVCs be kept generally to a maximum of 7 days' duration.[7,11] Further population-based studies, especially the study of UVC strategies in China, should be conducted.

ACKNOWLEDGMENTS

We thank Professor Xiaoxia Peng from Beijing Children's Hospital for her supervision in the proposal preparation and final data analysis of this study. We thank Dr. Xiangyu Gao at Xuzhou Central Hospital for his valuable suggestions in processing the data of this study.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

How to cite this article: Zheng X, He D, Yang Z, Chen L, Jiang M, Qi Y, et al. Dwell time and bloodstream infection incidence of umbilical venous catheterization in China. *Pediatr Investig.* 2023;7:239–246. https://doi.org/10.1002/ped4.12403