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Original research article

Tissue adhesives in the prevention of phlebitis and migration of PICC catheters in adults: a randomized prospective study

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Abstract
Aim: Tissue adhesives (TA) have been reported to improve the stability of various types of catheters. TA use for peripherally inserted central venous catheters (PICCs), however, remains largely unstudied. Here, we aimed to evaluate the effects of TA use on the development of phlebitis, bacterial colonization, and catheter migration in PICCs inserted in adult patients.
Methods: This prospective randomized trial was conducted over a 43-month period from May 2021 to December 2024. Patients were divided into treatment group (PICC secured with TA) and control group (no TA). Signs of phlebitis (evaluated using CLISA scale) and catheter migration were recorded on Days 1 and 7. Swabs for determining bacterial colonization were taken on Day 7.
Results: Of 253 patients included in the final evaluation, none developed phlebitis, although bacterial colonization was detected in 30 patients in the control group and 26 in the TA group on Day 7. Of these, however, only 4 samples contained potentially pathogenic bacteria. Migration > 20 mm occurred in < 5% of patients in both groups, minor migration < 20 mm in < 10% of patients in each group. No statistically significant differences were detected between the groups in any of the observed parameters.
Conclusion: In a setting with highly trained nursing staff using an anchoring device and dressing, the additional use of TA brought no benefits to the patients.

Keywords: External length; Migration; Phlebitis; PICC; Tissue adhesive

Introduction

Peripherally inserted central catheters (PICC) are used to provide medium to long-term venous access (Recommended practices SPKK 10/2019; Seckold et al., 2015). The correct care for the catheter and its proper use are crucial for preventing complications such as phlebitis (Recommended practices SPKK 10/2019), a common complication of PICC use (Charvát et al., 2016; Igarashi et al., 2021). In a systematic review, Seckold et al. (2015) stated that in the general population, phlebitis occurs in 6.7% of polyurethane PICC catheters; in cancer patients with an indwelling polyurethane PICC catheter, the reported incidence climbs to 14.5%. Another study reported the incidence of phlebitis in cancer patients with PICC ranging from 2.6% to 11.4% (Walshe et al., 2002).

However, there is a difference between mechanical and infective phlebitis. Mechanical phlebitis is caused by irritation of the vessel wall occurring during catheter movement. This can be caused, for example, by incorrect fixation or inappropriate catheter selection; the risk is higher if the patient is active and mobile. The incidence of mechanical phlebitis occurs typically within the first 48 hours after the catheter insertion (Nickel et al., 2024). Infective phlebitis is, on the other hand, caused by microorganisms entering the vein through the insertion site (Nickel et al., 2024; Recommended practices SPKK 10/2019) and can subsequently lead to the migration of the microorganisms along the entire catheter into the venous system, potentially resulting in catheter sepsis (Loveday et al., 2014). The use of cyanoacrylate tissue adhesive (TA) immediately after insertion at the puncture site (Di Puccio et al., 2018; Scoppettuolo et al., 2015) is one of the new trends in the prevention of both types of phlebitis. The properties of the TA prevent the mechanical movement of the catheter, while, at the same time, protecting the insertion site from the invasion of microorganisms (Guido et al., 2020; Pittiruti et al., 2022). Fixation with TA was reported to be three times stronger than fixation with transparent dressing alone (Nickel et al., 2024). It is hypothesized that TA can reduce the occurrence of phlebitis, both mechanical and infective, inhibit bacterial colonization, ensuring

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effective stabilization (prevent catheter migration), and, in effect, resulting in a prolongation of the life of PICC and Midline catheters (Nicholson and Hill, 2019).

The aim of this prospective randomized study was to evaluate the effect of TA on (1) the incidence of phlebitis one day and one week after insertion of the PICC using the CLISA scale – Suppl. materials Appendix 1, (2) for assessment of the bacterial colonization of the insertion site after one week, and (3) catheter migration after one day and one week from insertion.

Materials and methods

Study design, population, and data collection

This study was designed as a single-center, prospective, randomized interventional trial. Data were collected over three years at the University Hospital Ostrava, Czech Republic, from May 2021 to December 2024. Inclusion criteria comprised age ≥18 years, indication for PICC or Midline insertion, and signing an informed consent to participate. All patients meeting inclusion and exclusion criteria were included in the study by a person unaware of the subsequent assignment into groups. Patients were subsequently assigned into the control and TA groups, strictly alternating the order (i.e., every other patient was assigned to the same group). Having a person who was unaware of the future group assignments evaluate patients' eligibility for inclusion helped prevent the selection bias that might otherwise have arisen from the alternating group assignment. For each participant, age, sex, referring department, type and size of catheter, CLISA – Central Line Insertion Assessment Site scale, for PICC (Suppl. materials Appendix 1) or VIP – Visual Infusion Phlebitis scale, for Midline (Suppl. materials Appendix 2), and external length values (for migration) were collected on Days 1 and 7 after catheter insertion (Day 0). Swabs from the insertion site were taken on Day 7. The swabs were cultured to determine the presence and type of microorganisms (see details below). Data were recorded electronically by a trained and competent PICC team nurse.

Procedure for TA application

In all participants, PICCs/Midlines were inserted by PICC trained nurses using the GAVeCeLT guideline and following the eight steps of the Safe Insertion of PICC (SIP) protocol (Emoli et al., 2014). Insertions were performed at the bedside or in the interventional room. Pre-procedural ECG was obtained and stored. After the PICC was inserted, the tip was localized using IC-ECG.

Sterile TA SecurePortIV™ (Adhezion Biomedical) based on a mixture formula n-butyl-2-octyl-cyanoacrylate was applied to the patients from the TA group after PICC/Midline insertion, while no TA was applied to the control group. In both groups, the insertion area was subsequently covered with Excilon™ Antimicrobial Dressing (Cardinal Health, United Kingdom) and transparent dressing. Excilon™ contains Polyhexamethylene Biguanide Hydrochloride (PHMB), which helps to prevent bacterial colonization.

0.15 ml of TA was applied to each patient according to the manufacturer recommendations and left to dry completely before the application of Excilon™ and transparent semipermeable dressing. This amount of glue is sufficient to allow even distribution in drops around the entire circumference of the insertion site of the catheter.

CLISA/VIP assessment during dressing change

A day after insertion (Day 1), the dressing was removed and CLISA (Central Line Insertion Assessment Site scale; for PICC) or VIP (Visual Infusion Phlebitis scale, for Midline) and external length (for migration) of the catheter were assessed. After that, the insertion site was disinfected using 2% chlorhexidine solution with 70% alcohol for 1 minute, left to dry completely, and redressed using Chlorhexidine gluconate (CHG) dressing (Biopatch®, Ethicon), which remained in place until Day 7. On Day 7, the same procedure was repeated and a swab from the insertion site was taken. The CLISA scale was found to be effective and easy to use to assess the PICC insertion site by nurses. This score classifies the place of insertion into five groups (not visible/not assessable, 0 – normal; 1 – slight erythema below 3 mm; 2 – larger erythema 3–6 mm; 3 – purulent discharge or erythema >6 mm; see Gohil et al., 2020). For the evaluation of a possible inflammatory reaction of the Midline insertion site, the VIP was selected due to its validity and reliability (Jackson, 1998; Nickel et al., 2024; Ray-Barruel et al., 2014).

Swab collection and microbial analysis

In both groups, swabs were collected on Day 7 during dressing change (before the skin antisepsis) from an area with a radius of 0.5 cm around the insertion site, taking care not to contaminate the swab with the surrounding skin. The swabs were immediately transported to the laboratory where they were cultured on blood agar (BA) and McConkey agar (MC) for 24 hours at 35 ± 2 °C in aerobic atmosphere. After that they were cultured a) for 48 hours at 35 ± 2 °C in aerobic conditions on selective media (NaCl agar, ENT agar, and Sabourad agaru) and b) in brain heart infusion broth for 24 hours (aerobic cultivation at 35 ± 2 °C), after which the cultured sample was again used to inoculate BA and MC agar and cultured for 24 hours under the same conditions. Finally, isolates were identified by the MALDI-TOF MS mass spectrometry method.

Catheter migration assessment

Any change in the external length that exceeded 5 mm (baseline point) compared to the post-insertion status was recorded on both Day 1 and Day 7. Any external length change of more than 20 mm was considered a major migration because it could have led to withdrawing the distal tip of the catheter outside the recommended position in cavo-atrial junction (CAJ) from superior vena cava (SVC) (Johnston et al., 2014).

Statistical analysis

Basic statistical methods for the analysis of categorical variables (absolute and relative frequencies, significance testing using chi-square test for contingency tables, or Fisher exact test as appropriate) were used for evaluation. Numerical data (such as age) were presented using appropriate distribution characteristics (mean and standard deviation or median and interquartile range, and tested using Mann–Whitney test).

Results

In total, 258 patients were included, of which 113 (43.8%) were women and 145 (56.2%) men. However, Midline catheter was introduced only in five patients, all of whom were randomized in the control group. For this reason, we eventually decided to remove those five from the analysis, yielding a total of 253 patients (129 in the TA group and 124 in the control group) with a median age of 68 years (IQR: 58–76 years). The group characteristics are shown in Table 1.

Table 1. Group characteristics of the population included in the final evaluation

	Median (IQR) or *n* (%)			
	Total (*n* = 253)	TA group (*n* = 129)	Control group (*n* = 124)	*p*
Age (years)	68 (58; 76)	68 (58; 75)	68 (58; 77)	0.692
Sex				0.462
Female	111 (43.9)	60 (46.5)	51 (41.1)	
Male	142 (56.1)	69 (53.5)	73 (58.9)	

Note: The values represent the median and the interquartile range (IQR) or absolute and relative frequencies (%). The *p*-value was obtained with the Mann–Whitney test or the chi-square test of independence as appropriate. TA – tissue adhesive.

Of the 253 patients, all 129 in the TA group had a swab performed on Day 7. Of these 129 swabs, 30 were positive, showing 11 types of microorganisms. In the control group of 124 patients without TA, samples were not collected from two patients (one died, one pulled the catheter out using intentional force), totaling 122 samples. The results are summarized in Table 2.

No signs of mechanical or infective phlebitis were detected in any of the patients in either group on Days 1 or 7.

No internal migration was observed in any of the patients. The external length migration >5 mm was observed in 12 patients from the TA group and 11 patients in the control group ($p > 0.05$). Major migration over 20 mm was observed in 3 patients from the TA group and 6 patients from the control group (the patient who pulled the catheter out intentionally was not included in this number). No statistically significant difference was found for any of these endpoints between groups. The results are shown in Table 3.

Table 2. Overview of the culture results from the swabs of the PICC insertion area (pathogenic bacteria are highlighted in bold)

	TA group *N* (%)	Control group *N* (%)
Positive swabs/total swabs (%)	30/129 (23%)	26/122 (21%)
Total CoNS	23 (18%)	23 (19%)
S. epidermidis	13 (10%)	4 (4%)
S. hominis	6 (5%)	6 (5%)
S. haemolyticus	3 (2%)	1 (1%)
S. warneri	0 (0%)	1 (1%)
S. capitis	0 (0%)	1 (1%)
S. succinus	1 (1%)	0 (0%)
Unspecified CoNS	0 (0%)	10 (8%)
Other microorganisms		
Micrococcus luteus	2 (2%)	1 (1%)
Seratia marcescens	**1 (1%)**	**0 (0%)**
Bacillus sp.	1 (1%)	0 (0%)
Klebsiella pneumoniae	**0 (0%)**	**1 (1%)**
***Klebsiella pneumoniae* ESBL**	**0 (0%)**	**1 (1%)**
Streptococcus parasanguinis	1 (1%)	0 (0%)
Streptococcus non haemolyticus	1 (1%)	0 (0%)
Enterobacter cloacae	**1 (1%)**	**0 (0%)**

Note: CoNS-Coagulase-negative Staphylococci; TA – tissue adhesive

Table 3. Comparison of the signs of phlebitis (evaluated using CLISA score) on the site of PICC insertion and of PICC migration on Days 1 and 7

	n (%)			
	Total (*n* = 253)	TA group (*n* = 129)	Control group (*n* = 124)	*p*
Mechanical or infective phlebitis				
Day 1	0 (0.0)	0 (0.0)	0 (0.0)	–
Day 7	0 (0.0)	0 (0.0)	0 (0.0)	–
Not evaluated	2	0	2	
External length migration above 5 mm				
Day 1	0 (0.0)	0 (0.0)	0 (0.0)	–
Day 7	23 (9.2)	12 (9.3)	11 (9.0)	>0.999
Not evaluated	2	0	2	
External length migration above 20 mm				
Day 1	0 (0.0)	0 (0.0)	0 (0.0)	–
Day 7	9 (3.6)	3 (2.3)	6 (4.9)	0.323
Not evaluated	2	0	2	

Note: The values represent absolute and relative frequencies (%). The *p*-value was obtained with the chi-square test of independence or the Fisher's exact test. TA – tissue adhesive.

Discussion

In this study, we investigated the influence of the use of TA on the occurrence of bacterial colonization from the swab cultivation, phlebitis (mechanical and infective), and catheter migration in adult patients with PICC.

The presence of microorganisms was detected in both groups. Most of the detected microorganisms (46/56, 82.1%) were CoNS – a large group of Gram-positive cocci that are becoming frequently detected in hospital settings, although they are considered less pathogenic than *Staphylococcus aureus* and other members of the *S. aureus complex* (Michels et al., 2021). Although CoNS are known as commensal pathogens of the skin, they can be initiators of true infection, especially when it is related to foreign bodies (Nurjadi et al., 2020; Švec et al., 2015). Our results are not in line with those reported by Gilardi et al. (2021) who found no viable microorganisms before insertion and not even on Day 7. This is somewhat surprising as our methods were very similar (the only difference being that we did not perform culture from control swabs taken on Day 0 after antisepsis). It might be that their initial disinfection method could be more effective (although the same disinfectant was used), manipulation during insertion could be more meticulous in their setting, or that our culture method was more sensitive. The fact that our study includes 251 patients with swabs while theirs only includes 60 patients might also have contributed to this difference. In any case, we consider the fact that although colonization with (mostly non-pathogenic) microorganisms was observed, no signs of infective (or any) phlebitis occurred in our study. Hence, the clinical implications of our study are the same as those reported by Gilardi et al. (2021).

As mentioned above, despite the bacterial colonization revealed by the swabs, no local infection occurred in any of our patients according to the used visual scales. Therefore, no infectious complications occurred in any of the groups within a week of insertion. This is consistent with Gilardi et al. (2021) who, like us, reported no signs of inflammation/phlebitis during the first 7 days post catheter insertion in their smaller study (102 patients). Padilla-Nula et al. (2023) used the Maddox scale in their RCT with 216 patients, not differentiating between infective or mechanical phlebitis. In their study, 12 patients suffered from phlebitis as early as 24 hours after PICC insertion (4/109 in the control group, 8/103 in the TA group, not statistically significant). As this time point is very early after the PICC insertion, it is likely that these were mechanical phlebitis. After 7 days, signs of phlebitis were detected in five patients: 3/88 in the control group, 2/80 in the TA group. Again, the difference was not statistically significant. In our study, the zero phlebitis rate did not allow us to decide whether or not TA was superior in preventing phlebitis. However, it clearly indicates that careful insertion and subsequent care for the PICC catheter applied by well-trained nursing staff is associated with minimum risk of phlebitis development even if no TA is applied.

A possible cause for the better results in our study compared to those of Padilla-Nula et al. (2023) might be that we used the SecurAcath® anchoring device with Excilon™ dressing, further covered with transparent dressing after insertion; then, on Day 1, we removed the dressings, performed antisepsis and switched to Biopatch® antimicrobial dressing covered with a new transparent dressing. The SecurAcath® anchoring device stayed *in situ*. Padilla-Nula et al. (2023) used an adhesive fixation Grip-lok®, which was changed at every dressing, and this might have caused mechanical irritation of the insertion site and, in turn, phlebitis.

Where catheter migration is concerned, we only observed external migration, internal migration was not detected. In our study, we measured external migrations of the catheter exceeding 5 mm and more, importantly external migrations above 20 mm. The former is considered less serious because as long as the tip is correctly placed in the cavoatrial junction (CAJ), a migration of less than 20 mm is still likely to keep the tip within the CAJ. However, a external length change exceeding 20 mm is already certain to move the tip outside of the CAJ into the upper part of the superior vena cava, which is believed to be an unsuitable PICC tip location, increasing the risk of thrombosis (Fletcher and Bodenham, 2000; Pinelli et al., 2021; Verso et al., 2008). Moreover, after such a migration, it cannot be considered a proper central catheter anymore.

We observed similar rates of migration in both the TA (12 > 5 mm / 3 > 20 mm) and control (11/6) groups. This corresponds to <10% and <5% for minor and large migration, respectively. No significant differences between the groups were detected. Our result is similar to that of Chan et al. (2017) who reported a 6% migration rate of PICCs (this number, however, shows a combination of total dislocation when the catheter left the vein completely and partial migration when the distal tip left the superior vena cava).

Piersigilli et al. (2023) reported a drop from 13 migrations without TA to 1 after the use of TA in neonates. The fact that their study included only neonates could explain the differences in results – the catheter sizes are smaller, the dressing covers practically the entire arm, and the motion of neonates differs from that of adults. Moreover, they did not define what is meant by migration in their study (whether it meant complete removal of the catheter or just a partial migration). Our study monitored any catheter migration greater than 5 mm, and in adults we also used larger and longer catheters.

We included only adult patients and in our setting (with the SecurAcath® anchoring device) it appears that the use of TA had no effect on the PICC migration; and that even the combination of the two approaches (SecurAcath® + TA) cannot fully prevent migration of the catheter in active patients.

In view of the above, it appears that other factors that have not been evaluated in this study (e.g., first attempt insertion, training and experience of the team, the vein/catheter ratio, or proper knowledge of the products and its application protocol) can affect the rate of complications (Pinelli et al., 2021) possibly even more than the use of TA.

Two studies have previously investigated complications from the use of TA in PICC. Zhao et al. (2018) reported an almost 30% complication rate associated with the use of TA, with mechanical skin injury being the most common complication (17%). It should be noted that their study included solely oncology patients, while our cohort was more diverse. A similar result (36% of skin complications) was also reported by Chan et al. (2017). In our study, however, we have not detected any complications associated with the use of TA (such as adverse skin reactions, allergic reactions, mechanical skin injury, etc.). It could also be that this outcome was associated with the type of TA used in their study, while the one we used was more innovative, less aggressive, and left to dry before applying dressing.

Study strengths and limitations

Limitations of the study include the single-centre data collection. Also, no swab was taken before insertion, which could have shown if the patient's skin was colonized before insertion

and what microorganisms were present on the skin. From the practical point of view, however, this information is not crucial; the outcome (i.e., the presence or absence of infection) is much more important. The fact that no patient developed infective phlebitis within a week of catheter insertion indicates that the measures taken during the procedure were sufficient, regardless of the (possible) colonization of the skin before the procedure. Lastly, we only used a visual evaluation of the local signs of infection (CLISA scoring system). This method has, however, been shown to be a reliable and simple method for clinical application (Gohil et al., 2020). Our study did not focus on bleeding from the insertion site, either.

On the other hand, the strengths of our study include the largest patient group published on the use of TA after PICC insertion so far, randomized design, and consistent use of the bundle for PICC insertion and care by highly trained staff.

Conclusion

In our randomized study, we evaluated the benefits of using TA in adult patients after PICC insertion on the development of local phlebitis (infective and mechanical), bacterial colonization, and catheter migration. We found that under our conditions (use of subcutaneous anchoring devices, procedures performed by highly trained and experienced staff), the results can be very good (no signs of local phlebitis, catheter migration >20 mm in less than 5% of patients within 7 days), even without the use of the TA. The use of TA brought no significant improvement in any of these parameters.

Finally, performing RCT study as a research nurse was a challenging and difficult task, despite the great support from our management. In future, the role of a nursing researcher should be more supported and emphasized. There are many aspects of patient care which can be affected by nurses and their research, such as the delivery of optimal, evidence-based nursing care, the implementation of innovative interventions, identifying gaps in patient management, improving knowledge, transferring science to practice, developing and revising the healthcare policies, and more.

Ethical consideration

This study was approved by the Institutional Ethics Committee of the University Hospital Ostrava (approval number 376/2021) and performed in adherence with the Declaration of Helsinki. The purpose of the study was explained to all participants and written informed consent obtained. Participants were also informed that they could withdraw from the trial at any time. The analyzed data were anonymized and confidential.

CRediT authorship contribution statement

I. Constantine: conceptualization, investigation, methodology, writing – original draft, writing – review and editing. *M. Michaliková:* conceptualization, investigation, data curation. *Z. Figurová:* writing – review and editing. *A. Kondé:* statistical analysis, methodology. *A. Polanská:* writing – review and editing, methodology, supervision, funding acquisition. All of the authors have read and agreed to the published version of the manuscript.

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Conflict of interest

The authors have no competing interests to declare.

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