

PAPERS

Systematic Review of the Safety and Efficacy of CVAD Securement

Bell, et al, Journal of the Association for Vascular Access, Sept 2022

- Researchers conducted a systematic review of more than 8,000 studies to examine safety and efficacy outcomes related to CVAD securement.
- In the studies with good comparative data on rates of catheter migration and dislodgement, researchers found clear benefits for the subcutaneous anchor securement system.
- Subcutaneous anchor securement systems (SASS) are shown to be more effective at keeping central catheters in place, compared to either suture-based or adhesive device-based securement methods.
- The median incidence of migration and dislodgement for SASS was just 1.76%, compared to 6.77% for suture-based systems, and 9.69% for adhesive securement devices

Subcutaneously anchored securement for peripherally inserted central catheters: Immediate, early, and late complications

Brescia, et al, Journal of Vascular Access, June 2021

- Retrospective analysis of 639 adult cancer patients who had a PICC inserted and secured with SAS (SecurAcath), over 3 years and 93,078 catheter days.
- Average number of catheter days was 154 days per patient (range 32–657 days)
- Dislodgment occurred only in seven cases (1.1%); 4 were due to mismatched SecurAcath/Catheter OD; 3 were non-collaborative patients.
- Literature reports an incidence of dislodgment between 5% and 15% (when SAS not used)
- Our data confirm that subcutaneously anchored securement of PICCs is associated with very low risk of dislodgment and that this risk is limited to non-collaborative patients
- Overall incidence of CRBSI was 0.17 per 1000 catheter days; Symptomatic catheter related thrombosis was 1.9%; resolved with therapeutic doses of LMWH
- It is possible that an adequate stabilization of the catheter may have reduced the thrombotic risk and that the elimination of “in and out” micro-movement of the catheter at the exit site, as much as an optimal disinfection all around the exit site, might have reduced the risk of infection
- Subcutaneously anchored securement of PICCs was a safe and effective strategy for reducing the risk of dislodgment

Catheter Securement Impact on PICC-related CLABSI: A University Hospital Perspective

Rowe, et al, American Journal of Infection Control (2020) Vol. 48, Dec

- University of Arkansas for Medical Sciences (UAMS) analyzed 7,779 patients over four years of Central Line Associated Bloodstream Infection (CLABSI) data
- Analysis compared outcomes of patients whose PICCs were secured with a the SecurAcath to those secured with an adhesive device
- Study found a substantial difference in relative risk of CLABSI among securement devices
- Analysis showed those who had an adhesive device had a 288% increase in risk of CLABSI compared to those who had a SecurAcath

Choice and management of vascular access in the context of COVID-19 outbreak in Italy: Recommendations from clinical practice

Vailati, et al. Journal of Vascular Access (2020) Nov

- SIAARTI (“Società Italiana di Anestesia, Analgesia, Rianimazione e Terapia Intensiva”) Research Group on Vascular Access has formulated some essential recommendations for the optimization of the selection, insertion, and maintenance of the vascular access devices
- As regards securement, since COVID-19 patients are often treated by repeated pronation cycles, we suggest adopting long-term securement strategies (i.e. subcutaneously anchored securement devices) for all central lines (PICC, CICC, and FICC), in order to prevent accidental dislocations or removals.

Recommendations for the use of vascular access in the COVID-19 patients: an Italian perspective

Pittiruti and Pinelli, *Critical Care* (2020) 24:269, May

- Recommendations for the selection, insertion, and maintenance of the venous access devices, designed to protect the operator, to ensure the effectiveness of the maneuver, to reduce the risk of complications, and to save resources.
- As the risk of central venous catheter dislodgment is particularly high in the COVID-19 patient, particularly during the maneuvers of pronation-supination, consider the use of subcutaneously anchored securement

Retrospective survey from vascular access team Lombardy net in COVID-19 era

Gidaro, et al. *Journal of Vascular Access* (2021) Jan

- Multicenter, retrospective cohort study collected data from seven hospitals in Lombardy during the pandemic period from February 21st to May 31st 2020
- A total of 2206 VADs were evaluated, 1107 (50.2%) of which were inserted in COVID-19 patients
- A minority of “central tip” VADS were held by a subcutaneous securement device such as SecurAcath® (5 CICC and 40 PICC in COVID-19 and 78 PICC in non COVID-19)
- CRT, CRBSI, and accidental removal are significantly more frequent in COVID-19 patients. Accidental removals are the principal complication, for this reason, the use of subcutaneously anchored securement is recommended for a shorter period than usual

Ultrasound-guided cannulation of the superficial femoral vein for central venous access

Anetta, et al. *Journal of Vascular Access* (2021) Feb

- 98 non-tunneled central venous catheters
- Ultrasound-guided puncture of the superficial femoral vein at mid-thigh or in the lower third of the thigh
- All of them secured by subcutaneous anchorage
- Mean duration of the central line was 35 days (range 1–123 days)
- Follow-up of hospitalized patients (72.5% of all cases)
- Only one episode of catheter dislodgment, no episode of infection and no episode of catheter related thrombosis
- The approach to the superficial femoral vein may open new perspectives in the area of femorally inserted central catheters (FICC): it is a completely safe technique, which is not associated with any potential risk of severe insertion-related complication

GAVeCeLT - WoCoVA Consensus on subcutaneously anchored securement devices for the securement of venous catheters: Current evidence and recommendations for future research

Pinelli, et al, *The Journal of Vascular Access* (2020) July

- SAS (SecurAcath) is effective in reducing the risk of dislodgment when used for securing PICCs and other types of central VADs in adult patients as well as in children and neonates.
- SAS (SecurAcath) is associated with a low incidence of undesirable effects—most of them local and of low clinical relevance—which probably can be minimized by appropriate prevention and management.

Do subcutaneously engineered stabilisation devices reduce PICC migration? A product evaluation report

Culverwell, et al. *The Australian Journal of Cancer Nursing* (2020) Vol. 21, No. 2, Nov

- In 2013, a concerning trend in PICC migration complications and re-insertions related to catheter movement was identified
- In 2014, 150 (11%) PICCs required reinsertion due to migration
- Social costs in terms of patient suffering and delays in therapy, as well as financial implications in terms of associated additional costs, calculated to a value of NZ\$54,750
- Furthermore, in one of these cases of PICC migration, a fatality occurred that was linked to inadequate PICC securement
- Our findings showed that implementation of a SESD (SecurAcath) had benefits for both patients and staff
- The aim to reduce PICC migration rates and associated complications was achieved.

- The SESD used in this product evaluation proved a successful measure to reduce PICC migration events. An organizational decision was made to embed SESD as the preferred securement method in PICC care bundles for adult patients

Intravascular catheter migration: A cross-sectional and health-economic comparison of adhesive and subcutaneous engineered stabilisation devices for intravascular device securement

McParlan et al, J Vasc Access (2019) June

- PICC securement study from Belfast, Northern Ireland
- Compared one full year of Statlock use to one full year of SecurAcath use
- n = 1,111 patients with Statlock, n = 1,139 patients with SecurAcath
- Average dwell time 6 months
- 5.9% catheter replacement rate with Statlock, 0% replacement with SecurAcath
- Cost savings due to decrease in catheter replacement = £17,952
- Cost savings due to not changing out SecurAcath = £59,322
- Total savings = £77,274

Clinical Experience of a Subcutaneously Anchored Sutureless System for Securing Central Venous Catheters

Pittiruti, M. et al, British Journal of Nursing (2019) Vol. 28, No. 2, January

- Paper presents results of three prospective clinical studies of SecurAcath (SAS device) on PICCs and other central lines in different patient populations, 190 patients total
- Three clinical studies demonstrated a 98.4% efficacy of SAS in preventing catheter dislodgement
- SAS device proved to be safe and well tolerated since SAS-related complications were few and of little or no relevance
- SAS cost-effectiveness was very high in all studies

Evaluating Safety, Efficacy, and Cost-Effectiveness of PICC Securement by Subcutaneously Anchored Stabilization Device

Zerla, P. A., et al, Journal of Vascular Access (2017) February

- 30 patients with SecurAcath on PICCs
- Long-term oncology patients, average dwell time of 4.8 months
- 0% catheter replacement rate
- Cost savings due to not replacing SecurAcath at each dressing change = €3,354
- Previous catheter replacement rate of 7.9% with adhesive device
- Potential catheter replacement savings = €18,710

SecurAstaP trial: Securement with SecurAcath versus Statlock for Peripherally Inserted Central Catheters, a Randomised Open Trial

Goossens, L., et al, *BMJ Open* (2018); 8:e016058. doi: 10.1136/bmjopen-2017-016058

- RCT on PICCs
- N = 52 SecurAcath, n = 51 Statlock
- Primary end point - time needed to perform dressing change
- SecurAcath median time = 4.3 minutes
- Statlock median time = 7.3 minutes
- 3 minutes saved at each dressing change using SecurAcath
- No differences seen in migration, dislodgement or infections, study not designed or powered for

A new Subcutaneously Anchored Device for Securing External Cerebrospinal Fluid Catheters: our Preliminary Experience

Frassinito, et al, World Journal of Neurosurgery (2016) Sept

- SecurAcath was used for 25 ventricular catheters and 5 spinal drainages
- Period in place ranged from 1-4 weeks (median 22 days)
- No complication related to the use of the device was observed, in particular there was no case of dislocation or accidental removal of the catheter
- SecurAcath is a safe and effective device to secure CSF external catheters to the skin, with several relevant advantages

Reducing PICC Migrations and Improving Patient Outcomes

Hughes, M., British Journal of Nursing (2014) Jan Vol. 23, No. 2, pg. 16-21

- PICCs
- Prospective, non-randomized
- Site places 460 PICCs per year, 500 secured with SecurAcath to date
- Average PICC dwell time = 3 months
- 0% dislodgment rate, not a single catheter replacement since SecurAcath introduction
- Previous adhesive device catheter replacement rate was 4.6% (21/460)
- Annual cost savings (due to reduced dressing change, catheter replacement, x-ray and nursing time costs) to Velindre Cancer Center = £21,610

A Prospective Postmarket Study to Evaluate the Safety and Efficacy of a New Peripherally Inserted Central Catheter Stabilization System

Egan et al, Journal of Infusion Nursing (2013) May/June; Vol. 36, No. 3, pg. 181-188.

- Prospective, non-randomized study of SecurAcath on PICCs
- 3 sites, 68 patients
- Low dislodgment rate of 1.5% (0.7/1000 catheter days)
- Well tolerated by patients – average pain scores were very low (0.7 on 0-10 scale)
- 91.2% of patients had no securement-related malfunctions or device related complications

A Prospective Trial on a New Sutureless Securement Device for Central Venous Catheters

Cordovani, D., Cooper, R., Canadian Journal of Anesthesia (2013) May, Vol. 60, No. 5, pg. 504-505.

- Prospective, non-randomized study of SecurAcath on CVCs
- 2 sites, 74 patients
- 0% dislodgement
- No infections

PEDIATRIC

A GAVeCeLT bundle for central venous catheterization in neonates and children: A prospective clinical study on 729 cases

Pittiruti, et al, Journal of Vascular Access (2022) May

- Study evaluated the use of a procedure bundle in 729 pediatric central venous catheter placements
- Cases were separated into 3 groups, neonates (n=68), infants (n=173), and children (n=488)
- SecurAcath was used in 100% of the neonates, 81% of infants, and 72% of children, total of 77%, 555 of 729
- No dislodgement occurred with SecurAcath use
- “In our experience, the most effective securement—particularly in children—was subcutaneous anchorage. This method minimizes the risk of dislodgment and may theoretically reduce the risk of infection and venous thrombosis.”
- Absence of CRBSI in the first 2 weeks of follow up is secondary to the appropriate use of the currently recommended strategies for infection prevention, including SecurAcath
- Subcutaneous anchorage – by avoiding securement with skin-adhesive sutureless devices - might also have reduced the risk of CASI

Vascular Access in Pediatric Oncology and Hematology: State of the Art

Crocoli, et al. Children (2022) 9, 70.

- Catheter dislodgment and/or tip migration may lead to malfunction of the device and, in worst cases, to complete removal.
- Pediatric patients undergoing chemotherapy and/or high dose steroids are more prone to these complications
- Different approaches to reduce these events have been described, such as the use of non-cuffed third generation polyurethane secured with both suture-less devices and subcutaneously anchored securement systems (SASS)
- For children with cancer, catheter removal must also be considered as one of the many painful procedures they undergo during the course of disease, with additional stress for the patients and their families
- New devices with different securement systems (suture-less devices, cyanoacrylate glue and SASS) lead both to easier fixation and removal of the catheter if necessary, eliminating the issue of polyester cuff-equipped catheters, whose adoption should be progressively abandoned in pediatric patients with cancer.

Safety and effectiveness of subcutaneously anchored securement for tunneled central catheters in oncological pediatric patients: A retrospective study

Crocoli, et al, Journal of Vascular Access (2021) June

- Data from 311 tunneled catheters, all secured with subcutaneously anchored securement
- Approximately half of the catheters (51%) were non-cuffed.
- The range of duration of the central lines was 0.1–113 weeks (median: 24.9 weeks)
- No significant difference in complications comparing cuffed versus non-cuffed catheters, or CICC versus PICCs.
- SAS (SecurAcath) will be probably associated with even less risk of complications if compared to skin-adhesive sutureless securement, as suggested by our complication rate (1.35/1000 catheter days), better than any previously reported in pediatric literature.
- Rate of dislodgment was similar in cuffed and non-cuffed catheters, suggesting that the cuff may play a less important role in securement of tunneled CVADs
- SAS (SecurAcath) was very effective as securement of tunneled central catheters, since the incidence of dislodgment was very low 2.6% or 0.18/1000 catheter days, less than previously reported in literature, regardless of the presence of a cuff
- Securement device was very well tolerated by all patients
- This securement was not associated with any increased risk of CRBSI (extremely low in our experience: <1 episode/1000 CVAD days) or of symptomatic Catheter-Related Thrombosis (no case reported in our series)

Securement of central venous catheters by subcutaneously anchored suturless devices in neonates

D'Andrea, et al, *Journal of Maternal-Fetal & Neonatal Medicine* (2021) April

- Accidental dislodgement of central venous catheters is a frequent complication in NICU and it often requires catheter replacement
- Study evaluated safety and efficacy of Subcutaneous Anchored Securement (SAS) in neonates
- 72 central catheters were inserted, all secured with SAS
- The median duration of the line was 6 weeks
- SAS was effective in preventing accidental catheter dislodgement in 100% of cases
- Complications during insertion, maintenance and removal were negligible

Guidelines of the Italian Association of Pediatric Hematology and Oncology for the management of the central venous access devices in pediatric patients with onco-hematological disease

Cellini, et al. *The Journal of Vascular Access* (2020) Nov

- Important innovations have been developed recently in the field of CVADs, leading to new insertion methods, new materials and new strategy in the overall management of the device, especially in the adult population
- These guidelines recommend how to apply these innovations in the pediatric population
- Securement of CVAD is an important safeguard as it reduces one of the most important complications, that is, dislodgment.
- Securement must be chosen according to the following characteristics: it must prevent movements of the CVAD and avoid dislocation, prevent accidental removal, prevent micro-movements that generate damage to the vascular walls and protect the insertion site from microbial contamination maintaining skin integrity around the insertion site.
- The use of SAS is recommended for CVADs with a duration of more than 15 days or in situation at high risk for dislodgment

Centrally inserted central catheters in preterm neonates with weight below 1500 g by ultrasound-guided access to the brachio-cephalic vein

Barone, et al, *Journal of Vascular Access* (2020) June

- Thirty centrally inserted catheters were placed in 30 neonates
- Success rate of the procedure was 100%
- Insertion bundle included use of subcutaneously anchored securement (SecurAcath) to minimize dislocations
- No complications during the procedure and no late complications (infection, thrombosis, dislocation, or catheter malfunction).

Subcutaneously Anchored Sutureless Device for Securement of Chest Tubes in Neonates with Pleural Effusion: Three Case Reports

Rodriguez Perez, et al, *Case Reports in Pediatrics* (2020) March

- Three neonates, all of them premature, requiring the placement of a chest tube for drainage of a massive pleural effusion
- In all three patients, the chest tube was secured using a new subcutaneously anchored sutureless system (SecurAcath)
- In conclusion, we recommend SAS (SecurAcath) as a safe and effective alternative option for securing chest tubes in neonate: it is easy to insert and easy to remove; it is not associated with any undesired effect, not even in premature new-borns; most of all, it minimizes and virtually eliminates the risk of accidental dislodgment of the chest tube, an event associated with increased morbidity and increased health cost.

Potential Role of a Subcutaneously Anchored Securement Device in Preventing Dislodgement of Tunneled-Cuffed Central Venous Devices in Pediatric Patients

Dolcino, A., et al, *Journal of Vascular Access* (2017) Oct

- 173 pediatric patients receiving cuffed, tunneled catheters
- 122 secured with adhesive device, 51 secured with SecurAcath
- Dislodgement rates
 - Adhesive 14.4%
 - SecurAcath 1.1%

- Conclusion: "We strongly suggest this new securement device be adopted for the whole life of every tunneled CVC and for the first 3-4 weeks for all cuffed CVCs."

An observational study of the securement of central venous access devices with a subcutaneous anchor device in a paediatric population at a tertiary level hospital

Fitzsimmons, et al, Journal of Vascular Access (2020) May

- 52 consecutive paediatric patients, aged less than 18 years old, who required peripherally inserted central catheters and non-cuffed tunnelled centrally inserted central catheters.
- There was a reduction in securement failure from 2.58 per 1000 catheter days using historical data to 2.01 per 1000 catheter days with the use of SecurAcath
- We advocate the use of subcutaneous anchor devices (SecurAcath) in paediatric patients who require medium-term venous access

Securing CSF catheters to the skin: from sutures and bolt system to subcutaneous anchoring device towards zero complications

Frassanito, et al, Child's Nervous System (2020) June

- SecurAcath® was used in 209 patients (mean age 7 years) to secure 195 external cranial catheters and 16 spinal drainages
- Indwell time ranged from 5 to 30 days
- No complication related to the use of the device was observed. In particular, there was no case of dislocation or accidental pullout of the catheter. Rate of infection, or superinfection in case of ventricular catheter implanted for CSF infection, was null.
- **Conclusions** SecurAcath is a safe and effective device to secure CSF external catheters, with several relevant advantages, including easy placement and maintenance. Moreover, it may stay in place for the whole duration of the catheter without any skin tissue trauma and allows a complete antisepsis of the exit site, thus reducing local skin complications. This factor has significant impact on the reduction of infection rate of external CSF catheters.

POSTERS / PRESENTATIONS

A Decade of Security

McCormick, et al. Clatterbridge Cancer Center, NHS Trust. Poster presentation, World Congress on Vascular Access (WoCoVA) Athens, Greece, October, 2022.

- Data on patients for two securement devices (SecurAcath and an adhesive device) and removal data were collected from 2009 to 2020.
- Patients included n=9,257, and total catheter days were 1,251,613.
- The probability of reaching the end of need for one peripherally inserted catheter for patients with an adhesive securement device (ASD) was 68% at two years, and for patients with a subcutaneous anchored securement device (SASS) was over 95% at two years.
- Migration and dislodgement causing premature removal of the PICC occurred at 12% for ASD secured PICCs and 0.4% for SASS secured PICCs (p<.0001)
- The results demonstrate the SASS's superiority in reducing the incidence of migration and dislodgement
- The data accumulated for over 10 years of focusing on patients reaching the end of need with one catheter produced outcomes that clearly demonstrate SASS as the optimal securement to accomplish this goal

Effective PICC Securement – Creating an Ongoing Sustainable Environment

Culverwell, E., Canterbury District Health, Oral Presentation, IV Nursing New Zealand National Conference (2018) March

- Place approx. 1500 PICCs per year
- Started using SecurAcath 2 years ago
- PICC replacement rate of 9% with adhesive device
- SecurAcath had 0% replaced line rate, creating savings of \$59,250
- Infections dropped from 22 (1.4%) in 2015 (pre-SecurAcath use) to 10 (0.6%) with SecurAcath in 2017 creating savings of \$360,000
- Total hospital savings of \$419,250 per year in infection and replaced line costs by switching to SecurAcath

Securement of Central Venous Lines by Subcutaneously Anchored Sutureless Devices in Neonates and Children

Pittiruti, et al., ESPNIC Poster Presentation (2017) May

- 85 central lines, 48 CICC, 37 PICC
- 73 patients (age range 20 days to 12 years)
- Secured with SecurAcath
- SecurAcath was effective in preventing dislocation in 99% of patients
- Complications at insertion, during maintenance and at removal were negligible

Implementation of a Quality Improvement Initiative Reduces PICC Migrations in a Complex Continuing Care Hospital

Djurcic-Jovan, et al, The Ottawa Hospital, Poster Presentation, Canadian Vascular Access Association (2016)

- PICCs
- n = 54
- 0% migration or dislodgement
- Cost savings due to reduced transport, repeat CXR and catheter replacement = \$20,215

Introducing SecurAcath into a Haematology/Oncology Setting

Sandeluss, et al, Central Venous Access, Cancer Services, University College London Hospital NHS Foundation Trust, Poster Presentation AVA (2013)

- PICC lines
- n = 83
- 0% catheter dislodgement with SecurAcath, compared to a previous 7% rate with adhesive device
- No infections

Improving PICC Care in the Pediatric Patient

Stone, et al, Boston Children's Hospital, Boston, MA, Poster Presentation AVA (2013)

- PICC lines
- n = 42 pediatric patients
- 0% catheter dislodgement
- No complications or infections reported
- Experience in previous year showed 17 PICCs that had securement issues that resulted in compromised tip location when using adhesive securement device
- Trend indicates a significant reduction in catheter migration and dislodgement

Securing a More Stable PICC

Dougherty, L., RN, DClInP, MSc, Nurse Consultant, Intravenous Therapy, Nursing, Rehabilitation & Quality Assurance, The Royal Marsden NHS Foundation Trust, Poster Presentation AVA (2013)

- PICC lines
- n = 30 patients
- No infections reported
- Additional clinical data provided by the author:
 - 3.1% dislodgement rate in prior year using adhesive securement device
 - Dislodgement rate reduced to 1.0% in first year of SecurAcath use

Cutting Edge Technology: Central Venous Line Securement Device

Ballance, P., BS, RN-BC, VA-BC, Amanda Grant, RN, VA-BC, Wayne Memorial Hospital, Goldsboro, NC, Poster Presentation AVA (2013)

- PICC Lines
- Site places 800 PICCs per year or 67 per month.
- Data from month using adhesive securement had 5 dislodgements or a 7.5% rate
- Data from month with SecurAcath had one dislodgement or a 1.5% rate

Complete articles are available on the SecurAcath website:
<https://securacath.com///clinical-evidence/securacath-papers/>



181 Cheshire Lane, Suite 100
Plymouth, MN 55441 USA
+1.763.225.6699
www.securacath.com

www.securacath.com/patents
SecurAcath is a trademark of Interrad Medical, Inc.
© 2022 by Interrad Medical, Inc. All rights reserved.
1329-021 Rev M