Systematic Review of the Safety and Efficacy of Central Vascular Access Device Securement

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Highlights

- A systematic review evaluated safety and efficacy outcomes for CVAD securements.
- Many CVAD studies do not explicitly address securement methods.
- An engineered securement device must meet mandatory reporting and safety standards.
- Additional research must examine measurable effects of securement on patient outcomes.

Abstract

Background: Central vascular access devices (CVADs) are essential for patient care in modern medicine. Providing access to the central circulation, CVADs allow fluids and medications to be infused rapidly and hemodiluted. The placement of a CVAD requires knowledge of vascular access devices, optimal site selection, infection prevention protocols, and expert techniques to limit potential adverse outcomes. Research has been focused on how to safely and effectively place CVADs, but little effort has been made to investigate the securement of the catheter once it is in place.

Methods: This systematic review was performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses and registered through PROSPERO. Two systematic searches of the literature were conducted, the first in January 2021 and the second in January 2022, by using multiple medical databases. Of the 1127 titles that met initial inclusion criteria 117 were selected for evaluation and then 39 for study.

Results: Search results yielded various outcomes, making a direct comparison between studies challenging. However, it was clear that safety and efficacy were not applied to suture-based securement and have not been well researched despite its general use.

Conclusions: Randomized controlled studies are needed to measure the relative safety and efficacy of different securement modalities, their impact on CVAD complications, and ultimately patient outcomes.

Keywords: systematic review, central vascular access devices, securement, safety, efficacy

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Introduction

Central vascular access devices (CVADs) are essential for patient care in modern medicine. From patients in a critical care unit to the person requiring lifelong parenteral nutrition, the CVAD is a lifeline and essential to their treatment. Providing access to the central circulation, CVADs allow fluids and medications to be infused rapidly and hemodiluted. Unlike peripheral vascular access devices (PVADs), the sterile placement of the tip of a CVAD into larger central veins allow it to remain in situ for an indefinite period, provided it has appropriate securement.[1,2]

There are 2 classifications of percutaneous CVAD: the centrally inserted central catheter (CICC) and the peripherally inserted central catheter (PICC), both of which should terminate in the lower third of the superior vena cava (SVC). The femorally inserted central catheter (FICC), a subset catheter of the PICC, enters the femoral vein in the midthigh and terminates in the inferior vena cava. All central catheters have tip locations identified in the central circulation at or near the cavo-atrial junction.[2,3]

The placement of a CVAD requires knowledge of vascular access devices, optimal site selection, infection prevention protocols, and expert techniques to limit potential adverse outcomes. In temporal terms, the placement takes minutes, but the line will last for days, weeks, or months. Research has been focused on how to safely and effectively place CVADs, but little effort has been made to investigate the securement of the catheter once it is in place. While dressing a vascular device follows the principles of wound care, securement is a unique component that requires dedicated study.[4]

At their inception, CVADs were secured with wound closure devices like other percutaneous tubes due to a lack of alternative engineered devices. Vascular catheters were then developed with integrated suture wings to make it possible to secure them with a loop of suture and without the need for complicated loops and knots to trap the round catheter.[5] For this review, the variety of nonabsorbable sutures and techniques used will be grouped together as suture-based securement (SBS). Several SBS studies did not specify the suture parameters or techniques.

In the 1990s, adhesive securement devices (ASDs) were developed and introduced. At the same time, PICCs were increasingly used for central venous access.[6] As ASDs became the standard securement for PICCs, most PICC manufacturers came to include some form of adhesive securement in their insertion kits.[7] The CICC kits, however, continue to have sutures as a traditional, off-label securement component.[8]

In 2008, an integrated securement device (ISD) combined the catheter dressing with a form of ASD.[9] In 2012, a subcutaneous anchored securement system (SASS) was marketed as a distinctly different option for securement.[10] Tissue adhesive (TA) was introduced to the market as a liquid adhesive securement in 2017.[11]

Guidance on the securement of CVADs is often unclear and contradictory. Guidelines, standards, and government legislation to prevent the risk of needlesticks all discourage the use of sutures, but they remain ubiquitous. SBS is still commonly the prescribed securement method in physician and resident CVAD training and is readily available in procedural insertion kits.[2,8,12–15] During this project, the authors found multiple articles that discussed complications but did not explicitly identify the securement method. This lack of specificity assumes that the type of securement is a foregone conclusion: PICCs are held with ASD, while CICCs are sutured off-label.[7,8]

Many CVADs are secured with wound closure products despite published standards that advocate for sutureless securement to avoid the risk of needlestick injury (NSI).[12,13,16] NSIs have been identified as some of the most serious issues that affect the health and wellbeing of health care workers in most health care systems in developing countries[17] and can result in long-term debility for health care workers.[18] The World Health Organization reported NSIs and sharp injuries cause about 40% of hepatitis C and B infections and 2.5% of human immunodeficiency virus infections among health care providers (HCPs).[19] The Occupational Safety and Health Association (OSHA) standard 29 CFR 1910.103 requires an annual assessment for engineered controls to reduce or eliminate the need to suture medical catheters.[20,21]

A reporting mechanism exists for when an HCP receives a needlestick from the off-label use of sutures; although many HCPs inevitably experience NSIs, they are chronically underreported.[21–23] When the sutures fail to secure catheters, the issue is not routinely reported to risk management or governing authorities. Licensed independent practitioners who choose to use a wound closure device to secure vascular access catheters are practicing medicine and are responsible for the choice to improvise over available engineered securement.[24] Sutures could not pass the current U.S. Food and Drug Administration (FDA) approval process to demonstrate safety and efficacy when used for CVAD securement secondary to the multitude of engineered securement devices currently on the market and the unnecessary risk of NSI.[25]

Attempts to displace improvised suture securement of CVADs have been sporadic, and compliance has been poor.[26] Nearly 2 decades ago, Yamamoto et al.[27] demonstrated that engineered stabilization was not inferior to sutures in a randomized controlled study. Furthermore, guidelines by Bishop et al.[28] state, "Securing devices, for example, Statlok™ are preferable to stitches, and lines should not be sewn into or around the vein." Finally, almost a decade later, Frykholm et al.[29] wrote similar guidelines ignoring previous noninferiority studies by stating, "A monofilament suture should be used to fix catheters for short-term use."

The authors undertook a review of the literature to answer the question, "What is the safety and efficacy data found in a systematic review of CVAD securement?" In conducting this review, most studies were narrowly focused, nonspecific, and suboptimal when assessing CVAD securement.

Methods

This systematic review was performed following the preferred reporting items for systematic reviews and meta-analyses (PRISMA) and registered through PROSPERO.[30,31] In collaboration with a research librarian, a systematic search of the literature in multiple medical databases, including but not

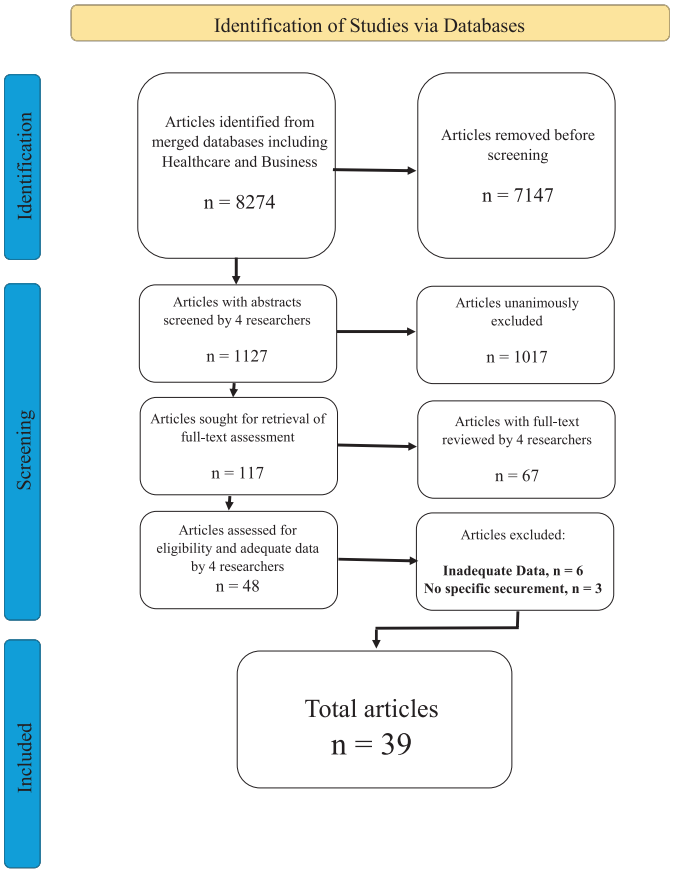

Figure 1. **PRISMA flow chart for article inclusion.**

limited to CINAHL, PubMed, and EMBASE, was conducted using search terms related to CVAD securement.

Eligibility Criteria

The first search was conducted in January of 2021, and a final search was conducted in January 2022 to include recently published data. The initial broad search included over 8000 titles, and these articles were filtered quickly based on obvious disqualification down to 1127 potentially relevant articles, see Figure 1.

Using Rayyan, a Web application for systematic review by multiple researchers, all authors independently screened articles for eligibility based on the remaining abstracts.[32] From the abstract review, 117 remaining studies were independently evaluated using the full text for final inclusion or exclusion. Inclusion disagreements were resolved by the authors using Rayyan. The final exclusion of full-text articles was conducted if the study did not have appropriate data for the summary table.

Inclusion Criteria

Original research articles were included if the following were present:

- discussion of CVAD securement;
- English or English translation available;
- randomized controlled trials, retrospective studies, or prospective studies;
- human subjects; and
- all age groups.

Exclusion Criteria

Articles were excluded if one or more of the following were present:

- conference abstracts, explanatory articles, teaching books, and expert opinions;
- specific CVAD securement device absent from the data;
- securement for vascular access devices other than CVADs; or
- missing or inconsistent data to enter into the summary table.

Data Collection Process

The following data were extracted from each article: study type and design, characteristics of the CVAD (location, tunneling, cuffed), age of the patient population, securement type, safety outcomes, and efficacy outcomes. Due to the significant heterogeneity in study designs, a systematic review was conducted, and a descriptive synthesis and approach were applied.

Eligible studies were divided among the authors for data extraction and insertion into the summary table. The lead researcher assessed the consistency of terms to create a table of like comparisons and standard terminology. However, many data points were absent due to the narrow focus of securement assessment on one outcome, either efficacy or safety, and rarely a broad assessment.

Data Items

The decisions to include specific data points resulted from the discussion between researchers, evaluation of similar systematic reviews, available data, aspects of safety, and efficacy as it relates to catheter securement. In Table 1, 3 general headings were established: demographics, safety, and efficacy.

Demographics chosen for this study had 6 categories: lead author and year of publication for an additional reference to the complete article and age of the study; an indication of the study design retrospective (Retro), prospective nonrandomized (PNR), or prospective randomized control trial (RCT). Whether the study was conducted at a single center (SC), multiple centers (MC), or was a pilot study is noted. The specific CVAD used in the study is identified as CICC, PICC, or FICC.

The placement and catheter characteristics of the CVAD were defined as tunneled (T) or tunneled with an integrated cuff (TC). For example, the acronym CICC indicates a percutaneous insertion, a T-PICC is tunneled only, and TC-FICC denotes a tunneled and cuffed catheter. One older SBS-related study compared different CVADs based on catheter material.[33] All cohorts were combined to assess SBS effectiveness, as catheter material was not considered a safety or efficacy issue for securement.

The securement and dressing specifications are often combined in studies, as most researchers do not consider these two components as separate entities to be investigated. Securement

Table 1. **Systematic Review of Securement**

Study demographics						Safety	
						Clinician	Patient
Lead author and year of publication	Study design	Central venous access device	Securement and dressings in the study	Subjects (n)	Age category	Exposures to the risk of needlestick injury	S/S site infection,[a] n (%)
Annetta, 2021[64]	Retro, MC	CICC, FICC	SASS	98	Adolescents and adults	0	NR
Barrett, 2004[65]	Retro, MC	CICC, FICC	SBS	734	Pediatrics	734	NR
Bevc, 2007[66]	PNR, SC	CICC, FICC	SBS	309	Adults	309	27 (8.7)
Brescia, 2021[3]	Retro, SC	PICC, T-PICC	SASS	639	Adults	0	NR
Cesaro, 2004[67]	PNR, SC	TC-CVAD	SBS	129	Pediatrics	129	31 (24.0)
Chan, 2017[57]	RCT, SC (pilot)	PICC	ASD	40	Adolescents and adults	0	9 (22.5)
			Tape	5		0	2 (40)
			ISD	43		0	12 (28.5)
			TA	36		0	22 (61)
Chopra, 2015[1]	PNR, SC	PICC	ASD	562	Adults	0	1 (0.2)
Cordovani, 2013[68]	PNR, MC	IJ-CICC	SASS	74	Adults	0	0
Corzine, 2010[69]	PNR, SC	PICC, FICC	Tape	491	Neonates	0	3.70
Crocoli, 2021[44]	Retro, SC	T or TC, PICC, CICC, FICC	SASS	311	Neonates, adolescents, and adults	0	2 (0.6)
Egan, 2013[55]	PNR, MC	PICC	SASS	68	Adults	0	1 (1.5)
Fitzsimons, 2020[70]	PNR, SC	T-CICC, PICC	SASS	52	Neonatal and pediatrics	0	1 (1.9)
Fohlen, 2021[43]	RCT, SC	PICC	ASD	194	Adults	0	NR
Gidaro, 2021[42]	Retro, MC	CICC, PICC, FICC	86% ASD and 14% SASS, not recorded by securement device.	852	Adults	0	NR
Karpanen, 2019[71]	RCT, MC	CICC, FICC	SBS	86	Adults	86	17 (19.8)
			ASD	85		0	19 (22.4)

Table 1. ***(Extended)***

Safety							
Patient			Efficacy				
CLABSI,[b] n (%)	Thrombus,[c] n (%)	MARSI,[d] n (%)	Dwell time	Migration and dislodgement, n (%)	Application or removal assessment	Securement device replacement	Other efficacy issues reported
1 (1.0)	NR	NR	Mean = 35 d	1 (1.0)	NR	1 device to complete therapy.	NR
9 (1.2)	7 (0.1)	NR	Median = 5.8 mo	44 (6)	NR	NR	NR
1 (0.3)	29 (9.4)	NR	Mean = 32.5 d	12 (4)	NR	NR	10.4% occlusion rate.
16 (2.5)	12 (1.9)	NR	Mean = 154 d	3 (0.47)	NR	1 device to complete therapy.	NR
2 (1.6)	NR	NR	Median = 122 d	30 (23.3)	NR	NR	51 occlusions
0	NR	12 (30%)	Median = 8.94 d	4 (10)	8.44[e]	Median = 3.68 d	NR
0	NR	1 (20%)	Median = 9.99 d	1 (20)	5.00[e]	Median = 5.21 d	NR
2 (4.7)	NR	9 (21%)	Median = 5.56 d	0	7.97[e]	Median = 3.53 d	NR
1 (2.8)	NR	1 (3%)	Median = 7.11 d	2 (6)	6.04[e]	Median = 3.41 d	NR
1 (0.2)	3 (0.5)	NR	Mean = 40.5 d	10 (2)	NR	NR	NR
0	NR	0%	Mean = 3.1 d	0	Testimonials reported	1 device to complete therapy.	NR
2.40	NR	3.70%	Mean = 11.4	11.4 (1.70)	NR	NR	NR
42 (13.5)	0	NR	Median = 175 d	8 (2.6)	NR	1 device to complete therapy.	NR
4 (4.4)	1 (1.5)	0%	Mean =22.6 d	2 (2.9)	Median time to place = 15 s	1 device to complete therapy.	91.2% completed therapy with 1 device
1 (1.9)	1 (1.9)	NR	Mean = 28.7 d	3 (5.8)	NR	1 device to complete therapy.	NR
17 (8.8)	5 (2.6)	6 (3.1%)	Median = 26 d	37 (19.0)	NR	Changed every 7 d and PRN.	Occlusion = 20 (10.0%)
9 (1.1)	13 (1.5)	NR	NR	40 (4.7)	NR	NR	NR
NR	NR	NR	Mean = 6.2 d	40 (46.5)	Satisfaction: application = 98.2% Removal = 96%	NR	31% of dressings changed secondary to excessive dressing lift.
NR	NR	NR	Mean = 7.6 d	58 (68.2)	Satisfaction: application = 88.9% Removal = 96.6%	Changed every 7 d and PRN.	25.5% of dressings changed secondary to excessive dressing lift.

Table 1. ***(Continued)***

Study demographics						Safety	
						Clinician	Patient
Lead author and year of publication	Study design	Central venous access device	Securement and dressings in the study	Subjects (n)	Age category	Exposures to the risk of needlestick injury	S/S site infection,[a] n (%)
Kleidon,2017[72]	RCT, SC (pilot)	PICC	ASD	32	Pediatrics	0	NR
			ISD	31		0	NR
			TA	32		0	NR
Knafelj, 2019[73]	PNR, SC	CICC, FICC	SBS	4	Adult	4	1
			ASD	32		0	0
Leal, 2017[74]	RCT, SC	CICC	SBS	62	Adult	62	8 (12.9)
Levy, 2010[54]	PNR, SC	PICC	ASD	279	Pediatrics	0	23 (8.2)
Lucas, 1996[33]	Retro, SC	CICC, FICC	SBS	151	Pediatrics	151	30 (20)
Matsumoto, 2020[37]	Retro, SC	TC-CICC, TC-FICC	SBS	5328	Adult	5328	191 (3.6)
McParlan, 2020[75]	Retro, SC	PICC	ASD	1111	Adult	0	NR
			SASS	1139		0	NR
Mitchell, 2019[38]	RCT, SC (pilot)	CICC, FICC	SBS	30	Adult	30	0
			SBS + TA	26		26	1 (3.8)
			ASD	29		0	0
			SBS + ISD	30		30	0
Molina-Mazon, 2018[76]	RCT, SC (pilot)	CICC, FICC, PICC	SBS	53	Adult	53	10 (37.7)
			ASD	47		0	6 (12.8)

Table 1. ***(Extended)***

Safety							
Patient			Efficacy				
CLABSI,[b] n (%)	Thrombus,[c] n (%)	MARSI,[d] n (%)	Dwell time	Migration and dislodgement, n (%)	Application or removal assessment	Securement device replacement	Other efficacy issues reported
0	0	4 (12.5%)	Mean = 8.0 d	3 (9.4)	Placement 9.6/10 Removal 7.4/10	Mean = 3.5 d	1 = breakage
0	1 (3.2)	4 (12.9%)	Mean = 7.0 d	3 (9.7)	Placement 9.7/10 Removal 9.2/10	Mean = 2.5 d	1 = breakage
0	0	10 (31.3%)	Mean = 7.1 d	4 (12.5)	Placement 9.7/10 Removal 6.1/10	Mean = 5.5 d	0 = breakage
0	NR	0%	NR	1 (25)	NR	NR	NR
0	NR	0%	NR	0	NR	NR	NR
NR	NR	NR	NR	12 (19.3)	NR	NR	4 (6.5%) kinking
4 (1.4)	NR	5 (1.8%)	Mean = 30 d	26 (9.3)	Testimonials reported	Testimonials reported	Occlusions = 21 (7.5%)
35 (26)	NR	NR	NR	19 (12.6)	NR	NR	NR
1019 (19.1)	8 (0.15)	16 (0.3%)	Mean = 36 d	224 (4.2)	Testimonials reported	Testimonials reported	NR
NR	NR	NR	NR	66 (5.9)	NR	Changed every 7 d and PRN.	NR
NR	NR	NR	NR	0	Testimonials reported	1 device per PICC	NR
5 (16.7)	0	0	Mean = 6.0 d	0	Mean application time = 5.8 min	Mean dressing time = 7.6 min; mean changes/pt = 1.27	Securement failure rate = 13 (43.3%)
1 (3.8)	1 (3.8)	1 (3.8%)	Mean = 5.6 d	1 (3.8)	Mean application time = 9.1 min	Mean dressing time = 10.2 min; mean changes/pt = 1.00	Securement failure rate = 10 (38.4%)
6 (20.7)	0	2 (6.9%)	Mean = 6.3 d	0	Mean application time = 6.7 min	Mean dressing time = 16.3 min; mean changes/pt = 1.00	Securement failure rate = 11 (38.4%)
2 (6.7)	0	0	Mean = 7.6 d	0	Mean application time = 6.9 min	Mean dressing time = 10.5 min; mean changes/pt = 1.53	Securement failure rate = 17 (56.7%)
0	NR	3 (5.7%)	Mean = 6 d	4 (7.5)	NR	NR	NR
4 (8.5)	NR	0	Mean = 6 d	15 (32.1)	Satisfaction: application = 66.7%, removal = 70%	NR	NR

Table 1. ***(Continued)***

Study demographics						Safety	
						Clinician	Patient
Lead author and year of publication	Study design	Central venous access device	Securement and dressings in the study	Subjects (n)	Age category	Exposures to the risk of needlestick injury	S/S site infection,[a] n (%)
Paquet, 2017[39]	RCT, MC	PICC	ASD	202	Adult	0	2 (1)
Paras-Bravo, 2016[77]	Retro, SC	PICC	ASD	603	Adult	0	43 (7.1)
Ramsey, 2011[78]	PNR, SC	TC-CICC	SBS	97	Adult	97	NR
Rickard, 2016[62]	RCT, SC (pilot)	CICC	SBS	111	Adult	111	0
			ASD	55		0	0
			TA	23		0	0
			SBS + TA	30		30	0
Rowe, 2020[56]	Retro, SC	PICC	ASD	838	Adults	0	NR
			SASS	6941		0	NR
Sansivero, 2011[79]	PNR, SC	PICC	SASS	50	Adult	0	None
Silva, 2018[47]	PNR, SC	CICC, FICC	SBS	196	Adults	196	44 (22.4)
Sundararajan, 2014[80]	PNR, SC	CICC, FICC	SBS	84	Adult	84	NR
			ASD	68		0	NR
Ullman, 2017[40]	RCT, SC (pilot)	T-CICC, T-FICC	SBS	11	Pediatrics	11	0
			ASD	13		0	0
			TA	12		0	0
			ISD	12		0	0

Table 1. ***(Extended)***

Safety							
Patient			Efficacy				
CLABSI,[b] n (%)	Thrombus,[c] n (%)	MARSI,[d] n (%)	Dwell time	Migration and dislodgement, n (%)	Application or removal assessment	Securement device replacement	Other efficacy issues reported
4 (2.8)	9(4.6)	3 (1.5%)	Mean = 38 d	21 (10.4)	NR	Changed every 7 d and PRN.	Occlusions = 11 (5.4%)
19 (3.2)	20(3.3)	NR	Mean = 171 d	79 (13.1)	NR	NR	Occlusions = 267 (44.3%)
NR	1 (1)	NR	Mean = 19 d	35 (36)	New suture technique to improve stability.	1 suture replaced	
0	NR	2 (2.0%)	NR	3 (3.0)	10/10[f]	NR	NR
0	NR	1 (1.8%)	NR	4 (7.3)	8/10	Changed every 7 d and PRN.	NR
0	NR	0%	NR	4 (17.4)	8.5/10	Changed every 7 d and PRN.	NR
0	NR	0%	NR	0	10/10	NR	NR
15 (1.79)	NR	NR	NR	NR	NR	Changed every 7 d and PRN.	NR
32 (0.46)	NR	NR	NR	NR	1 device applied by trained VAT member at insertion.	1 device to complete therapy.	NR
1 (2)	2 (4)	NR	Mean = 19.08 d	0	Average deployment of securement device was 11.6 s	1 device to complete therapy.	1 operator failure to deploy properly; 3 removed for discomfort at the site.
11 (5.6) suspected	NR	NR	Mean = 7.65 d	18 (9.2)	Research report a "variety" of suture techniques employed.	12 sutures fell out.	3.63% obstructed. 1% extravasation or infiltration. 0.5% bleeding. 0.5% leaking.
NR	NR	NR	NR	7 (8)	NR	NR	All subjects were on the delirium ward.
NR	NR	NR	NR	9 (13)	Testimonials	Changed every 7 d and PRN.	
0	0	2 (18%)	Mean = 14.7 d	0	8.8/10	NR	17
0	0	1 (8%)	Mean = 17.2 d	1 (8)	7.4/10	Changed every 7 d and PRN.	25
0	0	0%	Mean = 12.3 d	0	7.9/10	Changed every 7 d and PRN.	4
1 (9)	0	2 (17%)	Mean = 11.6 d	1 (9)	7.9/10	Changed every 7 d and PRN.	10

Table 1. ***(Continued)***

Study demographics						Safety	
						Clinician	Patient
Lead author and year of publication	Study design	Central venous access device	Securement and dressings in the study	Subjects (n)	Age category	Exposures to the risk of needlestick injury	S/S site infection,[a] n (%)
Ullman, 2019[41]	RCT, SC (pilot)	CICC, FICC	SBS	51	Pediatrics	54	0
			SBS + TA	59		59	0
			ISD	56		0	1 (1.8)
Waterhouse, 2014[53]	Retro + PNR, SC	PICC	ASD	30 (prospective)	Neonatal and pediatrics	0	NR
			SBS	30 (retrospective)		30	NR
Webber, 2020[81]	PNR, SC	PICC	TA	31	Adults	0	NR
			ASD	31		0	NR
Yamamoto, 2002[27]	PNR, SC	PICC	SBS	85	Adult	85	5 (5.8)
			ASD	85		0	3 (3.5)
Totals No. of subjects				23,028	Total risks	7699	

ASD = adhesive securement device; CICC = centrally inserted central catheter; CLABSI = central line-associated bloodstream infection; CVAD = central vascular access device; FICC = femorally inserted central catheter; IJ-CICC = internal jugular centrally inserted central catheter; ISD = integrated securement device; MARSI = medical adhesive-related skin injury; MC = multicenter; NR = not reported; PNR = prospective nonrandomized; PRN = as needed; RCT = randomized control trial; Retro = retrospective; SASS = subcutaneous anchored securement system; SBS = suture-based securement; SC = single center; T = tunneled; TA = tissue adhesive; TC = tunneled with an integrated cuff; VAT = Vascular Access Team

[a]Site infection (erythema, swelling, purulent discharge).

[b]CLABSI (suspected, confirmed, or unspecified).

[c]Thrombus (suspected, confirmed, or unspecified).

[d]MARSI (rash, blister, itch, skin tear).

[e]Mean days to first dressing change:

[f]Clinician ease of placement rating below: 0 = very difficult, 10 = very easy.

options in the summary table are coded as follows: SASS, ASD, ISD, TA, and SBS.[12] Although many studies specified dressing material, we did not indicate which transparent semipermeable membrane (TSM) was used. This review did not include any study that indicated no use of a TSM or site coverage of any kind.

The specific coated or impregnated catheters or antimicrobial discs were not specified in a review focused on securement. Age categories in the accepted studies range from neonates to geriatrics. Premature infant studies on securement data did not have sufficient or specific data related to CVADs.

The category of safety refers to those outcomes that would deem the device safe or unsafe to the clinician or patient. According to the FDA, the safety of a medical device must demonstrate that the use as intended outweighs the possible risks.[25] Safety in the data table was split between clinician and patient. Sutures create an unnecessary risk to the clinician and violate the OSHA and Needlestick Safety and Prevention Act[13] standards.[16,20] Patient safety issues include medical adhesive-related skin injury (MARSI) or catheter-associated skin injury (CASI), site infections, bloodstream infections (BSI), and thrombus. BSIs were not always distinguished between suspected or confirmed. For this reason, the data on central line-associated bloodstream infection (CLABSI) is marginally useful. These safety issues may have elements explicitly related to securement but may also be influenced by dressing adhesives, care, maintenance, patient history, and insertion practices.[2,34]

Efficacy is related to medical device performance under its FDA labeled indications.[25,35] To demonstrate efficacy, studies must show that the product does what it was intended to do. Therefore, migration or dislodgement outcomes serve as a primary measurement of securement performance.

Table 1. ***(Extended)***

Safety							
Patient			Efficacy				
CLABSI,[b] n (%)	Thrombus,[c] n (%)	MARSI,[d] n (%)	Dwell time	Migration and dislodgement, n (%)	Application or removal assessment	Securement device replacement	Other efficacy issues reported
1 (1.9)	1 (1.9)	2 (1.2%)	Mean = 2.69 d	3 (5.6)	NR	Short term (<7 d)	NR
0	1 (1.7)	2 (3.4%)	Mean = 2.18 d	3 (5.1)	NR	Short term (<7 d)	NR
0	1 (1.8)	3 (5.4%)	Mean = 2.23 d	0	NR	Short term (<7 d)	NR
0	NR	0%	Mean = 33.13 d	8 (30.8)	63% preferred ASD	Changed every 7 d and PRN.	NR
0	NR	NR	Mean =28.10 d	16 (59.3)	37% preferred SBS	NR	NR
NR	NR	NR	Mean = 6.1 d	0	NR	Changed every 7 d and PRN.	NR
NR	NR	NR	Mean = 6.4 d	6 (19.35)	NR	Changed every 7 d and PRN.	NR
8 (9.4)	1 (1.1)	NR	Mean = 35 d	21 (24.7)	Average 4.7 min per procedure.	Sutures not removed until end of therapy.	Detached or loose 18 (21.2%)
1 (1.1)	1 (1.1)	NR	Mean = 33 d	15 (17.6)	Average 2.7 min per procedure	Changed every 6 d and PRN.	Detached or loose 17 (20.0%)

Dwell time was included when available to put the efficacy assessment into perspective. Catheters remaining in place for less than 7 days were likely to have fewer overall issues related to catheter days. Long-term catheters may require a new securement device or reapplication at 7-day intervals as opposed to 1 device for the duration of therapy. When SBS was used, there was no indication of removal after 7–10 days, as indicated in the wound closure instructions for use (IFU).[36,37] Sutures are also well understood to lose tensile strength over time which may be accelerated by moisture, saline, and antiseptic solutions; these issues have not been studied relative to securement of external medical devices.[37]

Performance includes the ease of placement and replacement. The assessment of efficacy issues during the deployment of various securement devices is not consistently measured. When available, the information was placed in the table. Some articles had testimonials of staff or patients; those subjective assessments could not be included in the table.

Other performance issues included in the study were placed in the last column. One issue frequently mentioned was catheter occlusion. The ability of securement to limit kinking of the external portion of the catheter is a way to remove mechanical occlusion. However, thrombotic occlusions are a reportable event for the catheter and not securement. Precipitate and lipid buildup are related to drug compatibility and flushing protocols but have not been linked to securement. The report of occlusions was not specified as to the type, and the information is marginally useful.

Risk of Bias Assessment

A summary of the risk of bias assessment can be found in Table 2. Each study is identified by its potential bias in selection,

Submissions accepted until **January 17, 2023**

AVA 2023

October 14-17 Portland, Oregon

www.avainfo.org/CFP2023

Call for Topics and Presentations

WHO IS AVA?

AVA, The Association for Vascular Access, is a not-for-profit multidisciplinary professional organization uniquely positioned as the leader in vascular access education and research. Its mission is to improve patient safety, comfort and outcomes, define the vascular access specialty, promote a favorable public policy environment, optimize professionals' knowledge and skills, share best practices, and promote research in vascular access. AVA's membership includes clinicians from many disciplines including nursing, medicine, radiology, respiratory therapy, pharmacy, as well as consumers, professionals from industry, education, research, and others with an interest or specialization in vascular access and related fields.

Meeting attendees come from many countries and include professionals from:

Interventional Radiology • Oncology • Surgery • Education and Training • Critical Care • Home Care • Home Infusion • Hematology • Radiology • Pediatrics and Neonatology • Nephrology and Dialysis • Anesthesiology • Infectious Disease • Infection Prevention • Vascular Access • Research and Development • Sales and Marketing • Engineering

AVA ANNUAL SCIENTIFIC MEETING

2023 marks AVA's 36th Annual Scientific Meeting with at least 1,300 attendees, which include 60–70 industry partners. The meeting site is in **Portland, Oregon**. AVA demonstrates its leadership role in the art and science of vascular access. This four-day conference (**October 14-17, 2023**) provides attendees with opportunities to participate in educational sessions, hands-on training, facilitated discussion, and networking.

General Sessions focus on development of the vascular access specialty, clinical research, professional development, technological advances, and evidence-based practice.

Breakout Sessions will offer small group presentations emphasizing subjects of interest for the vascular access specialist and related disciplines; abstract and poster presentations allow participants to share original research, education projects and clinical innovations.

Platinum Showcases and **Exhibits** afford participants, corporate members, and exhibitors the opportunity to learn from each other, design and apply new technologies, science, and techniques in the most effective ways.

With separate registration fees, **an additional day of Pre-Meeting Workshops** (October 13, 2023) offers in-depth exploration of topics of critical importance to the vascular access community.

The Call for Topics seeks submissions from:

1) **Professionals who wish to submit a Topic for Presentation**
2) **Recommendations for speakers and/or topics to be included in the Scientific Meeting**

- Participation and submission of topic suggestions is NOT limited to AVA members
- Topics should address the general or specific interests of AVA members and meeting participants keeping in mind that AVA is an organization of clinicians, healthcare specialties, and industry/corporate professionals involved in vascular access and related fields
- Presentations must avoid any semblance of commercialism
- General Sessions are limited to 60 minutes in length
- Breakout Sessions may be scheduled from 30 to 60 minutes in length at the discretion of the selection committee
- Hands-On Workshops may be scheduled for a full day (8 hours) or for a half day (4 hours)
- A topic submitter may submit more than one topic, but please note that each speaker may be limited to presenting at only one invited session and one poster/oral abstract as the principal author
- AVA values diversity, inclusion, and professional mentoring among its membership and promotes these values in its topic and speaker selection processes
- AVA reserves the right to solicit additional and/or new speakers for any proposed topic

Get prepared for your Presentation Submission.

The information listed below is required to complete the submission process.
Each submission is reviewed by program committee members who score the key elements based on how closely the given criteria are met.

Presentation Title:

Use key words that describe the specific topic and content of the abstract. Catch phrases can be used but need to include a reference to the topic. For example, "Making a Difference" may get attention but does not suggest what the abstract is about. By adding a specific reference to the abstract subject matter, the abstract title becomes clearer; i.e., "Making a Difference: Ace Inhibitors in Hypertensive Patients."

Target Audience:

What population is this session designed to benefit most?

Level of experience of the target audience:

Basic, Intermediate, Advanced

What type of presentation is this?

General Session
Breakout Session*
Hands-On Workshop

**Breakout Sessions may be scheduled from 30 to 60 minutes in length at the discretion of the selection committee.*

Prerequisite:

Include the minimum knowledge and/or skills required to most benefit from this session.

Purpose/Goals:

This statement should be the most important primary information you want to convey for the abstract. This should be one or two sentences. The title should not be repeated.

Has this presentation been given before? Where?

Learning Objectives /Outcomes:

Minimum of three objectives are required. Provide three to five outcomes that complete the statement: *"By the end of this session the participant will be able to"*. **Do not** type this statement in the text box when entering each of your outcomes.

Content Description:

The content description should be concise yet comprehensive. Ask yourself as you are reading the session description, "As an attendee, do I know what this abstract is about and would I want to attend?" Ask a colleague to read it as well while considering the same question. (max. 1,000 characters including spaces)

Additional Text:

Any additional text that expands the content description to be used for the review process. This narrative is your opportunity to provide a convincing overview of the value of your proposed session. If the reviewers cannot clearly understand what this session is about, your odds of having your abstract selected are greatly reduced. Expansion of the content description must be written in a brief, well-organized, and focused manner. In one paragraph the potential speaker should have written a narrative that:

1. Identifies the key topics that will be addressed
2. Describes any special learning activities, such as case study analysis, audience participation, or interactive discussion.

Speaker Contact Information, CV/Resume, Presentation Experience, and Availability Over Meeting Dates.

Contracts are signed only with the primary presenter. Only the Primary Presenter may be eligible for any speaker incentives. All presenters must be aware that this application is being submitted.

Some applicants will be contacted by an AVA 2023 Annual Meeting Design Team Member for a phone interview between February and March of 2023 to discuss the presentation submission. Please try to return messages promptly. The interview is an integral part of the submission review process. Failure to participate, or be available for an interview may result in the elimination of the submission from the review process.

The program will be selected by **April 2023**. Applicants will receive notice by email.

Table 2. **Risk of Bias Assessment**

Study	Bias arising from the randomization process	Bias due to deviations from intended intervention	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of reported result	Manufacture Sponsored Study
	Selection Bias	Performance Bias	Attrition Bias	Detection Bias	Reporting Bias	Yes or No
Annetta, 2021[64]						NO
Barrett, 2004[65]						NO
Bevc, 2007[66]						NO
Brescia, 2021[3]						NO
Cesaro, 2004[67]						NO
Chan et al., 2017[57]						YES
Chopra, 2015[1]						NO
Cordovani, 2013[68]						YES
Corzine, 2010[69]						NO
Crocoli, 2021[44]						NO
Egan, 2013[55]						YES
Fitzsimons, 2020[70]						NO
Fohlen, 2021[43]						NO
Gidaro, 2021[42]						NO
Karpanen, 2019[71]						YES
Kleidon,2017[72]						YES
Knafelj, 2019[73]						NO
Leal, 2017[74]						NO
Levy, 2010[54]						NO
Lucas, 1996[33]						NO
Matsumoto, 2020[37]						NO
McParlan, 2020[75]						NO
Mitchell, 2020[38]						NO
Molina-Mazon, 2018[76]						NO
Paquet, 2017[39]						NO
Paras-Bravo, 2016[77]						NO
Ramsey, 2011[78]						NO
Rickard, 2016[62]						NO
Rowe, 2020[56]						NO
Sansivero, 2011[79]						NO
Silva, 2018[47]						NO
Sundararajan, 2014[80]						NO
Ullman, 2017[40]						NO
Ullman, 2019[41]						NO
Waterhouse, 2014[53]						NO
Webber, 2020[81]						YES
Yamamoto, 2002[27]						NO
KEY	High Probability	Some Concerns	Low Probability	Undetermined		

performance, detection, attrition, or reporting according to an assessment of each article and its stated limitations.

Synthesis of Methods

The demographics and data points were chosen before searching for relevant articles. Each assessment by the research team included a search for the article's attention to each data point listed previously. Although the chosen data points reflect safety and efficacy issues that should be assessed in every study of securement, only 5 studies assessed each securement-related outcome.[37–41]

All other studies addressed at least 1 of the outcomes and the demographics required to identify the study as securement related. One study included inappropriate data for this analysis, i.e., PVADs. In this study, the only data extracted were the percutaneous or tunneled CVAD securement outcomes.[42]

Several studies included securement with a variety of TSM configurations. In these cases, cohorts with the same securement but different TSMs are combined into a single securement group.[43,44]

Effect Measures

The prevalence of each safety and efficacy outcome is expressed as a percentage of the total number of subjects with a particular securement device. Referring to Table 1, under the heading of safety, the risk to the clinician for NSI is marked yes or no. Whether or not a clinician-reported a needlestick during the study is less significant than the element of unnecessary risk.[13]

The 4 patient safety outcomes are calculated as the prevalence of the issue reported in the study. When a study did not monitor a safety-related data point, the entry is marked as not reported (NR). The numerical entries of 0 or 0.00% indicate that the outcome was measured in a particular study, but no subject experienced that safety-related issue.

Multiple studies monitored the outcome of CLABSI but did not consistently indicate whether the infection was laboratory confirmed or suspected. Therefore, both suspected, confirmed, and unspecified CLABSI outcomes were counted in this safety data point for this analysis. Likewise, a report of thrombus was not often classified as clinically indicated or diagnosed; all reported thrombus was marked in this safety-related data point.

Efficacy for securement devices at a minimum should secure the catheter until the end of need or completion of therapy. Migration and dislodgement are combined into 1 column, as many studies did not indicate the degree of migration or the probable tip position of the CVAD. Dwell time was reported in most of the studies, although the report of this information varied. The researchers in these studies reported the mean, median, and total number of days. The context of catheter dwell time is a significant factor in assessing migration and dislodgement. Although the movement of the catheter out of its optimal position can occur at any time and may cause safety issues, delays in treatment, and further vein trauma, it may be more likely to occur the longer the catheter remains in situ.

Application and removal assessment was often not assessed or was explicitly aimed at the new, unfamiliar device. When measured, the results were placed in the evaluation of efficacy. If application or removal testimonials were described numerically, the table indicated that information. SBS was not reported as a standard method, and the learning curve for use was not quantified, although there are many variations.[45]

Securement device replacement information was usually not reported. In the case of sutures, the IFU for nonabsorbable wound closure should be removed at 7–10 days.[46] No discussion of removal or replacement of SBS appeared in the study articles. One study by Silva et al.[47] reported that 12 subjects had their sutures "fall out" without indicating the securement employed after the sutures failed.

ASD and ISD are scheduled to be replaced every 7 days routinely or earlier for dressing or adhesive failures. When TA is used for securement, it should be reapplied every 7 days. In the studies employing TA, reapplication of the securement liquid was not indicated.[2]

The study table reports other efficacy issues. These concerns included dressings lifting, detached, or loose which may affect adhesive-based securement. In addition, occlusions were reported in some dressing and securement studies. Although more likely to be a catheter or care and maintenance issue, securement may play a role by decreasing catheter movement or mechanical occlusions such as kinking. No studies are available to affirm this theory, but the information is reported as a possible efficacy issue.

Certainty Assessment

Four independent authors assessed the articles that qualified for this systematic review of securement to increase interrater reliability. Once the data were extracted, an independent statistician was sent the full text of all accepted research studies and the data table. The meta-analysis yielded an interquartile range for the primary endpoints of migration and CLABSI to be discussed in the results section.

Results

Search results yielded various outcomes, making a direct comparison between studies challenging. It was clear that safety and efficacy were not applied to SBS and have not been well researched despite its general use. A few older studies were included for information on cohort studies that included SBS.

Alternative securement technologies have been researched to determine noninferiority, safety, and efficacy to gain FDA approval for marketing and use.[6,9–11,48–52] Sutures have never been labeled as an external device securement tool by the FDA, yet noninferiority has been compared with this wound closure device for decades.[36,46]

Study Selection

Selection began with a broad search by a research librarian associated with a university library system. Rayyan intelligent systematic review software was employed to assess the 8274 articles for inclusion or exclusion by the 4 researchers.[32] The PRISMA flow chart for article inclusion can be found in Figure 1.

Screening of the articles took place over months, and complete agreement was obtained for the final 49 articles. Howev-

Table 3. **Primary Endpoints. Median Incidence and Interquartile Range of Migration and Dislodgement (M&D) and Central Line-Associated Bloodstream Infections (CLABSIs) for 5 Different Securement Types**

Securement	n	M&D	CLABSI
ASD	23	9.69 (12.8)	1.13 (2.86)
ISD	4	4.17 (8.67)	2.33 (5.57)
SASS	13	1.76 (3.47)[a]	1.96 (4.25)
SBS	22	6.77 (18.4)	0.78 (5.96)[a]
TA	5	5.56 (12.5)	0 (0.694)

ASD = adhesive securement device; ISD = integrated securement device; SASS = subcutaneous anchored securement system; SBS = suture-based securement; TA = tissue adhesive.
[a]Minimum nonzero values.

er, the data extraction process reduced that number to 39 and excluded studies for further evaluation secondary to inadequate data reporting.

Study Characteristics

The 39 studies chosen included 29 prospective trials, 12 randomized, and 11 retrospective studies. In addition, a study by Waterhouse et al.[53] included retrospective information on SBS and a prospective comparison using ASD. Most, 33 Single Center, 6 Multi-center used in 39 studies, with the highest number being 23 that included CICCs, followed by 21 studies assessing PICCs.

Only 1 study represented securement with tape and a TSM.[54] There were only a few studies with engineered securement using ISD and TA at 5 and 8, respectively. Top engineered securement studies were ASD, 22, and SASS, 13. SBS had 19 qualified articles with all clinicians in these studies at unnecessary risk for NSI. Specific age groupings included 4 neonatal, 11 pediatric, 4 adolescent, and 29 adult studies, often with overlapping age ranges.

A total of 23,959 subjects were assessed throughout all 39 included studies. The patient-related safety and efficacy issues were entirely assessed in 5 studies. [37,40,41,54,55] Those reporting signs and symptoms of infection at the insertion site were 24; CLABSI, suspected or confirmed, data were reported in 33 studies. Indications of data collected on thrombus or MARSI were reported in 18 and 33 studies, respectively. However, the length of dwell time for a catheter would be significantly affected by the ability of the securement to anchor the catheter; this information was recorded in only 33 studies.

Migration and dislodgement were reported in all studies but 1. Rowe et al.[56] focused retrospectively on laboratory-confirmed CLABSI outcomes in 2 different securement devices, ASD and SASS. Other efficacy outcomes, including ease of application and removal and replacement information, were recorded in 19 and 10 articles. Replacement information as a function of efficacy should be assessed by the number of securement devices required to complete the therapy as in ASD, ISD, and TA every 7 days or more and SASS for the duration of the catheter implant. Sutures were either not removed as indicated by the IFU for nonabsorbable wound closure or lacked an indication of replacement with an alternative device.

Results Syntheses

The prevalence of a particular data point can be viewed as a percentage of the total number of subjects with each securement device and sutures in Table 1. Analysis of the primary safety endpoint of CLABSI was marginally useful, as some studies did not report suspected versus laboratory confirmed. Table 3 shows the median incidence and interquartile range for CLABSI in the 5 securement types. For nonzero values, SBS had the lowest incidence. In the same table, the migration and dislodgement primary endpoint for efficacy showed a significant decrease associated with SASS use.

A Forest plot of CVAD securement type and migration incidence can be viewed in Figure 2. The lowest incidence of migration or dislodgement is found in the SASS and the highest incidence in the various ASDs.

Certainty of Evidence

Four researchers working independently through Rayyan assessed the articles for inclusion in this systematic review.[32] Once the articles were limited to the 48 securement-related studies, researchers scrutinized each article for appropriateness of research strategies and data collection. An additional 9 articles were eliminated during the process of extracting data for the summary Table 1. All researchers assessed the table information for the certainty of evidence and accuracy. Additionally, an independent statistician was sent the summary table and corresponding articles for a critique of data extraction accuracy.

Due to the assortment of the studies included in this review, a summary of consistently reported data was only accomplished on the primary efficacy endpoint by combining migration and dislodgement. Migration measurements varied significantly between studies and as a percentage of the total catheter. For example, a 2 cm migration in an adult may equate to total dislodgement from the SVC in a neonate.

As reported previously, CLABSI, a significant catheter-related safety issue, was not consistently reported between and

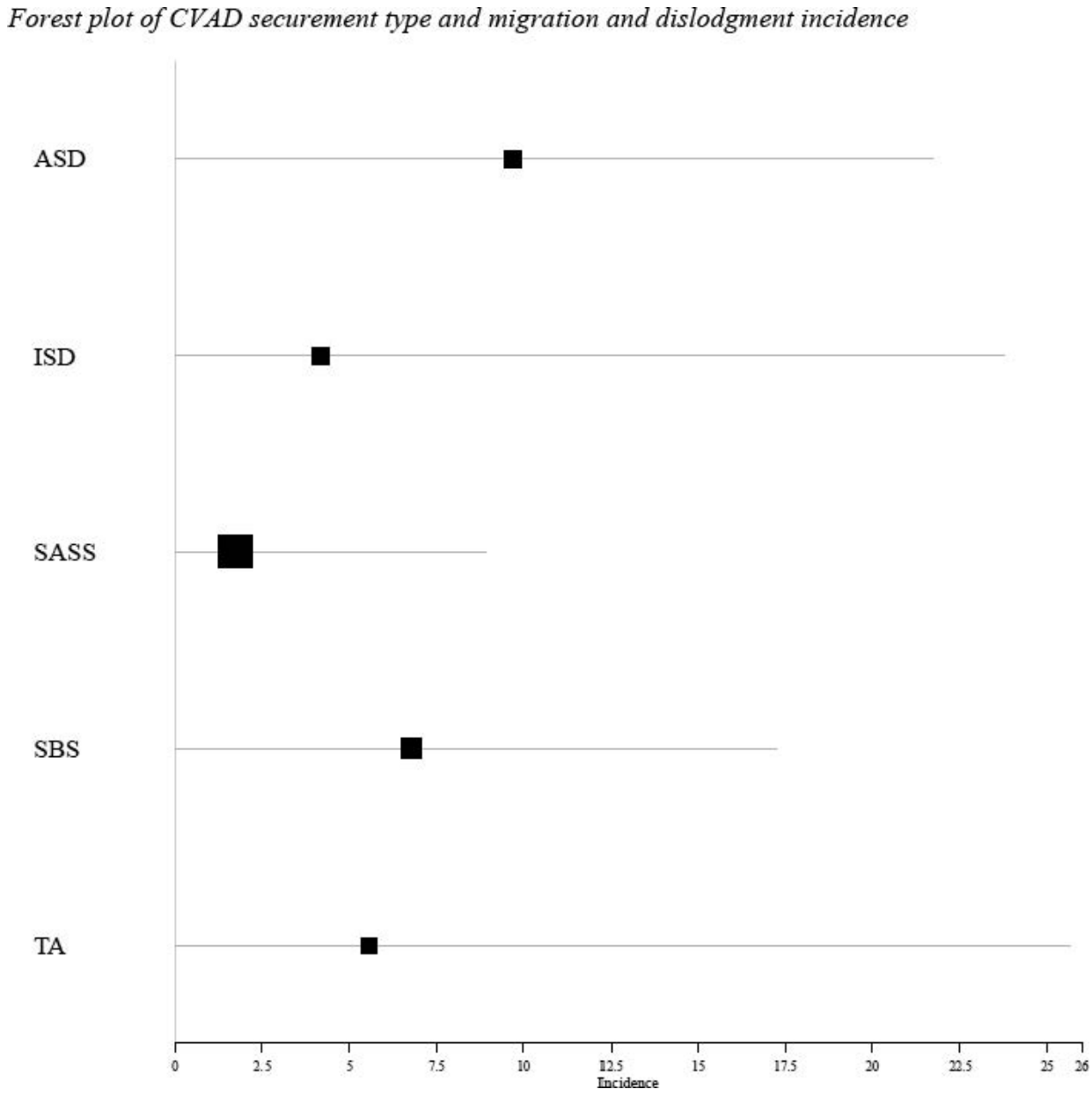

Figure 2. **Forest plot of migration and dislodgement. Forest plot of central vascular access device securement type and migration and dislodgment incidence.**

even within studies. In addition, the certainty that the reported data were laboratory-confirmed CLABSIs was not available in every study.

To ensure evidence certainty in future securement-related studies, researchers should report on all aspects of safety and efficacy reported in this review. Additionally, thrombus should be confirmed with diagnostic testing rather than noting a clinical suspicion, as the diagnosis or lack thereof changes patient management.

Several studies demonstrated the correlation between specific securement and complications. Chan et al.[57] found that "Poor securement potentiates all complication types." Cotogni et al.[58] noted that, "There was a significant correlation between the use of suture and dislocation." (p. 382). Furthermore, "in Hohn catheters, securement using a sutureless device reduces the risk of CRBSI and dislocation." Dolcino et al.[59] concluded that the "use of SASS significantly reduces the incidence of dislodgment in high-risk patients, particularly in the very first postoperative period."

Discussion

Securement is simply the act of securing. Securing has 2 definitions: "fix or attach (something) firmly so that it cannot be moved or lost" and "protect against threats; make safe."[60] Both of these definitions apply to vascular devices. The securement of CVADs should keep these catheters from moving and prevent harm to the patient. Patient harm related to CVADs would be physical in that the loss of the catheter may necessi-

tate a subsequent invasive procedure to regain vascular access and possibly the need to extend therapy due to interruptions caused by malpositioned or displaced CVAD.[61] Harm can also occur in the care of the device with repeated adhesive-related injury or additional skin injury from SBS.[34]

The ideal securement should be safe against threats to the patient and providers and effectively keep the line secure from malposition or movement including micropistoning. Securement can be divided into 3 areas: transdermal, cutaneous, and subcutaneous. Transdermal methods secure the catheter through the skin. Cutaneous secures the catheter to the skin, while subcutaneous secures the catheter under the skin. Sutures are considered transdermal, ASDs, TA, and integrated securement dressings are considered cutaneous, whereas the subcutaneous anchor securement system is subcutaneous securement. While the safety of sutures has not been well researched, it is difficult to see how piercing the skin of the patient at multiple locations near a track that enters the bloodstream would be prudent in the presence of workable alternatives. Avoiding needlesticks by the clinicians is an obvious safety issue in which OSHA has mandated the use of devices that eliminate the risk when possible.[13,20] Also, while SBS is relatively inexpensive and readily available, displacement rates of 3% to 59.3% with a minimum of 30 subjects call into question its justification for securing CVADs off-label.[53,62]

Engineered stabilization devices (ESDs) have been extensively researched and vetted by the FDA and foreign regulating bodies. Their safety and efficacy have been studied and demonstrated. More studies are needed that directly compare a variety of ESDs in random controlled trials. Research is also needed to examine the link between securement and poor patient outcomes related to CVAD complications.

An industry standard for the amount of movement allowed for devices claiming to secure external devices would be helpful for clinicians in choosing the correct device to secure an invasive catheter. In addition, removing SBS from insertion trays as the option to force an off-label medical act over ESDs would eliminate unnecessary risk and improve catheter securement, as shown by this meta-analysis on migration and dislodgement, Figure 2.

OSHA has promulgated the Occupational Safety and Health Standards. Standard 1910.1030 states, "Engineering controls that reduce the potential for needlesticks by eliminating the need to suture medical catheters in place are one option for healthcare employers to consider. As part of their annual review of methods to reduce needlesticks, employers must review options for securing medical catheters and consider appropriate engineering and work practice controls."[13,16,20]

It is baffling how continued use of wound closure sutures for catheter securement can be in line with this standard when so many options exist. In 2006, the Centers for Disease Control and Prevention identified that a quarter of all medical sharps injuries were related to suture needles and that needlesticks are vastly underreported.[19,63]

Conclusions

In our review of the literature, we found that the safety and efficacy of CVAD securement have not been systematically studied. Guidelines regarding securement say that ESDs should be used rather than SBS to avoid injury to patients and providers. The evidence that engineered stabilization is noninferior to SBS is substantial. However, evidence comparing different forms of securement is lacking. Random controlled studies are needed to measure the relative safety and efficacy of different securement modalities and their impact on CVAD complications and ultimately patient outcomes.

Disclosures

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: JB, MH, and MG have worked for Interrad Medical, the makers of SecurAcath. We attest that all authors contributed significantly to the creation of this manuscript, each having fulfilled criteria as established by the International Committee of Medical Journal Editors.

Editor note

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