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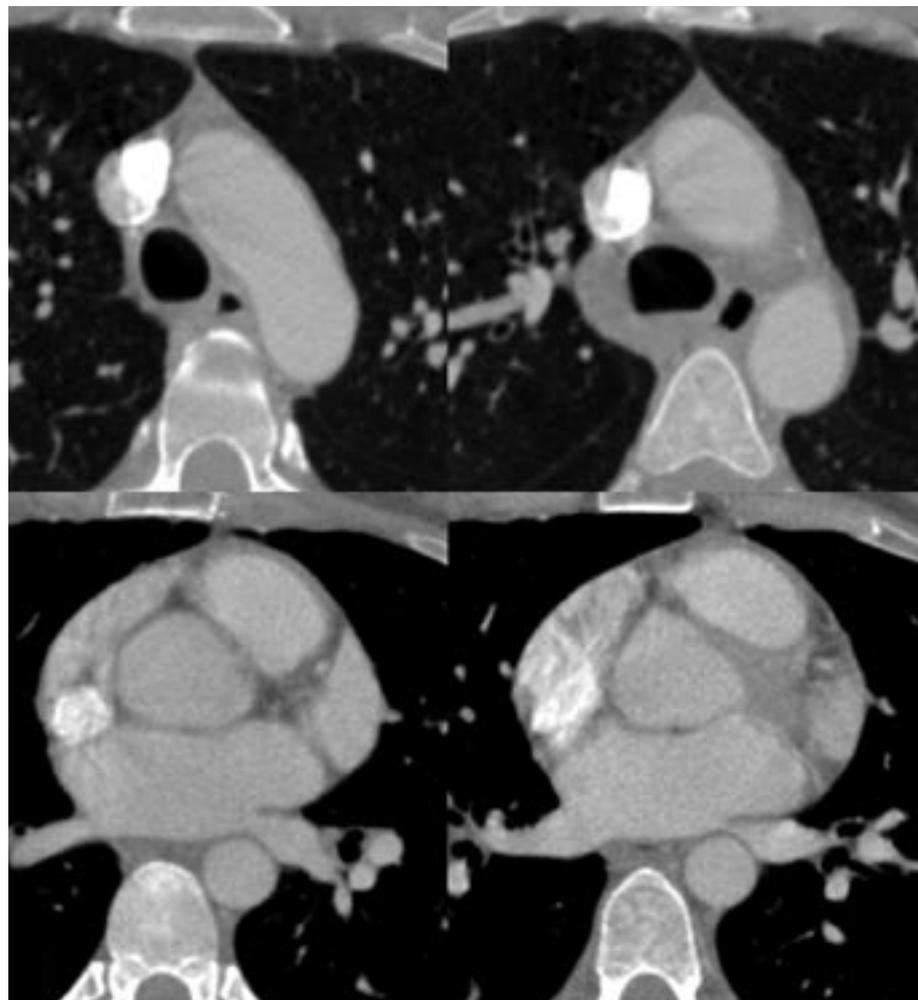
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# Clinical Performance of a New Transparent Chlorhexidine Gluconate Central Venous Catheter Dressing

Carol Olson, RN-BC and the Vascular Access Team of Abbott Northwestern Hospital and James M. Heilman, BS

## Abstract

*As the sciences of vascular access and infection prevention rapidly advance healthcare professionals are often faced with new technologies designed to help, but which are often so complicated to use that they cause unforeseen problems. As a vascular access team at a major mid-western hospital, we evaluated the ease-of-use and the performance characteristics of a new transparent catheter dressing, 3M Tegaderm CHG IV Securement Dressing® (3M Health Care™, St. Paul, MN) containing the antimicrobial chlorhexidine gluconate (CHG), with a variety of central venous catheters insertion sites in comparison to a standard non-antimicrobial dressing Tegaderm® (3M Health Care™, St. Paul, MN). Following IRB approval, sixty-three consenting patients were enrolled and randomized; 33 in the CHG antimicrobial dressing group and 30 in the standard dressing group. Thirty six patients had peripherally inserted central catheters (PICCs), 20 had intrajugular insertions (IJ), and 7 had subclavian insertions. The new 3M Tegaderm CHG IV Securement Dressing® (3M Health Care™, St. Paul, MN) was evaluated for its ability to permit visualization of the insertion site, ease of use, ease of using correctly, ability to secure the catheter and absorb exudates and remain transparent.*

*The new 3M Tegaderm CHG IV Securement Dressing® (3M Health Care™, St. Paul, MN) was found to be as easy to use in central venous catheter care clinical practice as the standard of care non-antimicrobial transparent adhesive dressing. No additional training or education was required to properly use it. This dressing was applied and removed like standard transparent adhesive dressings, but offered many advantages over standard dressings. Advantages include that it is antimicrobial, handles moderate bleeding, remains transparent and appears to offer greater catheter securement than the Tegaderm® (3M Health Care™, St. Paul, MN) standard dressing. The CHG gel pad also conformed well to the catheter.*

## Introduction

There are approximately 7 million central venous catheters (CVCs) placed in the U.S each year (Richardson, 2007). Catheter-related bloodstream infections (CR-BSIs), resulting from intravenous catheters, are a serious medical problem (O'Grady 2002; Maki, 1982; Maki, Goldman & Rhame, 1973). The patient's own skin flora is considered to be the single most important source of catheter colonization and infection for central venous catheters in place for 10 days or less, and it is believed that 60% of CR-BSIs originate from

the patient's own skin flora (Mermel, 1991; Maki, 1982). Although antiseptic agents are used to disinfect the skin prior to catheter insertion, bacteria remain on the skin and bacterial regrowth will occur over time (O'Grady, 2002; Tanzer, Miller & Richards, 1994; Bjornson et al., 1982; Hendley & Ashe, 1991; Maki, 1977). As the sciences of vascular access and infection prevention rapidly advance, healthcare professionals are often faced with new technologies designed to help. However, these new technologies can be so complicated to use that they may cause unforeseen problems. This dilemma is exemplified by the increase in infections seen with the introduction of numerous variations of needleless devices (Rupp, 2007).

A chlorhexidine gluconate (CHG) catheter dressing called BIOPATCH® Antimicrobial Dressing (Johnson & Johnson™, Somerville, NJ), has been shown to reduce catheter-related

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bloodstream infections (O'Grady, 2002; Mermel, 2001; Maki et al., 2000), but BIOPATCH® can be difficult to use in clinical practice (MAUDE, 2007). With BIOPATCH® the CHG containing disk is not transparent so the insertion site cannot be visually inspected for complications. The disk needs to be covered with a standard transparent adhesive dressing (TAD) necessitating multiple steps in its application. Too often it is used incorrectly, such as being applied upside down, necessitating continued training of staff in its proper use (MAUDE, 2007).

### Objective

The purpose of this study was to evaluate a new chlorhexidine gluconate catheter dressing, 3M Tegaderm CHG IV Securement Dressing® (3M Health Care, St. Paul, MN) for its practicality of use in clinical practice on central vascular access devices in patients in the intensive care units, and acute and sub-acute medical-surgical units. The 3M Tegaderm CHG IV Securement Dressing® (3M Health Care, St. Paul, MN) consists of a standard transparent adhesive dressing with an integrated transparent gel pad containing chlorhexidine gluconate (CHG), a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity (Milestone, Passaretti & Perl, 2008; Denton, 2001; Larson, 1995; Food and Drug Administration, 1994). The gel of the pad conforms around the catheter and is adhesive. The antimicrobial efficacy of the new CHG Dressing has been demonstrated in other studies and has been approved by the FDA (Food and Drug Administration), and is now commercially available. The new 3M Tegaderm CHG IV Securement Dressing® (3M Health Care, St. Paul, MN) was evaluated for its ability to permit visualization of the insertion site, ease of use, ease of using correctly, ability to secure the catheter, absorb exudates, and remain transparent. The primary outcome was the investigator's overall satisfaction with catheter securement based on a five point scale of 1 = very good to 5 = very poor.

### Methods

The Allina Hospitals and Clinics Institutional Review Board (IRB) reviewed and approved the study prior to the enrollment of the first patient. The IRB holds a Federal-Wide Assurance (FWA00002425) from the Office of Human Research Protection (OHRP), Department of Health and Human Services (DHHS). Modifications made to the protocol at the suggestion of the IRB included the exclusion of subjects whose first language was not English and/or those who were pregnant. Only the IRB approved consent form, bearing the IRB's dated approval stamp was used in the consent process. Proxy consents were not used. Patients who were incapable of giving their consent (heavily sedated, confused, comatose patients) were not enrolled. The participants were provided information and education regarding the study. Time was given to each patient to review the information and read the consent. The patients were then asked to reiterate the purpose of the study and their understanding of the consent. Patients were free to withdraw their consent at any time during the study. The IRB was to be notified immediately of any changes or modification to the protocol, consent form or supporting documents. The IRB was also to be immediately informed of the early removal of study participants, serious adverse events or of events that occurred at a frequency or intensity greater than that described in



*3-Lumen Subclavian catheter with CHG Dressing*



*3-Lumen IJ Catheter with CHG Dressing*



*2-Lumen PICC with CHG Dressing*

the consent form. Study findings were reported to the IRB at the conclusion of the study.

All patients admitted to the hospital requiring a central venous catheter with a peripherally inserted central catheter (PICC), intra-jugular (IJ), subclavian, or femoral insertion, expected to remain in place for at least three days, were eligible to participate. From this population a sampling of patients, who met the inclusion and exclusion criteria and were willing and able to consent, were enrolled. Any patient who met the following inclusion criteria were eligible to participate in the study.

**Inclusion criteria:**

- a. Males or females at least 18 years old.
- b. Patients with an existing, or newly inserted, intrajugular (IJ), peripherally inserted central venous (PICC), subclavian, or femoral catheter.
- c. Patients likely to require the catheter for at least 3 to 5 days.
- d. Patients whose first language was English.
- e. Patients who were cooperative and willing to sign the Consent Form.

**Exclusion criteria:**

- a. Patients who had a known history of sensitivity to chlorhexidine gluconate (CHG), alcohol, or adhesive skin products.
- b. Patients with any form of dermatitis, burns, lesions or tattoos at the insertion site.
- c. Patients using skin protectants at the insertion site.
- d. Patients who were pregnant.
- e. Patients who were heavily sedated, confused or comatose.
- f. Patients whose first language was not English.

The total consented sample was 63 subjects. No statistics were kept on total sample size asked to participate. Patients (N = 63) were randomized to either the new CHG Dressing (3M Tegaderm CHG IV Securement Dressing®, 3M Health Care, St. Paul, MN) or a traditional non-antimicrobial transparent adhesive dressing (Tegaderm®, Catalogue # 1626, 3M Health Care, St. Paul, MN). All other care was identical for the two study groups. The randomization was stratified by type of catheter (IJ, PICC, subclavian and femoral). Randomization assignments were kept inside sealed envelopes with the patient enrollment number marked on the outside of the envelope. These envelopes were used in sequence, from the appropriate randomization strata, as patients were enrolled. Because the jugular insertion site presents the most difficult challenge for insertion site dressings, a minimum of 20 patients with IJs were to be included. Because PICCs are the most common insertion site a minimum of 20 patients with PICC lines were to be included in the study. The dressings were assessed by the primary investigator, or a trained member of the vascular access team, for various performance features at least once daily for up to a maximum of seven days as shown in Table 1. The time of day varied from within the day shift (7:00-3:30 pm) and the evening shift (3:00-11:30 pm). The assessment time and dressing change times were recorded.

The primary efficacy variable was the investigator's *overall satisfaction with catheter securement*, assessed at the end of each patient's study participation, based on a five point scale of 1 = very good to 5 = very poor. The clinician's *overall satisfaction with the dressing* was also assessed using the same five point scale. The *ability to see the insertion site* through the dressing and gel pad was assessed daily on a five point scale (1 = very easy to 5 = very difficult). The *ease of applying a dressing* and the *ease of applying the dressing correctly* were assessed each time a dressing was applied using the same 1-5 scale. *Dressing adherence* was assessed daily using a 4-point scale with 0 = no edge lift, 1 = slight edge lift, 2 = marked edge lift, 3 = tunneling, and 4 = site exposed. *Skin stripping, maceration, erythema and edema* were all graded on a 0-3 scale adapted from Berger and Bowman (1984).

Erythema (Range = 0 to 3)	
None	= No evidence of irritation (Grade 0)
Mild	= Minimal erythema, barely perceptible (Grade 1)
Moderate	= Moderate erythema, readily visible; or minimal edema; or minimal papular response (Grade 2)
Severe	= Strong erythema; or erythema and papules (Grade 3)
Edema (Range = 0 to 3)	
None	= No evidence of edema (Grade 0)
Mild	= Barely perceptible edema (Grade 1)
Moderate	= Edema with well defined edges (Grade 2)
Severe	= Severe edema (Grade 3)

**Statistical Methods**

This study was powered to detect a 0.6 point difference between the 3M Tegaderm CHG IV Securement Dressing® (3M Health Care, St. Paul, MN) and the standard Tegaderm® dressing (3M Health Care, St. Paul, MN), on the 5-point rating scale of overall dressing securement. The sample size of 30 subjects per group was calculated assuming a standard deviation estimate of 0.8 points with power = 80% and 2-sided alpha = 0.05. The primary outcome of overall satisfaction with the dressing's securement was assessed using Student's t-test on the average rating of securement for the 3M Tegaderm CHG IV Securement Dressing® (3M Health Care, St. Paul, MN) compared to that of standard Tegaderm® dressing (3M Health Care, St. Paul, MN). Additional variables were assessed daily. These were summarized across the daily assessments and adjusted for the number of assessments, prior to analysis. If the variable of interest was ordinal, the mean score across assessments was calculated for each patient. If the variable was dichotomous, the percentage of assessments for which the variable was present were calculated for each patient. These percentages were then averaged across patients. Differences between groups were analyzed using Student's t-test. Significance was assessed at  $p < 0.05$ , 2-tailed.

**Results**

Sixty-three patients were enrolled into the study, 30 in the control group (Tegaderm®) and 33 in the CHG Dressing group (3M Tegaderm CHG IV Securement Dressing®). Thirty-two were male and 31 were female. The ages of the patients ranged from 28 to 88 years. The mean age of the patients was 65 years in the control group and 59 years in the CHG Dressing group. Of these 63 patients 36 (57%) had peripherally inserted central catheters (PICCs), 20 (32%) had intrajugular insertions (IJ), and 7 (11%) had subclavian insertions. There were no patients enrolled with femoral inserted catheters. Of the catheters 39 were dual-lumen, 22 were multi-lumen and 3 were single-lumen. Most of the study dressings (59) were applied during dressing changes. Four dressings were placed right after the initial catheter insertion and all four were the 3M Tegaderm CHG IV Securement Dressing®. There were no statistically significant differences in demographic and background variables between the

**Table 1: Study Procedures**

	STUDY DAY <sup>A</sup>							
	0	1	2	3	4	5	6	7
Informed Consent & HIPAA	X							
Inclusion/Exclusion, Medical History	X							
<b>Assessments</b>								
Dressing Application	X	X <sup>B</sup>						
Ease of Dressing Application	X	X <sup>B</sup>						
Correctness of Application	X	X <sup>B</sup>						
Adherence of Dressing		X	X	X	X	X	X	X
Catheter Securement		X	X	X	X	X	X	X
Transparency (Site Visibility)		X	X	X	X	X	X	X
Skin Condition (under dressing)		X	X	X	X	X	X	X
Moisture & Blood		X	X	X	X	X	X	X
Patient Comfort		X	X	X	X	X	X	X
Ease of Dressing Removal		X <sup>C</sup>	X					
Skin Condition (upon dressing removal)		X <sup>C</sup>	X					
Clinician's Overall Satisfaction with Dressing Securement								X <sup>A</sup>
Clinician's Overall Satisfaction with Dressing Performance								X <sup>A</sup>
Safety Assessments		X	X	X	X	X	X	X

A – Patient's participation in the study was expected to be up to 7 days. If for medical reasons the catheter was removed, the patient discharged or transferred prior to Day 7 the final assessments were completed at that time.

B – If the dressing was changed and new dressing applied

C – If the dressing was removed.

patients in the 3M Tegaderm CHG IV Securement Dressing<sup>®</sup> and control (Tegaderm<sup>®</sup>) dressing groups (see Table 2).

The *clinician's overall satisfaction with the dressing's catheter securement*, and *overall satisfaction with the dressing* were assessed at the end of the study and measured on a five point scale (1 = very good to 5 = very poor). Satisfaction with catheter securement was rated very good, good, or acceptable 88% of the time with the

new 3M Tegaderm CHG IV Securement Dressing<sup>®</sup> compared to 59% of the time for the standard Tegaderm<sup>®</sup> (3M Health Care, St. Paul, MN) transparent adhesive dressing (TAD). The average rating was 3.10 for the control group and 2.21 for the CHG IV Securement Dressing group. This difference was significant (p<0.0009) in favor of the CHG IV Securement Dressing. *Overall satisfaction* with the dressings was very good, good, or acceptable 94% of the

**Table 2: Demographics and Background Characteristics**

Background Characteristics	Control Dressing (Tegaderm <sup>®</sup> 3M Health Care, St. Paul, MN) (N=30)	CHG Dressing (3M Tegaderm <sup>®</sup> CHG IV Securement Dressing, 3M Health Care, St. Paul, MN) (N=33)	P-Value
Age (years) (mean, sd)	64.8 ± 17.1	58.8 ± 14.1	0.1378
Female Gender n (%)	15 (50.0%)	16 (48.5%)	1.0000
Insertion Site			0.6194
Jugular n (%)	10 (33.3%)	10 (30.3%)	
PICC n (%)	18 (60.0%)	18 (54.5%)	
Subclavian n (%)	2 (6.7%)	5 (15.2%)	
Number of Lumens			0.5652
Single n (%)	1 (3.3%)	2 (6.1%)	
Dual n (%)	20 (66.7%)	18 (54.5%)	
Multi n (%)	9 (30.0%)	13 (39.4%)	

Table 3: Variables Assessed and the End of the Study

Variables Rated* at the End of the Study	Control Dressing (Tegaderm®, 3M Health Care, St. Paul, MN). (N=29)		CHG Dressing 3M Tegaderm® CHG IV Securement Dressing, 3M Health Care, St. Paul, MN). (N=33)		P-Value
	Mean	SD	Mean	SD	
Overall Satisfaction with Dressing Securement	3.10	1.08	2.21	0.93	0.0009
Overall Satisfaction with Dressing	2.90	1.08	1.97	0.92	0.0005

\*1=Very Good 2=Good 3=Acceptable 4=Poor 5=Very Poor

Table 4: Variables Assessed Daily or at Each Dressing Change

Variables Assessed Each Day or at Dressing Change	Control Dressing (Tegaderm®, 3M Health Care, St. Paul, MN). (N=30)		CHG Dressing 3M Tegaderm® CHG IV Securement Dressing, 3M Health Care, St. Paul, MN) (N=33)		P-Value
	Mean	SD	Mean	SD	
Ease of Application*	2.36	0.66	2.23	0.71	0.4384
Ease of Applying Correctly*	2.36	0.74	2.05	0.63	0.0767
Dressing Adherence**	0.83	0.67	0.70	0.51	0.3790
Ability to Assess Skin Through Dressing*	1.74	0.40	1.99	0.45	0.0224
Ease of Removal*	2.59	0.81	2.43	0.80	0.4325
Patient Discomfort***	0.16	0.31	0.19	0.35	0.7290

\* 1=Very easy 2=Easy 3=Reasonable 4=Difficult 5=Very difficult

\*\* 0=No edge lift 1=Slight edge lift 2=Marked edge lift 3=Tunneling 4=Site exposed

\*\*\* 0=None 1=Mild 2=Moderate 3=Severe

Table 5: Skin Condition Variables Assessed Daily or at Each Dressing Change

Variables* Assessed Each Day or at Dressing Change	Control Dressing (Tegaderm®, 3M Health Care, St. Paul, MN). (N=30)		CHG Dressing 3M Tegaderm® CHG IV Securement Dressing, 3M Health Care, St. Paul, MN) (N=33)		P-Value
	Mean	SD	Mean	SD	
Erythema During Wear	0.28	0.52	0.35	0.49	0.6259
Erythema on Removal	0.62	0.68	0.49	0.66	0.4874
Skin Stripping on Removal	0.04	0.14	0.04	0.18	0.9444

\*0=None 1=Mild 2=Moderate, 3=Severe

time for the CHG IV Securement Dressing and 69% of the time for the standard TAD (Tegaderm®). The average rating was 2.90 for the control group and 1.97 for the CHG IV Securement Dressing group. This difference was statistically significant in favor of the CHG IV Securement Dressing group (p<0.0005). Table 3 provides a summary of these results.

Table 4 provides a summary of results from the assessments implemented daily or at each dressing change. The *ease with which the dressings were applied* and *ease of applying the dressing correctly* were assessed each time a dressing was applied using the 1 to 5 scale (1 = very easy to 5 = very difficult). The average ease of application for the CHG IV Securement Dressing was 2.2 compared

to 2.4 for the standard TAD control dressing (Tegaderm®), and the ease of applying the dressing correctly was 2.1 for the CHG IV Securement Dressing compared to 2.4 for the standard TAD (Tegaderm®) control dressing. These slight differences were not statistically different between the dressings. The *ability to see through the dressing* was assessed daily on a five point scale (1 = very easy, 2 = easy, 3 = reasonable, 4 = difficult and 5 = very difficult). The average rating for the CHG IV Securement Dressing was 2.0 compared to 1.7 for the control (Tegaderm®). The rating of 2.0 for the CHG IV Securement Dressing indicated that it was easy to assess the skin and insertion site through the CHG IV Securement Dressing (score 2 = easy) but it was slightly, but significantly easier (p =

0.0224) to assess skin through the control. *Dressing adherence* was assessed daily on a 0 (no lift) to 4 (site exposed) scale. The average dressing adherence was between no lift (0) and slight edge lift (1). The average rating of adherence (lift) was 0.7 for the CHG IV Securement Dressing and 0.8 for the standard TAD (Tegaderm®) control dressing. The *ease of removing* the dressings was assessed each time a dressing was removed using a 1-5 scale (1 = very easy to 5 = very difficult). Again, the CHG IV Securement Dressing was as easy to remove as the standard TAD dressing (Tegaderm®).

There were no adverse events with the CHG IV Securement Dressing, and there were no significant differences noted in skin irritation as judged by erythema or skin stripping between the CHG IV Securement Dressing and the standard (Tegaderm®) non-antimicrobial control dressing (Table 5). Edema was reported twice in the control group and was not seen in the CHG IV Securement Dressing group. The only instances of erythema were rated mild. No maceration of the skin was observed with either dressing.

### Limitations

The study was limited to inpatients 18 years and older and to only two study products. The study did not trial the complex patient in the intensive care unit with challenging vascular access devices such as pulmonary artery catheters due to the patient not meeting criteria. Many of the variables were clinical assessments of parameters which are inherently subjective in nature. The evaluators met collectively initially to go over the study's assessments and documentation requirements and the principal investigator reviewed each assessment. The fact that nine evaluators were involved in making the assessments raises the possibility that clinicians applied different definitions to terms such as "easy" versus "very easy", or "slight" versus "moderate", however, over 65% of the assessments were completed by two clinicians and there was no imbalance of study group per clinician.

### Discussion

This study evaluated the practical use of the new CHG IV Securement Dressing (3M Tegaderm CHG IV Securement Dressing®, 3M Health Care, St. Paul, MN) in clinical practice in comparison to a non-antimicrobial transparent adhesive dressing (Tegaderm®, 3M Health Care, St. Paul, MN) in standard use as an insertion site dressing. No statistical differences were observed in the dressing wear time, number of dressing changes, ease of application, ease of applying correctly and ease of removal between the new CHG IV Securement Dressing and the standard non-antimicrobial treatment dressing (Tegaderm®, 3M Health Care, St. Paul, MN). The ability to see the insertion site through the dressings was rated easy for both dressings, although it was somewhat easier to assess skin through the non-antimicrobial dressing (Tegaderm®, 3M Health Care, St. Paul, MN). The new CHG IV Securement Dressing did absorb blood and exudates, but when used immediately after a new insertion with large volumes of blood, the dressing couldn't always keep up with bleeding, and the accumulation of blood under the dressing could obscure the visualization of the site. The dressing is probably not a good replacement for gauze dressings when there is heavy bleeding, but is much better in this

regard than standard transparent adhesive dressings. We were able to evaluate only one style of the dressing but look forward to seeing it available as a bordered dressing.

The new CHG IV Securement Dressing (3M Tegaderm CHG Dressing®; 3M Health Care, St. Paul, MN) was as easy to use in central venous catheter care clinical practice as the standard of care non-antimicrobial transparent adhesive dressing (Tegaderm®, 3M Health Care, St. Paul, MN). No additional training was required for its use. It was applied and removed like standard transparent adhesive dressings, but offered many advantages over standard dressings. It is antimicrobial, handles moderate bleeding and remains transparent, and appears to offer greater catheter securement than the standard dressing. The CHG IV Securement gel pad conformed well to the catheter.

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