Clinical evidence compendium

Optimising patient care and improving clinical outcomes with peripheral intravenous catheters

A summary of the key clinical and *in vitro* studies supporting the use of BD peripheral intravenous catheters

BD

Dear reader,

Choosing the right peripheral intravenous catheter (PIVC) is a crucial step in vascular access management. Different PIVCs feature different technologies and offer different benefits, both for patients and healthcare professionals. Some national and international guidelines underline the importance of selecting a PIVC based on its intended purpose.

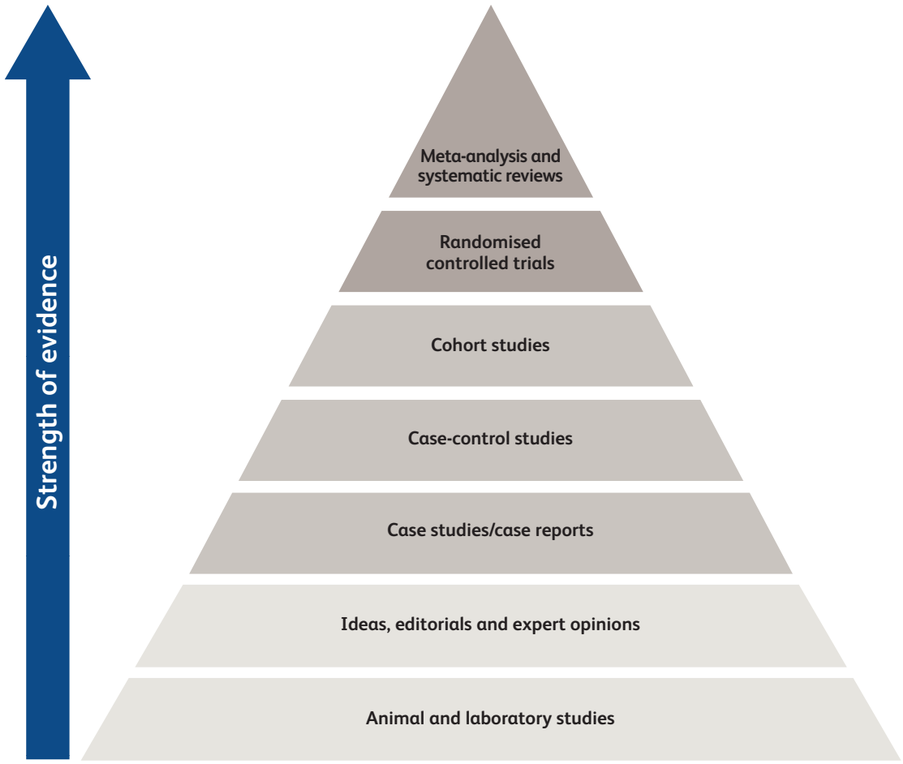
Becton, Dickinson and Company (BD) is committed to continuing the advancement of patient and healthcare professionals' safety solutions related to intravenous (IV) therapy management. BD offers a large range of PIVCs to increase both patient and healthcare professional safety throughout IV procedures. The products feature different technologies to enable healthcare professionals to choose the right PIVC for the right clinical and patient needs.

This evidence summary was compiled to facilitate access to current literature relevant to the use of BD PIVCs. All studies in this compendium were found via a literature search, and the summaries are provided as a courtesy to you, the reader. All information in this summary is current as of February 2019, and BD is not liable for any inaccuracies therein.

Ask your local account manager for access to full text copies of the studies.

Pyramid of evidence

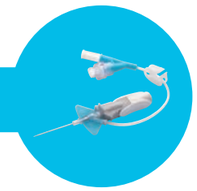
Based on ability to control for bias and to demonstrate cause and effect in humans



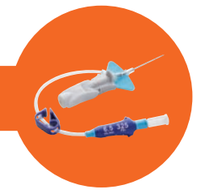
Adapted from:
OCEBM Levels of Evidence Working Group. The Oxford 2011 Levels of Evidence. Oxford Centre for Evidence-Based Medicine. Available at https://www.cebm.net/2016/05/ocebm-levels-of-evidence/ (Accessed May 2018)

Table of contents

This compendium contains highlights from the clinical papers listed below.
Please contact your local BD representative should you require any further information or if you have any questions regarding the compendium or BD PIVCs.

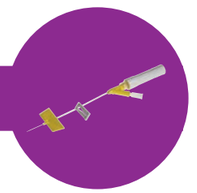


BD Nexiva™ closed intravenous catheter

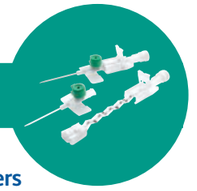


BD Nexiva Diffusics™ closed IV catheter

BD Insyte™ Autoguard™



BD Saf-T-Intima™



BD Venflon™ Pro Safety

Multiple products

A clinical trial of a new all-in-one peripheral-short catheter

Study author(s)

Mcneil EE, Hines NL and Phariss R

Publication

JAVA 2009
DOI: 10.2309/java.14-1-8

Study design (level of evidence)

Survey

Study location

United States

Study objective

To assess the BD Nexiva™ closed IV catheter with a built-in stabilisation platform in comparison with an existing catheter system using a self-developed evaluation tool

Study length

18 months (July 2006–December 2007)

Study protocol

- Open-label, non-randomised, pre- and post-use survey
- Study was conducted in three phases:
  - Phase 1: A hospital-wide survey of pre-trial PIVC securement practices over 3 days
  - Phase 2: 2-week evaluation of the BD Nexiva™ closed IV catheter system SorbaView® 2000 dressing within four selected hospital units
  - Phase 3: A final satisfaction survey among all clinicians involved in phase 1 and 2
- 122 BD Nexiva™ catheters were inserted during the 2-week trial period (phase 2)
- 42 clinicians in total were surveyed to determine user satisfaction

Patient population

Medical-surgical patients at a single 851-bed acute care facility

Key endpoints

- Catheter restarts
- Catheter security
- Complication rates
- Clinician satisfaction

Study limitations

- Single-centre study
- Major focus on stabilisation system
- The evaluation tool used to assess outcomes was self-developed
- Study design was a user acceptance evaluation and not designed to allow statistical comparisons

Study findings

>50% reduction in catheter restarts*

62% existing catheter restarts *versus* **28%** BD Nexiva™ catheter restarts

0 clotting complications using the BD Nexiva™ compared with 5 (22%) events using the existing catheter

Only 1 (8%) BD Nexiva™ restart due to infiltration *versus* 6 (26%) existing catheter restarts

8% leakage rate for the BD Nexiva™, compared with 30% for the existing catheter system

97% overall user satisfaction for BD Nexiva™ related to its ability to penetrate the vessel, and start and secure IV

*% reduction = ([62-28)]/62)x100

Key points

Introduction of the BD Nexiva™ resulted in a significant reduction in catheter restarts and complication rates

BD Nexiva™ catheter placement was rated as secure by clinicians

The BD Nexiva™ had excellent clinician satisfaction and most clinicians were willing to adopt the BD Nexiva™ in their own practice

Study conclusions

Using the BD Nexiva™ closed IV catheter with built-in stabilisation improved clinical outcomes, with improved catheter securement, reduced complications and increased dwell-time, and it was well accepted by clinicians

A randomized controlled trial to compare the complications of 2 peripheral intravenous catheter-stabilization systems

Study author(s)
Bausone-Gazda d, Lefaiver CA and Walters S-A

Publication
J Infus Nurs 2010
DOI: 10.1097/NAN.0b013e3181f85be2

Study design (level of evidence)
Randomised controlled trial

Study location
United States

Study objective
To compare the PIVC securement-related complication rates and cost of two different stabilisation systems: the BD Nexiva™ with a built-in stabilisation platform and extension tubing with specially designed 3M™ Tegaderm™ IV securement dressing (investigational group), and the Bard StatLock® device with a non-winged catheter (control group)

Study length
16 months (September 2008–December 2009)

Study protocol
- Open-label, prospective, randomised, non-inferiority study
- 302 patients were randomised to receive either the BD Nexiva™ (n=150) or the non-winged catheter (n=152)
  - The BD Nexiva™ catheter insertion site was covered using 3M Tegaderm IV securement dressing
  - The comparator non-winged Introcan Safety® catheter (B. Braun) was combined with Bard StatLock®, was covered with transparent dressing
- Daily assessments evaluated catheter stabilisation, performance of the stabilisation device and any complications
- Reason for removal, ease of removal and the nurse's overall satisfaction with the catheter and stabilisation device were also recorded

Patient population
Patients admitted to a large academic, Magnet-designated, Level I trauma centre, with an anticipated 96-hour need for PIVC

Key endpoints
- Securement
- Catheter-related complications (CRCs)
- Cost analysis
- Clinician satisfaction

Study limitations
- Single-centre study
- Only patients with an anticipated 96-hour need for a PIVC were included
- Recruitment relied heavily on the primary nurse to alert the venous access device team when a PIVC insertion was needed; however, most referrals were due to difficulties inserting the PIVC rather than every patient requiring a PIVC

Study findings

90.7% insertion success rate for the BD Nexiva™ group *versus* 82.2% for the control group (p=0.036)

↓ **26%** in risk of securement-related complications for the BD Nexiva™ group compared with the control group (hazard ratio [HR] 0.74; 95% confidence interval [CI]: 0.53–1.034)

↓ Significantly lower rates of catheter dislodgements (p=0.017)

↓ **98%** in blood exposure rate*:

1 blood exposure incident during catheter insertion in the BD Nexiva™ group compared with 44 incidents in the control group (p=0.001)

↓ **25%** cost using the BD Nexiva™ system: $1.91 (€1.72**) saved per PIVC inserted

↑ Significantly higher nurse satisfaction when using the BD Nexiva™ catheter system *versus* control, rated by the ease of:
- Catheter use (p<0.001)
- Stabilisation device application (p<0.001)
- Removal (p=0.0037)

*% reduction = ([44-1)]/44)x100
**Euros converted from US dollars as of 10/2019 by XE.com

Key points

Compared with the control stabilisation device, the BD Nexiva™ with a built-in stabilisation platform and specially designed 3M Tegaderm IV securement dressing benefitted from:
- Higher first-attempt success
- Higher level of nurse satisfaction
- Lower blood exposure
- Lower overall complication rates, including catheter dislodgement
- Reduced supply costs

Study conclusions

The BD Nexiva™ with an integrated stabilisation platform and specially designed dressing is an alternative to current PIV stabilisation practices preferred by nursing staff, cost efficient and provides similar performance in complication prevention

Implementing and standardising the use of peripheral vascular access devices

Study author(s)

Easterlow D, Hoddinott P and Harrison S

Publication

J Clin Nurs 2010
DOI: 10.1111/j.1365-2702.2009.03098.x

Study design (level of evidence)

Case study, pre- and post-implementation survey

Study location

United Kingdom

Study objective

To assess the impact of a change initiative relating to the use of PIVCs on hospital-acquired infections (HAIs) in an acute hospital. The change included introduction of the BD Nexiva™, as well as improved documentation

Study length

12 months (December 2006–December 2007)

Study protocol

- A baseline audit was conducted to identify areas for change
- Based on the audit findings, a change initiative was implemented, which included the introduction of a non-ported safety cannula (BD Nexiva™), together with practice changes in PIVC care
- Following the change initiative, repeat audits were conducted, and HAI and CRC rates were recorded

Patient population

Patients with PIVC lines at a large teaching hospital with over 500 beds

Key endpoints

- HAI rates
- Methicillin-resistant *Staphylococcus aureus* (MRSA) rates

Study limitations

- Initial significant increase in investment
- Initial low rates of compliance
- Staff inserting the BD Nexiva™ catheter required additional training

Study findings

In the 8 months post introduction of BD Nexiva™:

35% in the incidence of HAIs

53% in the incidence of MRSA

0 incidence of phlebitis (6% rate prior to using the BD Nexiva™)

93% in needlestick injuries*

Only **1** needlestick injury compared with 15 prior to switching to the BD Nexiva™

*% reduction = ([15-1]÷15)x100

Key points

Following introduction of BD Nexiva™ catheter and major practice changes, there was an overall reduction in phlebitis, catheter-related HAIs, MRSA HAIs and needlestick injuries associated with PIVCs

Study conclusions

Implementation of the BD Nexiva™ aided in reducing overall HAIs and MRSA HAIs associated with PIVCs, as well as reducing phlebitis and needlestick injury rates

Catheter-related HAIs are multifactorial, thus only a bundle approach and change in practice would impact patient care

Indwell times, complications and costs of open *vs* closed safety peripheral intravenous catheters: A randomized study

Study author(s)

González López JL, A. Arribi Vilela A, Fernández del Palacio E, *et al.*

Publication

J Hosp Infect 2014
DOI: 10.1016/j.jhin.2013.10.008

Study design (level of evidence)

Randomised controlled trial

Study location

Spain

Study objective

To compare indwell times, complication rates and cost effectiveness between a closed-system PIVC (BD Nexiva™) with an open-system PIVC (B. Braun Vasocan® Safety)

Study length

108 days (March–July 2008)

Study protocol

- Prospective, open-label, parallel-group trial (COSMOS study), with intention-to-treat analysis
- 1,199 catheters (642 inpatients) were randomised (BD Nexiva™, n=584; Vasocan®, n=599 [16 PIVCs were lost early])
- 283 catheters were selected at random, and tips were cultured to determine baseline colonisation rates
- Insertion success, indwell time without complications, CRCs and the number of needlestick injuries were recorded
- A cost analysis of each catheter system was performed (including nurse time and material cost)

Patient population

Patients receiving PIVCs for at least 24 hours at three medical (61 beds) and surgical (154 beds) wards at a 1,000-bed tertiary university hospital

Key endpoints

- Effectiveness
- Efficacy
- Cost analysis
- Safety

Study limitations

- Single-centre, unblinded study
- Staff inserting the BD Nexiva™ catheter required additional training; the variability in the experience of nurses may have affected the results

Study findings

137 hours median indwell time for BD Nexiva™ PIVCs *versus* 96 hours for comparator PIVCs (p=0.001)

25% decrease in catheter-related complications overall with BD Nexiva™ (p<0.001)

- **36%** in phlebitis rate (grade 2+; p=0.004)
- **24%** in infiltration rate (p=0.021)

1 CRC is avoided for every 8 BD Nexiva™ PIVC used

€88,605 savings estimated per year in the cost of devices using BD Nexiva™ PIVC (based on indwell time >72 hours, replacements every 144 hours, estimated using the study hospital's cost and clinical practices)

Resulting in up to **€274,714 savings per year** in total IV therapy costs

Key points

The study demonstrated that the BD Nexiva™ PIVC had significantly longer indwell times with a reduced risk of complications compared with the alternative open-system PIVC

The advantages of using the BD Nexiva™ system are estimated to result in a significant cost saving per year

Study conclusions

The BD Nexiva™ closed integrated catheter system was superior to the Vasocan Safety open system PIVC, in terms of efficacy, safety and cost-effectiveness

Unfavorable peripheral intravenous catheter replacements can be reduced using an integrated closed intravenous catheter system

Study author(s)

Tamura N, Abe S, Hagimoto K, *et al.*

Publication

J Vasc Access 2014
DOI: 10.5301/jva.5000245

Study design (level of evidence)

Controlled trial

Study location

Japan

Study objective

To investigate the clinical usefulness of the BD Nexiva™ in comparison to an existing straight safety catheter (Medikit™)

Study length

9 months (October 2010–June 2011)

Study protocol

- Partially randomised, open, single-centre study
- 359 patients were eligible for the study (BD Nexiva™, n=194; Medikit™, n=165)
- Adverse events during catheter insertion, catheter replacements during the initial 72 hours, and catheter survival rate at 72 hours were recorded
- A cost analysis of each catheter type was calculated

Patient population

Patients at a 286-bed general hospital who required a PIVC for at least 72 hours

Key endpoints

- Adverse events
- Catheter survival rates
- Causes of catheter removal
- Cost analysis

Study limitations

- Single-centre study, with patients not fully randomised
- Adequate sample size per group was not achieved
- Staff only had a 1-month training period with the BD Nexiva™; a longer period may have reduced the number of failed insertion attempts

Study findings

Significantly higher catheter survival rate with BD Nexiva™ than with comparator catheter (**83.7% *vs* 62.6%**; p=0.0085)

0% incidence of bending/kinking and loosening with BD Nexiva™ catheter

9.1% incidence of extravasation with BD Nexiva™ compared with 24.8% with the comparator catheter (p=0.0009)

Over 72 hours, the total cost per patient was only $0.70 (€0.63) more with the BD Nexiva™ catheter. However, the cost per patient for unplanned replacement was much lower for the BD Nexiva™ ($3.93 [€3.54]) than for the comparator catheter ($7.04 [€6.34])*

*Euros converted from US dollars as of 10/2019 by XE.com

Key points

Using the BD Nexiva™ resulted in lower catheter replacement rates, and statistically significant lower incidence of extravasation

The cost per patient for catheter insertion and replacement was comparable despite the higher initial cost of the BD Nexiva™ catheter. This is due to the high survival rate and the reduced need for unplanned replacement at 72 hours when using the BD Nexiva™ catheter

Using the BD Nexiva™ could reduce the number of unpleasant catheter replacements and avoid associated costs

Study conclusions

Significantly lower restart rates and incidences of extravasation with the BD Nexiva™ can offset the higher initial insertion cost

BD Nexiva™ offers a number of potential cost-saving advantages

Peripheral intravenous catheters: Improving outcomes through change in products, clinical practice and education

Study author(s)
deRosenroll A

Publication
Vascular Access 2017

Study design (level of evidence)
Observational (cohort)

Study location
Canada

Study objective
To evaluate the effect on the rate of PIVC complications following implementation of the BD Nexiva™ and new practice

Study length
2 years

Study protocol

- The two hospital sites changed their PIVC products and developed procedures to align with the 2011 Infusion Nurses Society Standards of Practice
- The BD Signature Solutions™ Seek, Solve and Sustain Model was used. This three-phase data collection approach consisted of:
  - Phase 1: Pre-implementation (baseline) of product change
  - Phase 2: Post-implementation of product change
  - Phase 3: Sustained phase
- 431 PIVC site maintenance assessments were collected during the study
- PIVC restart rates, phlebitis rates, practice consistency and policy compliance were collected

Patient population
Patients in medical and surgical units, emergency departments and surgical short stay units at two hospital sites

Key endpoints

- Catheter restarts
- Phlebitis rate
- Best practice compliance
- Safety

Study limitations

- Initial significant investment
- Initial low rates of compliance
- Staff inserting the BD Nexiva™ catheter required additional training

Study findings

An overall increase in positive patient outcomes over assessment period:

- ↓ **45%** in accidental/dislodged PIVCs
- ↓ **67%** in positional PIVCs*
- ↓ **36%** in leakage
- ↓ **42%** in restarts due to kinking
- ↓ **10%** phlebitis at 6 months
- ↓ **21%** in phlebitis at 18 months
- **77.5%** staff compliance at 18 months
- **0** blood exposure to clinicians and patients

*Positional PIVCs: catheters placed in awkward sites that can cause flow rate problems

Key points

BD Nexiva™ implementation combined with staff education resulted in staff compliance to best practice and decreased CRCs, such as phlebitis

Study conclusions

Findings consistent with published literature demonstrating that adoption of a closed catheter system with a securement dressing improves catheter stability and can decrease the risk of phlebitis

Education alongside implementation is paramount in achieving the outcomes studied

Innovative IV catheter improves patient outcomes

Study author(s)
Clark T

Publication
Poster presented at AVA Annual Scientific Meeting 2013

Study design (level of evidence)
Case-report

Study location
United States

Study objective
To evaluate the 22 G BD Nexiva Diffusics™ closed IV catheter for administering IV contrast for imaging, in comparison with larger gauge catheters (18–20 G)

Study length
7 weeks

Study protocol

- Initially, 71 catheter insertions using an existing IV catheter were performed and data (gauge size, flow rate, insertion attempts and patient wait time) were collected over three weeks
- Training for using the BD Nexiva™ was provided for 1 week
- During the following 3 weeks, 51 BD Nexiva Diffusics™ insertions were performed and relevant data were collected

Patient population
Patients requiring a PIVC for imaging at a single hospital

Key endpoints

- Insertion success rate
- Specialist insertion requirement
- Patient wait time
- Flow rate

Study limitations

- Study was not blinded or randomised
- Staff were only given 1 week to familiarise themselves with the BD Nexiva Diffusics™; successful insertion attempts may have improved if training was longer

Study findings

- Number of attempts at successful catheter insertion decreased from 1.54 to 1.07 with BD Nexiva Diffusics™ compared with traditional IV catheters
- **37%** in specialised IV team calls for catheter insertion assistance
- **Higher flow rate** of 4.24 mL/s of IV contrast using 22 G BD Nexiva Diffusics™, compared with 3.35 mL/s using the traditional 18–20 G catheters
- **50%** in patient wait times for catheter insertion using BD Nexiva Diffusics™

Key points

Optimal flow rates of contrast were achieved, and not compromised despite a smaller gauge of cannula

Patient wait times for cannula insertion are reduced by over half, and the need for specialist staff to insert IV cannulas was significantly reduced

Study conclusions

Implementation of BD Nexiva Diffusics™ improved number of insertion attempts, patient wait times and departmental efficiency

IV contrast administration with dual source 128-MDCT: A randomized controlled study comparing 18-gauge nonfenestrated and 20-gauge fenestrated catheters for catheter placement success, infusion rate, image quality, and complications

Study author(s)

Johnson PT, Christensen GM, and Fishman EK

Publication

Am J Roentgenol 2014
DOI: 10.2214/AJR.13.11730

Study design (level of evidence)

Randomised controlled trial

Study location

United States

Study objectives

To compare the performance of the 20 G BD Nexiva Diffusics™ with an 18 G non-fenestrated catheter for IV contrast infusion during multi-detector computed tomography (MDCT) scanning

Study length

Unknown

Study protocol

- 205 patients were randomised to receive either the 18 G non-fenestrated IV catheter or the 20 G BD Nexiva Diffusics™ catheter
- A third cohort consisted of 33 patients who were initially randomised to the 18 G non-fenestrated group but had poor venous access. These patients received the 20 G BD Nexiva Diffusics™ catheter
- The number of catheter attempts, placement success, infusion rate, contrast volume, maximum pressure and any CRCs were recorded
- Image quality was evaluated by the clinician, and also by a fellowship-trained radiologist with 7 years of experience in body CT. The radiologist was blinded to catheter type and reviewed each arterial phase series for subjective image quality (acceptable *vs* unacceptable) and measured aortic enhancement levels

Patient population

Adult outpatients at a single hospital who required a MDCT scan

Key endpoints

- Catheter placement success
- Contrast media infusion rate
- Maximum pressure
- CRCs
- Aortic enhancement levels

Study limitation

- Staff inserting the BD Nexiva Diffusics™ required an additional 2-week training session

Study findings

94% first insertion success rate with BD Nexiva Diffusics™ (97% with a 18 G non-fenestrated catheter)

5.58 mL/s mean flow rate with 20 G BD Nexiva Diffusics™ and 5.74 mL/s for 18 G non-fenestrated catheter (p=0.06)

230.5 psi maximum infusion pressure with BD Nexiva Diffusics™, compared with 215.6 psi with the 18 G non-fenestrated catheter (p<0.001)

No difference in aortic enhancement levels between BD Nexiva Diffusics™ and 18 G non-fenestrated catheter

The group who received the 20 G BD Nexiva Diffusics™ because of poor venous access had:

84.5% insertion success rate for patients with small veins (*vs* 60.6% first insertion success rate using the 18 G non-fenestrated catheter)

5.46 mL/s mean flow rate, significantly lower than the 18 G non-fenestrated group

Key points

BD Nexiva Diffusics™ provided high first-time access rates, maintained aortic enhancement levels (despite lower infusion rates) and achieved higher infusion pressures

Study conclusions

20 G BD Nexiva Diffusics™ performs similarly to an 18 G non-fenestrated catheter with respect to image quality

BD Nexiva Diffusics™ proved beneficial in patients with difficult venous access

Selection of peripheral intravenous catheters with 24-gauge side-holes *versus* those with 22-gauge end-hole for MDCT: A prospective randomized study

Study author(s)

Tamura A, Kato K, Kamata M, *et al.*

Publication

Eur J Radiol 2017
DOI: 10.1016/j.ejrad.2016.12.005

Study design (level of evidence)

Randomised controlled trial

Study location

Japan

Study objectives

To compare the side-hole 24 G BD Nexiva Diffusics™ catheter with an end-hole 22 G catheter in terms of safety, injection pressure, and contrast enhancement on injection of IV contrast for MDCT

Study length

19 months (November 2014–May 2016)

Study protocol

- Randomised, open, single-centre study
- 180 patients needing a MDCT scan were randomised to receive either the 24 G BD Nexiva Diffusics™ catheter or the 22 G end-hole catheter
- CT image quality was evaluated by a CT technologist by measuring the CT numbers (Hounsfield units) on arterial phase images

Patient population

Patients referred to a single hospital for suspected pancreatic disease

Key endpoints

- Safety (during IV contrast media administration)
- Arterial phase enhancement levels
- CRCs

Study limitations

- Study was not fully blinded
- Single-centre study

Study findings

Using the 24 G BD Nexiva Diffusics™ provided:

92.2% first insertion success

1.2% occurrence of extravasation on injection of contrast compared with 1.1% in the end-hole catheter group (non-inferiority p=1)

Higher maximum pressure of 8.16 kg/cm^2, compared with 4.79 kg/cm^2 with a 22 G catheter (p<0.001)

Key points

BD Nexiva Diffusics™ provided a high first-time catheter placement rate, low rates of extravasation of contrast medium and high pressure capabilities despite a smaller gauge

Image qualities in arterial phase, volume of contrast and volume handling were comparable between devices

Study conclusions

The 24 G BD Nexiva Diffusics™ is safe and suitable for delivering contrast material and may contribute to the care of some patients, such as patients who have fragile and small veins

The usefulness of fenestrated intravenous catheters compared with nonfenestrated catheter for cardiac multidetector computed tomography

Study author(s)

Kim J, Kim EJ and Ham JO

Publication

J Comput Assist Tomogr 2019
DOI: 10.1097/RCT.0000000000000855

Study design (level of evidence)

Randomised controlled trial

Study location

South Korea

Study objective

To compare the fenestrated catheter IV (BD Nexiva Diffusics™) and non-fenestrated conventional IV catheter in terms of contrast enhancement and injection pressure for coronary computed tomography angiography

Study length

Unknown

Study protocol

- Patients suitable to receive a 20 G IV catheter were randomised to either:
  - Group 1 (n=100): 20 G comparator IV catheter
  - Group 2 (n=100): 20 G BD Nexiva Diffusics™ catheter
- Group 3 (n=100) consisted of patients unsuitable for a 20 G catheter, and received a 22 G BD Nexiva Diffusics™ catheter
- CT images were analysed to determine the Hounsfield units at specific locations: ascending aorta, left coronary artery, left ventricular (LV) cavity, descending aorta at the level of the left bronchus

Patient population

Adult patients requiring coronary computed tomography angiography at a single hospital

Key endpoints

- Improvement of coronary contrast delivery (contrast enhancement and injection pressure)
- Image quality after downsizing

Study limitation

- Single-centre study

Study findings

20 G BD Nexiva Diffusics™ outcomes *versus* 20 G comparator catheter:

↑ Significantly higher mean density of the left main coronary artery, LV cavity and descending aorta images (p<0.001)

↓ Significantly lower psi (p=0.006)

22 G BD Nexiva Diffusics™ *versus* 20 G comparator catheter shows:

↑ Significantly higher mean density of the left main coronary artery, (p=0.016), LV cavity (p=0.029) and descending aorta images (p=0.001)

No significant difference in psi

Key points

The fenestrated BD Nexiva Diffusics™ enhanced image quality compared with a non-fenestrated IV catheter

The image quality was not compromised when downsizing from a 20 G to a 22 G BD Nexiva Diffusics™ catheter

Study conclusions

Using either a 20 G or 22 G BD Nexiva Diffusics™ catheter improved computed tomography angiography compared with a non-fenestrated IV catheter, and has a potential merit in patients with fragile and small veins

Prevention of needle-stick injury: Efficacy of a safeguarded intravenous cannula

Study author(s)

Asai T, Matsumoto S, Matsumoto H, *et al.*

Publication

Anaesthesia 1999
DOI: 10.1046/j.1365-2044.1999.00749.x

Study design (level of evidence)

Randomised controlled trial

Study location

Japan

Study objective

To compare the ease of use between two IV cannulas: BD Insyte™ and BD Insyte™ Autoguard™

Study length

Unknown

Study protocol

- 100 patients were randomly allocated to receive:
  - 18 G comparator BD Insyte™ IV cannula (n=50)
  - 18 G BD Insyte™ Autoguard™ IV cannula (n=50)
- Before insertion, a metal tray containing absorbable paper was placed on the floor as close as possible to the PIVC site, and after insertion the needle/shaft was placed on the tray
- Insertion attempts were recorded and the amount of blood visible on the tray was assessed
- The 10 cm visual analogue scale (VAS) was used to assess ease of handling (safe–dangerous) and ease of insertion (easy–difficult)

Patient population

Patients scheduled for elective surgery who required an IV infusion at a single hospital

Key endpoints

- Ease of use
- Insertion attempts
- Safety
- Needlestick injury
- Blood contamination

Study limitations

- Single-centre study
- The study only used 18 G catheters, and patients who needed smaller cannulas were not included
- Some findings were subjective because they were based on VAS scores

Study findings

Handling the withdrawn needle was judged as significantly safer in the BD Insyte™ Autoguard™ group compared with the BD Insyte™ group (p<0.001)

Blood contamination on the tray from needle withdrawal placement:

0 using the BD Autoguard™ cannula

39 using the comparator cannula (p<0.001)

Blood contamination from the needle to staff, patients or equipment:

5 using the BD Insyte™ Autoguard™ cannula **7** using the comparator cannula

0 needlestick injuries in either group

No significant difference in ease of insertion between the groups

≤2 insertion attempts for all patients

Key points

Staff felt that the BD Insyte™ Autoguard™ cannula was safer to use than the comparator cannula

The BD Insyte™ Autoguard™ cannula reduced the incidence of blood contamination after needle withdrawal, potentially minimising blood-borne infections. No needlestick injuries or difference in ease of use were reported

Study conclusions

Compared with the comparator catheter, the BD Insyte™ Autoguard™ cannula provided safer handling of a used needle and reduced the incidence of blood contamination, without compromising ease of insertion

Efficacy of catheter needles with safeguard mechanisms

Study author(s)

Asai T, Hidaka I, Kawashima A, *et al.*

Publication

Anaesthesia 2002
DOI: 10.1046/j.1365-2044.2002.02571.x

Study design (level of evidence)

Randomised controlled trial

Study location

Japan

Study objective

To compare the efficacy and safety of two different types of safety catheters and a comparator catheter for IV and intra-arterial cannulation

Study length

Unknown

Study protocol

- 300 patients were included in the two-part study:
  - Part 1: IV cannulation; 18 G catheter (n=150)
  - Part 2: Intra-arterial cannulation; 20 G catheter (n=150)
- Patients were randomly allocated to 1 of 3 groups:
  - Comparator catheter (BD Insyte™; n=50)
  - BD Insyte™ Autoguard™ (n=50)
  - Protective Acuvance® (n=50)
- The 10 cm VAS was used to assess ease of handling (safe–dangerous) and ease of insertion (easy–difficult)
- The number of insertion attemps, needlestick injuries and blood contaminations were recorded

Patient population

Patients scheduled for elective surgery at a single hospital who required a PIVC (Part 1 of study) and also patients who required intra-arterial cannulation (Part 2 of study)

Key endpoints

- Ease of use
- Insertion attempts
- Safety handling
- Needlestick injury
- Blood contamination

Study limitation

- The study did not evaluate catheter use in patients with small veins or hard to locate arteries

Study findings

0 needlestick injuries using the BD Insyte™ Autoguard™ catheter

0 blood stains reported using the BD Insyte™ Autoguard™ needle (compared with 5 blood stains using the comparator and 2 using the Acuvance®)

IV cannulation success rates were similar for all three groups

Insertion of the BD Insyte™ Autoguard™ and Acuvance® catheters were significantly more difficult than the comparator catheter ($p<0.005$, for both)

Staff felt significantly safer when handling withdrawn BD Insyte™ Autoguard™ needles than both other needles ($p<0.001$, for all comparisons)

The BD Insyte™ Autoguard™ group had significantly lower cases of blood contamination from tray placement of the withdrawn needles compared with both the comparator and Acuvance® groups ($p<0.001$)

Key points

The BD Insyte™ Autoguard™ catheters needle was the safest when handling used needles and had the lowest incidence of blood contamination. The ProtectIV™ Acuvance® needle had issues with slow backflow of blood into the chamber during IV cannulation

Study conclusions

The BD Insyte™ Autoguard™ needle is more suitable for intravenous cannulation, and the Acuvance® is more suitable for intra-arterial cannulation

Evaluation of a new safety peripheral IV catheter designed to reduce mucocutaneous blood exposure

Study author(s)

Onia R, Eshun-Wilson I, Arce C, *et al.*

Publication

Curr Med Res Opin 2011
DOI: 10.1185/03007995.2011.581275

Study design (level of evidence)

Randomised controlled trial

Study location

United Sates

Study objective

To evaluate the performance and clinical acceptability of a new PIVC designed to reduce blood exposure during catheter insertion

Study length

3 weeks

Study protocol

- Two-phase study involving 78 clinicians and 233 healthy volunteers
  - Phase 1: The BD Insyte™ Autoguard™ Blood Control (BC) shielded IV catheter and the BD Insyte™ Autoguard™ shielded IV catheter (reference PIVC) were evaluated
  - Phase 2: Two insertions of the BD Insyte™ Autoguard™ BC catheter were evaluated: one with venous compression and one without
- Clinicians received training prior to performing catheter insertions
- Following each successful catheter insertion, the clinicians filled in a questionnaire on their perceptions of blood exposure and other catheter performance characteristics, and were asked to evaluate overall device acceptability for each type of catheter
- Following phase 2, clinicians were also asked to assess whether the BD Insyte™ Autoguard™ BC eliminated the need for venous compression to prevent blood leakage, and to evaluate the likelihood for insertion success

Patient population

Healthy volunteers at a clinical research centre

Key endpoints

- Blood exposure
- Clinician satisfaction
- Insertion success rate
- Safety
- Needlestick injury

Study limitations

- Single-centre, unblinded study
- The BD Insyte™ Autoguard™ BC was not evaluated in patients with small veins, which may have affected the complications rate if included
- The results do not reflect a true clinical environment consisting of clinicians with varying skill levels. Clinicians only had two insertion attempts in either arm of a patient. If unsuccessful, all *further* data for that patient were excluded from the analysis.

Study findings

Approximately 20 times less blood leakage using the BD Insyte™ Autoguard™ BC (2%) compared with the reference PIVC (39.1%)

Rates were similar with or without venous compression (2.6% and 1.3%, respectively)

3.5 times more protection from blood exposure using the BD Insyte™ Autoguard™ BC PIVC (98.7% of clinicians agreed), compared with the reference PIVC (28.5%)

98.7% of clinicians felt the BD Insyte™ Autoguard™ BC is clinically acceptable

Clinicians perceived the BD Insyte™ Autoguard™ BC to be at least equivalent in performance to the reference PIVC

100% of clinicians believed IV catheter insertion success with BD Insyte™ Autoguard™ BC would be at least as good as that with the reference PIVC

98.7% of clinicians agreed that when using the BD Insyte™ Autoguard™ BC device, venous compression was not needed

94.5% and 100% insertion success rate using BD Insyte™ Autoguard™ BC during phase 1 and phase 2, respectively

Key points

The BD Insyte™ Autoguard™ BC provides superior protection against blood exposure and equivalent performance to the reference PIVC, and enables clinicians to perform cannulation without venous compression

Study conclusions

The BD Insyte™ Autoguard™ BC PIVC reduced blood leakage without needing venous compression to control blood flow during PIVC insertion

Medico-economic assessment of the implementation of the BD Saf-T-Intima® micro-infuser in a geriatric ward

Study author(s)

Chéreau J, M. Noël, V. Metz, *et al*

Publication

Le Pharmacien Hospitalier et Clinicien 2015
DOI: 10.1016/j.phclin.2015.07.008

Study design (level of evidence)

Survey

Study location

France

Study objective

To evaluate the interest and the cost implications of switching from using a short PIVC to the BD Saf-T-Intima™ micro-infuser for rehydrating patients in the geriatric ward

Study length

Unknown

Study protocol

- Open-label, non-randomised, post-use survey
- BD Saf-T-Intima™ was evaluated by the nurses on geriatric wards in terms of:
  - Handling and grip
  - Insertion characteristics
  - Catheter fixation
  - Time efficiency
- Key patients outcomes were also evaluated:
  - Skin tolerability
  - Pain
  - Reason for catheter removal
- The cost of implementing the BD Saf-T-Intima™ on the ward was calculated

Patient population

Geriatric ward patients

Key endpoints

- Clinician satisfaction
- Patient satisfaction
- Cost analysis
- Time efficiency
- Catheter security

Study limitations

- Single-centre study
- Study design was a user acceptance evaluation and not designed to allow statistical comparisons

Study findings

>90% of nurses were satisfied with the using the BD Saf-T-Intima™

No oedema or skin lesions were observed even after prolonged use (96 hours)

Patient outcomes:

↓ in pain and ↑ skin tolerability

€1.95 ($2.17*) saved (excluding tax) **per one inserted BD Saf-T-Intima™**

The BD Saf-T-Intima™ cost/unit (excluding tax) is €2.85 ($3.17*) more than the short catheter, which needs to be replaced daily, but cost savings were made due to the longer indwell time of the BD Saf-T-Intima™ and the lower need for catheter changes

↓ **4,106** insertions per year (from 5,475 to 1,369; based on an average of 15 insertions/day)

€2,668 ($2,967*) saved per/year (excluding tax)

↓ nursing time required due to catheter replacements

*US dollars converted from Euros as of 10/2019 by XE.com

Key points

The BD Saf-T-Intima™ was less traumatic for patients and had a high satisfaction rate among nurses

Using the BD Saf-T-Intima™ on the geriatric ward contributed to major cost savings

Study conclusions

The BD Saf-T-Intima™ provided more comfort for patients as they needed only one insertion every 96 hours rather than four. In a geriatric ward, using the BD Saf-T-Intima™ resulted in cost and time savings, and was highly favoured by nurses

Mucocutaneous blood contact: Blood release behavior of safety peripheral intravenous catheters

Study author(s)

Wittmann A, Köver J, Kralj N, *et al.*

Publication

Am J Infect Control 2013
DOI: 10.1016/j.ajic.2013.02.015

Study design (level of evidence)

In vitro

Study location

Germany

Study objective

To determine the volume of blood droplets splashing that puts the user at risk of infection

Study protocol

- Five 20 G safety PIVCs were compared:
  - Four with passive mechanisms: Vasofix® Safety/Introcan Safety® (B. Braun), BD Venflon™ Pro Safety, Terumo Surshield™ Surflo® II, Troge TRO-VENSITE (Poly Medicure)
  - One with an active 'push button' mechanism: BD Insyte™ Autoguard™
- An industrial robot simulated needle withdrawal from catheters at two angles: straight (correct) and offset at 8 mm upwards (incorrect)
- A paper screen attached 30 cm above the catheter was used to detect the radioactive human blood splatter, which was measured by scintigraphy

Key endpoint

Blood exposure

Study limitations

- *In vitro* study that simulates clinical scenarios, therefore results may differ during real-life situations
- The volume of blood detected on the paper screen above the catheter is higher than the amount of blood that would realistically be splashed on to mucous membranes

Study findings

The volume of blood splashing detected was <1 nL for all devices

The Vasofix® Safety/Introcan Safety® and the BD Venflon™ Pro Safety generated the least mean blood contamination when inserting the catheter at an incorrect angle with a blood-filled luer adapter:

Vasofix® Safety/Introcan Safety®	0.66 nL
BD Venflon™ Pro Safety	0.67 nL
Troge TRO-VENSITE Safety	0.84 nL
BD Insyte™ Autoguard™	x0.90 nL
Terumo Surshield™ Surflo® II	0.90 nL

Blood splashing varied significantly between brands of catheters ($p<0.05$)

Key points

BD Venflon™ Pro Safety generated one of the least amount of blood contamination after safety mechanism activation. Taking the normal viral load of patients with human immunodeficiency virus or hepatitis B and C viruses as a basis, the amount of blood produced from all safety devices (<1nL) is unlikely to transmit an infectious viral load to users

Study conclusions

The risk of contracting an infectious disease through blood splashing from a safety PIVC is negligible

Fluid dispersal from safety cannulas: An in vitro comparative test

Study author(s)

Rosenthal VD and Hughes G

Publication

Am J Infect Control 2015
DOI: 10.1016/j.ajic.2014.11.020

Study design (level of evidence)

In vitro

Study location

United Kingdom

Study objective

To compare the number of blood droplets generated from two different 20 G safety PIVCs with passive mechanisms: BD Venflon™ Pro Safety and Vasofix® Safety (comparator)

Study protocol

- Ten cannulation replicates were performed in an artificial vein at five angles for each device based on two scenarios:
  - Best case: Simulates cannulation by an experienced anaesthetist in a controlled environment
  - Worst case: Simulates cannulation by an inexperienced clinician in a busy environment
- Photographic paper placed underneath the apparatus collected blood droplets that were generated during needle withdrawal and safety mechanism activation

Key endpoint

Blood exposure

Study limitation

- *In vitro* study that simulates clinical scenarios, therefore results may differ during real-life situations

Study findings

0 fluid droplets from withdrawing the BD Venflon™ Pro Safety at any angle under both case scenarios (0/100 experiments)

Comparator catheter generated blood splatter in:

48% (24/50) of best-case scenarios

60% (30/50) for worst-case scenarios

Comparator catheter mean fluid droplet counts at 0°, 1°, 2°, 3° and 4° angles were:

Best case: 0, 0, 3.9, 77.8, 164

Worst case: 0, 1.7, 17.2, 109, 174

Comparator catheter distance range of fluid droplets at 0°, 1°, 2°, 3° and 4° angles were:

Best case: 0, 0, 2–15, 13–33 and 22–43 cm

Worst case: 0, 3–7, 6–16, 15–29 and 29–41 cm

No statistical analysis was performed on the BD Venflon™ Pro Safety as no blood splatter was detected

Both the angle and scenario significantly affected the number of droplets generated from the comparator catheter ($p<0.001$)

Key points

The BD Venflon™ Pro Safety resulted in no blood splatter from needle withdrawal under all conditions

When the comparator catheter needle is withdrawn at an angle, there is potential for the device to generate blood splatter. Blood splatter was significantly affected by insertion angle and the scenario, potentially increasing the risk of contamination for comparator cannula users

Study conclusions

Safety devices need to be evaluated to avoid hazards for healthcare workers due to blood splatter risk

Peripheral venous catheter use in the emergency department: Reducing adverse events in patients and biosafety problems for staff

Study author(s)

Vecina ST, Duarte JM, Marcos MO, *et al.*

Publication

Emergencias 2016

Study design (level of evidence)

Prospective cohort observational study

Study location

Spain

Study objective

To reduce the rate of adverse events in patients and the rate of staff safety problems associated with PIVC insertion

Study length

10 weeks

Study protocol

- Non-post-authorisation, prospective, multicentre study
- Study was divided into two phases:
  - Phase 1: Training, implementing a protocol for using conventional PIVCs and monitoring practice
  - Phase 2: Introducing the BD Nexiva™ and the BD Insyte™ Autoguard™ safety PIVC sets, in conjunction with BD Saline prefilled IV flushing syringe (BD PosiFlush™), according to patient needs
- A comparative analysis was conducted between both phases to assess which had the greatest influence in reducing adverse events: training along or training plus recorded BD Nexiva™ and BD Insyte™ Autoguard™

Patient population

Patients who attended the emergency departments of five hospitals across Spain and required PIVC insertion

Key endpoints

- Adverse events
- Safety
- Blood exposure

Study limitation

- Non-randomised study

Study findings

50% relative reduction in phlebitis following introduction of either BD Nexiva™ or BD Insyte™ Autoguard™

0.5% incidence of phlebitis when using BD Insyte™ Autoguard™ compared with 4.9% using BD Nexiva™

9.4% incidence of haematomas with both BD Insyte™ Autoguard™ and BD Nexiva™

36% risk reduction in blood splatter occurence with both BD Insyte™ Autoguard™ and BD Nexiva™ compared to conventional catheter system

Key points

The introduction of BD Nexiva™ and BD Insyte™ Autoguard™ into the emergency department, alongside a triage protocol and PIVC choice based on patient assessment and treatment duration, reduced rates of phlebitis and extravasation, and significantly reduced HCW blood exposure

Study conclusions

Use of BD Nexiva™ or BD Insyte™ Autoguard™ in conjunction with BD PosiFlush™ , aids in reducing CRCs, as well as providing increased user safety compared with conventional PIVCs

Extended dwell peripheral catheters in patients with difficult venous access: Comparison of a peripheral intravenous catheter and midline catheter

Study author(s)

Alexandrou E, Mifflin N, McManus C, *et al.*

Publication

Vascular Access 2018

Study design (level of evidence)

Observational (cohort)

Study location

Australia

Study objective

To compare outcomes from using two extended dwell peripheral devices in patients with difficult venous access: the BD Nexiva™ catheter and the PowerGlide® midline (Bard Access) longer-length device

Study length

9 months (November 2015–August 2016)

Study protocol

Three-step study:

- An insertion algorithm based on vessel depth and diameter determined which device and size (18 G or 20 G) was used for each patient
- Catheters were placed using ultrasound guidance in 192 patients (BD Nexiva™: 18 G, n=21; 20 G, n=10; PowerGlide®: 18 G, n=82; 20 G, n=79)
- Patient data were collected through routine surveillance by the hospital's central venous access service

Patient population

Patients with difficult venous access requiring an extended dwell PIVC in general medical and surgical wards at a 877-bed tertiary referral hospital

Key endpoints

- Indwell time
- Reasons for device removal
- Insertion rates
- Failure rates

Study limitations

- Single-centre study
- Non-randomised, as product choice was determined using a insertion algorithm based on vessel depth and diameter using an ultrasound assessment. This resulted in an uneven distribution of product cohorts (BD Nexiva™, n=31 *vs* PowerGlide®, n=161)

Study findings

4 of every 5 devices inserted were PowerGlide® catheters

90% first-time insertion success rate with BD Nexiva™ (18 G, n=19/21; 20 G, n=9/10) *versus* 80% using the PowerGlide® (18 G, n=66/82; 20 G, n=63/79)

6 days median indwell time for all devices (interquartile range: 3–11)

No significant difference in survival rates between catheter groups (p=0.4)

Significant differences in dislodgement and occlusion rates between all four catheter groups (p<0.001)

↑ Highest occlusion rate with BD Nexiva™ 20 G (28.6/1,000 catheter days) compared with PowerGlide® catheters

↑ Higher infiltration rate with BD Nexiva™ compared with PowerGlide® catheters (BD Nexiva™ 10% *vs* PowerGlide® 2%)

Key points

Higher insertion success rate using the BD Nexiva™; however, the PowerGlide® was the appropriate choice of catheter for 80% of the cohort according to ultrasound-guided assessment of patients' veins

Low complications rates observed with both devices, and longer indwell times using the PowerGlide® catheters

Study conclusions

Using PIVCs for extended dwell periods results in minimal phlebitis and catheter-related bloodstream infection

Ultrasound guidance for PIVC placement resulted in a high insertion success rate among patients with difficult venous access

Abbreviations list

AVA: Association for Vascular Access

BC: Blood control

CI: Confidence interval

CRC: Catheter-related complication

ECR: European Congress of Radiology

G: Gauge

HAI: Hospital-acquired infections

HR: Hazard ratio

IV: Intravenous

LV: Left ventricular

MDCT: Multi-detector computed tomography

MRSA: Methicillin-resistant *Staphylococcus aureus*

PIVC: Peripheral intravenous catheter

psi: Pounds per square inch

VAS: Visual analogue scale

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0000CF04125 Issue 1, October 2019