



IV Catheters

Clinical Evidence Summary

Content Overview

Blood Exposure & Spillage

Page 3

1. Multi-blood control IV catheters help to prevent blood leakage and improve process efficiency

Introduction of a non-ported peripheral intravenous catheter with multi-use blood control septum offers improvements in the overall efficiency of the procedure and is clinically well accepted.

Cooper DM, Whitfield M, Newton D, Chiarella J, Machacyek K, Introduction of a non-ported peripheral intravenous catheter with multi-use blood control septum offers improvements in the overall efficiency of the procedure and is clinically well accepted. International Journal of Healthcare Technology and Management. 2016;15(3):177-193. DOI: 10.1504/JJHTM.2016.078336.

Page 4

2. Multi-blood control IV catheters shorten cannulation time and help reducing blood exposure

Efficacy and ease of use of an intravenous catheter designed to prevent blood leakage: a prospective observational trial.

Haeseler G. Hildebrand M. Fritscher J. Efficacy and ease of use of an intravenous catheter designed to prevent blood leakage: a prospective observational trial, Journal of Vascular Access. 2015;16(3):223–6. DOI: 10.5301/jva.5000334.

Page 5

3. IV cannulation comes with blood exposure risk

Nursing 2011 survey results: Blood exposure risk during peripheral I.V. catheter insertion and removal.

Jagger J, Perry J, Parker G, Phillips EK. Nursing2011 survey results: Blood exposure risk during peripheral I.V. catheter insertion and removal. Nursing2021 2011; 41(12):45–49. DOI: 10.1097/01.NURSE.0000407678.81635.62.

Page 6

4. Blood control IV catheters help decrease blood leakage and exposure

Clinical performance of a new blood control peripheral intravenous catheter: A prospective, randomized, controlled study.

Seiberlich LE, Keay V, Kallos S, Junghans T, Lang E, McRae AD. Clinical performance of a new blood control peripheral intravenous catheter: A prospective, randomized, controlled study. International Emerging Nursing. 2016 Mar;25:59–64. DOI: 10.1016/j.ienj.2015.08.005.

Page 7

Introcan Safety® 2

Closed IV catheter with multi-access blood control septum

1. Multi-blood control IV catheters help to prevent blood leakage and improve process efficiency

Cooper DM, Whitfield M, Newton D, Chiarella J, Machacyek K, Introduction of a non-ported peripheral intravenous catheter with multi-use blood control septum offers improvements in the overall efficiency of the procedure and is clinically well accepted. International Journal of Healthcare Technology and Management. 2016;15(3):177-193. DOI: 10.1504/IJHTM.2016.078336.

1.1 Topic



Process Efficiency



Blood Exposure

1.2 Design

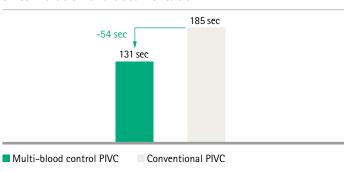
- Time and cost efficiency analysis that compares the use of multi-blood control vs. conventional peripheral IV catheters (PIVC) as well as clinical acceptance of blood control device
- Observation and measurement of time of cannulations (n=103)
- Evaluation of feedback forms from clinicians (n=212)
- Products used: multi-blood control PIVC (Introcan Safety® 3, B. Braun), conventional PIVC (Vasofix® Safety, B. Braun)

1.3 Method

 Prospective, non-blinded, controlled single-centre post market study

1.4 Results

Time taken from skin cleansing through to completion of cannulation and documentation:



- 69% of users agree/strongly agree that there was a minimal change in technique
- 87 % of clinicians agree/strongly agree that the multi-blood control PIVC helps to prevent blood leakage
- Overall 82 % of clinicians would use the multi-blood control PIVC in clinical practice

1.5 Key Findings

- The study revealed a time saving of ~29 % per cannulation (54 s), compared to standard cannulation practices, providing possible efficiency savings
- Majority of clinicians agree that the multi-blood control PIVC helps to prevent blood leakage.

2. Multi-blood control IV catheters shorten cannulation time and help reducing blood exposure

Haeseler G. Hildebrand M. Fritscher J. Efficacy and ease of use of an intravenous catheter designed to prevent blood leakage: a prospective observational trial, Journal of Vascular Access. 2015;16(3):223-6. DOI: 10.5301/jva.5000334.

2.1 Topic



Efficiency



Exposure

2.2 Design

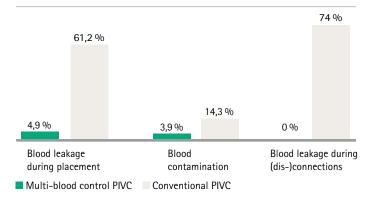
- Assessment of multi-blood control peripheral IV catheter (PIVC) under routine clinical conditions and comparison with conventional PIVC (n=200)
- Products used: multi-blood control PIVC (Introcan Safety® 3, B. Braun); conventional PIVC (Introcan® Safety, B. Braun).

2.3 Method

- Prospective observational trial of establishing peripheral IV access
- Documentation and comparison of: blood leakage incidence; duration of placement; handling conditions

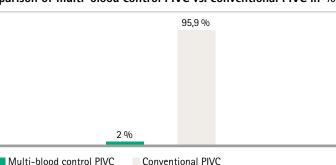
2.4 Results

2.4.1 Blood leakage and contamination incidence rate of multi-blood control PIVC vs. conventional PIVC in %:



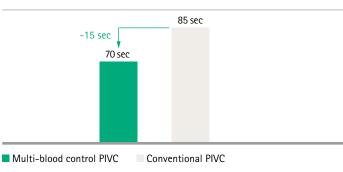
- The use of a multi-blood control PIVC effectively helps to prevent blood leakage
- The use of a multi-blood control PIVC fully eliminates blood leakage during catheter manipulation (dis-/connections)
- The use of a multi-blood control PIVC helps to reduce the risk of blood contamination and related cleaning and disinfection workload

2.4.2 Need to occlude vein when removing the needle - comparison of multi-blood control PIVC vs. conventional PIVC in %:



- Multi-blood control PIVC
- Occlusion of vein can be omitted for multi-blood control PIVC which helps to improve and shorten IV catheter placement ("both hands free")
- 80% of users see an improvement of IV catheter placement due to omission of vein occlusion

2.4.3 Duration of placement of multi-blood control PIVC vs. conventional PIVC in seconds:



 The use of a multi-blood control PIVC shortens the time of IV catheter placement

2.5 Key Findings

The use of a multi-blood control IV catheter:

- Helps to significantly reduce blood leakage and contamination during catheter placement
- Prevents blood leakage during repeated (dis-)connections
- Helps to omit the need of vein occlusion
- Shortens the duration of IV catheter placement



3. IV cannulation comes with blood exposure risk

<u>Jagger J, Perry J, Parker G, Phillips EK. Nursing2011 survey results: Blood exposure risk during peripheral I.V. catheter insertion and removal.</u> Nursing2021 2011; 41(12):45-49. DOI: 10.1097/01.NURSE.0000407678.81635.62.

3.1 Topic



3.2 Design

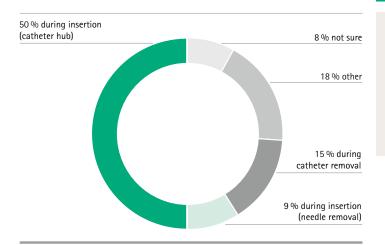
- Survey with 14 questions carried out by Nursing 2011 to investigate blood exposure occurrences during IV catheter handling (insertion and removal)
- Self-selected respondents (n=404).
- Product used: unspecified

3.3 Method

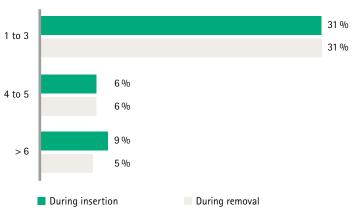
- Investigated topics include: number of IV catheter insertions and removals, occurance of blood exposures during IV catheter handling, experience with at-risk exposures and its reporting, use of personal protective equipment and general support
- Descriptive data analysis of survey, organized and presented with comments describing question and respective results estimations

3.4 Results

3.4.1 Cause of respondents most recent blood exposure occurrence:



3.4.2 Blood exposure experience during insertion and removal (times per month, excluding needlesticks), modified:



- Almost half of all respondents (46%) claimed that they experienced at least one blood exposure a month during IV catheter insertion (calculated average blood exposure rate of 4.4/100 IV catheter insertions)
- 12 % of respondents reported blood exposure to nonintact skin while 13 % reported mucous membrane exposure
- 69% of mucous membrane exposures were unreported
- Majority of respondents (84%) wear gloves as personal protective equipment

3.5 Key Findings

- 46% of respondents have experienced at least one blood exposure a month
- Total at-risk blood exposure rate is calculated at 128/100,000 insertions, being more than 10 times higher compared to needle-stick injury rates
- 50% of blood leakage is reported to occur from catheter hub during insertion

4. Blood control IV catheters help decrease blood leakage and exposure

Seiberlich LE, Keay V, Kallos S, Junghans T, Lang E, McRae AD. Clinical performance of a new blood control peripheral intravenous catheter: A prospective, randomized, controlled study. International Emerging Nursing. 2016 Mar;25:59-64. DOI: 10.1016/j.ienj.2015.08.005.

4.1 Topic



Process Efficiency



Blood Exposure

4.2 Design

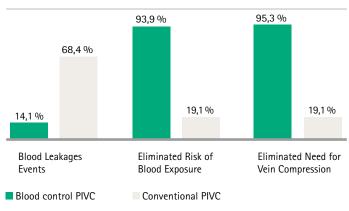
- Performance comparison of peripheral IV catheter (PIVC) with blood control vs. conventional IV catheter
- N=152 PIVC insertions (73 blood control, 79 standard)
- Products used: blood control PIVC (ViaValve® Safety PIVC, Smiths Medical); conventional PIVC (ProtectIV® Safety PIVC, Smiths Medical).

4.3 Method

- Prospective, non-blinded, randomized, controlled, singlecenter post-market study
- Feedback collection from clinicians on each successful PIVC insertion regarding clinical acceptability, blood exposure risk, blood leakage, use of vein compression, insertion success, securement, and clinical usability (ease of use)

4.4 Results

Benefits observed from the blood control device:



• Compared to conventional devices, blood control PIVCs allow for a **lower incidence of blood leakage** (14.1 % vs 68.4 %), are believed to **reduce the blood exposure risk** (93.9 % vs 19.1 %), **decrease the need for vein compression** (95.3 % vs 19.1 %) while having **similar insertion success rates** (95.9 % vs 93.7 %) and clinical acceptability

4.5 Key Findings

 Blood control PIVC help to decrease blood leakages and the risk of blood exposure for both clinicians and patients during catheter insertion

Introcan Safety® 2

Closed IV catheter with multi-access blood control septum

Introcan Safety® 2



1 Multi-access blood control septum

- Controls the blood coming out of catheter hub
- Helps to prevent blood exposure during catheter insertion and while disconnecting a device from the catheter hub¹
- Reduces the need for vein compression ¹
- Improves process efficiency 1,2
- Supports a reduction in the overall duration of IV catheter placement¹
- Helps to reduce cleaning time and associated costs ¹
- Works multiple times

2 Passive safety shield

- Helps eliminating needlestick injuries³
- Deploys automatically
- Cannot be bypassed
- Requires no user activation



The safety mechanism of Introcan Safety® 2 is activated when the needle is removed. As septum closes when needle is removed, need for vein compression is reduced.



Since the septum is closed, blood flow is controlled – even when connecting and disconnecting a Luer device.

Literature: 1. Haeseler G. Hildebrand M. Fritscher J. Efficacy and base of use of an intravenous catheter designed to prevent blood leakage: a prospective observational trial. 2015. J Vasc Access: 1-4. | 2. Cooper D. Whitfield M.D. Newton D. Chiarella J. Machaczek KK. Introduction of a non-ported peripheral intravenous catheter with multiuse blood control septum offers improvements in the overall efficiency of the procedure and is clinically well accepted. Int. J of Healthcare Techn and Mgmt. January 2016; 1-20. | 3. Tosini W. et al. Needlestick Injury Rates According to Different Types of Safety-Engineered Devices: Results of a French Multicenter Study. Infection Control & Hospital Epidemiology. April 2010; 31(4): 402-407.