

Office of Evidence Based Practice – Patient Safety Question: Heparin vs. Normal Saline

Specific Care Question:

In the pediatric population with central lines, which flushing solution, heparin versus normal saline, is superior using line patency and reduced blood stream infection as outcomes?

Team Members: Heparin Work Group, Team Leader Elizabeth Monsees, RN, MSN, MBA, CIC

Significance and Importance of the Question:

The question of using heparin vs. saline to flush central intravenous access devices is significant for two reasons: patient safety and cost benefits. As with any medication intervention, the use of heparin to maintain central line patency has been associated iatrogenic complications which affect the patient's recovery along with increasing health care costs with prolonging length of stay. Cost has to be balanced between the iatrogenic events of the intervention and the associated costs of using heparin or saline to flush the lines.

Plain Language Summary from The Office of Evidence Based Practice - Summary:

Based on very low quality evidence there is no statistically significant difference between flushing central lines with heparin versus normal saline to maintain line patency or reducing blood stream infections. Most of the literature reviewed was with adult patients and generalizing this information to a pediatric population should be done with caution.

While the results suggest there is less occlusion and blood stream infections when flushing with heparin, the clinical and statistical inconsistency of the included studies are too significant to ignore. A recommendation between heparin versus normal saline cannot be made due to the lack of reported evidence. Also, a recommendation for heparin flushing frequency, volume, and concentration cannot be made as these were not identified as outcomes in the included studies.

The review formally looked at efficacy in terms of endpoints (blood stream infection and line occlusion) and cannot say anything about safety and harm.

To fill this gap in providing care, establishing a guideline based on consensus, best practice and values will create a platform by which outcomes can be measured and monitored using the endpoints of catheter occlusion and infection.

Search Strategy and Results:

("Central Venous Catheters"[Mesh] OR "Venous Thrombosis/prevention and control"[Mesh] OR "Catheterization, Central Venous"[MAJR]) AND ("flush"[tiab] OR "Vascular Patency"[Mesh]) Filters: Clinical Trial, Comparative Study, Guideline, Meta-Analysis, Randomized Controlled Trial, Systematic Reviews, Controlled Clinical Trial, Humans, English

Studies Included in This Review:

Bowers, L., Speroni, K. G., Jones, L., & Atherton, M. (2008). Comparison of occlusion rates by flushing solutions for peripherally inserted central catheters with positive pressure Luer-activated devices. *Journal of Infusion Nursing*, 31(1), 22-27.

Cesaro, S., Tridello, G., Cavaliere, M., Magagna, L., Gavin, P., Cusinato, R., . . . Carli, M. (2009). Prospective, randomized trial of two different modalities of flushing central venous catheters in pediatric patients with cancer. *J Clin Oncol*, 27(12), 2059-2065. doi: 10.1200/jco.2008.19.4860

Goossens, G., Jérôme, M., Janssens, C., Peetermans, W., Fieuws, S., Moons, P., . . . Stas, M. (2013). Comparing normal saline versus diluted heparin to lock non-valved totally implantable venous access devices in cancer patients: a randomised, non-inferiority, open trial. *Annals of oncology*, mdt114.

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López-Briz, E., Ruiz Garcia, V., Cabello, J. B., Bort-Marti, S., Carbonell Sanchis, R., & Burls, A. (2010). Heparin versus 0.9% sodium chloride intermittent flushing for prevention of occlusion in central venous catheters in adults. *The Cochrane Library*.

Schallom, M. E., Prentice, D., Sona, C., Micek, S. T., & Skrupky, L. P. (2012). Heparin or 0.9% sodium chloride to maintain central venous catheter patency: a randomized trial. *Crit Care Med*, 40(6), 1820-1826. doi: 10.1097/CCM.0b013e31824e11b4

Schiffer, C. A., Mangu, P. B., Wade, J. C., Camp-Sorrell, D., Cope, D. G., El-Rayes, B. F., . . . Levine, M. (2013). Central venous catheter care for the patient with cancer: American Society of Clinical Oncology clinical practice guideline. *J Clin Oncol*, 31(10), 1357-1370. doi: 10.1200/jco.2012.45.5733

Method Used for Appraisal and Synthesis:

Twenty one articles were read, and six were included in this review. Four randomized control trials (Bowers, Speroni, Jones, & Atherton; Cesaro et al.; Goossens et al.; Schallom, Prentice, Sona, Micek, & Skrupky), one meta (López-Briz et al.), and one guideline were reviewed (Schiffer et al). RevMan and Grade Pro were used to appraise and synthesize the studies. Meta analysis was performed using RevMan. Adult and pediatric patients were included in the review. Outpatient, hemodialysis, and NICU patients were excluded

Literature Review:

A Cochrane meta-analysis of adult patients (López-Briz et al., 2010) found no significant difference in number of central venous catheter (CVC) occlusions and CVC related sepsis between normal saline and heparin flushes. The Cochrane meta-analysis included six adult studies. Three of these studies are included in this synthesis; the three other studies were excluded due to the exclusion criteria; hemodialysis patients, non-English study, and 5000 International Units/1mL heparin dose. The results of the three included studies were interpreted to mean either intervention was as effective as the other when the outcome of line patency and blood stream infection was studied. The heparin concentrations were very different (10-5000 International Units/mL) among the studies. No conclusive evidence of important differences were found when heparin was compared with normal saline

The American Society of Clinical Oncology Clinical Practice Guideline (Schiffer et al., 2013) recommended routine flushing with saline in cancer patients with CVC. Heparin was not recommended for routine flushing. Specific recommendations on frequency of flushing were not provided.

The results of the combined findings from the four randomized control trials are detailed below (Bowers, Speroni, Jones, & Atherton, 2008; Cesaro et al., 2009; Goossens et al., 2013; Schallom, Prentice, Sona, Micek, & Skrupky, 2012). While the four studies suggest a higher rate of occlusion and blood stream infection in the normal saline populations, there was considerable inconsistency among the studies. Three of the four studies used different units of analysis for the outcomes including number of participants, number of catheters, and number of times the line was accessed. The frequency of flushing was different in all studies from every eight hours to twice a week (Cesaro et al.; Schallom et al.). Bowers et al. (2008) and Goossens et al. (2013) did not provide an exact frequency for flushing. Also, heparin volume and concentration were different between the studies (10 International Units/ml to 200 International Units/mL). New research is very likely to change confidence in the effect seen with these four studies.

Only one study (Cesaro et al.), $N = 203$ showed significantly more occlusions and blood stream infections in the saline group in the pediatric population (Zero months to 17 years of age). It should be noted this study used different flushing protocols when comparing heparin without positive pressure caps and normal saline with positive pressure caps. The data provided indicates a higher effectiveness with heparin flushes (3 mL of normal solution [the CAT author assumed the authors meant normal saline] and heparin 200 International Units/mL twice a week with a standard CVC cap) than with flushing with normal saline only at least weekly with a positive-pressure CVC valve cap device. The normal saline group reported an occlusion rate of 2.16 per 1000 line days versus the heparin group of 1.11 per 1000 line days. In addition, the normal saline group reported a bacteremia of 0.62 per 1000 line days versus the heparin group with 0.24 per 1000 line days.

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Bowers et al. (2008) randomized adult patients, $N = 102$, with single-lumen peripherally inserted central catheters (PICC) with positive pressure Luer-activated devices. The data showed no significant difference in occlusion when flushing with heparin versus normal saline. Flushes occurred a minimum of once per day or after each line access for medications and blood draws. Heparin dose was 100 International Units/mL but the exact frequency and number of flushes were not provided. The mean number of PICC days was 2.1 days (± 4.0) for normal saline and 2.9 days (± 5.7) for heparin.

Goossens et al. (2013) included adult and pediatric patients, $N = 802$. Normal saline was reported as a safe and effective locking solution in implantable ports if combined with a strict protocol for device insertion and maintenance. The incidence rate of occlusion was 3.7% (95% CI 2.91-4.69%) and 3.92% (95% CI 3.09%-4.96) for normal saline and heparin, respectively. Catheter-related bloodstream infections were 0.03 per 1000 catheter days in the NS group and 0.10 per 1000 catheter days in the heparin group. Standard normal saline flushing was done before and after blood sampling. Heparin (100 International Units/mL) was used to lock the implantable port before the needle was removed. Total number of catheter days/patients were 152.4 days (38.9) for normal saline and 150.9 days (40.7) for heparin.

Schallom et al. (2012) studied three hundred forty one adult patients and found no significant difference between heparin and normal saline flushes with regard to catheter occlusion with short-term use CVCs. The normal saline group received: 10 mL 0.9% NaCl every 8 hours, or more frequently if lumen needed for infusions. The heparin group received 10 mL 0.9% NaCl followed by 3 mL heparin lock flush solution (10 International Units/mL) every 8 hours. Though not statically significant the number of blood stream infections were reported as 3.1 per 1000 line days versus 0 per 1000 line days in normal saline and heparin, respectively.

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Summary:

1. A recommendation between heparin versus normal saline cannot be made due to the lack of evidence. Also, a recommendation for heparin flushing frequency, volume, and concentration cannot be made.
2. A Cochrane (López-Briz et al., 2010) meta-analysis of adults found no significant difference in the number of CVC occlusions and CVC related sepsis between the normal saline and heparin flushes.
3. Of the found studies, four answered the question with statistical data: Bowers (2008) Cesaro (2009) Schallom (2012) Goossens (2014). New research is very likely to change confidence in the effect seen with these four studies.
4. The literature synthesis suggests there is less occlusion and blood stream infections when flushing with heparin. Although, the clinical and statistical inconsistency of the included studies are too significant to ignore.
5. A guideline should be established to standardize care, while reducing variability within the hospital, while measured with clinically relevant process, health outcomes and balancing measures.

Characteristics of Excluded Studies:

Arora, R. S., Roberts, R., Eden, T., & Pizer, B. (2010). Interventions other than anticoagulants and systemic antibiotics for prevention of central venous catheter-related infections in children with cancer. *Cochrane Database Syst Rev*, 12. **Does not answer question**

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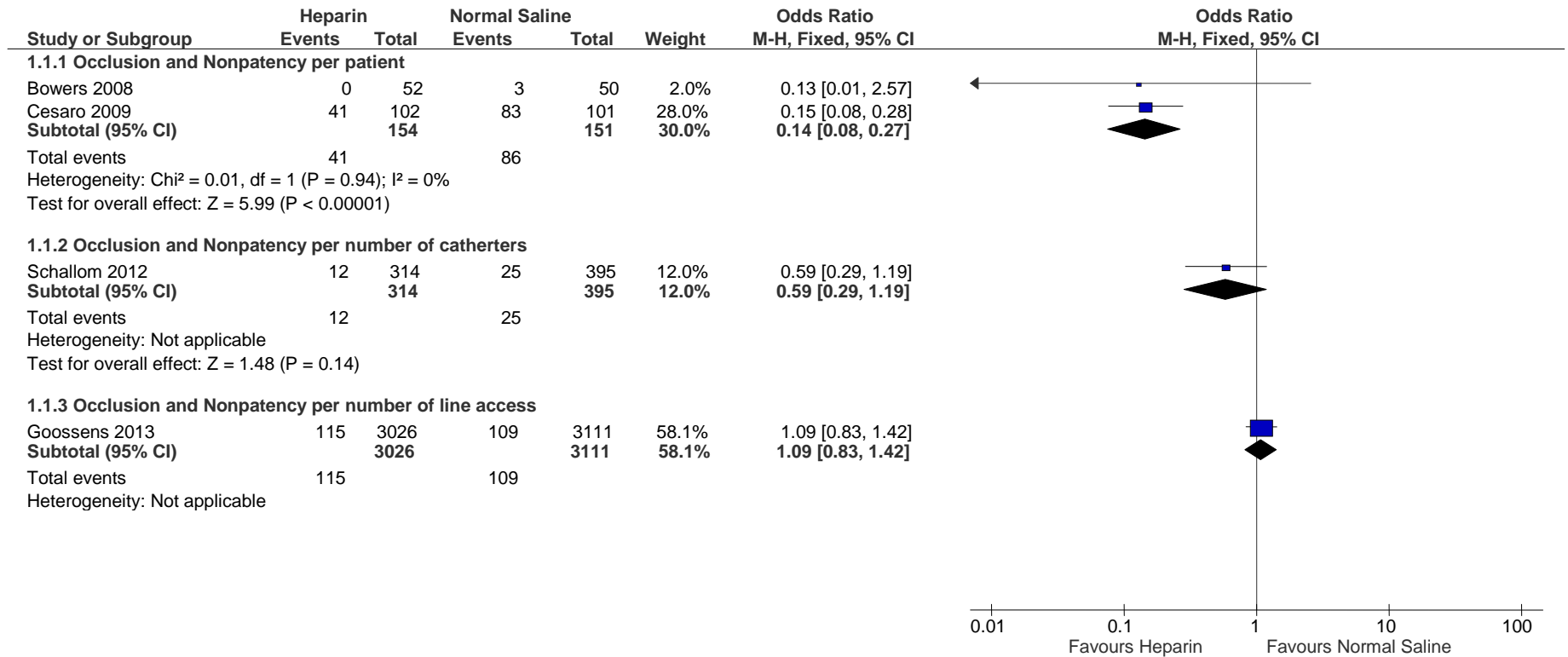
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- Beigi, A., HadiZadeh, M., Salimi, F., & Ghaheri, H. (2014). Heparin compared with normal saline to maintain patency of permanent double lumen hemodialysis catheters: A randomized controlled trial. *Advanced Biomedical Research*, 3(1), 121. **Hemodyalisis patients**
- Bravery, K. (2010). Flushing CVADs: heparin or sodium chloride 0.9%? *Br J Nurs*, 19(10), S5. **Narrative review**
- Buchini, S., Scarsini, S., Montico, M., Buzzetti, R., Ronfani, L., & Decorti, C. (2014). Management of central venous catheters in pediatric onco-hematology using 0.9% sodium chloride and positive-pressure-valve needleless connector. *Eur J Oncol Nurs*, 18(4), 393-396. doi: 10.1016/j.ejon.2014.03.010 **Cohort that only used normal saline.**
- Conway, M. A., McCollom, C., & Bannon, C. (2014). Central Venous Catheter Flushing Recommendations: A Systematic Evidence-Based Practice Review. *J Pediatr Oncol Nurs*, 31(4), 185-190. doi: 10.1177/1043454214532028 **Narrative review**
- Cook, L., Bellini, S., & Cusson, R. M. (2011). Heparinized saline vs normal saline for maintenance of intravenous access in neonates: an evidence-based practice change. *Adv Neonatal Care*, 11(3), 208-215. doi: 10.1097/ANC.0b013e31821bab61 **NICU patients**
- Dal Molin, A., Allara, E., Montani, D., Milani, S., Frassati, C., Cossu, S., . . . Rasero, L. (2014). Flushing the central venous catheter: is heparin necessary? *J Vasc Access*, 15(4), 241-248. doi: 10.5301/jva.5000225 **Systemtic review using the same studies we reviewed.**
- Jonker, M. A., Osterby, K. R., Vermeulen, L. C., Kleppin, S. M., & Kudsk, K. A. (2010). Does low-dose heparin maintain central venous access device patency?: a comparison of heparin versus saline during a period of heparin shortage. *JPEN J Parenter Enteral Nutr*, 34(4), 444-449. doi: 10.1177/0148607110362082 **Total patients not included.**
- Kannan, A. (2008). Heparinized saline or normal saline? *J Perioper Pract*, 18(10), 440-441. **Review question**
- Lyons, M. G., & Phalen, A. G. (2014). A randomized controlled comparison of flushing protocols in home care patients with peripherally inserted central catheters. *J Infus Nurs*, 37(4), 270-281. doi: 10.1097/nan.0000000000000050 **Outpatients**
- Mitchell, M. D., Anderson, B. J., Williams, K., & Umscheid, C. A. (2009). Heparin flushing and other interventions to maintain patency of central venous catheters: a systematic review. *J Adv Nurs*, 65(10), 2007-2021. **Systemtic review using the same studies we reviewed.**
- Rabe, C., Gramann, T., Sons, X., Berna, M., González-Carmona, M., Klehr, H.-U., . . . Caselmann, W. (2002). Keeping central venous lines open: a prospective comparison of heparin, vitamin C and sodium chloride sealing solutions in medical patients. *Intensive Care Medicine*, 28(8), 1172-1176. doi: 10.1007/s00134-002-1379-2 **High concentration of Heparin used (5000 iu/1ml)**
- Sona, C., Prentice, D., & Schallom, L. (2012). National survey of central venous catheter flushing in the intensive care unit. *Crit Care Nurse*, 32(1), e12-19. doi: 10.4037/ccn2012296 **Survey**
- Toft, B. (2010). The dangers of heparin flushes. *Postgrad Med J*, 86(1012), 65-66. doi: 10.1136/qshc.2008.028324 **Narrative review**

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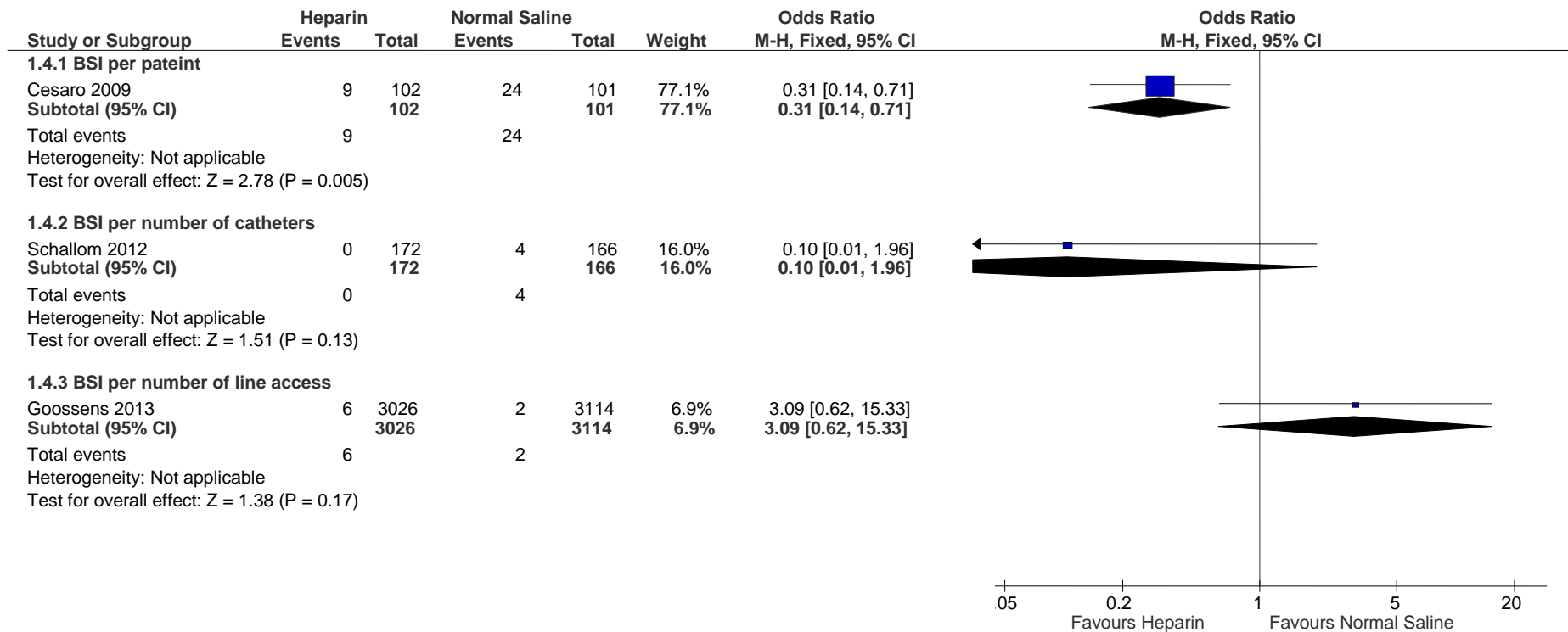
Figure 1. Heparin versus Normal Saline, Outcome: Occlusion



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Figure 2. Heparin versus Normal Saline, Outcome: Blood Stream Infections



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Bowers 2008

Methods	Randomized Control Trial
Participants	<p>Setting: USA, urban hospital</p> <p>Randomized into study: Did not mention if all that were randomized also completed the study</p> <p>Completed study: Treatment group: normal saline flush (NS) n=50 and control group: heparinized saline flush (HS) n=52</p> <p>Age (mean in years, no SD reported): NS group 53.8 and HS group 54.9</p> <p>Gender: NS group 40% male and HS group 60% male</p> <p>Inclusion criteria: ≥18 years of age, Required a PICC for intermittent access, Had a single-lumen PICC placed by the interventional radiology staff at the hospital</p> <p>Exclusion criteria: Known allergy to heparin, PICC inserted more than 24 hours before admission, End-stage renal disease or kidney transplant with potential need for graft or fistula in ipsilateral extremity, Ipsilateral radiation therapy, Burn or limb surgery involving ipsilateral extremity, Existing infection in or history of central vein obstruction, Participation in an investigational study in last 30 days.</p> <p>Power analysis: powered to detect significant differences in occlusion rates of 15% or more between the 2 flushing methods. A 10% margin of error was included, generating a sample size of 102</p>
Interventions	<p>HS group: received SASH method and did not require a Luer-activated device (LAD): S = 10 mL 0.9% sodium chloride flush (saline flush); A = administer medication or draw blood; S = 10 mL saline flush; H = 3 mL HS flush; n=52</p> <p>NS group: received SAS method and required LAD: S = 10 mL saline flush; A = administer medication or draw blood; S = 10 mL saline flush; n=50 Flushes occurred at a minimum of daily or after each access for medications and blood draws.</p>
Outcomes	Ease of flushing: yes or no to question: "Did the PICC flush easily? Occlusion status: partial or complete occlusion. Need and reason for removal. For occlusions, the ability to restore patency with alteplase
Notes	Occlusion requiring removal: NS group n=3 and HS group n=0 No infection data reported

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Bias	Scholars' Judgment	Support for Judgment
Random sequence generation (selection bias)	Low Risk	A random block design with concealment was used.
Allocation concealment (selection bias)	High Risk	The HS group had an extra flush that was given; therefore, it would be known what group the subject was in.
Blinding of participants and personnel (performance bias)	High Risk	The HS group had an extra flush that was given; therefore, it would be known what group the subject was in.
Blinding of outcome assessment (detection bias)	High Risk	Nurses that were giving the flushes had to answer whether the line would draw easily or not.
Incomplete outcome data (attrition bias)	Unclear Risk	Did not report if any subject that was randomized dropped out. They only reported on subjects that completed the study, but still met power.
Selective reporting (reporting bias)	Low Risk	Not detected
Other bias	Unclear	Not detected

Cesaro 2009

Methods Randomized Control Trial

Participants **Setting:** Tertiary referral center for pediatric oncology patients, Italy
Randomized: 203 total patients, Control:N=102 pts, Tx:N=101 pts (2 pts refused random assignment, put in standard procedure group)
Age: Pediatric patients ages 0-17, Control: less than 5 yrs=41, greater than/equal to 5 yrs=61; Tx: less than 5 yrs=39, greater than/equal to 5 yrs=62
Completed: Control: 102, Tx: 101
Gender: Control: 59% (male) Tx: 59% (male)
Inclusion criteria: Pediatric pts 0-17 yrs with malignant or nonmalignant hematologic or oncologic disease who required Broviac-Hickman type CVC for the purpose of chemotherapy or hematopoietic stem cell transplantation
Exclusion criteria: None mentioned in study
Power analysis: Met power, Needed 93 patients in each tx arm to accomplish

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Interventions **Treatment Group:** Insertion of CVC in the operating theater by an experienced pediatric surgeon or anesthetist, Flushing of CVC with normal saline only at least weekly, using a positive-pressure CVC valve cap device, CVC antireflux device was changed every 7 days per manufacturer's instructions, Weekly cleansing of the exit site with povidone-iodine solution, and skin covered with sterile gauze dressing.

Control Group: Insertion of CVC in the operating theater by an experienced pediatric surgeon or anesthetist, Flushing of CVC with 3 mL of normal solution and with heparin 200 IU/mL twice a week using a standard CVC cap, CVC cap changed at every flushing with heparin solution, Weekly cleansing of the exit site with povidone-iodine solution, and skin covered with sterile gauze dressing.

Outcomes **Primary:** decrease CVC complication rates from CVC occlusion, dislocation, bacteremia/fungemia, exit-site infection, or thrombosis
Secondary: Improve CVC survival rates

Notes "Standard flushing" not defined very well. Article even states that "frequency of this maneuver [flushing] and the concentration of heparin solution vary between centers."
 Article also states that "in both arms, the frequency of CVC flushing could be increased according to patient needs." - seems like this would affect the accuracy of results if lines are being flushed MORE than the 1 or 2 times per week what the study is suggesting.

Bias	Scholars' Judgment	Support for Judgment
Random sequence generation (selection bias)	Low Risk	Computer generated randomization drawn up by statistician
Allocation concealment (selection bias)	Low Risk	Results stored in sequentially numbered sealed envelopes
Blinding of participants and personnel (performance bias)	Unclear Risk	Incomplete blinding, only concealed to investigators until completion of recruitment, neither participants or those administering tx were blinded during study, but the outcome is not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias)	Unclear Risk	No blinding of outcome assessment, but outcome measurement is not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias)	Low Risk	No missing outcome data, met power for groups tested
Selective reporting (reporting)	Low Risk	Both primary and secondary results are reported on thoroughly

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bias)

Other bias

High Risk

The study used different flushing schedule for Heparin (twice per week) vs Normal Saline (once per week). Also different caps were used by both groups.

Gossens 2013

Methods

Randomized Control Trial

Participants

Setting: Tertiary teaching hospital in Belgium

Randomized: Control (heparin)-398 allocated, 383 included in analysis

Tx (NS)-404 allocated, 382 included in analysis

Age: Control- 54.9, Tx-56.7

Completed: Control-383, Tx-382

Gender: Control-135 males, Tx-143 males

Inclusion criteria: Older than 1 yr, scheduled for first time TIVAD insertion through SVC system, had onco-hematologic malignancy, had sufficient life expectancy to complete planned follow up of 180 days in center

Exclusion criteria: Adult patients unable to sign informed consent, inability to stand for post-op chest x-ray, patients with therapeutic IV heparin administration, hx of HIT or abnormal clotting tests, coincident participation in other clinical trials

Power analysis: Needed 307 patients per group, met power with both groups

Interventions

Control- hep lock of 300U/3ml in TIVADS before Huber needle removal

Treatment- Standard NS flushing protocols (10 ml NS flush before/after blood sampling, 20 ml flush at end of blood component administration)

Outcomes

Primary-number of functional complications, 'easy injection, impossible aspiration'

Secondary- catheter associated bacteremia

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Risk of Bias Table

Bias	Scholars' Judgment	Support for Judgment
Random sequence generation (selection bias)	Low Risk	computer randomised numbers
Allocation concealment (selection bias)	Low Risk	concealed from researchers who enrolled patients, numbers kept in separate room
Blinding of participants and personnel (performance bias)	High Risk	Unclear whether participants were blinded during study, personnel were only blinded until consent was obtained and participant was assigned to group, knew which solution they were locking the TIVAD with during study
Blinding of outcome assessment (detection bias)	High Risk	Impossible to blind outcome assessment if personnel knew which solution they were locking with
Incomplete outcome data (attrition bias)	Unclear Risk	used 'as treated' analysis after some participants did not complete study (22 attributed to attrition in NS, 15 in heparin).
Selective reporting (reporting bias)	Low Risk	Reported on primary and secondary outcomes appropriately, identified several methodological limitations of study
Other bias	Unclear Risk	

Schallom 2012

Methods

Single-center, randomized, open label trial

Participants

341 patients with multilumen central venous catheters

Setting: Medical intensive care unit and Surgical/Burn/Trauma intensive care unit at Barnes-Jewish Hospital, St. Louis, MO

Randomized: 166 patients allocated to NaCl, 172 allocated to heparin

Age: NaCl 58.3 ± 17.5 years, heparin 59.1 ± 15.2 years

Completed: 165 NaCl, 167 heparin

Gender: NaCl 55.3% male, heparin 46.9% male

Inclusion criteria: must have a newly inserted (≤12 hours) multilumen CVC performed by personnel at the institution and all lumens had to be patent.

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Exclusion criteria: Patients with multilumen dialysis or pheresis catheters, peripherally inserted central catheters (PICC), long-term use catheters, pulmonary artery catheters, implanted ports, large bore single lumen sheath catheters, and multilumen catheters threaded through large bore sheath catheters. Also a known heparin allergy, a diagnosis of HIT, bleeding risk identified by attending physician, age less 18 years, and pregnancy.

Power analysis: Assuming a 10% lumen nonpatency rate in the 0.9% NaCl group, it was calculated that 684 lumens used for intermittent infusions would be needed to detect a 5% absolute difference in lumen patency in the heparin group compared with the 0.9% NaCl group, with 80% statistical power and a two-sided α value of 0.05.

Interventions	0.9% NaCl flush solution group: 10 mL 0.9% NaCl every 8 hours, or more frequently if lumen needed for infusions Heparin lock flush solution group: 10 mL 0.9% NaCl followed by 3 mL heparin lock flush solution (10 units/mL) every 8 hour.
Outcomes	Primary - lumen nonpatency, defined as inability to both withdraw blood and flush through a lumen. This was determined after troubleshooting with nursing interventions of repositioning patient and changing needleless access device. Secondary - loss of blood return, flush failure, rates of central line associated bloodstream infection and HIT.
Notes	Different brands and types of catheters were included in this study: Arrow, Arrow pressure injectable, Edwards, and cook pressure injectable. Triple lumen and Quad lumens were used, as well.

Risk of Bias Table

Bias	Scholars' Judgment	Support for Judgment
Random sequence generation (selection bias)	Low Risk	Randomization was performed according to the Consolidated Standards for the Reporting of Trials (CONSORT) guidelines.
Allocation concealment (selection bias)	Low Risk	A random allocation sequence was created using a computerized random number generator in Microsoft Excel. Simple randomization was done such that consecutively numbered cards with the flush assignment according to the randomization schedule written on the back of each card. The allocation sequence was concealed until the card was retrieved upon obtaining patient consent.
Blinding of participants and personnel (performance bias)	High Risk	Neither personnel nor patients were blinded.

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Blinding of outcome assessment (detection bias)	High Risk	Neither personnel nor patients were blinded.
Incomplete outcome data (attrition bias)	Low Risk	Low attrition rates balanced between groups. 1 saline group lumen did not actually receive saline. 5 heparin group lumens did not actually receive heparin.
Selective reporting (reporting bias)	Low Risk	All outcomes reported on. A small number of flushes were either missed or not documented but not enough to significantly impact results.
Other bias	Unclear Risk	

Date: 2015-01-08

Question: Normal Saline vs Heparin for flushing CVC

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