Title

Patterns of Use and Outcomes of Peripherally Inserted Central Catheters in Hospitalized Patients with Solid Tumors: A Multi-Center Study

Authors

Urvashi Mitbander MD, Marcus Geer MD, Knut Taxbro MD PhD, Jennifer Horowitz MA, Qisu Zhang MPH, Megan O'Malley PhD, Nithya Ramnath MBBS, Vineet Chopra MD MSc

Table of Contents

Content	Page Number
Michigan Hospital Medicine Safety (HMS) Collaborative Audit Process	3
Definition of Solid Tumor Cancers	5
Supplemental Tables	7
Supplemental Table 1. Antimicrobial Coated Catheters and complications	7
Supplemental Table 2. Antithrombotic Catheters and complications	7
Additional References	8

Michigan Hospital Medicine Safety (HMS) Collaborative Audit Process

Details on the HMS Databases

HMS has three (3) databases, or registries, currently in production, one of which is PICCs/Midlines. The database is used as the primary hub of case abstraction, data reporting, case volume analysis, resource gathering, and abstraction queries.

Audits are conducted to ensure that the data is being collected consistently across all participating hospitals. The goal is to identify issues with the abstraction process so that they can be appropriately addressed via education and/or changes to the data entry system. Each HMS-participating hospital is audited by a trained member of the Coordinating Center at least once per year. On average, more than 50 audits have been conducted per year since the launch of HMS in 2011. This number increases each year as new hospitals join the collaborative. It is the expectation that each audited site will attain a 95% or greater rate of accuracy. To determine the audit score, the auditor calculates a score for each individual case based on the average number of audit fields as noted below (see Medical Record Review). Then using the individual scores for each case, an overall audit score is calculated by averaging all of the audit cases combined. If a site receives a score of less than 95% on an audit, every attempt will be made to re-audit that site in the same year.

The audit consists of four parts: medical record review, review of eligibility lists, review of inclusion/exclusion criteria and practices, and post-audit follow up.

Medical Record Review:

The primary focus of the audit is a medical record review of pre-selected cases by one to three HMS auditors. Key complication cases related to Central Line Associated Bloodstream Infection (CLABSI), Deep Vein Thrombosis (DVT), and Pulmonary Embolism (PE) are required to be audited to ensure accurate outcome measures for reporting purposes. Prior to the audit, the primary auditor queries the data analytics team to obtain the list of required complication cases that are due for audit and a random sample of additional non-complication cases. An average of 7 to 10 cases are audited if one auditor is present, and each case includes more than 1,700 fields. If a site has a large number of unaudited complication cases, a second or third auditor will join to complete additional cases. The list of cases is distributed to the abstractor 1 to 2 weeks in advance of the audit. Prior to sending the list of audited cases, the abstractor is locked from making updates to previously completed cases. At the on-site audit, the auditor(s) independently reviews the medical documentation for each case from the hospital's Electronic Medical Record (EMR) and compares it to what was entered into the HMS database. At the end of the audit day, the auditor's case findings and discrepancies between the EMR and the information entered into the HMS databases (if applicable) will be reviewed in detail with the abstractor. At the resolution of the audit, these discrepancies (if validated as incorrect by both

the abstractor and auditor), are corrected in the database by the abstractor to ensure case accuracy. The auditor will also provide additional education, as needed, as issues are identified. If during the medical record review a completed eligible case is determined by the auditor to be ineligible, a score of 90% is assigned to the case and added to the overall average score.

Eligibility List Review:

The second item reviewed during an audit is the eligibility/discharge lists and coding at the site being audited. Prior to the audit, the abstractor connects with their hospital's information technology (IT) group for the coding used to generate their eligibility/discharge lists for the PICC/Midline initiative. This coding is reviewed by the auditor and feedback is provided regarding updates that need to be made to the coding, if applicable.

Inclusion/Exclusion Criteria Review:

The final item reviewed during an audit is inclusion/exclusion criteria. The purpose of this review is to ensure that the abstractor understands the inclusion/exclusion criteria for each project and is applying those criteria appropriately when reviewing cases. At least one PICC/Midline case that was deemed ineligible by the abstractor is randomly selected and reviewed with the auditor(s). Once a case is identified, the abstractor shows the auditor(s), in the medical record, the reason the case was excluded from abstraction. If a case was deemed ineligible by the abstractor, but was determined through the review process that it was actually eligible for abstraction, another case from the same project will be reviewed until a legitimate ineligible case is found. If the abstractor has incorrectly identified a case as ineligible, the auditor(s) will provide additional on-site education about eligibility criteria. If more than 2 randomly-selected cases were deemed ineligible by the abstractor, but are determined to be eligible for abstraction after review, a score of 90% will be added to the final audit summary for each additional case that is found to be eligible.

Post-Audit Follow Up:

After the audit has concluded, the primary auditor composes a summary of the findings, including specific areas to update in the HMS databases, education provided to the site during the audit, and a summary of any findings from the eligibility/discharge list review. The final audit summary is provided to the site within two to three weeks of completion of the audit. This summary will be sent to the site's abstractor(s), quality administrator, and physician champion. The summary will include a percentage score for the audit, which is calculated based on the average of the scores for all cases reviewed. Upon receiving the final audit summary, the abstractor(s) has three months from the date of receipt to make all updates in the HMS database noted in the final report. The final audit score is then factored into the site's performance index scorecard for the given year. During a typical year, 5% of the performance index is associated with the audit score(s) completed during the performance year.

Definition of Solid Tumor Cancers

Medical Record Abstraction - Solid Tumor Type

The medical record was reviewed as follows to determine the type(s) of cancer, indicating only primary site of the cancer and not sites of metastasis.

"Bladder" if the medical record indicates that the patient has a past/present history of bladder cancer. Includes bladder cancer, cancer of the bladder.

"Breast" if the medical record indicates that the patient has a past/ present history of breast cancer. Includes breast cancer, mammary cancer.

"Colon" if the medical record indicates that the patient has a past/present history of colon cancer. Includes colon cancer, colorectal cancer, bowel cancer, gastrointestinal cancer, rectal cancer, rectosigmoid cancer.

"Kidney" if the medical record indicates that the patient has a past/present history of kidney/renal cancer. Includes renal cell carcinoma (RCC), renal cell cancer, kidney cancer, renal cancer, renal sarcoma.

"Liver" if the medical record indicates that the patient has a past/present history of liver/hepatic cancer. Includes liver cancer, hepatic carcinoma, hepatic cancer, hepatocellular carcinoma, hepatic adenocarcinoma, cholangiocarcinoma.

"Lung- Small cell" if the medical record indicates that the patient has a past/present history of lung cancer- small cell. Includes Small cell lung cancer (SCLC) (not to be mistaken for squamous cell lung cancer), Oat-cell carcinoma.

"Lung-Non-small cell" if the medical record indicates that the patient has a past/present history of lung cancer- non-small cell. Examples include (but not limited to): non-small cell lung cancer (NSCLC), adenocarcinomas, epidermoid carcinoma, large cell carcinomas, squamous cell carcinoma.

"Malignant brain tumor" if the medical record indicates that the patient has a past/present history of malignant brain tumor. Includes (but not limited to) Chordomas, Gliomas, Glioblastoma, schwannoma, meningioma, etc.

"Melanoma" if the medical record indicates that the patient has a past/present history of melanoma. Includes melanoma, malignant melanoma.

"Metastatic with unknown primary" if the medical record indicates that the patient has a past/present history of metastatic cancer with an unknown primary. Includes cancer with an unknown primary location, Metastatic Cancer with unknown origin, original cancer location cannot be identified.

"Ovarian" if the medical record indicates that the patient has a past/ present history of ovarian cancer. Includes epithelial ovarian tumor, Germ cell tumor, sex cord stromal ovarian tumor. "Pancreas/Pancreatic" if the medical record indicates that the patient has a past/present history of pancreas/pancreatic cancer. Includes pancreatic cancer, cancer of the pancreas, pancreatic adenocarcinoma.

"Prostate" if the medical record indicates that the patient has a past/ present history of prostate cancer. Includes prostate cancer, prostate adenocarcinoma, Gleason Score X of X. Excludes benign prostatic hyperplasia.

"Rectal/Rectum" if the medical record indicates that the patient has a past/present history of rectal/rectum cancer. Includes rectal cancer, cancer of the rectum.

"Stomach/Gastric" if the medical record indicates that the patient has a past/present history of stomach/gastric cancer. Includes stomach cancer, gastric cancer, spindle cell cancer, GIST tumor.

"Uterine" if the medical record indicates that the patient has a past/ present history of uterine cancer. Includes uterine cancer, endometrial cancer, cervical cancer.

"Other, not including basal cell" if the medical record indicates that the patient has a past/present history of cancer not listed above, not including basal cell carcinoma. Includes cancer type not listed above, Fibrosarcoma, Squamous cell carcinoma (non-lung derived), Histiocytoma, Malignant pleural effusion without the type of cancer specified, appendiceal cancer, testicular cancer, esophageal cancer, esthesioneuroblastoma, tonsillar cancer, Kaposi Sarcoma. Exclude Basal cell carcinoma.

"Unknown" if the medical record is silent as to the type of cancer.

Supplemental Tables

	Antimicrobial	No antimicrobial	P-value	Total (n=3235)		
	Coating	coating				
	(n = 177)	(n = 3058)				
CLABSI	6 (3.4%)	76 (2.5%)	0.457	82 (2.5%)		
Catheter	40 (22.6%)	292 (0.20/)	<0.001	222 (10.0%)		
Occlusion		282 (9.2%)	<0.001	322 (10.0%)		

Supplemental Table 1. Antimicrobial Coated Catheters and complications

Supplemental Table 2. Antithrombotic Catheters and complications

	Antithrombotic Coating (n = 89)	No antithrombotic coating (n = 3146)	P-value	Total (n=3235)
CLABSI	2 (2.3%)	80 (2.5%)	0.861	82 (2.5%)
Catheter Occlusion	13 (14.6%)	309 (9.8%)	0.137	322 (10.0%)

Abbreviations:

CLABSI, central line-associated bloodstream infection

Additional References

- 1. Bénet T, Vanhems P. Correlation of nosocomial bloodstream infection incidences: an ecological study. J Hosp Infect. Nov 2009;73(3):217-24. doi:10.1016/j.jhin.2009.07.018
- 2. Worth LJ, Black J, Seymour JF, Thursky KA, Slavin MA. Surveillance for catheter-associated bloodstream infection in hematology units: quantifying the characteristics of a practical case definition. Infect Control Hosp Epidemiol. Apr 2008;29(4):358-60. doi:10.1086/528879
- 3. Mollee P, Jones M, Stackelroth J, et al. Catheter-associated bloodstream infection incidence and risk factors in adults with cancer: a prospective cohort study. J Hosp Infect. May 2011;78(1):26-30. doi:10.1016/j.jhin.2011.01.018
- Luft D, Schmoor C, Wilson C, et al. Central venous catheter-associated bloodstream infection and colonisation of insertion site and catheter tip. What are the rates and risk factors in haematology patients? Ann Hematol. Dec 2010;89(12):1265-75. doi:10.1007/s00277-010-1005-2
- Dettenkofer M, Wilson C, Gratwohl A, et al. Skin disinfection with octenidine dihydrochloride for central venous catheter site care: a double-blind, randomized, controlled trial. Clin Microbiol Infect. Jun 2010;16(6):600-6. doi:10.1111/j.1469-0691.2009.02917.x
- Chaberny IF, Ruseva E, Sohr D, et al. Surveillance with successful reduction of central lineassociated bloodstream infections among neutropenic patients with hematologic or oncologic malignancies. Ann Hematol. Sep 2009;88(9):907-12. doi:10.1007/s00277-008-0687-1
- 7. Ram R, Gafter-Gvili A, Raanani P, et al. Surveillance of infectious complications in hematooncological patients. Isr Med Assoc J. Mar 2009;11(3):133-7.
- Apostolopoulou E, Raftopoulos V, Terzis K, Elefsiniotis I. Infection Probability Score, APACHE II and KARNOFSKY scoring systems as predictors of bloodstream infection onset in hematology-oncology patients. BMC Infect Dis. May 2010;10:135. doi:10.1186/1471-2334-10-135
- Meyer E, Beyersmann J, Bertz H, et al. Risk factor analysis of blood stream infection and pneumonia in neutropenic patients after peripheral blood stem-cell transplantation. Bone Marrow Transplant. Feb 2007;39(3):173-8. doi:10.1038/sj.bmt.1705561
- Debourdeau P, Kassab Chahmi D, Le Gal G, et al. 2008 SOR guidelines for the prevention and treatment of thrombosis associated with central venous catheters in patients with cancer: report from the working group. Ann Oncol. Sep 2009;20(9):1459-1471. doi:10.1093/annonc/mdp052
- Maki DG, Kluger DM, Crnich CJ. The risk of bloodstream infection in adults with different intravascular devices: a systematic review of 200 published prospective studies. Mayo Clin Proc. Sep 2006;81(9):1159-71. doi:10.4065/81.9.1159

- Bouza E, Burillo A, Muñoz P. Catheter-related infections: diagnosis and intravascular treatment. Clin Microbiol Infect. May 2002;8(5):265-74. doi:10.1046/j.1469-0691.2002.00385.x
- Gao Y, Liu Y, Ma X, Wei L, Chen W, Song L. The incidence and risk factors of peripherally inserted central catheter-related infection among cancer patients. Ther Clin Risk Manag. 2015;11:863-71. doi:10.2147/TCRM.S83776
- 14. Liu Y, Gao Y, Wei L, Chen W, Ma X, Song L. Peripherally inserted central catheter thrombosis incidence and risk factors in cancer patients: a double-center prospective investigation. Ther Clin Risk Manag. 2015;11:153-60. doi:10.2147/TCRM.S73379
- 15. Karthaus M, Doellmann T, Klimasch T, Krauter J, Heil G, Ganser A. Central venous catheter infections in patients with acute leukemia. Chemotherapy. Jul 2002;48(3):154-7. doi:10.1159/000064922
- 16. Harter C, Salwender HJ, Bach A, Egerer G, Goldschmidt H, Ho AD. Catheter-related infection and thrombosis of the internal jugular vein in hematologic-oncologic patients undergoing chemotherapy: a prospective comparison of silver-coated and uncoated catheters. Cancer. Jan 2002;94(1):245-51. doi:10.1002/cncr.10199
- Cotogni P, Barbero C, Garrino C, et al. Peripherally inserted central catheters in nonhospitalized cancer patients: 5-year results of a prospective study. Support Care Cancer. Feb 2015;23(2):403-9. doi:10.1007/s00520-014-2387-9
- Bertoglio S, Faccini B, Lalli L, Cafiero F, Bruzzi P. Peripherally inserted central catheters (PICCs) in cancer patients under chemotherapy: A prospective study on the incidence of complications and overall failures. J Surg Oncol. May 2016;113(6):708-14. doi:10.1002/jso.24220
- Al-Asadi O, Almusarhed M, Eldeeb H. Predictive risk factors of venous thromboembolism (VTE) associated with peripherally inserted central catheters (PICC) in ambulant solid cancer patients: retrospective single Centre cohort study. Thromb J. 2019;17:2. doi:10.1186/s12959-019-0191-y
- Cheong K, Perry D, Karapetis C, Koczwara B. High rate of complications associated with peripherally inserted central venous catheters in patients with solid tumours. Intern Med J. May 2004;34(5):234-8. doi:10.1111/j.1444-0903.2004.00447.x
- 21. Jones D, Wismayer K, Bozas G, Palmer J, Elliott M, Maraveyas A. The risk of venous thromboembolism associated with peripherally inserted central catheters in ambulant cancer patients. Thromb J. 2017;15:25. doi:10.1186/s12959-017-0148-y