Reviewer’s report

Title: Incidence of catheter-related complications in patients with central venous or hemodialysis catheters: a health care claims database analysis

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Reviewer: E. Vincent Faustino

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In this study by Napalkov et al, the authors determined the incidence rates of catheter-related complications using a claims database. They report that complications are more common in the CVC cohort in the first 90 days after insertion and that infection was the most common complication.

Major Compulsory Revisions

1. Although not specifically stated in the text, the authors aimed to determine the complications attributable to CVC and HD catheters. The authors acknowledged that because of the use of the claims database, they are unsure whether the complications that they report is the result or the cause of the line placement. This is problematic because the authors are unable to answer the hypothesis they set out to answer.

2. It is unclear why patients were divided into CVC and HD groups. Also, if patients had both HD and CVC, the complications were attributed to HD. This is again a problem because the authors set out to attribute complications to a particular catheter type. In the presence of both catheters, it is unclear whether the complication, particularly infection, was due to which catheter.

3. Because of multiple reasons that affect the risk of catheter complications, the absence of adjustment for confounders is concerning. Since the authors used Poisson regression, confounders should have been entered in the model to adjust for their effects.

Minor Essential Revisions

Background

1. The background should be significantly trimmed down to at most 1.5 pages. It needs to focus on the question the authors were trying to answer.

2. The background should provide information on why patients were divided into CVC and HD groups.

3. Please write what the aim/hypothesis was for the study. Was the aim to determine the incidence rate or just the development of a complication? The regression model to be used depends on the hypothesis (i.e. Poisson if rates/counts are the outcome measure of logistic if the outcome is just the presence or absence of a complication).
Methods

1. Because I am unfamiliar with the database used, is it possible that the database introduced any bias in the selection of the patients analyzed in the study?

2. The authors analyzed data from 2000-2007 which is at least 6 years old. Why was newer data not used? Current infection rates may be different because of initiatives to decreased catheter-related infections.

3. If the hypothesis was to determine incidence rates of any complication, why was catheter-days censored after the first complication? Because patients can have multiple counts of the same complication or different complications, the at risk period should include the entire time that the catheter was in place including after a complication was detected. This brings up the importance of having a well-specified hypothesis/aim.

4. What type of CVC were included? Different CVC types tend to have different complication rates.

5. Why are intracranial hemorrhage and major bleeding events considered catheter-related complications? What was considered a major bleeding event?

6. If the purpose of the study was to determine incidence rates, all complications should be included in the analysis and not just the first occurrence of the event.

7. What was the rationale for dividing the patients into different age groups and duration of catheter placement? This should be included in the background. In the absence of clear rationale, it's best to analyze these as continuous variables and attempt to categorize them based on your data.

8. Poisson is appropriate for rates but it is not clear whether this was what the authors wanted because of the prior paragraphs where only the first event was included in the analysis. In the latter case, logistic regression would have been more appropriate.

9. The number of days that the patient was at risk should be from catheter placement to removal and not up to day of first complication. Patients were still at risk for the same or different complication after the first event.

10. Since the authors used regression, why was Fisher's exact test used to compare cancer and non-cancer patients? A more elegant way of analyzing the data would have been to use a regression model including the presence of CVC/HD, presence of cancer and other covariates. The predicted incidence rate could then be estimated from this model. This would have been better than dividing the cohort into a number of small groups leading to unadjusted stratified analyses.

Results

1. The incidence rates based on duration of catheter placement would have been
better analyzed using survival analysis (e.g. Cox-proportional hazard) then presented as Kaplan-Meier curves rather than arbitrarily dividing the duration of catheter days.

Discussion

1. The sensitivity analysis should be moved to the methods section and results presented in the results section.

2. How will matching improve on the data presented?

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests