‘How many audits do you really need?’: Learnings from 5-years of peripheral intravenous catheter audits

Title: 'How many audits do you really need?': Learnings from 5-years of Peripheral Intravenous Catheter Audits

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ABSTRACT

Rationale, aims and objectives

Peripheral intravenous catheters (PIVCs) are medical devices used to administer intravenous therapy but can be complicated by soft tissue or bloodstream infection. Monitoring PIVC safety and quality through clinical auditing supports quality infection prevention however is labour intensive. We sought to determine the optimal patient 'number' for clinical audits to inform evidence-based surveillance.

Method

We studied a dataset of cross-sectional PIVC clinical audits collected over five years (2015-2019) in a large Australian metropolitan hospital. Audits included adult medical, surgical, women's, cancer, emergency and critical care patients, with audit sizes of 69 to 220 PIVCs. The primary outcome was PIVC complications for one or more patient reported symptom/auditor observed sign of infection or other complications. Complication prevalence and 95% confidence interval (CI) were calculated. We modelled scenarios of low (10%), medium (20%) and high (50%) prevalence estimates against audit sizes of 20, 50, 100, 150, 200, 250, and 300. This was used to develop a decision-making tool to guide audit size.

Results

Of 2,274 PIVCs evaluated, 475 (21%) had a complication. Complication prevalence per round varied from 7.8% (95% CI, 4.2- 12.9) to 39% (95% CI, 32.0- 46.4). Precision improved with larger audit size and lower complication rates. However, precision was not meaningfully improved by auditing >150 patients at a complication rate of 20% (95% CI 13.9%- 27.3%), nor >200 patients at a complication rate of 50% (95% CI 42.9% -57.1%).

Conclusion

Audit sizes should be 100 to 250 PIVCs per audit round depending on complication prevalence.

Keywords

Peripheral intravenous catheter, infection, vascular access device, clinical indicators, assessment, quality measurement, audit, surveillance, sample size.

INTRODUCTION

More than 70% of hospitalised patients require a peripheral intravenous catheter (PIVC) during their admission for the short-term administration of intravenous therapy[1]. As more than one-third of PIVCs fail before the completion of treatment [2-5], PIVC insertion practices and post insertion care are important areas for clinical auditing. Phlebitis (vein irritation), infiltration (intravenous fluid in tissue), occlusion, dislodgement and infection are frequently audited PIVC complications[6,7]. Line associated bloodstream infections (LABSIs) are the most serious complication associated with PIVCs and frequently occur as a result of the skin breach at the catheter insertion site, creating a portal for pathogens to enter the body and the patient's bloodstream[8,9]. Although LABSIs are more commonly associated with central venous access devices[8], infections associated with PIVCs are just as significant by sheer volume of use globally each year (>2 billion) [10,11].

The benefit of PIVC clinical audits is they allow health services to monitor quality of care, contribute to improved patient care and health outcomes by systematically comparing practice against pre-established standards of care[12]. This is an important quality improvement process to ensure patients receive the most effective, relevant and up-to-date evidence-based care[13,14]. Clinical audits are generally conducted by peers working within the hospital or health service[15]. By collecting quantifiable and objective data, key hospital stakeholders and health professionals can establish whether clinical practice is compliant with hospital policy, relevant clinical guidelines and national quality indicators[16]. Implementing an audit and feedback process for PIVCs allows the early detection of PIVC complications and the presence of redundant catheters which are known to increase patients risk of LABSI[17]. Auditing allows for benchmarking of the presence of infection or other complications with different clinical areas or hospitals, and encourages the improvement of health professionals' performance by identifying areas requiring clinical innovation or focused retraining and education[13,18]. The auditing process typically requires significant human and financial resourcing, including health professionals' time away from clinical care[19].

Although international guidelines highlight the importance of conducting PIVC audits, they fail to provide recommendations on the number of PIVC assessments necessary per audit round[20,21]. Due to the large volume of PIVCs used in hospitals and a stretched infection prevention workforce, it is not feasible to audit all PIVCs. With no guidance to healthcare providers on required audit numbers it is unclear if current PIVC audit processes accurately reflect clinical practice[16]. In order to understand PIVC-related risk, prevalence estimates must be presented with an indication of precision, such as 95% confidence intervals (CI). Otherwise, if two small audits show large 'differences' in prevalence of complications between two hospital wards, or between two time periods, it is not clear whether this difference is within the bounds of random sampling error or whether the audit results are systematically different. Further, the required audit size needed is influenced statistically by the prevalence (i.e. whether few or many complications). The aim of this study was to create a decision-making tool for the number of PIVC assessments needed per audit round that considered both the prevalence of complications and the precision of the estimate.

METHODS

Analysis of a large prospectively collected database of PIVC audits conducted in a single metropolitan hospital over a 5-year period. This xxx-bed quaternary and tertiary referral teaching hospital is the largest provider of health care service for Queensland, Australia. Ethics exemption (LNR/2018/QRBW/49270) was obtained from the hospital ethics committee.

The study had two primary objectives:

1. Identify the relationship between number of patients audited and the precision of the estimate of PIVC complication prevalence; and
2. Develop a decision-making tool to guide the number of PIVC audits needed to reliably detect complications rates of 10%, 20% and 50%.

Data collection

Nurses from the hospital Vascular Access, Surveillance and Education team (VASE), conducted 16 hospital wide PIVC cross-sectional audits between June 2015 and April 2019. A total of 2,274 PIVCs were audited using direct patient assessment and documentation from medical charts. Each audit round assessed between 69 and 220 PIVCs, and rounds occurred at time intervals of one to seven months. The number audited, and frequency of auditing, were dictated by the volume of patients admitted with a PIVC at the time of audit round, and availability of VASE nurses. Each round included medical, surgical, cancer care, women's (obstetrics and gynaecology), emergency and critical care departments, but did not mandate a particular number per area. Neonatal patients were excluded.

Each PIVC was assessed once on the day of audit. Data collected included: patient gender; insertion data (e.g. PIVC gauge, site of insertion); maintenance data (e.g. dressing condition – clean, dry, intact); and PIVC site assessment (e.g. presence of erythema, oedema, palpable cord or purulent discharge).

The primary outcome was PIVC complications, which were coded as a binary variable (yes/no). A complication was recorded if one or more of the following characteristics were present on assessment: patient reported symptom (pain, itching/burning, tingling/numbness, leaking, swelling, occlusion, kinking); and/or auditor observed sign of infection or complication (oedema/inflammation, bruising/haematoma, erythema, palpable cord/vein tracking, discharge at site (i.e. purulence), hardness/induration, leaking, phlebitis, dislodgment, skin reaction, pain on infusion, warmth).

Statistical analysis

Patient and PIVC characteristics were summarised as frequencies and percentages. Complication prevalence and its 95% CI were calculated using exact binomial CIs. We modelled a range of scenarios to understand how the precision of prevalence estimates changed according to actual

complication prevalence and the audit size. Three prevalence estimates were chosen, 20% (representing the expected prevalence in our audits), 10% (a low prevalence estimate) and 50% (a high prevalence estimate). Seven sample size scenarios were investigated, with samples of 20, 50, 100, 150, 200, 250, and 300 patients. Statistical analysis was undertaken using Stata software v14.0 (StataCorp, College Station, TX, USA).

RESULTS

PIVC Complications

There were 2,274 PIVCs assessed over 16 audit rounds. Demographic and PIVC-related characteristics of patients are displayed in Table 1. Overall, 475 (21%) PIVCs had a complication. The prevalence of complications varied between audits from 7.8% (95% CI, 4.2 to 12.9%) to 39% (95% CI, 32.0 to 46.4%) as seen in Figure 1. Of these 345 (15.2%) PIVCs had a patient reported symptom on assessment, with pain described for 95.4% (n=329) of these (Table 2). Complications were observed in 197 PIVCs with oedema or inflammation (19.8%) and/or bruising (18.8%) the most common. Significant fluctuations over time were identified, with complication prevalence ranging from 10% (95%, CI, 6.3 to 14.8%) in August 2015 to 34.8% (95%, CI, 27.5 to 42.6) in August 2017 and 17.1% (95%, CI 12.0 to 23.3) in September 2018 (Supplementary Table 1).

Insert Table 1: Demographic and PIVC-related characteristics of audited patients (n=2274)

Insert Figure 1: Percent of complications per audit round

Insert Table 2: Table 2: PIVC Complications in 2274 audited patients

Decision making tool for the number of PIVCs per audit

Table 3 and Figure 2 display the effect of increasing audit size on the width of the 95% CIs (true hospital wide rate) for the complications in three prevalence scenarios, 10%, 20%, and 50% (Figure 2). The 95% CIs narrowed considerably when the number of patients audited increased from 20 to 50, and again from 50 to 100, regardless of the complication prevalence. At low (10%) prevalence,

95% confidence intervals narrowed only marginally if audit sizes increased from 100 patients (4.9%, 17.6%) to 150 patients (5.7%, 16%). At an average (20%) PIVC complication rate, auditing 150 patients provided 95% confidence of 13.9% to 27.3%, whereas increasing the audit size to 300 patients only slightly narrowed the 95% CI to 15.6% to 25%. If complication prevalence was much higher, at 50%, then auditing 200 PIVCs provided a 95% CI of 42.9% to 57.1%, with negligible change observed in the 95% CI when auditing 300 devices of 44.2% to 55.8%.

Insert Table 3: Ninety-five percent confidence intervals for seven sample sizes and three complication percentages

Insert Figure 2: Whistle plot of PIVC complication prevalence (10%; 20%; 21%, 50%)

DISCUSSION

Surveillance of hospital acquired infections is at the forefront of international patient safety agendas[8,22]. Although auditing all patients PIVC sites may be achievable in small or regional hospitals, this is difficult to achieve in large hospitals. Our study is the first to explore the minimum number of PIVC audits required to establish reasonable precision of complication prevalence, supporting hospital infection prevention and control practices. This is important for hospitals to know, both to prevent wasted audit time (over-auditing), and to correctly identify trends in complication rates (a risk with under-auditing). Our audits ranged from 7. 8% complications to 38% of PIVCs with complications, which without consideration of precision, could have been incorrectly interpreted as detecting significant variation in care quality between some time periods.

By considering the calculated 95% CI, which is an interval which will contain the true prevalence on 95% of occasions, hospitals can decide what is an acceptable audit number for them. Ideally, the optimal audit sample size is small enough for rapid data collection but large enough to be representative[12]. We demonstrated the 95% CIs narrowed considerably when the number of patients audited increased from 20 to 50, and again from 50 to 100, with more marginal

improvements in precision beyond 100, regardless of the complication prevalence. Consequently 100 assessments should be the minimum number of audits for most clinical settings. Small audits are clearly very imprecise for example 20 patients at an observed complication prevalence of 20% has a 95% CI ranging from 5.7% to 43.7%, from which it is impossible to know if the audited hospital is doing very well or very badly. At the upper end of our sample size scenarios, there was no negligible change in precision if audit size was increased from 250 to 300 PIVCs regardless of the complication prevalence, therefore there is no benefit to auditing more than 250 PIVCs.

The effect of baseline prevalence on required sample size and resultant precision is knowledge of value to clinical managers. For example, an audit of 100 patients with an observed average complication prevalence of 10% would give a 95% CI ranging from 4.9% (staff should be congratulated) to 17.6% (requires further improvements). However, auditing 100 patients with an estimated complication prevalence of 50% would provide a 95% CI ranging from 39.8% to 60.2%, with both statistics confirming a severe quality problem.

The strength of our decision-making tool is that it was based on repeated measures at the same institution and realistic scenarios given our observed complication prevalence of 21%, which is comparable to previous local (24.7%) [7] and international audits[23]. The international study was conducted in 51 countries (PIVCs=40,620) and found 10% (*n*=4,204) of PIVCs were painful or symptomatic of phlebitis (pain, redness or swelling at insertion site), and a further 10% (*n*=3,879) had signs of PIVC malfunction such as leakage or dislodgement[23]. The similarity in complication numbers between our study and other hospitals included in the international audit highlight the generalisability of our results and the potential usefulness of our decision-making tool to guide hospitals' PIVC audit numbers.

Understanding and reporting audit data is important for clinical governance and helps identify gaps in knowledge to focus future education programs[18]. However, there are significant costs associated with the audit process[19], not only for trained health professionals to collect data but for the collation

of data and reporting of outcomes. With rising healthcare costs and a drive from patients for hospitals to maintain transparency of performance, clinical audits, although costly to conduct, are an important measure to improve patient outcomes[24]. This is recognised by the Australian Commission on Safety and Quality in Healthcare, who recommend clinical auditing for priority areas in order to promote safe, high-quality health care[13,25,]. Hand hygiene is a clinical priority where guidance for the number of episodes required for audit has been established based on the number of acute inpatient hospital beds for participating sites [26, 27]. However, international guidelines for PIVCs recommend surveillance but provide no direction on sample size[20,21]. Without guidance there is a potential for under auditing and therefore not accurately representing PIVC outcomes; or over auditing which involves unnecessary staff time and therefore increased hospital costs.

We do not dismiss other potential benefits associated with PIVC auditing regardless of sample size. One is the early detection of potential complications and in particular early signs of infection, which can lead to appropriate intervention (e.g. PIVC removal), therefore avoiding staff time and treatment costs associated with the negative sequalae of caring for a PIVC complication[28]. Auditing staff are at the bedside and may be able to give "just-in-time" education to patients and nursing staff. Furthermore, the audit and feedback process promotes a 'Hawthorne effect' encouraging staff to maintain vigilance, support quality improvement and prevent negative patient outcomes[21]. By repeating audits over time, hospitals can internally benchmark their results and evaluate the benefit of education, equipment and policy initiatives[14]. It also creates an opportunity for external benchmarking with relevant institutions[14]. However, for successful external benchmarking future research needs to focus on developing standardised terminology and an agreed upon minimum data sets for monitoring PIVC care and complication outcomes[29].

The strength of this study is that the decision-making tool was based on cross-sectional data collected prospectively over five years, therefore accounting for fluctuations over time, creating a truer determination of PIVC outcomes from multiple audits and time periods. We acknowledge that

100% audit of all PIVCs in the hospital would have provided even more valuable insights, however we were limited by the data available. Our work was undertaken in a large metropolitan hospital and we acknowledge that the results may be less applicable for smaller hospitals or those with a different patient population.

Conclusion

Auditing of PIVC care is an effective method to promote infection prevention practice and improve quality of care. Ideally, every PIVC would be audited but this is rarely feasible. To ensure hospitals capture timely and resource efficient data that also reasonably reflects the quality of care our decision-making tool provides healthcare planners and policy makers with guidance as to the number of audits required. We have established that at a minimum, hospitals should audit 100 PIVCs and that there is no meaningful benefit in conducting more than 250 assessments per audit round.

Ethics

Ethics exemption (LNR/2018/QRBW/49270) was obtained from the hospital ethics committee.

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Conflicts of Interest

NM reports Griffith University has received, on her behalf, investigator-initiated research grants from manufacturers of vascular access device products (Becton Dickinson and Cardinal Health), speaker fee from 3M; and a consultancy payment for expert advice from Becton Dickinson. EL reports Griffith University has received, on her behalf, from manufacturers of vascular access device products: an investigator-initiated research grant from Cardinal Health (formerly Medtronic); and a conference scholarship attendance supported by Angiodynamics. CR reports Griffith University has received, on her behalf, from manufacturers of vascular access device products: unrestricted investigator-initiated research or educational grants from BD-Bard and Cardinal Health; and consultancy payments from BD-Bard and 3M. Nil conflicts of interest for other authors.

Authorship statement

NM, EL, BH and CR participated in the conceptualization of this study. EM and RW conducted statistical analysis. NM drafted the first version of the paper and all authors provided critical input into the paper. All authors approved the manuscript.

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Table 1: Demographic and PIVC-related characteristics of audited patients (n=2274)

Variable (n)*	**n (%)**
Gender, male (n=2,109)	1,146 (54.4)
Number of PIVC this admission (n=1506)	
0	24 (1.8)
1	451 (33.7)
2	397 (29.6)
3	138 (10.3)
4	62 (4.6)
5 or more	82 (6.1)
ambulance service / hospital transfer	19 (1.4)
Unknown	167 (12.5)
Insertion setting (n=2,274)	
Hospital	1,867 (82.1)
Unknown (not documented)	264 (11.6)
Other hospital	86 (3.8)
Ambulance	56 (2.5)
Inserting health professional (n=1,362)	
Doctor	591 (43.4)
Nurse	293 (21.5)
Ambulance officer/paramedic	34 (2.5)
Other	11 (0.8)
Unknown	432 (31.7)
Gauge (n=1,077)	
16	32 (3.0)
18	135 (12.5)
20	514 (47.7)
22	267 (24.8)

24	6 (0.6)
Unable to visualise	123 (11.4)
Insertion location (n=1,077)	
Left arm	541 (50.3)
Right arm	522 (48.5)
Left or right leg	13 (1.2)
PIVC site (n=2,274)	
Anterior cubital fossa	272 (12.0)
Other site of flexion	627 (32.0)
Away from a site of flexion	1,248 (54.9)
Unknown	25 (1.1)
Number of insertion attempts (n=1,506)	
1	856 (63.4)
2	130 (9.6)
3	62 (4.6)
4	33 (2.5)
5 or more	38 (2.8)
Unknown	230 (17.1)
Approved dressing used (n=1,362)	1,141 (83.8)
Exit site visible (n=1,362)	1,069 (78.6)
Dressing soiled (n=2,274)	384 (16.9)
Dressing wet (n=2,274)	169 (7.4)
Dressing loose or lifting (n=2,274)	636 (28.0)
Use of secondary securement (n=2,273)	1,242 (54.6)
Types of secondary securement (n=1,242) ‡	
Tape or strips	838 (67.5)
Bandage or tubular bandage	261 (21.0)
Non-sterile paper tape	441 (35.5)
Polyurethane dressing	20 (1.6)

Other	120 (9.7)
Dwell time (n=2,274)	
<72 hours	1,509 (66.4)
>72 hours	265 (11.7)
Unable to assess (missing/no documentation)	499 (22.0)

**number of audits for which this variable was collected; ǂ more than one value able to be selected;*

Table 2: PIVC Complications in 2274 audited patients

Variable (*n*)	***n* (%)**
PIVC complication (n=2,274)	475 (21)
Symptoms of complications (n=2,274)	345 (15.2)
Reported symptoms (n=345)	
Pain	329 (95.4)
Itching/burning	12 (1.5)
Leaking‡	5 (1.5)
Tingling/numbness	1 (0.3)
Swelling	1 (0.3)
Occlusion	1 (0.3)
Kinking	1 (0.3)
Uncomfortable	
Sings of complications (n=2,274)	197 (9.1)
Reported signs (n=197)	
Oedema/inflammation	39 (19.8)
Bruising/haematoma	37 (18.8)
Erythema	33 (16.8)
Palpable cord/vein tracking	31 (15.7)
Discharge at site (including purulence)	26 (13.2)
Hardness/Induration	12 (6.1)

Leaking	5 (2.5)
Phlebitis	4 (2.0)
Partial dislodgment	3 (1.5)
Skin reaction	3 (1.5)
Pain on infusion	2 (1.0)
Warmth	1 (0.5)
Other	3 (1.5)

Table 3: **PIVC audit size decision-making tool** (95% confidence intervals for seven sample sizes and three complication percentages)

Sample size	**Complication percentage**	**Complication percentage**	**Complication percentage**
	10%	20%	50%
300	6.8% to 14.0%	15.6% to 25.0%	44.2% to 55.8%
250	6.6% to 14.4%	15.2% to 25.5%	43.6% to 56.4%
200	6.2% to 15.0%	14.7% to 26.2%	42.9% to 57.1%
150	5.7% to 16.0%	13.9% to 27.3%	41.7% to 58.3%
100	4.9% to 17.6%	12.7% to 29.2%	39.8% to 60.2%
50	3.3% to 21.8%	10.0% to 33.7%	34.5% to 64.5%
20	1.2% to 31.7%	5.7% to 43.7%	27.2% to 72.8%

Confidence intervals calculated using exact binomial method

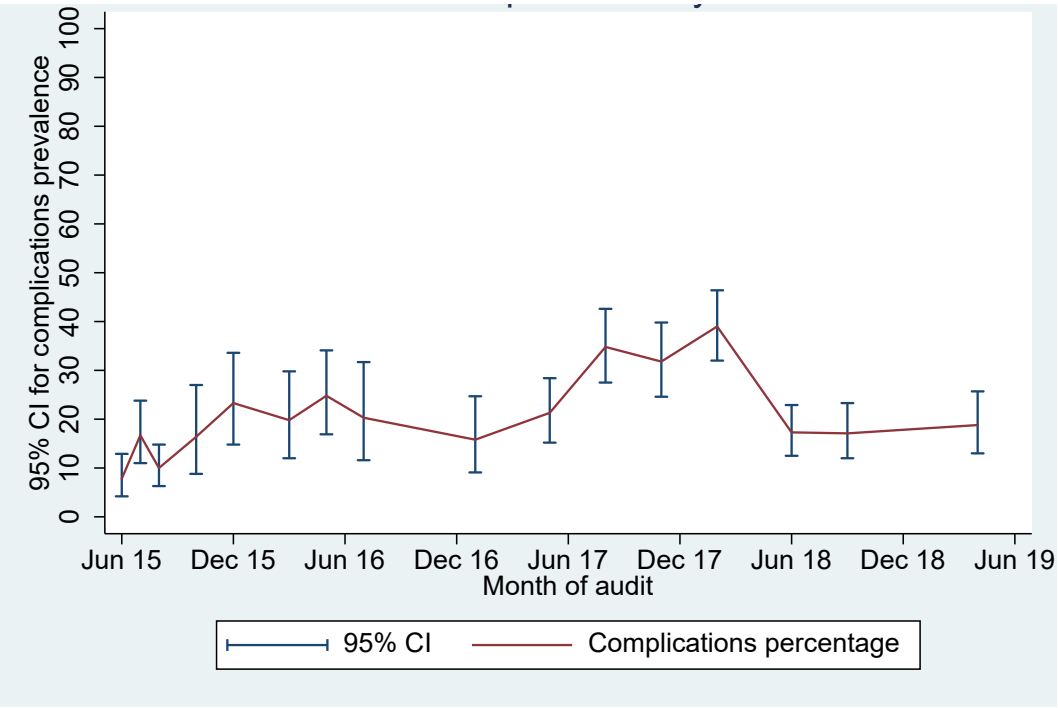

Figure 1: Percent of complications per audit round

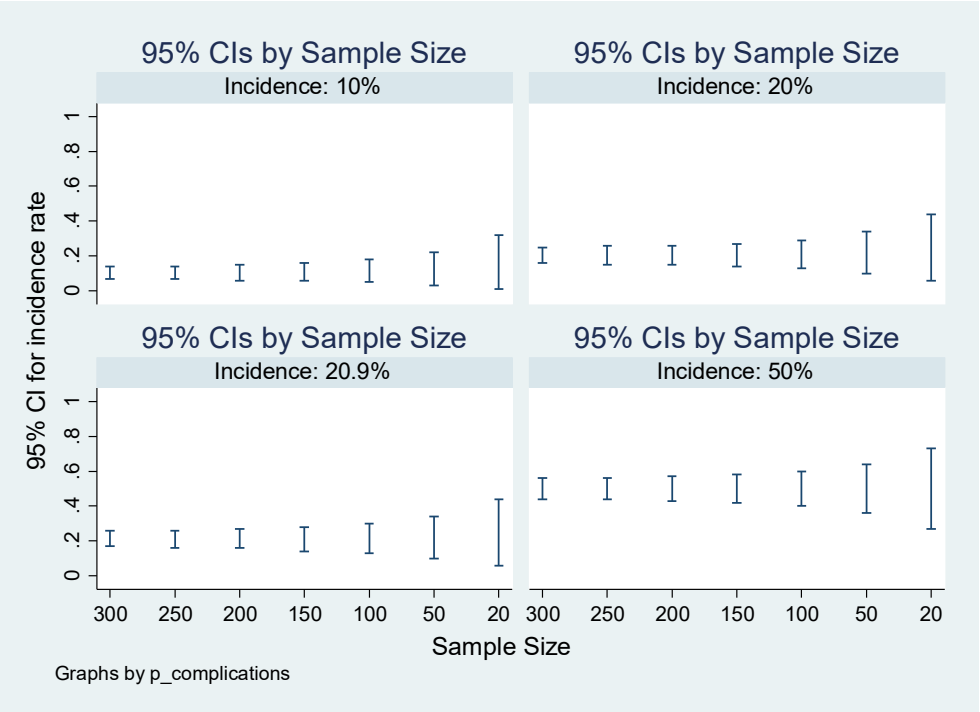

Figure 2: Whistle plot of PIVC complication prevalence (10%; 20%; 21%, 50%)