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Incidence of peripheral intravenous catheter failure and complications in paediatric patients: Systematic review and meta analysis

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ABSTRACT

Background: Most paediatric patients have at least one peripheral intravenous catheter insertion during their hospitalisation. Despite the important function of peripheral intravenous catheters for delivery of intravenous therapy, failure and complications rates are widely reported; however these results have not been synthesised.
Objective: To provide an overall estimate of peripheral intravenous catheter failure and related complications in the paediatric population.
Design: Systematic review and meta-analysis
Data sources: The electronic databases, Cochrane Central Register of Controlled Trials, US National Library of Medicine National Institutes of Health, Cumulative Index of Nursing and Allied Health, Embase, Joanna Briggs Institute databases and ProQuest Dissertations and Theses, from January 2000 to January 2019 was conducted.
Review methods: Observational studies and randomised controlled trials were independently screened by paired reviewers, and then eligible studies had data extracted and assessed for quality. Key outcomes of interest were any peripheral intravenous catheter complication, either as a composite measure or individually reported, including infiltration, extravasation, phlebitis, accidental removal, occlusion, leakage, local or catheter-associated infection. Results were pooled for analysis or summarised in a narrative synthesis.
Results: Thirty-two studies met the inclusion criteria. Overall, the pooled incidence of peripheral intravenous catheter failure as a composite measure was 38% (n = 6,492; 95% CI 0.32 – 0.45) by device and 34% (n = 3,654, 95% CI 0.29 – 0.39) by patients. Infiltration was the most common individual reason for failure with 10% pooled incidence (95% CI 0.07 – 0.14) followed by accidental removal, occlusion, and leakage. Incidence of total phlebitis (any symptoms) was 5% (95% CI 0.02 – 0.10), with extravasation at 1% (95% CI 0.00 – 0.02). Studies ranged in methodological quality as appraised by the relevant tool.
Conclusions: Peripheral intravenous catheter failure and complications in paediatrics patients are a significant problem globally. Therefore, continued efforts from health care providers are required to decrease the incidence of these complications.

What is already known about the topic?

- Peripheral intravenous catheters are widely used in hospitals to deliver intravenous therapies.
- The pooled incidence of PIVC failure in adults from published studies is ~30%, but the figure in children is unknown.

What this paper adds

- PIVC failure in children is high with a pooled incidence of 38% by device and 34% by patient calculated from rigorous review and analysis of published studies globally.
- Pooled incidence indicates that infiltration is the most common individual reason for failure, followed by accidental removal, occlusion, leakage, phlebitis (any symptoms), and extravasation.

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1. Background

Peripheral intravenous catheters (PIVC) are venous access devices commonly used for drug or fluid administration, monitoring, and diagnostics, both in adult and paediatric patients, in hospitals worldwide (Alexandrou et al., 2018). It is estimated that nearly two billion peripheral intravenous catheters are used in hospitalised patients globally (Data Bridge Market Research, 2018). Despite the ubiquity and essential nature of PIVCs, they are not without complications. Rates of PIVC complications are reportedly high in studies in the paediatric population, ranging from 34 to 56% (Ben Abdelaziz et al., 2017; Legemaat et al., 2016; Unbeck et al., 2015; Vinograd et al., 2018), in comparison to PIVC complications in the adult population, which range from 20% to 32% (Alexandrou et al., 2015; Marsh et al., 2018a; New et al., 2014).

PIVC complication and failure in paediatric patients is associated with increased morbidity. Re-insertion procedures are painful and anxiety-provoking for children as well as their parents (Kennedy et al., 2008; Scott-Warren and Morley, 2015). Failure to obtain and maintain a patent peripheral intravenous access may also delay diagnostic and subsequent medical treatments (Vinograd et al., 2018). *Re*-insertion attempts and premature PIVC removal consequently increase hospital costs, including not only expenses for PIVC devices but also for medical and/or nursing time. When you factor in all this in average replacement cost per PIVC procedure and care is calculated to be $85 USD and $69.30 AUD (Goff et al., 2013; Tuffaha et al., 2014). PIVC related complications can also be costly for patients, not only in terms of patient experience and morbidity (e.g., pain, delayed treatment) but also for treatment-related out of pocket expenses in some healthcare systems (Goff et al., 2013; Jones, 2018). Patients may need to stay in hospital for a longer period because of PIVC complications: this is particularly evident for catheter-related blood stream infections (CRBSI). Furthermore, the additional cost for treatment of CRBSI is estimated to be $ 29,500 to $68,983 AUD per episode (Jones, 2018; Stuart et al., 2013).

Individual studies have examined the incidence of PIVC failure and complications in the paediatric population (Ben Abdelaziz et al., 2017; Malyon et al., 2014; Unbeck et al., 2015). But an overall estimation of catheter failure and each type of complication for this population has not been established. The aim and objective of the review was to systematically search published studies, conduct pooled analysis of findings and compile a detailed description of PIVC failure and complications, overall and by age group and region, to provide evidence-based data to enable the solutions to be appropriately targeted to prevent PIVC failure as well as to guide future trial research on how to improve PIVC insertion and maintenance.

2. Methods

2.1. Protocol and registration

The protocol of this systematic review and meta-analysis was registered on the PROSPERO website (registration number CRD42018111084). This review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009).

2.2. Search strategy and eligibility criteria

Searches were conducted in the Cochrane Central Register of Controlled Trials (CENTRAL; The Cochrane Library), US National Library of Medicine National Institutes of Health (PubMed and Medline), Cumulative Index of Nursing and Allied Health (CINAHL), Embase, Joanna Briggs Institute (JBI) databases and ProQuest Dissertations and Theses (PQDT) for all studies that reported PIVC failure or PIVC-related complications in paediatric patients. In addition, reference lists of the included studies were searched. This review included studies written in either English or Indonesian from January 2000 to January 2019. This date range enabled the identification of outcomes related to contemporary PIVC practices and products. The search keywords and strategies are available in online supplementary appendix 1.

All experimental and epidemiological study designs were included in this review. Participants included neonatal or paediatric patients (age 0–18) (Hardin and Hackell, 2017) with a PIVC in any hospital or healthcare setting. Studies were eligible if participants were followed from the insertion of the PIVC until removal.

2.3. Outcomes

The outcome of interest was PIVC failure due to any complication at catheter removal. This included a composite measure of PIVC failure and individual complications such as phlebitis, occlusion, infiltration, extravasation, accidental removal/dislodgement, leakage, and infection (all causes or laboratory confirmation). Outcomes evaluated were author-defined within the study, which introduces potentially heterogeneity but increases generalisability.

2.4. Study selection and data extraction

Two authors (FI and SK) independently screened titles and abstracts against the inclusion criteria. Where required, translation was made possible by the lead author. Full copies of relevant studies were reviewed independently (FI, SM, JM, and SK) and assessed against the eligibility criteria. Studies fulfilling the inclusion criteria were then assessed for their methodological quality (FI, JM, and SK), utilising the Cochrane Risk of Bias (RoB2) (Higgins et al., 2016) for RCTs, the Cochrane Risk of Bias In Non-randomised studies-of Interventions (ROBINS-I), (Sterne et al., 2016) and for cohort studies (Wells et al., 2001), for assessment of methodological quality. Independent quality assessment was undertaken by paired reviewers, and a third reviewer was utilised for arbitration.

2.5. Data collection process

Four authors (lead author FI plus independent second author SM, JM, or SK) independently extracted data from the included studies using a data extraction form designed for this review and piloted for functionality. Extracted data included the following: authors, study design, title, year of publication, country, setting, characteristics of participants (e.g., age, diagnosis, and sex), unit of measurement (PIVC or patients), and outcomes: the incidence of composite PIVC failure and each individual PIVC complication. In experimental studies, data was only extracted from the control group (not intervention) to obtain data that reflected ‘usual care’ at that time.

2.6. Statistical analysis

Meta-analysis of individual study incidence estimates were carried out using STATA version 15.0 (STATA, College Station, TX, USA) and its “metaprop” command. The “metaprop” command comprises the Freeman-Tukey double arcsine transformation and DerSimonian-Laird random-effects model. The Freeman-Tukey double arcsine transformation procedure transforms proportions from individual studies by stabilising the variances between studies. The pooled estimate of incidence is subsequently then computed using the DerSimonian-Laird random-effects model with the estimate of heterogeneity being taken from the inverse-variance fixed-effect model. In this modelling approach, transformed proportions were

pooled using random-effects meta-analysis with exact confidence intervals, and results were displayed in forest plots. Heterogeneity between estimates was assessed using the I^2 statistic. An I^2 value above 75% indicates high heterogeneity (Higgins and Thompson, 2002). Assuming the high heterogeneity of the studies included in this review, a random-effects model was utilised to generate pooled incidences for each outcome.

Subgroup analyses were conducted for the composite failure by country classification (developed and developing countries using Organisation for Economic Co-operation and Development (OECD) classification) and by age (neonatal and paediatric). Composite failure was reported using both patients and devices as the unit of analysis, but otherwise, patients were used as the unit of analysis independent from the device for other individual complications. Patients were used as the unit of analysis to avoid repeated measures (Whiting-O'Keefe et al., 1984). Further, to conform to the incidence proportion calculation properties, where the numerator was only new cases and the denominator was the number of persons in the population at the start of the observation period (Celentano, 2019).

3. Results

3.1. Study selection

Fig. 1 illustrates the study selection process. The initial search identified a total of 587 potentially relevant articles published between January 2000 and January 2019. After removal of duplicates, and title and abstract screening, 40 full-text articles were assessed for eligibility. Thirty-two studies met the inclusion criteria (see online supplementary appendix 2), and eight studies were excluded in the final synthesis (see online supplementary appendix 3).

3.2. Study characteristics

The included studies reported on 11,100 patients and 13,202 PIVCs collectively. among the 32 studies included in the review, 19 were cohort studies (Ben Abdelaziz et al., 2017; Birhane et al., 2017; Danski et al., 2016; de Lima Jacinto et al., 2011; Fonzo-Christe et al., 2018; Foster et al., 2002; Gomes et al., 2011; Gupta et al., 2003; Hetzler et al., 2011; Hollaway et al., 2017; Legemaat et al., 2016; Malyon et al., 2014; Özalp Gerçeker et al., 2018; Paladini et al., 2018; Park et al., 2016; Rozsa et al., 2015; Shenoy and Karunakar, 2014; Unbeck et al., 2015); six were RCTs (Dalal et al., 2009; Förberg et al., 2016; Kalyn et al., 2000; Machado et al., 2008; Tripathi et al., 2008; White et al., 2011); and seven were quasi-experimental/non randomised studies (Callaghan et al., 2002; Förberg et al., 2012; Laudenbach et al., 2014; Perez et al., 2012; Pondinas, 2008; Sriupayo et al., 2014; Vinograd et al., 2018). Twenty-one of the studies (65.6%) were conducted in high-income countries (Callaghan et al., 2002; Chenoweth et al., 2018; Fonzo-Christe et al., 2018; Förberg et al., 2012; Förberg et al., 2016; Foster et al., 2002; Hetzler et al., 2011; Hollaway et al., 2017; Kalyn et al., 2000; Laudenbach et al., 2014; Legemaat et al., 2016; Malyon et al., 2014; Özalp Gerçeker et al., 2018; Paladini et al., 2018; Park et al., 2016; Perez et al., 2012; Pondinas, 2008; Rozsa et al., 2015; Unbeck et al., 2015; Vinograd et al., 2018; White et al., 2011) and 11 (34.4%) studies(Ben Abdelaziz et al., 2017; Birhane et al., 2017; Dalal et al., 2009; Danski et al., 2016; de Lima Jacinto et al., 2011; Gomes et al., 2011; Gupta et al., 2003; Machado et al., 2008; Shenoy and Karunakar, 2014; Sriupayo et al., 2014; Tripathi et al., 2008) were conducted in developing countries. The age of the included participants in the reviewed studies ranged from 0 to 19 years old. Studies that included patients older than 16 years old involved oncology (Förberg et al., 2012; Förberg et al., 2016) or neurological (Rozsa et al., 2015) units and these units often provided ongoing care for continuity or during the transition to adult services. The gender of the participants was only reported in 20 studies (Ben Abdelaziz et al., 2017; Birhane et al., 2017; de Lima Jacinto et al., 2011; Fonzo-Christe et al., 2018; Förberg et al., 2012; Förberg et al., 2016; Foster et al., 2002; Gomes et al., 2011; Kalyn et al., 2000; Laudenbach et al., 2014; Legemaat et al., 2016; Machado et al., 2008; Malyon et al., 2014; Özalp Gerçeker et al., 2018; Paladini et al., 2018; Park et al., 2016; Sriupayo et al., 2014; Tripathi et al., 2008; Unbeck et al., 2015; White et al., 2011) and most of them were male (n: 5348; 58%).

Table 1
Summary of study characteristics.

Characteristics	Number of studies (n = 32)
Type of studies	
Cohort	19
RCT	6
Non-Randomised	6
By Country (OECD)	
Developed country (USA, Australia, Sweden Switzerland, Netherland, Canada, Turkey, Italy, and South Korea)	21
Developing country (India, Brazil, Tunisia, Ethiopia, and Thailand)	11
Age	
Neonatal	8
Paediatric	12
Neonatal & paediatric	12
Diagnosis	
Acute	3
Chronic	1
Chronic & acute	9
Not stated	19
Gender	
Stated (mostly male)	18
Not stated	14
Wards	
NICU	8
PICU	1
PICU & NICU	1
PICU/NICU & general paediatric	5
General or medical surgical	10
Other	7
Composite failure outcome by device & by patient	
Composite PIVC failure by device	18
Composite PIVC failure by patient	9
Individual complications	
Infiltration	19
Extravasation	8
Phlebitis & sign of phlebitis	18
Accidental removal/dislodgment	17
Occlusion/obstruction	16
Leakage	6
Infection (any)	6
Unspecified cause and other causes	8

OECD: Organisation for Economic Cooperation and Development.
NICU: Neonatal Intensive Care Unit.
PICU: Paediatric Intensive Care Unit.
RCT: Randomised Controlled Trial.

A summary of the characteristics of the studies included in this review is shown in Table 1.

3.3. Risk of bias within studies

The RCTs were assessed via the following five domains: selection, performance, detection, attrition, and reporting bias using the ROB2 tool (Higgins et al., 2016). All of the studies were rated as high risk of bias, mainly due to poor reporting of the randomisation and allocation concealment procedures (Dalal et al., 2009; Förberg et al., 2016; Kalyn et al., 2000; Machado et al.,

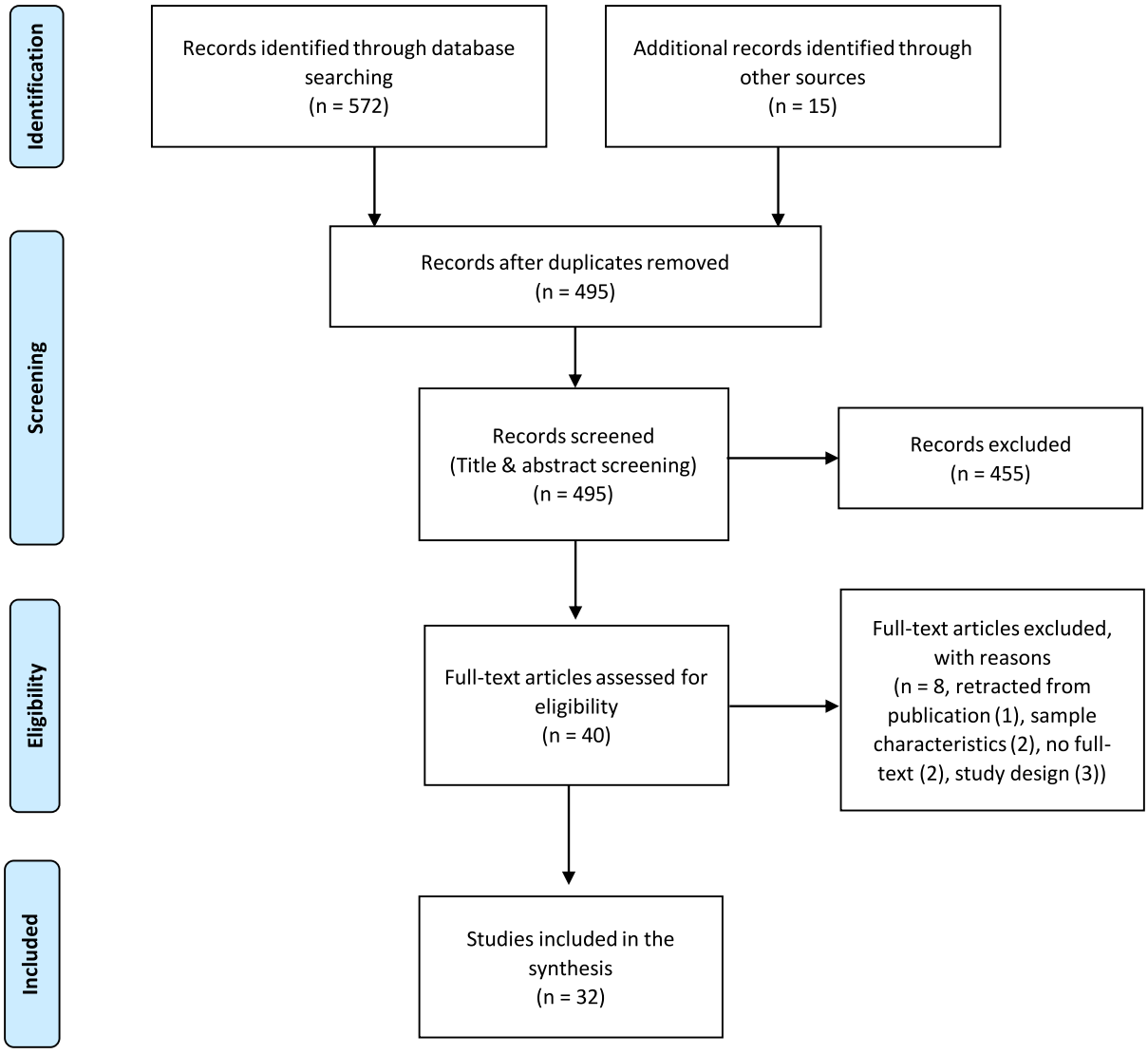

Fig. 1. PRISMA Flow diagram.

2008; Tripathi et al., 2008; White et al., 2011). Based on the ROBINS assessment tool (Sterne et al., 2016), quasi-experiment and non-randomised studies included in this review had moderate to serious overall risk of bias. Three studies had moderate overall risk of bias (Förberg et al., 2012; Laudenbach et al., 2014; Perez et al., 2012) and four studies had serious overall risk of bias (Callaghan et al., 2002; Pondinas, 2008; Sriupayo et al., 2014; Vinograd et al., 2018). The main reasons for the serious overall risk of bias were poor control for confounders (Callaghan et al., 2002; Pondinas, 2008; Sriupayo et al., 2014; Vinograd et al., 2018) unclear methods to classify participants (allocation) (Callaghan et al., 2002; Laudenbach et al., 2014; Pondinas, 2008; Sriupayo et al., 2014; Vinograd et al., 2018) and uncertainty of assessors' blinding (Callaghan et al., 2002; Laudenbach et al., 2014; Perez et al., 2012; Pondinas, 2008; Sriupayo et al., 2014; Vinograd et al., 2018). The cohort studies assessed for selection, comparability and outcome domains using (Wells et al., 2001), ranged from good to moderate/fair quality. The majority of these studies contained unclear descriptions of the exposed and non-exposed cohorts (Birhane et al., 2017; Chenoweth et al., 2018; Danski et al., 2016; de Lima Jacinto et al., 2011), poor reporting of the ascertainment of exposures (Hollaway et al., 2017; Paladini et al., 2018; Shenoy and Karunakar, 2014), and unclear methods to control for confounders (de Lima Jacinto et al., 2011; Hollaway et al., 2017; Özalp Gerçeker et al., 2018). The detailed risk of bias assessment can be accessed in online supplementary appendix 4.

3.4. Outcomes

3.4.1. Composite failure

Fig. 2 shows the pooled incidence of composite PIVC failure by device from 18 studies as 38% (n = 6492, 95% CI 0.32–0.45) and indicates high heterogeneity between studies (I^2 = 95.62%, p = 0.00). As per Fig. 3, the pooled incidence of composite PIVC failure by patients in nine studies is 34% (n = 3654, 95% CI 0.29–0.39), I^2 = 84.72%, p = 0.00. Sub group analysis of the composite PIVC failure based on countries (online supplementary appendix 5a), demonstrated that the incidence of PIVC failure in developed countries is comparable between lower and middle-income countries with overall pooled incidence 33% (n = 3218, 95% CI 0.28 - 0.29, I^2 = 84.43%, p = 0.00) vs 31% (n = 436, 95% CI 0.27–0.38, I^2 = 0.00, p = 0.00), respectively. Only one neonatal study (Chenoweth et al., 2018) reported composite failure by patients, therefore, subgroup analysis on the incidence of composite PIVC failure between

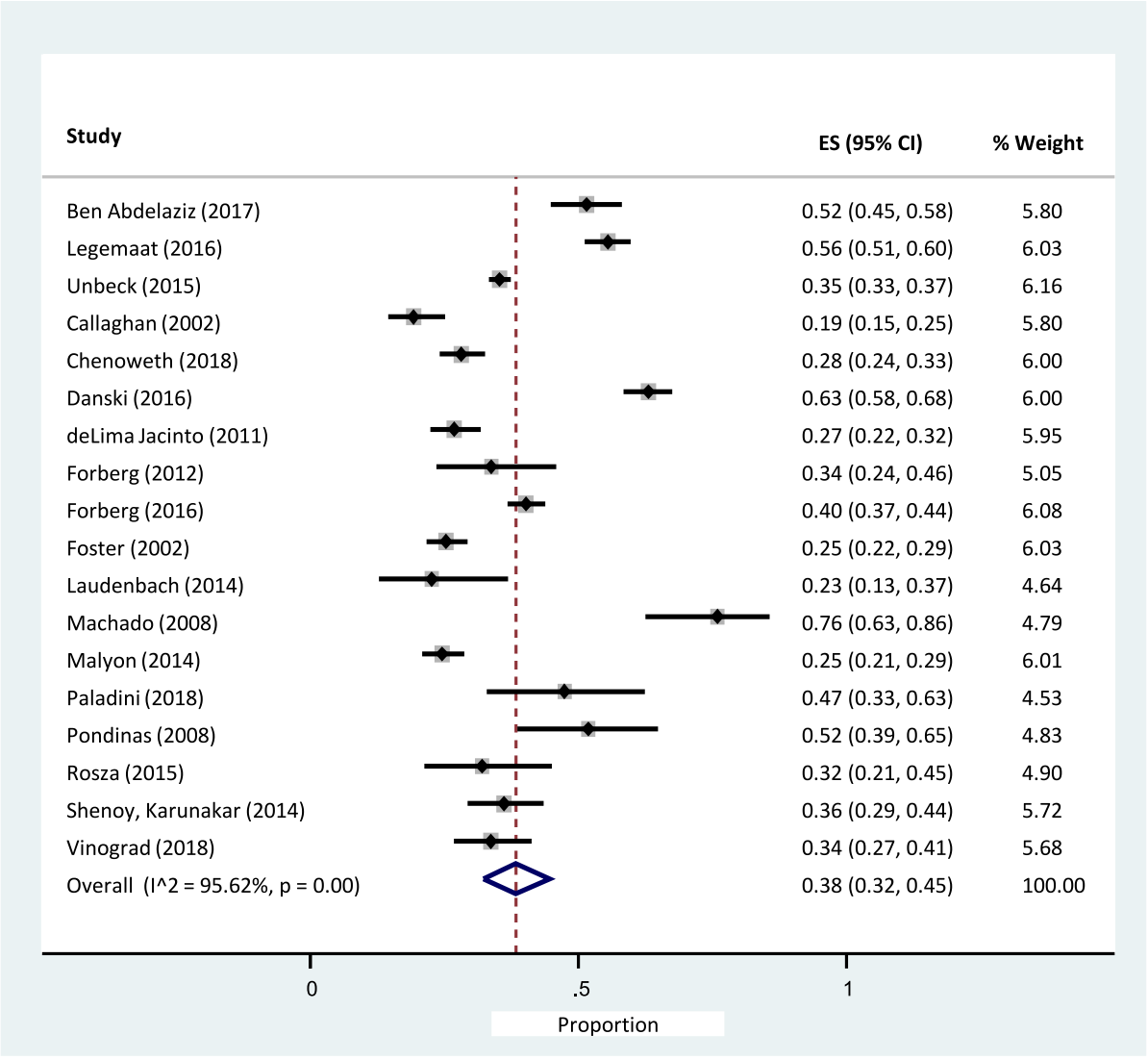

Fig. 2. Incidence of composite PIVC failure by device.

Table 2
Summary of pooled incidence of PIVC complication by patient.

Complications	*n* study	n patient	Pooled Incidence (%)	95% CI	I^2 (%)	*p-value*
Composite failure	9	3654	34%	0.29 – 0.39	84.72%	<0.001
Infiltration	9	6839	10%	0.07 – 0.14	94.83%	<0.001
Phlebitis & sign of phlebitis	8	5578	5%	0.02 – 0.10	96.47%	<0.001
Accidental removal	7	3356	8%	0.03 – 0.15	95.98%	<0.001
Occlusion	6	2924	8%	0.03 – 0.14	93.13%	<0.001
Leakage	4	688	6%	0.03 – 0.09	41.24%	0.16
Extravasation	2	476	1%	0.00 – 0.02	0.00%	<0.001

neonatal and paediatric patients were reported by device: the incidence in neonatal patients was 49% (n = 1376, 95% CI 0.29–0.69) and the incidence in paediatric patients was 36% (n = 2360, 95% CI 0.29–0.43) (see online supplementary appendix 5b).

In addition to individual forest plots, the pooled incidence of each PIVC complication by patients including infiltration, phlebitis, and signs of phlebitis, accidental removal, occlusion, leakage, and extravasation is summarised in Table 2.

3.4.2. Infiltration

The incidence of infiltration was reported in 20 studies. Eleven studies reported the incidence by device (Ben Abdelaziz et al., 2017; Danski et al., 2016; Förberg et al., 2016; Gomes et al., 2011; Gupta et al., 2003; Hetzler et al., 2011; Legemaat et al., 2016; Machado et al., 2008; Özalp Gerçeker et al., 2018; Perez et al., 2012; Tripathi et al., 2008) and nine studies reported by patients (Chenoweth et al., 2018; de Lima Jacinto et al., 2011; Malyon et al., 2014; Park et al., 2016; Pondinas, 2008; Sriupayo et al., 2014; Unbeck et al., 2015; Vinograd et al., 2018; White et al., 2011). Only studies that reported the infiltration incidence by patients were included in the meta-analysis, with the pooled incidence at 10% (n = 6839, 95% CI 0.07 – 0.14) (see Fig. 4.). The incidence of infiltration by device ranged from 6% to 87% (Ben Abdelaziz et al., 2017; Danski et al., 2016; Förberg et al., 2016; Gomes et al., 2011;

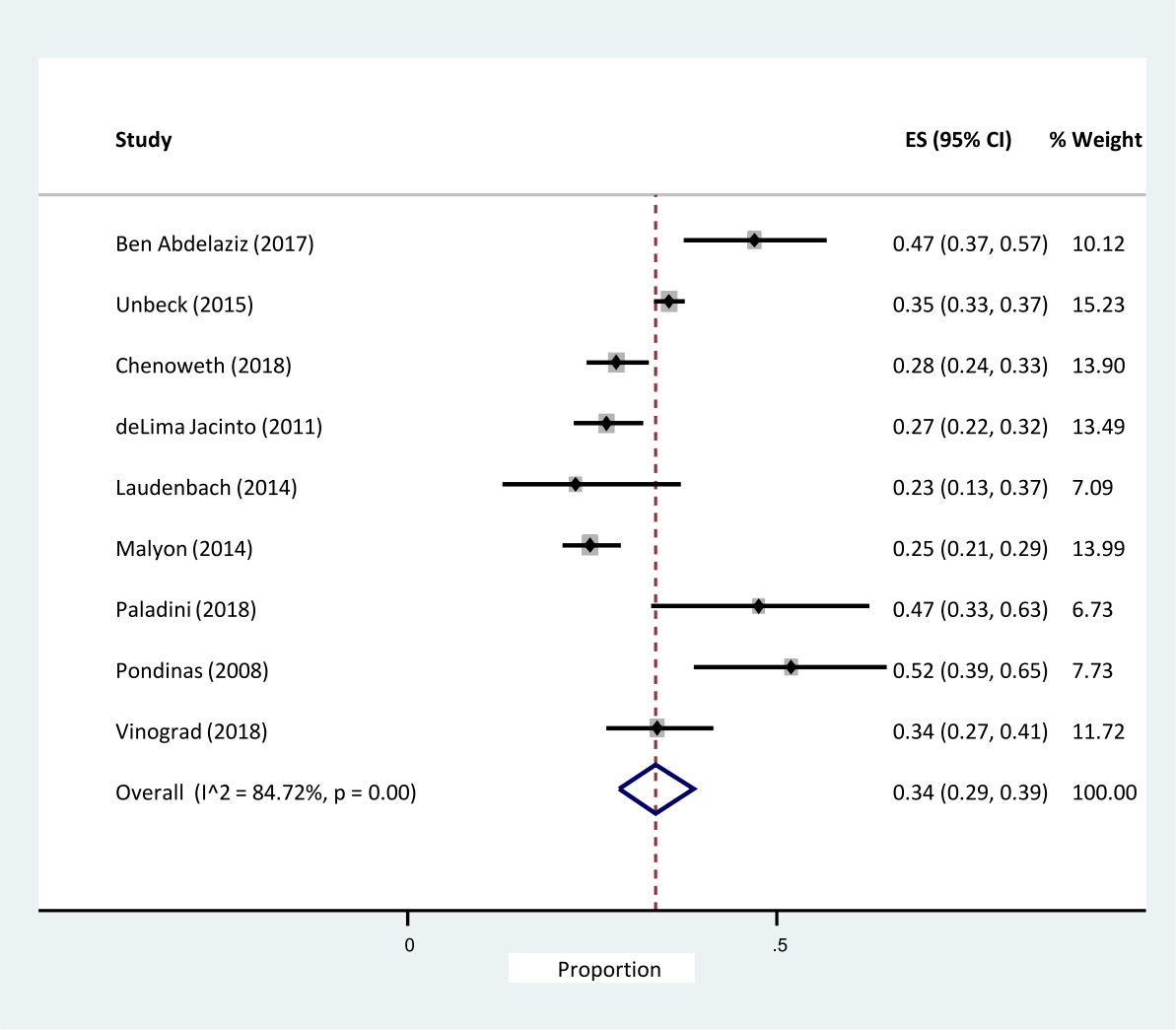

Fig. 3. Incidence of composite PIVC failure by patient.

Gupta et al., 2003; Hetzler et al., 2011; Legemaat et al., 2016; Machado et al., 2008; Özalp Gerçeker et al., 2018; Perez et al., 2012; Tripathi et al., 2008) with variability of the PIVC dwell time across the studies.

3.4.3. Phlebitis

Phlebitis as a composite measure and/or individual sign of phlebitis (pain) were reported by 19 studies (11 by device (Ben Abdelaziz et al., 2017; Callaghan et al., 2002; Danski et al., 2016; Förberg et al., 2016; Foster et al., 2002; Gupta et al., 2003; Hetzler et al., 2011; Machado et al., 2008; Perez et al., 2012; Rozsa et al., 2015; Tripathi et al., 2008) and eight by patients (Chenoweth et al., 2018; Malyon et al., 2014; Pondinas, 2008; Sriupayo et al., 2014; Unbeck et al., 2015; Vinograd et al., 2018; White et al., 2011)). Meta-analyses of eight studies reporting the incidence by patient was conducted (Fig. 5). Overall total phlebitis incidence is 5% (n = 5578, 95% CI 0.02 - 0.10). Other signs of phlebitis such as redness and swelling, were only reported by single studies and therefore, could not be meta-analysed. The pooled incidence for signs of phlebitis (pain) was 14% (n = 244, 95% CI 0.00–0.38, I^2 = 93.52%) and phlebitis (composite author-defined) was 3% (n = 5334, 95% CI 0.01–0.07, I^2 = 97.48%). The incidence of phlebitis stated in studies that reported the incidence of phlebitis by device ranged between 0.6% and 18% (Ben Abdelaziz et al., 2017; Callaghan et al., 2002; Danski et al., 2016; Förberg et al., 2016; Foster et al., 2002; Hetzler et al., 2011; Machado et al., 2008; Perez et al., 2012; Rozsa et al., 2015; Tripathi et al., 2008). The signs of phlebitis by device such as swelling and redness were also reported by one study with the incidence of swelling at 45% and redness at 5%. (Gupta et al., 2003).

3.4.4. Accidental removal/dislodgement

Seven studies (Birhane et al., 2017; Chenoweth et al., 2018; Laudenbach et al., 2014; Malyon et al., 2014; Pondinas, 2008; Unbeck et al., 2015; Vinograd et al., 2018) were included in the meta-analysis (see online supplementary appendix 5c), with the pooled incidence by patient at 8% (n = 3356, 95% CI 0.03 – 0.15). Ten other studies (Ben Abdelaziz et al., 2017; Callaghan et al., 2002; Danski et al., 2016; Fonzo-Christe et al., 2018; Förberg et al., 2016; Gomes et al., 2011; Machado et al., 2008; Özalp Gerçeker et al., 2018; Rozsa et al., 2015; Shenoy and Karunakar, 2014) reported the incidence by device, indicating that the incidence of accidental removal of PIVC in the mix paediatric-neonatal studies ranged from 2% to 32% (Ben Abdelaziz et al., 2017; Callaghan et al., 2002; Danski et al., 2016; Fonzo-Christe et al., 2018; Förberg et al., 2016; Gomes et al., 2011; Machado et al., 2008; Özalp Gerçeker et al., 2018; Rozsa et al., 2015; Shenoy and Karunakar, 2014) and from 14% to 31.8% in the studies conducted only in neonatal patients (Danski et al., 2016; Gomes et al., 2011).

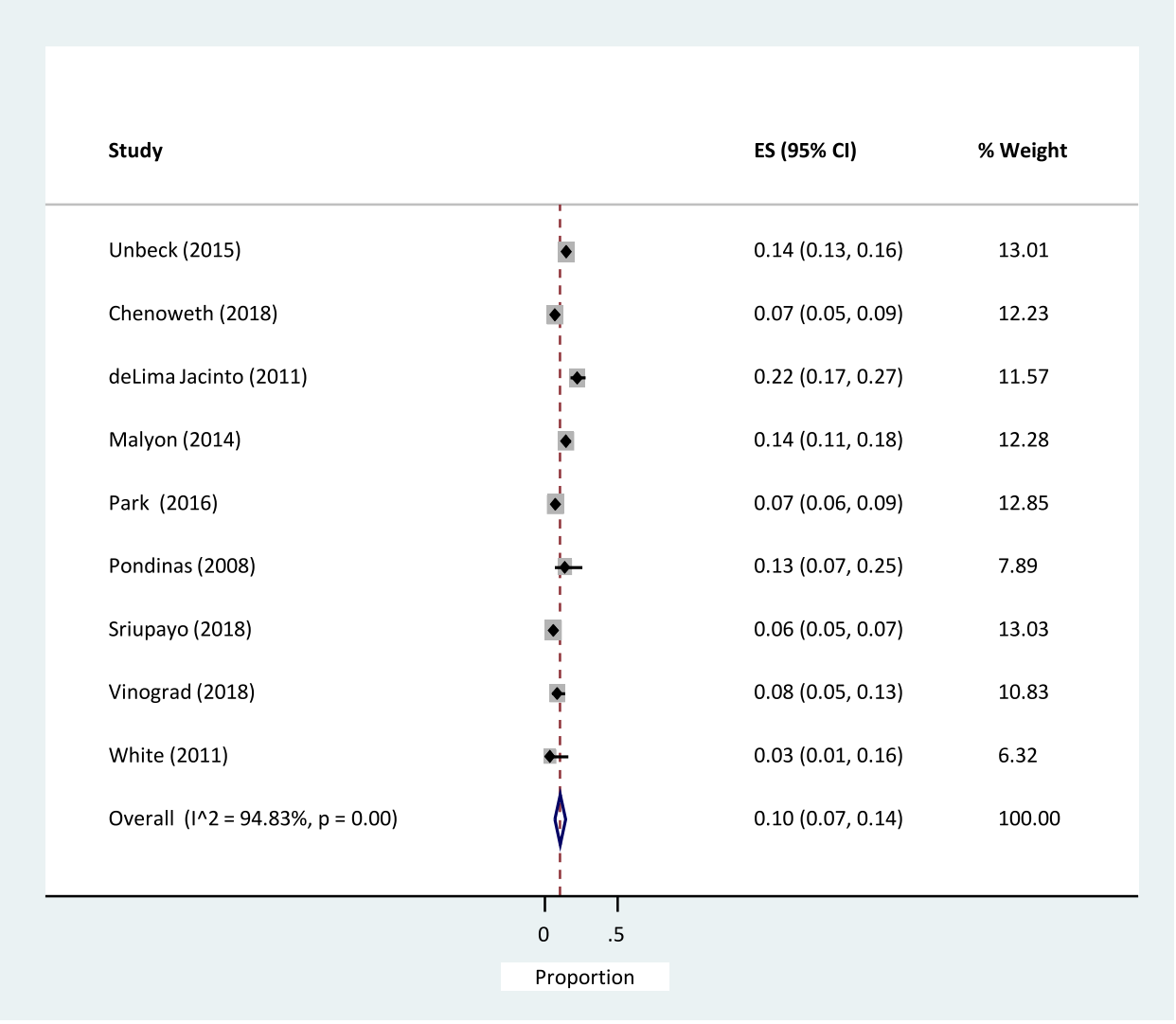

Fig. 4. Incidence of infiltration by patient.

3.4.5. Occlusion

Six (Birhane et al., 2017; Laudenbach et al., 2014; Malyon et al., 2014; Pondinas, 2008; Unbeck et al., 2015; Vinograd et al., 2018) and ten studies (Danski et al., 2016; Fonzo-Christe et al., 2018; Förberg et al., 2016; Gupta et al., 2003; Kalyn et al., 2000; Legemaat et al., 2016; Machado et al., 2008; Özalp Gerçeker et al., 2018; Perez et al., 2012; Shenoy and Karunakar, 2014) reported the incidence of occlusion by patient and by device, respectively. The pooled incidence of occlusion by patients was 8% (n = 2924, 95% CI 0.03 – 0.14) (see online supplementary appendix 5d). The lowest incidence of PIVC by device stated in the ten studies was 5.2% (Legemaat et al., 2016), and the highest occlusion incidence reported was 56% (Özalp Gerçeker et al., 2018).

3.4.6. Leakage

Leakage was reported in six studies with four studies reporting the incidence by patients (Chenoweth et al., 2018; Laudenbach et al., 2014; Pondinas, 2008; Vinograd et al., 2018). The pooled leakage incidence by patient was 6% (n = 688, 95% CI 0.03 – 0.09) with low heterogeneity between studies 41.24% (see online supplementary appendix 5e). By device, the incidence of leakage ranged between 18% and 27% (Gupta et al., 2003; Legemaat et al., 2016).

3.4.7. Extravasation

Extravasation was reported in eight studies, six by device (Callaghan et al., 2002; Dalal et al., 2009; Fonzo-Christe et al., 2018; Gomes et al., 2011; Özalp Gerçeker et al., 2018; Shenoy and Karunakar, 2014) and two by patient (Chenoweth et al., 2018; Laudenbach et al., 2014). The pooled extravasation incidence by patient was 1% (n = 476, 95% CI 0.00 – 0.02) (see online supplementary appendix 5f), whereas the extravasation incidence by device ranged from 2% to 77% (Callaghan et al., 2002; Dalal et al., 2009; Fonzo-Christe et al., 2018; Gomes et al., 2011; Özalp Gerçeker et al., 2018; Shenoy and Karunakar, 2014). In one study where the reason of removal was only available for 30% of their patients, the incidence of extravasation by device was 4.5 in 100 PIVC days (Fonzo-Christe et al., 2018).

However, understanding that the definitions of infiltration, extravasation and leakage often overlap, we have pooled all data (infiltration, extravasation and leakage) together and found that the overall incidence of infiltration-extravasation-leakage was 8% (n = 7983, 95% CI 0.05 – 0.11, I^2 = 93.85%, p = 0.00) (see online supplementary appendix 5 g). This result is not significantly different compared to the pooled incidence of infiltration alone, which was 10% (n = 6839, 95% CI 0.07 – 0.14).

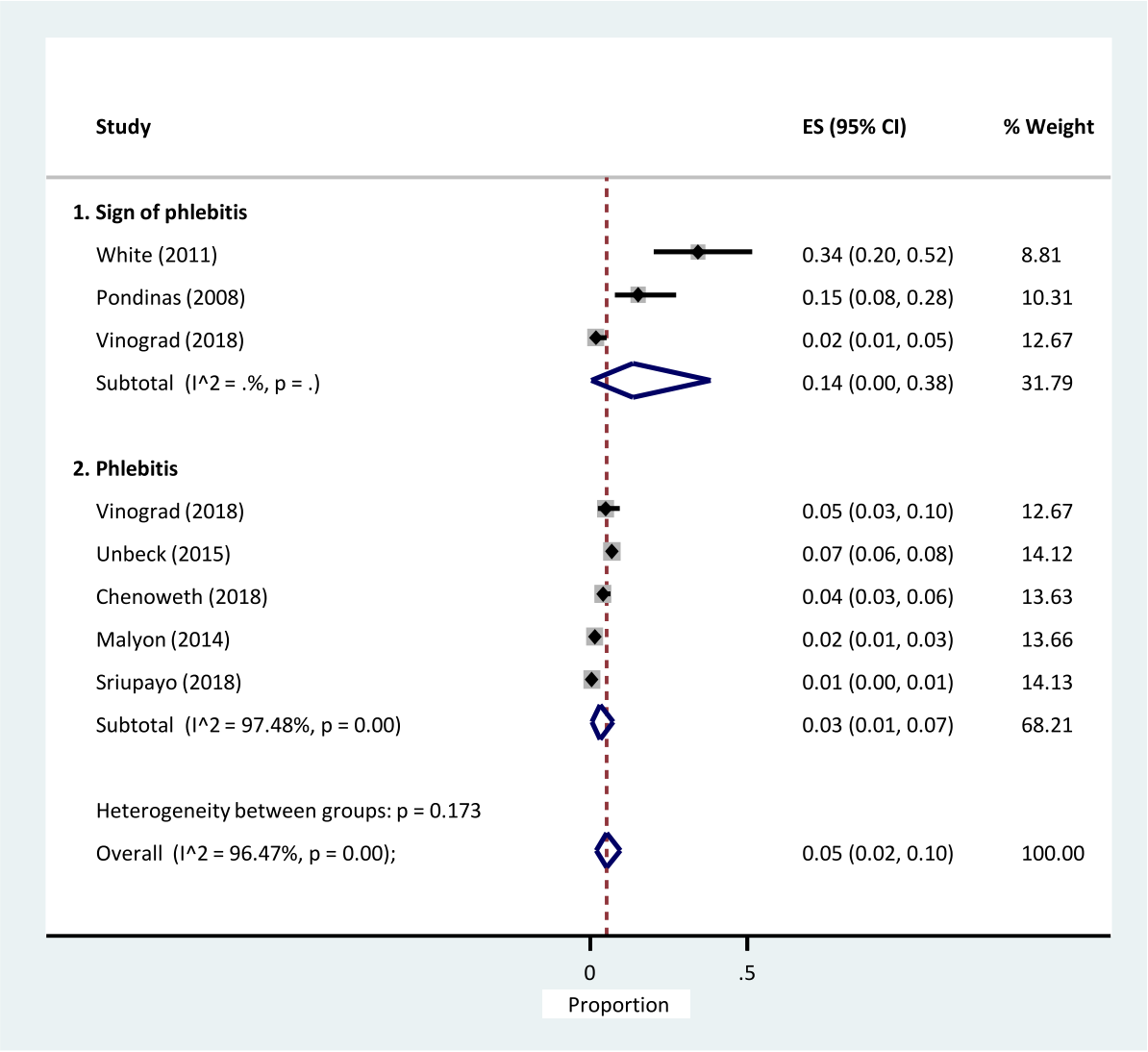

Fig. 5. Incidence of Phlebitis.

3.4.8. Infection

Infection was reported by device in three studies (n = 1296) (Förberg et al., 2016; Foster et al., 2002; Shenoy and Karunakar, 2014) and by patient in three studies (n = 2791) (Hollaway et al., 2017; Paladini et al., 2018; Unbeck et al., 2015). However, because of different definitions of infection in each study, meta-analysis was not possible. One study reported that the incidence of suspected PIVC related infection (without microbial culture) by patient was 0.3% (1.1 per 1000 PIVC days) (Unbeck et al., 2015). Other studies reported the incidence by patients, indicating that the incidence of suspected and or local infection incidence reported by two studies was 0.8% (Hollaway et al., 2017) and 35% (Paladini et al., 2018) respectively. By device, one study described local inflammation/infection (12%) (Shenoy and Karunakar, 2014) one study reported infection positive bacterial culture from PIVC (5%) (Foster et al., 2002) and one study reported suspect of infection (1%) (Förberg et al., 2016).

3.4.9. Unspecified and other causes

Unspecified and/or other causes of PIVC complications were reported by eight studies (n = 3815) (Birhane et al., 2017; de Lima Jacinto et al., 2011; Legemaat et al., 2016; Machado et al., 2008; Malyon et al., 2014; Paladini et al., 2018; Vinograd et al., 2018; White et al., 2011). The other causes reported in the studies included hives, bleeding, blanching (Vinograd et al., 2018), blood in the catheter, bruising and burning (White et al., 2011). Skin necrosis (Ben Abdelaziz et al., 2017) was reported by device in one study and wound pressure was reported by device in one study (Förberg et al., 2016) and by patient in one study (Unbeck et al., 2015).

4. Discussion

To our knowledge, this review is the first to systematically assess and synthesise the incidence of PIVC failure and complications in paediatric patients. The results show that PIVC failure is a significant problem in paediatric patients with 1 in 3 PIVCs inserted in paediatric patients failing before the completion of the therapy. This is comparable to rates reported in a recent incidence systematic review in the adult population (Marsh et al., 2018b). The results from this paediatric review were derived from studies reporting failure as a composite measure of occlusion, infiltration, dislodgment, and local infection or inflammation. However, only nine studies with patient as the unit of analysis used this. Eighteen studies with device as the unit of analysis employed composite

outcome measure and failure was higher at 38%. This result combined with other reviewed studies evaluating individual complications, suggest that the overall rate of PIVC complication and failure is even higher than the relative pooled analysis of each variable. It is hard to separate each individual complication from the another. Often multiple paths to failure are intertwined (e.g., an occluded catheter associated with leaking and infiltration or poor securement leads to gradual local irritation of the vein and dislodgment). Where a single primary variable cannot be selected from multiple measurements associated with the primary objective, another useful strategy is to integrate or combine the multiple measurements into a single or 'composite' variable. This also increases precision and (statistical) efficiency, as with time-based variables, the use of a composite measure leads to higher event rates and thus enabling smaller sample sizes or shorter follow-up (or both) (Freemantle et al., 2003). Reduced patency takes various pathways to the same endpoint, and any PIVC failure is the outcome of importance to patients.

Subgroup analysis by age group (pre-term and neonates compared to paediatrics) showed comparable rates of failure. PIVCs are often the primary and are the most common vascular access device inserted during hospitalisation (Alexandrou et al., 2018; Ullman et al., 2015). Failed PIVCs need to be removed and replaced, which means repeated painful needle sticks for the patient, associated risks of infection and increased healthcare costs due to additional staff time and resources (Kennedy et al., 2008; Scott-Warren and Morley, 2015; Tuffaha et al., 2018). Much of this failure is potentially avoidable with quality, evidence-based and consistent insertion and maintenance practice.

The incidence of PIVC failure in this study between high-income countries compared to the low-middle income countries as defined by OECD (Organisation for Economic Cooperation and Development, 2019) was comparable, with a difference in the pooled incidence of just 2%. It might be assumed that limited resourced settings would be associated with poorer outcomes, but the data from this review found outcomes across settings analogous.

Among the individual type of PIVC complications reported, the pooled incidence of PIVC infiltration was described to be the most prevalent with 10% cases. Extravasation was reported in eight studies with rates from a low 2% to as high as 78% (Callaghan et al., 2002; Dalal et al., 2009; Fonzo-Christe et al., 2018; Gomes et al., 2011; Özalp Gerçeker et al., 2018; Shenoy and Karunakar, 2014). This high figure was reported in a study of critically ill children in an intensive care unit where infants received intravenous phenytoin and mannitol infusate. Medications with high osmolality (greater than 600 mOsm/L) such as mannitol and acid/basic drugs (pH <5 or >9) such as phenytoin can predispose the patient to extravasation by irritating the endothelial lining of the vein (Beall et al., 2013). Children, particularly premature and sick infants, are vulnerable to infiltration and extravasation because of their immature immune systems. The inadequate anti-inflammatory response in infants may fail to release free radical scavengers leading to endothelial apoptosis and injury of cell membranes and vessels (Beall et al., 2013). Furthermore, the challenges of assessing pain accurately in preverbal infants, and additional occlusive fixtures and bandage that are commonly applied as securement devices add to difficulties in identifying early stages of infiltration or extravasation, and thus timely cessation of therapy and treatment to minimise harm (Sangam, 2019; Wilkins and Emmerson, 2004). Late detection of infiltration or extravasation by clinicians may lead to severe complications such as deep tissue necrosis (August et al., 2019; Wilkins and Emmerson, 2004) or even limb amputation in paediatric patients (Gault, 1993). In addition to optimising visualisation of the site and regular assessment, the complication of infiltration and extravasation can be avoided by choosing the correct venous access devices for certain types of infusion therapy (Chopra et al., 2016). If the inserters find that the purpose of the venous catheter insertion is to deliver intravenous fluids or medications not suitable to be administered through peripheral intravenous catheters, they should recommend another access device, such as central venous catheters (Infusion Nurses Society, 2016).

Other PIVC complications such as accidental removal (8%), occlusion (8%), leakage (6%), total phlebitis (5%) and extravasation (1%) could likely be improved with consistent and quality insertion and maintenance practices. The Infusion Nurses Society (INS) standard of practice makes comprehensive suggestions, with a specific recommendation for paediatrics and neonates offering further specific guideline for pre term, neonates, infants and children PIVC insertion and management practices (Infusion Nurses Society, 2016). Studies of PIVC care bundle have demonstrated improved outcomes (DeVries and Strimbu, 2019; Kleidon et al., 2019; Rhodes et al., 2016; Sriupayo et al., 2014). These included increased first insertion success rate, improved monitoring and documentation, extended dwell time of PIVCs ($>$ 96 h) without infection or complications or conversely less redundant or 'idle' PIVs *insitu*. However, there was a significant degree of heterogeneity between interventions tested. High-quality evidence through the conduct of RCTs and meta-analyses to guide maintenance is lacking, and optimal dressing and securement plus flushing and infusion regimens are yet to be determined.

The total pooled incidence rate of phlebitis in this study was lower than in the adult population (Marsh et al., 2018a). This might be due to variability in the way the researchers report phlebitis or different physiological response in infants and children and delayed detection (Ullman and Kleidon, 2019). Several studies, instead of reporting phlebitis as a composite measurement, reported the signs of phlebitis including pain, skin redness, swelling, and palpable cord are reported in the included studies (Pondinas, 2008; Vinograd et al., 2018; White et al., 2011). However, this may be reflective of the variation in the tools used to measure phlebitis rather than the prevalence of the condition itself (Ray-Barruel et al., 2014). Generally, phlebitis is characterised by a combination of tenderness/pain, erythema, oedema, purulent discharge, or a palpable cord, and results in failure and removal of the device (Mihala et al., 2018). However, even one sign, (e.g., erythema) can be an indication of underlying phlebitis (Mihala et al., 2018; Tagalakis et al., 2002).

Infections of variable definitions were reported in reviewed studies, equally variable results ranging from 0.3% to 35%. (The higher result being local inflammation/infection.) No included studies reported the incidence of CRBSI, perhaps due to the difficulties to assess CRBSI incidence, as laboratory results are needed to establish a diagnosis of CRBSI. The center for Disease Control (CDC)'s National Health and Safety Network (NHSN) (Centers for Disease Control Prevention, 2019) have specific criteria for the definition of bloodstream infection related to PIVCs, which should be used in monitoring and research for consistency. Though it is worth noting that although the reported rate of PIVC infection is low (Rickard et al., 2018), the quantity of devices in use (approximately 2 billion globally) and the primary source organism of *Staphylococcus aureus* make the reduction of PIV BSI a significant preventative goal in quality PIVC care (Austin et al., 2016; Stuart et al., 2013; Trinh et al., 2011). Good insertion and maintenance practice always starts with the reinforcement of skin decontamination and aseptic non-touch technique to minimise extra luminal and intraluminal infection (O'Grady et al., 2011). The removal and replacement of PIVCs in children, as clinically indicated (not routinely at 72 or 96 h), is standard practice and further underscores the need for regular and quality maintenance and assessment (NHMRC, 2019; O'Grady et al., 2011).

5. Limitations

Our review results should be carefully interpreted due to several limitations. The pooled incidence of PIVC failure and complications in this study is reported as incidence proportion. Time-based analysis (e.g., PIVC failure and complications incidence per catheter days or hours) is considered to be a more valid analysis reflection of the incidence variable. This was largely not in reviewed studies and nor was dwell time for the respective cohort. Consequently, meta-analysis of rates was not possible in this review. Furthermore, the unavoidable high heterogeneity of the included population, settings and definition of the complications in each study may affect the generalisability of the results. However, subgroup analysis addressed some of these limitations, and these limitations are also reflective of the pragmatic nature of clinical trials which enhance generalisability.

6. Conclusions

This systematic review describes the pooled incidence of PIVC failure and complications in the paediatric patient population globally. The incidence of PIVC complications and failure is high, in spite of multiple guidelines and recommendations. However, the body of evidence for some recommendations is limited, e.g. optimal dressing and securement, flushing mode and frequency. Quality trial evidence is urgently required to guide maintenance care. Where there is evidence to support specific practice or product use, support for training and resources, including vascular access clinicians and specialists, could optimise insertion practice and outcomes. The most salient point to emerge from the data was the lack of consensus in outcome definitions, e.g., phlebitis and infection. Consensus on surveillance and definitions is required to accurately monitor and report outcomes in research and practice.

Conflict of interest

SK's current and previous employer have received on her behalf monies from BD Medical for educational consultancies, investigator-initiated grant and unrestricted grants in aid for the research. Other authors have no financial relationships relevant to this review to declare.

CRediT authorship contribution statement

Ferika Indarwati: Conceptualization, Data curation, Resources, Formal analysis, Writing - original draft, Writing - review & editing. **Saira Mathew:** Data curation, Resources, Formal analysis, Writing - review & editing. **Judy Munday:** Conceptualization, Data curation, Resources, Writing - review & editing. **Samantha Keogh:** Conceptualization, Data curation, Resources, Writing - review & editing.

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All relevant data are within the paper and its supporting information files.

Supplementary material

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