Adverse Effects of IV Cannula a Medical Device - Patient's Perspective and Its Regulation in India

Jigna T. Patel[1]*, Pankaj Kapupara[2]
[1,2]Faculty of Pharmacy, RK University, Rajkot, Gujarat India, Email: jpatel128@rku.ac.in
*Faculty of Pharmacy, RK University, Rajkot, Gujarat India.
Email: jpatel128@rku.ac.in

Abstract
Intravenous (IV) access is very common procedures performed in hospitals for administration of therapeutics. It has various complications some may be serious/life threatening. However, their incidences are often underestimated during treatment and reporting them to regulatory authorities. Reporting of adverse effects of them will help in development of better-quality devices to ensure better outcomes. Aims: The aim of this study was to document the various local complications of cannula and to identify the risk factors associated with it and reporting to regulatory authorities. Settings and Design: The study was carried out in seven hundred fifty and the period of study was 1 year. Methods and Material: Indication of IV access, site, size of IV cannula used, category of personnel involved as well as local complications at access site were documented. Statistical Analysis Used: Results analysed using SPSS software (IBM Inc). Frequency calculated as average and percentage. Chi-square test was used for statistical significance. Results: Females, overweight, diabetics and smokers were found at more risk and some patients had serious complications. Conclusions: Our study shows that local complications of cannula are very common in more than fifty percent patients. Several risk factors are identified. However many of the complications are observed but none of them are being reported to regulatory authorities and investigated also none of the device has been recalled in India. Investigations and studies will help in development of better quality devices and improved reporting systems.
Keywords: Intravenous, local complications, medical device, serious

1. Introduction

Intravenous (IV) cannula a medical device is the most common and frequently used for administration of therapeutics for treatment of diseases [1,2] It being an invasive procedure and has complications during and after administration. However, cannula is considered of having low risk and Class A type medical device classified in India. Complications are often disregarded and not reported to the regulatory authorities. Cannulation is normally done by medical professionals but increase in burden of patients are increasing in hospitals resulting the complications arising from it cannot be ignored. The complications are more observed in developing and under developed countries where the healthcare system are not organized because they have rural and urban populations and patients are unaware of such complications and their reporting mechanisms [3]. In addition of proper practice of cannulation and reporting of adverse events will not only reduce the complications but also improves the quality standards IV cannula manufacturing and to conduct clinical studies. In the present study we have documented various local complications of IV cannula, risk factors and adverse reporting to regulatory authorities.

2. Subjects And Methods

The study was carried out various hospitals in four major cities of Gujarat (Gandhinagar, Ahmedabad, Mehsana and Vadodara). The total number of subjects were 750 patients of age between 18 to 70 years. The study was conducted for the period of one year (April 2019-March 2020). The initial consent and clearance were taken from patients and doctors. They were consulted and observed during the treatment and questioned for problems faced upon cannulation for intravenous therapy. Patients having chronic infections/and on immune-compromised therapy where not included in the study. In the study IV access, size of cannula, category of personnel and local complication were documented. Cannulations were done by medical professionals and size of cannula was decided based on various parameters like surgery, clinical status, condition of veins etc by medical professionals. The dressings were changed between 48-72 hours and cannulation site was changed if any complication was observed. Statistical analysis was done by using SPSS (IBM Corp.)

3. Results

The mean age of patients was around 40 yrs (range 18 yr - 70yrs). Among the study subjects 71 % were male (n = 532). 62 %of the patients (n = 465) had a normal BMI, 18.% of patients were diabetic (n = 135) and history of smoking was documented in 30.6% patients (n = 230) [Table 1]. Major surgery was the indication of IV access in most patients (62.0 % n = 503) [Table 2]. Forearm was the commonest site of access (46.2%, n = 347) and the most commonly used catheter gauge was 18G

doi.org/10.31838/hiv22.02.826 Received: 12.07.21, Revised: 10.08.21, Accepted: 12.09.22

(56.5%*n* = 424) [Table 3]. A total number of 392 patients were documented where complications out of 750 patients (52.2 %). The commonest complication was phlebitis (21.6%, *n* = 162) followed closely by infiltration (14%, *n* = 105) [Table 4]. Ten patients developed localized allergic reaction to adhesive plaster used to secure the IV cannula. Complications were seen more in female patients n = 250 than compared to male 142 (*m* = 36.2 % f = 63.8% *P* = 0.0494). IV access for major surgery was a risk factor when compared to minor surgery or non-operative management [*p* = 0.0015], and 85.71% of patients having access in the cubital fossa had complications which was higher than other sites and it was statistically significant (*p* = 0.00001) [Table 5].

Table 1: Demography of patients in the study

	Number of cases (n)	Percentage
Gender		
Male	532	71
Female	218	29
BMI		
Underweight	167	22.5
Normal	465	62
Overweight	82	10.9
Obese	36	4.6
Smoking		
Yes	230	30.6
No	520	69.33
Diabetes		
Yes	132	18
No	618	82

Table 2: Types of patients for intravenous access

	Number of cases (n)	Percentage
Major Surgery	503	67
Minor Surgery	210	28
Non operative management	38	5

Table 3: Site of IV access and size of cannula

	Number of cases (n)	Percentage
Site		
Hand	204	27.2
Fore Arm	347	46.2
Cubital Fossa	105	14.0
Foot	30	4.0
Wrist	37	5.0
Internal Jugular	28	3.7
Size of cannula used (G)		
18	424	56.5
20	219	29.2
22	68	9.0
24	40	5.3

Table 4: Complications of Cannula

Complications	Number of cases (n)	Percentage
Phlebitis	162	21.6
Infiltration	105	14.0
Hematoma	42	5.6
Thrombophlebitis	13	1.7
Abscess	8	1.0
Cellulitis	8	1.0
Bleeding	17	2.3
Arterial Bleed	5	0.7
Extravasation	13	1.7
Allergy	10	1.3
Skin necrosis	10	1.3
	392	**52.2**

Table 5: Relationship of complications with respect site of access in involved personnel

	Number of cases (n)	No. of Complication	Percentage	*P*
Type of Surgery				
Major	503	284	56.5	P=0.0015
Minor and Non operative management	248	83	33.3	
Site				
Hand	204	97	47.56	P=0.00001
Fore Arm	347	137	39.56	
Cubital Fossa	105	90	85.71	
Foot	30	20	66.66	
Wrist	37	27	73.33	
Internal Jugular	28	20	72.72	

4. Discussion

IV access is the most commonly performed invasive procedure undergone by patients admitted in hospital wards [1,2]. However, less or no clinical attention is given to it because of universal procedure for administration of therapeutics, even though complications are fairly common and can be serious [4,5]. In our study complications were more in female and in overweight patients which is similar to findings reported by Dychter SS *et al*. [6] Forni C *et al*. [7] and Smita Prakash *et al*. [8]. The presence of relatively more subcutaneous fat in females and in overweight patients might make the process of obtaining an IV access more difficult [5]. Studies have recommended real-time ultrasound guided placement in patients with difficult peripheral venous access there by reducing procedure time, number of attempts, vascular, infectious as well as neurological complications [9]. Increased complication in diabetic

patients can be due to age related fragility of veins [10] as well as anatomically distorted veins due to more frequent hospitalization in diabetic patients [11] Chance of complication like dislodgement and infiltration are more if the access site is exposed to repeated movement i.e. over a joint. We had more complications when the site was cubital fossa followed by wrist area which is similar to findings in previous studies [12]. In a country like India, building and empowering primary health care teams have been proposed to address the gross disparity in healthcare access of rural populace compared to urban population. This includes proper training of the primary healthcare team for providing comprehensive healthcare [13]. IV access is the essential step in providing fluid therapy and in primary health care with limited resources and expertise, a proper and durable intravenous access helping in prompt institution of treatment often before referral to higher centres may be an important clinical factor influencing patient prognosis. We also found that complication risk significantly increases in patients having major surgeries ($P < 0.0001$). That also explains the increased complication rates in patients undergoing major surgery. Therefore if we change the access site regularly the complication rate may decrease. Findings of the study by Claire M Rickard *et al* also found that access change is more beneficial when clinically indicated rather than based on duration [16]. On the other hand, this study is in agreement with more recent Cochrane data base systematic review by Joan Webster *et al*. that routine replacement of catheter reduces not only the rate of infiltration, but also the rates of blockage [17]. It should be rational to recommend that IV cannula to be removed if not required anymore than keeping it for future requirement.

In this study, out of 750 patients 52.2% developed complications (392). 91.7% of the complications were managed medically (antibiotics, limb elevation, anti- inflammatory drugs [oral/topical] and those patients who developed serious local complications such as suppurative thrombophlebitis, large ulcers, abscess and local tissue necrosis, required surgical intervention like incision and drainage, debridement and even split skin grafting for coverage of residual wound. Considering that the most of the serious complications were infective in nature and preventable, the essentiality of maintaining strict asepsis cannot be overemphasized.

We also checked our medical device regulatory website CDSCO for any adverse event reports of cannula, but very sorry to say that non of the adverse events were reported. It may improper knowledge of our medical professionals to report such serious adverse events so regulatory body can act and take action for further studies and reports. When compared to US FDA they had reported 21 device problems in the period of 2010 to 2020 and have recalled devices in the year 2013, 2014 and 2015 and in India none of the device problems were reported and recalled. This shows that the medical device regulation of US and other developed countries are more stringent and the people and medical professionals are more aware of reporting systems. This study indicates that we have to develop better regulation by not classifying on the risk levels of devices but on complications resulting from the use of medical devices.

References

Gelena HJ. Complications occurring from diagnostic venepuncture. J Fam Pract1992;34: 582-4.

World Health Organization. WHO guidelines on drawingblood: Best practices in phlebotomy. 2010.

Barik D, Thorat A. Issues of unequal access to public healthin India. Front Public Health 2015; 3: 245.

Lacostena-Pérez ME, Buesa-Escar AM, Gil-Alós AM. Complications related to the insertion and maintenance of peripheral venous access central venous catheter. Complicacion esrelacionad as con la inserción y elmantenimiento del catétervenoso central de acceso periférico. Enferm Intensiva 2019; 30: 116-26.

Armenteros-Yeguas V, Gárate-Echenique L, Tomás-López MA, Cristóbal-Domínguez E, Moreno-de Gusmão B, Miranda-Serrano E, et al. Prevalence of difficult venous access and associated risk factors in highly complex hospitalised patients. J Clin Nurs 2017; 26: 4267-75.

Dychter SS, Gold DA, Carson D, Haller M. Intravenous therapy: A review of complications and economic considerations ofperipheral access. J Infus Nurs 2012; 35: 84-91.

Forni C, Loro L, Tremosini M, Trofa C, D'Alessandro F, Sabbatini T, et al. Cohort study of peripheral catheter related complications and identification of predictive factors in a population of orthopedic patients. Assist Inferm Ric 2010; 29: 166-73.

Prakash S, Arora G, Rani HS. Peripheral venous access inthe obese patient. Indian J Anaesth 2015; 59: 692-3.

Franco-Sadud R, Schno brich D, Mathews BK, Candotti C, Abdel-Ghani S, Perez MG, et al. Recommendations on the use of ultrasound guidance for central and peripheral vascular access in adults: A position statement of the society of hospital medicine. J Hosp Med 2019; 14: E1-22.

Xu X, Wang B, Ren C, Hu J, Greenberg DA, Chen T, et al.Age-related impairment of vascular structure and functions. Aging Dis 2017; 8: 590-610.

Fields JM, Piela NE, Au AK, Ku BS. Risk factors associated with difficult venous access in adult ED patients. Am J Emerg Med 2014; 32: 1179-82.

Kagel EM, Rayan GM. Intravenous catheter complications in the hand and forearm. J Trauma 2004; 56: 123-7.

Mohan P, Kumar R. Strengthening primary care in rural India: Lessons from Indian and global evidence and experience. J Family Med Prim Care 2019; 8: 2169-72.

O'Grady NP, Alexander M, Burns LA, Dellinger EP, Garland J, Heard SO, et al. Guidelines for the prevention of intravascular catheter-related infections. Clin Infect Dis 2011; 52: e162-93.
Schmid MW. Risks and complications of peripherally and centrally inserted intravenous catheters. Crit Care Nurs Clin North Am 2000; 12: 165-74.
Rickard CM, McCann D, Munnings J, McGrail MR. Routine resite of peripheral intravenous devices every 3 days did not reduce complications compared with clinically indicated resite: A randomised controlled trial. BMC Med 2010; 8: 53.
Webster J, Osborne S, Rickard CM, Marsh N. Clinically indicated replacement versus routine replacement of peripheral venous catheters. Cochrane Database Syst Rev2019; 1: CD007798.