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ORIGINAL ARTICLE

Limb Splinting in Infant during Peripheral Intravenous Cannula Placement: A Randomized Control Trial

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ABSTRACT

Objective: To determine the effect of limb splinting on the functional duration and complications of Intravenous cannulation in infants.

Study design: A randomized control trial.

Place and duration of study: Trial was carried out in pediatric department of Saidu Teaching Hospital, Swat from September 2018 to December 2018.

Material and methods: Consecutive sampling technique was used for participant selection followed by randomization. Infant admitted in the ward with expected admission duration ≥72 hours were included in the study.

Results: The mean functional duration of splint group was 36.76 h SD=36.87, and in no-splint group 40.75 h SD=23.28. Independent sample t. test was applied the result shows p=0.361 which is statistically not significant. Chi-squared test was applied for independence in complication of splint group and no-splint group. The p=0.133 which is not significant. Most frequent complication was occlusion 41.94% followed by accidently removal and infiltration 27% both. Phlebitis reported was 3.23% and no case of extravasation was reported.

Conclusion: We concluded that use of splint during PIVC does not prolong functional duration so the use of splint in infant may not be suggested further because it consumes time and resources in current setup.

Key Words: *Peripheral intravenous catheter, PIVC, IV cannulation, Pediatric cannula placement, Limb splinting, Joint immobilization.*

INTRODUCTION

Peripheral intravenous cannulas/catheters (PIVCs) are inserted for the administration of drugs and fluid in pediatric patients most commonly.[1,2] It is most common universal invasive medical device used in patients admitted in hospitals, emergency department, day care, perioperative and some time at home for medication.[3] More than 90% hospitalized patients requires Intravenous (IV) therapy.[4,5]

PIVC is a foreign object inserted to the body that need securement and dressing at outer side to prevent dislodging or fallen out, and to prevent the damage of surrounding tissues and vein. Properly secured catheter allows less movement and prevent fallen out.[6] Poorly secured PIVC significantly leads to complications.[7] Poorly

secured cannula allows motion and micro-motion within the vein that can cause injury and leads to further complication.[7]

PIVC failure is common with complications such as phlebitis, infiltration, occlusion and accidental removal that indicate the premature removal of the PIVC.[8,9]

PIVC related complications, ultimately postpone in treatment and effect on patients family satisfaction. PIVC placement in pediatric population may be challenging and time consuming due to numerous probable issues such as, smaller veins, less visible veins, lack of cooperation, and greater adipose tissue in infant patient as compared to older children and adults.[1] Children feels more pain and get complication related to IV line insertion.[10]

Intravenous cannula securement and maintenance play a key role in intravenous therapy and its continuation.[11] Studies had been conducted to compare the use of dressing and securement devices but still there is limited evidence on the effective method for securing and dressing of IV cannula[7,11-13] A systematic review in 2015 suggests that there is limited evidence on PIVC securement in children and further studies are needed in this area.[12] Effective measure to prolong the functionality of cannula can decrease the chances of adverse effects. Immobilization of joint by splint during cannulation is used traditionally for prolonging the functional duration of cannula.[14,15]

The aim of the study was to determine the effect of joint immobilization through use of splint during intravenous catheter placement in infant. In clinical practice when we are placing IV cannula to a pediatric patient's joint (ankle, elbow and wrist) we often use a splint to immobilize the joint. There is limited recommendation regarding the immobilization of joint during intravenous cannula placement.

MATERIALS AND METHODS

A randomized control trial study design was used. The trial was non-blinded, prospectively monitored, parallel group superiority trials. In this trial blinding was not possible so there were no blinding in the study. The participants were recruited from pediatric department of Saidu Teaching Hospital. Data was collected from September 2018 to December 2018. Study target population was the infants (1 month age to 12 months age) who needed cannulation. Calculated sample size was 200 Cannulation (splint group 100, non-splint group 100).[16]. In the study the investigator used consecutive sampling method for sampling.

Simple randomization was done in this trial through lottery method. Strategy use for randomization was lottery method.

For sample selection the following inclusion criteria were used.

- ✓ All infants (1 month to 1 year's age group) admitted in pediatric ward and who needed PIVC placement were included in the study.
- ✓ Patient expected duration of admission in ward equal to or more than 72 hours were included in the study.

Following criteria were used for exclusion.

- ✓ Unconscious patients were excluded from the study because the investigator assumed the patient may have diminished active movements which can confound the outcome.
- ✓ Patients receiving sedation therapy were also excluded from the study because of suppressed movements of the patients due to drugs effect, which may also confound the study.
- ✓ Patients cannulated before admission to the ward was excluded because of unknown cannulation time.
- ✓ Patient's cannula inserted other than elbow, wrist, and ankle Joint was excluded because the study focused on cannulation in joints.

Tools used in the study for interventional group (splint group) and control group (no-splint group) are following. The procedure for IV cannulation and participant selection was same for both groups, only additional splint was applied for the splint group participants.

For the interventional group and control group participants the following method was followed.

The cannulations were performed by the nurse, as standard procedure used in hospital.

1. Appropriate size cannula (24, 22 G) Introcan ® - conventional IV catheter B. Braun Germany (made of polyurethane) was used.
2. The area (skin preparation) was clean with alcohol swab (methyl alcohol) available in hospital setting.
3. The cannula was secured only by applying paper tape (paper sticking)
4. Then Splint of appropriate size was applied.

   Splint only for splint group:

   Hard Paper from medicine (packing) vial cover was used.

   The hard Paper of Medicine vial cover was folded and properly taped.

   Size:

   Length: One inch from each side of the joint.

   Width: The size of extremity width.

   No cotton or gauze pieces were used.

   The splints were tightened by applying paper tape on each end of the splint around the extremity.

   The splints were applied so loose to not interrupt the blood flow or fluid.
5. The cannulas were monitored and assessed routinely when the nurse came in contact with IV cannula of the patient.
6. The observations and interventions were recorded in IVC Checklist.

The study was approved by Advance studies and research board (AS & RB) and Ethical review board of Khyber Medical University (KMU) Peshawar. Permission for data collection was taken from office of chief Executive Officer of Saidu Teaching Hospital.

Before starting data collection informed consent was taken and sign from the nurses working in pediatric department of Saidu Teaching Hospital (STH) Swat. The agreed nursing Staffs were trained for uniform procedure of peripheral intravenous cannulation, stabilization, monitoring, identification of complication, and documentation. They were also trained for filling the data collection form and randomization of the study participants.

A self-developed data collection form named “IV cannula assessment and monitoring form” was used for monitoring and assessment. The form was validated by experts (2 two pediatrician, and 1 pediatric nurse specialist) prior to commencement of the study.

The eligible participant parents’ consent was obtained for inclusion in the study. The eligible participants were randomly allocated into interventional and control group through simple randomization. Stapled sealed envelopes of same size and shape containing hidden signs for control group and intervention group were put into a jar. Each time for every eligible cannulation a sealed envelope was collected from the jar through lottery, which decided for the participant to receive intervention of splint group or non-splint group.

The data collection and monitoring form was initially filled by the nurse who assigned the patient into splint group or non-splint group through randomization. After successful cannulation, allocation into group, and securement the participants were prospectively followed.

The cannula was followed till termination (sign of removal such as infiltration, occlusion, extravasation, and phlebitis, or no need of any IV therapy) or discharge of the patient from the hospital.

The appearance sign of complication at cannula site was dealt with removal of cannula and the patients were treated as par hospital protocol.

After termination of intravenous cannula (IVC) the filled forms were collected by investigator and secured for further processing.

The filled forms were ordered and split into splint group and non-splint group. Each sample (case) was given an identification number. The forms were analyzed for completion in every respect. The time of cannula indwell was calculated as the time range between insertion and removal or discharge of the patient. The collected data on forms were entered into SPSS version 22.0 software and analyzed accordingly. In the study the data were analyzed as intention to treat analysis.

Descriptive statistics were applied; frequency, percentage, mean, mode, and ranges were calculated. Frequency and percentage were calculated for categorical data. Cumulative time

was calculated for all cannulation and indwelling time. Cumulative incidence of complication was measured. Distribution of complication in gender, and cannula site were also measured for the study.

For inferential statistics the statistical tests were applied such independent sample t test, Levene's Test for Equality of Variances, chi square, and Phi and Cramer's test.

RESULTS

During the data collection period of trial 4713 patients admitted in pediatric department of Saidu Teaching Hospital, Swat in which 2268 infants were eligible. Total 200 samples were obtained for the study. 100 cannulation followed in splint group and 100 cannulation followed in no-splint group.

Out of 200 infants, 142 (71%) were male and 58 (29%) were female. Distribution of gender with splint and non-splint group of male was 68 and 74 respectively, and female with splint and non-splint group were 32 and 26 respectively.

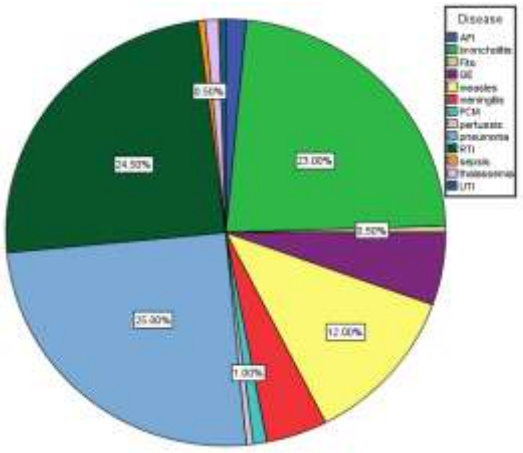

Fig 1: Disease status/diagnosis of the participants.

The mean weight in of study participants was 6.2 Kg with standard deviation of 1.6, and range from 2.5 Kg to 12 Kg. The disease status and frequencies have been showed in fig 1. Most frequently occurring cases/participants were respiratory tract infection (pneumonia, and bronchiolitis). The entire study participant were cannulated with 24 Gauge Introcan ®. Conventional IV catheter B. Braun Germany. Cannula 22 gauge was not used during the study.

Table 1 shows summarized results of the study in which overall complication rate was 62/200, 31%. Distribution of complications in study is summarized in fig 2. Most frequent complication was occlusion 41.94% followed by accidently removal and infiltration (27% each). Phlebitis reported was 3.23% and no case of extravasation was reported.

Intravenous medicine received by the majority of patient was cefotaxime, ampicillin, and dexamethasone. Other drugs like antibiotics (ceftriaxone, vancomycine, piperacillin + tazobactam, clarithromycine and amikacine), steroids (hydrocortisone), and antiemetic were also used.

Most frequent IV fluid used was Plabolyte M (Electrolyte solution). Other intravenous fluids were rarely used such as 1/5th dextrose saline, normal saline, and Ringer's Lactate.

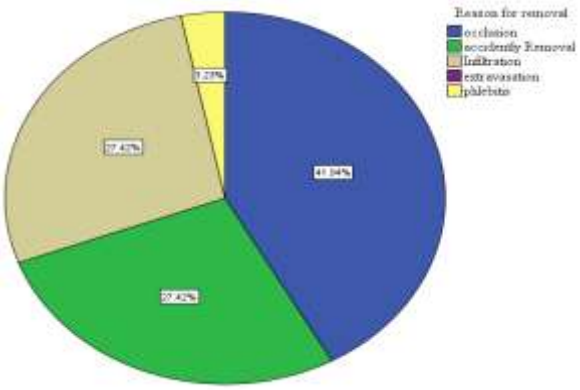

Fig 2: Complications related to PIVC.

The mean functional duration for splint group was 36.76 with SD 3.68 hours and for no-splint group was 40.75 with SD 23.28 hours. Independent t-test and Leven's Test for Equality of Variances were applied on functional duration in splint group and no-splint group. The results show no statistical difference in functional duration because the p value calculated was more than 0.05. The t-test p value was p=0.361 and for Levene's Test of Equality of Variances was p=0.159.

TABLE 1: Summarized results

	Splint N=100 n (%)	No-Splint N=100 n (%)	Total N=200 n (%)	Sig p=0.05
Sex				
Male	68(68)	74(74)	142(71)	
Female	32(32)	26(26)	58(29)	
IVC Site				
Wrist	69 (69)	53 (53)	122 (61)	
Elbow	0 (0)	0 (0)	0 (0)	
Ankle	31(31)	47 (47)	78 (39)	
Mean Functional duration	36.76 h SD=36.87	40.75 h SD=23.28	t. test sig = 0.36	
Cannula size				
24G	100 (100)	100 (100)	200 (100)	
22G	0 (0)	0 (0)	0 (0)	
Complication	**25(25)**	**37(37)**	**62(31)**	
Occlusion	10 (10)	16 (16)	26 (13)	Chi-squared test
Accidently Removal	8 (8)	10 (10)	18 (9)	sig= 0.133
Infiltration				
Extravasation	7 (7)	9 (9)	16 (8)	
Phlebitis	0 (0)	0 (0)	0 (0)	
	0 (0)	2 (2)	2 (1)	
frequent medicine				
Cefotaxime	68 (68)	69 (69)	137 (68)	
Ampicillin	56 (56)	55(55)	111 (55)	
Dexamethasone	46 (46)	36 (36)	49 (25)	
IV fluid frequent				
Electrolytes Solution	46 (46)	57(57)	103(51)	

The null hypothesis of the study was that there is no difference in functional duration of splint group and no-splint group. So we concluded that the null hypothesis is failed to reject for difference in complication between splint and no-splint group.

The hypothesis two of the study was that there is no difference in complication of splint group and no-splint group. To obtain the result for this hypothesis Pearson Chi-Square test was applied the p value calculated was p=0.133 which statistically not significant. So we concluded that the null hypothesis is failed to reject for difference in complication between splint and no-splint group. Phi and Cramer's V tests were also applied their p value was also p=0.133 which is also statistically not significant.

DISCUSSION

In this study the mean functional duration of the PIVC was found 38.7 hours with SD=30.8, ranges from one hour to two hundred forty four hours. A study conducted in Ethiopia in 2016 on infants demonstrated that functional duration of PIVC was 59 to 60 hours. Similar studies upon PIVC functional duration on children in Australia[17] and in Tunis[18] concluded that the functional duration were median 29 h (13-58h IQR) and mean 68.82 with SD=35.71 hours respectively. But in both studies the population age was from 0.1 year to 18 years. This study is the first in its nature to be done on infant population (1 m to 12 m). There is difference in functional duration time which may be due to different setups, different study sample size, different age group and different study designs. Experts conclude that there should be narrow range age to correctly identify the effects in specific population especially in pediatric trials.[19]

The mean functional duration in splint group and no-splint group were 36.765 SD=36.781 and 40.755 SD=23.281 hours. First null hypothesis of the study was that there is no difference in functional duration of splint group and no-splint group conversely the alternate hypothesis was that there is difference in functional duration in splint and no-splint groups. So the result of the

study in statistical test t-test show p value 0.361, which is not significant. A study conducted in India on pediatric population (age range from 1 day to 12 years) concludes that there is statistical difference in splint group functional duration and no-splint group. The result shows mean functional duration in splint group and in no splint group were 50.29 SD 20.92, 39.75 SD 21.39 respectively and p value was less than 0.05 which was statistically significant.[20]. The difference in result may be due to included age group difference because in our study the included population was infant's age 1 month to 12 months.

Other studies which are RCTs conducted on neonatal population use of splint during PIVC placement shows that there is no statistical difference in function duration.[14,15].

In this study the complication rate was 31% (62 out of 200). The frequency of occlusion in complication was most frequent 26/62 (41.94%) and accidently removal 17/62 (27.42%), infiltration 17/62 (27.32%), phlebitis 2/62 (3%) in the study. No case of extravasation was observed in the study.

A study by Baraka et al concludes that complication rate was 49.7% in pediatric population. Infiltration was 72% most common, mechanical causes complication was 22%, and phlebitis was 6%. The study also concludes that smaller gauge of cannula has more risk of complication as compared to large size. The 24 gauge catheter complication rate was 62.1%.[21].

Our study results demonstrate less frequency of complication as compared to the above cited study. The difference in complication rate may be due to difference in sample size, setting, population and study design. The second null hypothesis of the study was that there is no difference in complication of splint and no-splint group. To test this hypothesis chi square test was applied the result shows that there is no difference in complication. Similarly a study by Raghavan and Praveen, on neonatal population in the use of splint has no statistical difference in complication. Another study by Dalal and colleagues also concludes that there were no statistical difference in complication rate of splint and no-splint group.[14,15]. Both study result are similar to the study that indicates that there is no difference in complication of splint group verses no-splint group.

CONCLUSION

The study aimed to identify the effect of splint on function duration and complication of PIVC. The results of the study conclude that there is no statistical difference in functional duration and complication of splint. In other words, we can say that there is no evidence to reject null hypothesis. The null hypothesis was that there is no difference in functional duration of splint verses no-splint. Further research is needed in other settings to validate the result of the study and for further recommendation.

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