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RESEARCH ARTICLE

COMPARISON OF EFFICACY OF NORMAL SALINE WITH HEPARINISED SALINE FLUSHING ON PATENCY OF PERIPHERAL INTRAVENOUS CATHETERS – A RANDOMIZED DOUBLE BLIND CLINICAL TRIAL

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ABSTRACT

Background and objective: The purpose of the study was to compare the efficacy of normal saline with heparinized saline flushing on patency of peripheral intravenous catheters among hospitalized children.

Material and Methods: The research design used in this study was randomized double blind clinical trial. Population of the study comprised of all the children in the age group 2 months to 1 year who were admitted and received intravenous medications in the Paediatric medical ward of JIPMER. 100 samples were selected and assigned to normal saline group (50 samples) and heparinized saline group (50 samples) by simple randomization technique using computer generated random numbers sealed in opaque envelops. Data Collection was done overa period of two months. After obtaining the formal permission from the institution and written informed parental consent, children were allocated to two groups by using simple randomization technique to receive either normal saline or heparinized saline flushing. The respective flush solutions were administered to the patients through the IV catheter after giving intravenous medications. The main outcome of the study was total duration of patency of the IV catheter and phlebitis grades.

Results: There was no significant difference between the normal saline and heparinized saline groups in terms of total duration of patency and phlebitis grades of peripheral intravenous catheters. The duration of patency of peripheral intravenous catheters is influenced by the age of the children and frequency of medication administration in the normal saline group.

Conclusion: As no difference in patency could be established, use of normal saline as a flush solution is preferable to heparinized saline in peripheral IV catheters in children.

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INTRODUCTION

Every year, millions of children are admitted in hospitals and most of them need some forms of intravascular access as a vital component of their health care. Venous access allows for sampling of blood as well as administration of medications, chemotherapy, fluids, parenteral nutrition and blood products. The practice of using peripheral intravenous catheters for the administration of medications and fluids is a general procedure in health care practice. Webster (2008) quoted that in current clinical practice, loss of peripheral intravenous catheter patency is the common existing problem. To minimize client's discomfort and to avail cooperation from the client, the patency of these intravenous catheters need to be maintained.

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Hence, it is advantageous that once the intravenous cannula is insitu, its patency need to be maintained as long as possible. A variety of management strategies has been employed to prolong the lifespan of cannulae. One among them is flushing the cannula using a flush solution. Flint (2005) stated that there is a controversial aspect concerning the choice of flush solution for maintaining the patency of peripheral intravenous catheters. This practice varies between hospitals. Commonest solutions used for maintain the patency of IV cannula are normal saline solution and heparinized saline solution. Numerous clinical trials and research have been done to determine the efficiency of normal saline over heparin in catheter patency and associated complications. There is still a significant amount of ambiguity around the issue because of the heterogeneity in studies and variability in clinical practice. Hence the researcher identified the need for conducting research regarding the comparison of normal saline with heparinised saline flushing

on patency of peripheral intravenous catheters among hospitalized children.

MATERIALS AND METHODS

A prospective randomized double blind clinical trial was carried out to compare the efficacy of normal saline flushing and heparinised saline flushing on patency of peripheral intravenous catheters, in paediatric medical ward of a tertiary care center.

Inclusion Criteria

Included, children in the age group of 2 months to 5 years, who were having fresh peripheral intravenous catheters in upper extremities, who were getting BD or sixth hourly IV medications and those children whose parents were willing to give consent.

Exclusion criteria

Was children on continuous IV infusion, who were getting eighth hourly IV medications, who were getting heparin as part of treatment and who were having contraindications to heparin therapy.

Sampling: Simple random sampling technique was used.

Instruments

Subject data sheet had a set of questions that was oriented to the demographic & clinical data of subjects. To assess and grade the signs of phlebitis Jackson's Visual Infusion Phlebitis Scale was used.

Data collection procedure

Informed consent was obtained from the parents after explaining the study. Children were assigned into two groups,

Table 1. Distribution of demographic variables of children in both groups (N = 100)

Sl. No.	Demographic variables	Normal saline (n=50)		Heparinised saline (n=50)		Statistical significance
		n	%	n	%	
1	Age					
	2 months – 1 year	24	48	27	54	$X^2 = 1.176$
	1-3 years	20	40	15	30	p=0.555
	3-5 years	6	12	8	16	df=2
2.	Gender					
	Male	20	40	34	68	$X^2 = 7.89$*
	Female	30	60	16	32	p=0.034
						df=1

*p<0.05

Table 2. Distribution of Clinical Variables of children in both groups

(N=100)

Sl. No.	Clinical variables	Normal saline (n=50)		Heparinised saline (n=50)		X^2 value
		n	%	n	%	
1	Diagnosis					
	Infectious diseases	34	68	37	74	$X^2 = 0.437$
	Non-infectious diseases	16	32	13	26	p=0.509
						df=1
2.	Drugs received					
	Only antibiotics	33	66	35	70	$X^2 = 0.184$
	Other drugs	17	34	15	30	p=0.668
						df=1
3.	Type of therapy					
	Monotherapy	25	50	32	64	$X^2 = 1.99$
	Combination therapy	25	50	18	36	p=0.159
						df=1
4.	Frequency of medication					
	BD	32	64	37	74	X^2=1.169
	Q6H	18	36	13	26	p=0.280
						df=1
5.	Size of cannula					
	22G	16	32	17	34	X^2=0.045
	24G	34	68	33	66	p=0.832
						df=1
6.	Site of cannulation					
	Hand	43	86	42	84	X^2=0.078
	Antecubital region	7	14	8	16	p=0.779
						df=1
7.	Side of hand					
	Right	23	46	28	56	X^2=1
	Left	27	54	22	44	p=0.317
						df=1
8.	Use of splint					
	Yes	4	8	2	4	X^2=0.709
	No	46	92	48	96	p=0.4
						df=1

Table 3. Comparison of total duration of peripheral IV catheters in both groups

(N=90)

Group	Mean (hours)	SD	Statistical significance
Normal Saline group (n=45)	61.37	23.778	t=0.639
Heparinised Saline group (n=45)	64.88	28.142	p=0.524

Table 4. Comparison of grades of phlebitis in both groups

(N=90)

Day	Grade of phlebitis	Normal saline group (n=45)	Heparinised saline group (n=45)	U value
Day 1	0	45	44	U=1
	1	0	1	p=0.500
Day 2	0	26	27	U=0.525
	1	13	12	p=0.600
	2	6	6	
Day 3	0	8	11	
	1	10	12	U=1.338
	2	19	15	p=0.181
	3	2	1	
Day 4	0	1	4	
	1	11	10	U=0.521
	2	6	9	p=0.602
	3	0	0	
Day 5	0	1	1	
	1	2	2	U=0.362
	2	8	10	p=0.776
	3	1	1	
Day 6	0	0	0	
	1	0	2	U=1.33
	2	2	1	p=0.400
	3	1	0	
Day 7	0	0	0	
	1	0	0	
	2	0	2	
	3	0	0	

Table 5. Association between total duration of patency of peripheral intravenous catheters and demographic variables of children in both groups (N=90)

		Normal Saline group (n=45)				Heparinised saline group (n=45)			
Sl. No.	Demographic variables	n	Mean (hours)	SD	t or F value	n	Mean (hours)	SD	t or F value
1.	Age								
	2 months-1 year	20	60.08	22.910	F=3.351*	25	63.40	27.511	F=2.325
	1-3 year	20	56.60	22.154	p=.045	14	58.26	27.736	p=.110
	3-5 year	5	85.60	23.223		6	86.50	32.421	
2.	Gender								
	Male	17	66.94	24.017	t=1.232	30	60.56	29.270	t=1.477
	Female	28	57.99	23.413	p=0.225	15	73.53	24.379	p=.147

*p<0.05

Table 6. Association between total duration of patency of peripheral intravenous catheters and clinical variables of children in both groups (N=90)

		Normal Saline group (n=45)				Heparinised saline group (n=45)			
Sl. No.	Clinical variables	n	Mean (hours)	SD	t or F value	n	Mean (hours)	SD	t or F value
1.	Diagnosis								
	Infectious diseases	30	59.52	24.265	t=0.734	36	66.01	29.637	t=0.534
	Noninfectious diseases	15	66.07	23.138	p=0.467	9	60.37	22.012	p=0.596
2.	Drugs received								
	Only antibiotics	30	62.59	26.611	t=.482	33	66.05	27.122	t-.457
	Other drugs	15	58.93	17.339	p=.633	12	61.67	31.822	p=.650
3.	Type of therapy								
	Monotherapy	22	66.6	26.806	t=1.463	27	67.39	28.517	t=0.729
	Combination therapy	23	56.36	19.781	p=0.151	18	61.11	27.948	p=0.470
4.	Frequency								
	BD	29	67.62	25.290	t=2.514*	33	67.03	27.142	t=0.847
	Q6H	16	50.04	15.877	p=0.016	12	58.97	31.190	p=0.401
5.	Size of the cannula								
	22G	14	64.93	21.918	t=0.671	15	61.17	26.429	t=0.621
	24G	31	59.76	24.749	p=0.506	30	66.74	29.219	p=0.538
6.	Site of cannulation								
	Hand	40	60.34	24.102	t=0.818	38	65.62	26.724	t=0.408
	Antecubital region	5	69.60	21.455	p=0.418	7	60.86	37.168	p=0.685
7.	Side of the cannulated arm								
	Left	26	63.05	27.862	t=0.550	19	63.42	30.092	t=0.294
	Right	19	59.07	17.154	p=0.770	26	65.95	27.187	p=0.770

*p<0.05

Group A and Group B, by simple randomization technique. The two flush solutions, normal saline and heparinised saline, were prepared daily and labeled as "A" and "B" and handed over to the investigator. The flush solution was administered to the patients through the IV cannula by the researcher after giving intravenous medications. Group A received 1 ml of solution 'A' and Group B received 1 ml of solution 'B' as flush. In both the groups, obstruction of the cannula was assessed by the investigator while giving IV medications. The IV catheter sites were observed by the investigator four times a day. The occurrence of signs of phlebitis was assessed and grades were given and recorded in the assessment data sheet using Jackson's visual infusion phlebitis scale.

Ethical considerations

Ethical committee permission was obtained before commencement of the study. Written informed consent was got from the parents of all children before starting data collection. Assurance was given to subjects that anonymity and confidentiality would be maintained. Participants were given the freedom to leave from the study at any time.

Data analysis

The distribution of categorical variables related to the demographic and clinical variables of the samples was expressed as frequencies and percentages. The comparison of categorical data between the groups was carried out by using chi square test. The data on total duration of patency was summarized as mean with SD. Grades of phlebitis was compared between the groups using Mann-Whitney U test. Independent student t test were used to determine the association between the patency of peripheral intravenous catheters and selected demographic and clinical variables.

RESULTS

- Most of the children were infants in the normal saline and heparinised saline group. The least proportions of children were preschoolers in both groups. There were more males in the heparinised saline group than normal saline group.
- Antibiotics were most commonly administered in both normal saline and heparinised saline groups. In heparinised saline group, monotherapy was more but in normal saline group, the proportion of mono therapy and combination therapy was same.
- In both groups, most of the children received BD medications. For children in both normal saline and heparinised saline groups 24G cannula was used the most. Most of the cannulas were present in the hand in both the groups.
- More cannulas were in the left hand in normal saline group whereas in heparinised saline group, cannulas were more in the right hand. Majority of the cannulas were without splint in both the groups.
- The mean duration of patency of cannula was 61.37 hours in the normal saline group and 64.88 hours in the heparinised saline group. The mean duration of patency was compared between the two groups using independent t test. The results showed that there was no statistically significant difference in the duration of patency of the peripheral intravenous catheters between the groups.
- The phlebitis grades were compared between the normal saline and heparinised saline group using Mann-Whitney U test. The results revealed that there is no significant difference between the groups in terms of grades phlebitis.
- The study showed that duration of patency was significantly associated with age of the children in normal saline group with highest duration of patency for preschoolers and least duration for toddlers.
- The study revealed that there was significant association between the duration of patency of peripheral intravenous catheters and frequency of medication administration in the normal saline group.

DISCUSSION

The study results showed that there was no statistically significant difference in the duration of patency of peripheral intravenous catheters between the groups.

The above findings were supported by the following studies:

- Arnts IJ *et al.* (2011) assessed the effectiveness of heparinized saline against normal saline to retain the patency of intravenous catheters among neonates. The study was conducted among 88 neonates who were randomly assigned to two groups (42 in heparin group and 46 in the normal saline group). Findings of the study revealed that the duration of the patency of intravenous catheters was same in both the groups.
- Mitsiou-Tzortzi & Koutelekos reported that the effectiveness of normal saline and heparin solution was the same for the patency of peripheral intravenous catheters.
- The findings of the study were consistent with the double blind randomized controlled trial conducted by LeDuc among children. Efficacy of normal saline vs heparinized saline solution for maintaining peripheral IV catheter patency was compared in the study. Statistical analysis found that the two groups were not significantly different.

Conclusion

The findings of the study conclude that both normal saline and heparinised saline is equally effective in maintaining the patency of peripheral intravenous catheters. In view of the cost and possible adverse effects of heparin, normal saline can be used as a cheap, cost effective alternative to heparinised saline for flushing the peripheral intravenous catheters among children.

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