



## An Open-Labelled, Randomized Clinical Trial to Study the Performance and Safety of an Intravenous Line Organizer (IVO) in a Tertiary Care Hospital

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### Abstract

**Background:** Medical line and tube entanglement poses a significant threat causing unintentional consequences to the patients. **Objectives:** To study the clinical performance and safety of the IVO (intravenous line organizer) for providing patient autonomy, mobility, and comfort. **Methods:** Patients aged <18 years (pediatrics) and >18 years (adults) who were admitted to the hospital for treatment were included in the study. Tools like the Global Scale, Ease of Operability Scale, Severity of Intravenous Line Entanglement by Medical Line Entanglement Scale, Subjective Presumption Questionnaire, and Skin Irritation Scale, and adverse and serious adverse events were assessed and analyzed. **Results:** A total of 120 subjects who participated in the study were randomized into Groups-A (with IVO) and B (without IVO). The majority of patients in Group-A demonstrated better autonomy toward lines and tubes compared to Group-B in both adult and pediatric populations (86.3% vs 20%: Pediatric, 83.3% vs 26.6%: Adult),  $p < 0.0001$ . Also, on mobility the Group-A patients reported improved movements with reduced restriction compared to Group-B (76.3% vs 26.6%,  $p < 0.0001$ ). Further, on the design and usability of IVO, 73.3% of patients in Group-A showed greater interest in the operability and usability compared to 27% in Group-B. No entanglement was reported in Group-A compared to the 12 (10%) patients facing potential harm of levels 2 & 3 who were in the standard-of-care group (without IVO). No significant adverse events were reported in patients using IVO. **Conclusion:** The IVO provided patients with the safe organization of intravenous tubes with greater autonomy, mobility, and comfort in managing the IV lines.

**Keywords:** Intravenous Line Organizer, Autonomy, Mobility, Comfort, Entanglement

**Article Summary:** Submitted: 07-October-2024 Revised: 28-November-2024 Accepted: 12-December-2024 Published: 30-December-2024

#### Quick Response Code:



**Web Site**  
<http://ijmsnr.com/>

**DOI**  
10.55349/ijmsnr.202444315

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### Introduction

In clinical practice, patients often receive multiple infusions via intravenous (IV) lines, which is a complex and risk-prone activity. IV lines and tubes connected to peripheral or central intravenous catheter devices for delivering medication and fluids become tangled, wrapped, impinged upon the surface, or dislodged around the patient's limbs or neck at the time of transport or mobility, which can sometimes potentially harm the patient. [1] In critical care units, the entwining of tubes and wires at the bedside referred to as "spaghetti syndrome" is a significant challenge resulting in poor clinical outcomes among the patients. [2] In such a scenario, clinicians, and nurses face difficulty in providing an appropriate rate of infusion, dose adjustment, or change in medication resulting in infusion mix-up errors and delays, which is concerning during emergency conditions. Studies showed that patients in intensive care unit (ICU) settings, oncology units, and trauma/emergency units use a higher number of drugs being infused via IV lines, which are more likely to have adverse drug events. [3] As a result, infusion mix-up errors occur, especially with high-attention agents being used (e.g., insulin, antibiotics). Further, multiple IV lines and tubing impact the patient's ability to do minimal physical activities like walking, sitting, accessing the toilet, and eating food. In 2015, the US FDA called for urgent action to improve multiple infusion management and rated infused mix-ups as among the top health technological hazards. [4]

**How to cite this article:** Vikram B, Venkatesh R, Shetty S, Priyanka DS, Kumar SS, Burke D. An Open-Labelled, Randomized Clinical Trial to Study the Performance and Safety of an Intravenous Line Organizer (IVO) in a Tertiary Care Hospital. *Int J Med Sci and Nurs Res* 2024;4(4):3–15. DOI: 10.55349/ijmsnr.202444315

In India, there was limited evidence suggesting the serious implications of multiple lines and potential hazards reported by clinicians, nurses, and patients. However, studies have shown that a 7% incidence of bloodstream infection and contamination of IV lines occurs in medical, surgical, and neurosurgical ICUs. Further, at times of patient shifting from bed or ward, multiple line or unlabeled tubes twinning results in dragging of line and dislodging of central line causing failure in intravenous catheter fixation. [5] The National Centre for Disease Control (NCDC) sets up guidance on the preparation and maintenance of IV lines and recommends that to keep away from dragging of intravenous IV lines to the floor, and contamination. [6] The IVO is easily wearable and is designed to hold the IV lines to prevent entanglement and allow it to be strapped to the patient's body. In this study, we evaluate the clinical performance and safety of IVOs in patients admitted to tertiary care hospitals.

## Material and Methods

### Study design

An open-labeled, randomized, parallel-group, active-controlled trial was conducted at Sathagiri Medical College and Hospital, Kolar, India. A total of 120 patients admitted to ICU, general medicine, hematology, and pediatrics were randomized between December 2022 and 2023. The study was carried out as per the good clinical practice (GCP) guidelines and the Declaration of Helsinki ethical standards (**Protocol No:** DERYL/ILO/2022/09). Institutional ethical clearance (IEC) approval was obtained from the participating sites. This trial was registered with the Clinical Trials Registry of India (CTRI/2023/01/049072). Written consent forms were obtained from the participants.

### Study population

Patients aged above 18 years (adults) and less than 18 years (children) of either gender, willing to provide informed consent and having been admitted for fluid replacement (hydration), hematology, general medicine, pediatrics, ICU, oncology, chemotherapy, anesthesiology, geriatrics, daycare units were included in the study.

### Intervention

Open-labeled, run-in period, eligible patients were parallelly allocated in a 1:1 ratio by using randomization software to receive either intervention group IVO (Group A) (N=60) or standard of care without IVO group (Group B) (N=60). The study device was dispensed at baseline only.

### Efficacy assessments

The primary efficacy outcome was to assess the performance and safety of those patients with and without IVOs in patients admitted to tertiary care hospitals. The secondary efficacy outcomes were to evaluate the performance and safety of those patients.

### Safety assessment

During the trial, safety was evaluated by changes in vital signs, and physical examination. The investigators closely monitored and evaluated adverse events (AEs).

## Statistical Analysis

The minimum sample size was 120 patients (60 patients per group) with an assumed drop-out rate of 15% during the study and a power of 90% joint power for IVO group compared to without IVO group at the same time, 90% power for each comparison, a standard deviation of 0.8%, and a 0.4% mean difference.

Descriptive statistics were applied to conduct a statistical analysis of the collected data, with mean and standard deviation being used for all the data. Significant mean differences between Groups A and B were assessed using a paired t-test. A p-value of less than 0.05 was considered to indicate a statistically significant difference. The statistical analyses were done using SPSS software version 25.0 [IBM Corp., Armonk, NY, USA] and Microsoft Excel – 2019.

## Results

### Demographics

Out of 120 patients, 60 were adults (50%) and 60 were pediatric patients (50%) with a ratio of 1:1. The patients were randomized into two groups: Group-A (with IVO) and Group-B (without IVO) in both pediatric and adults. Among the pediatric population, the mean age of children was 9.7 years (SD=3.3) with an average height of 127.16 cm (SD=28.72) and weight of 26.82 kg (SD=12.98) observed in Group-A and with Group-B the mean age of 8.93 years (SD=2.72) with a mean height of 127.43 cm (SD=23.37) and weight of 33.07 kg (SD=10.71) was observed. In the adult population, the mean age was 43.53 years (SD=17.67) with an average height of 136.75 cm (SD=58.84) and weight of 64.83 kg (SD=16.9) observed in Group-A and with a mean age of 46.4 years (SD=16.89) with a mean height of 151.95 cm (SD=40.47) and weight of 67.2 kg (SD=9.14) observed in Group B. Further, on the gender-wise distribution, there was a higher proportion of male patients who participated in the study than females (65% vs 35%: pediatric; 60% vs 40%: Adults). On the level of education, the majority of the pediatric patients were in primary to high school education (95%, n=55) compared to adults of intermediate to graduation (48.3%, n=29). No statistically significant difference between Groups A and B was observed at the baseline ( $p > 0.05$ ) as shown in **Table – 1**.

### Comparison of greater autonomy, mobility, and comfortability of patients using IVO and without IVO in the pediatric and adult population using a global scale

Children in Group A, who managed their IV lines independently, showed greater confidence (n=24, 80%) compared to those in Group B without IVOs (n=6, 20%) who exhibited no confidence in managing their IV lines. This difference between the groups was statistically significant. Similarly, in the adult population, 25 (84%) patients in Group A reported higher confidence toward self-management of their IV line, and 6 (20%) patients reported neutral response, followed by 24 (80%) patients in Group B who depicted no confidence in independently manage the IV lines.

**Table-1 Distribution of the demographic characteristics of patients between groups**

Characteristics	Pediatric (n=60)		p-value <sup>#</sup>	Adults (n=60)		p-value <sup>#</sup>
	Group-A (n=30)	Group-B (n=30)		Group-A (n=30)	Group-B (n=30)	
Age (in Years), Mean (SD)	9.7 (3.3)	8.93 (2.72)	0.330	43.53 (17.67)	46.4 (16.89)	0.523
Height (in Cm), Mean (SD)	127.16 (28.72)	127.43 (23.37)	0.968	136.75 (52.84)	151.95 (40.47)	0.216
Weight (in Kg), Mean (SD)	26.82 (12.98)	33.03 (10.71)	0.048	64.83 (16.9)	67.2 (9.14)	0.502
<b>Gender, n (%)</b>						
Female	10 (33.33)	11 (36.67)	0.787	14 (46.67)	10 (33.33)	0.430
Male	20 (66.67)	19 (63.33)		16 (53.33)	20 (66.67)	
<b>Marital Status, n (%)</b>						
Married	0 (0)	0 (0)	0.386	21 (70)	27 (90)	0.052
Unmarried	30 (100)	30 (100)		9 (30)	3 (10)	
<b>Level of Education, n (%)</b>						
Graduate/ Post Graduate	0 (0)	4 (13.33)	0.749	1 (3.33)	4 (13.33)	0.740
High School	4 (16)	7 (23.33)		3 (10)	10 (33.33)	
Intermediate	0 (0)	4 (13.33)		1 (3.33)	5 (16.67)	
Middle school	7 (28)	8 (26.67)		8 (26.67)	5 (16.67)	
Primary school	12 (48)	2 (6.67)		16 (53.33)	3 (10)	
Profession or Honors	0 (0)	2 (6.67)		0 (0)	0 (0)	
Illiterate	2 (8)	3 (10)		1 (3.33)	3 (10)	

n (%) – Number (percentage); SD- Standard deviation; <sup>#</sup> Independent t-tests were conducted to assess mean differences between Groups-A and B; Chi-square test for Independence was used to evaluate associations between Groups-A and B in pediatric and adult populations

Further, patients' overall autonomy in making a line adjustment at the bedside was higher among Group-A compared to Group-B (73.3% vs 20%,  $p < 0.0001$ ) in the pediatric group and improved competencies toward handling lines among the adults (73.3% vs 20%,  $p < 0.0001$ ). The majority of patients in Group-A demonstrated better autonomy toward bedside lines in both adult and pediatric populations (83.33% vs 20%: Pediatric) compared to those in Group-B (83.3% vs 26.6%),  $p < 0.0001$ . The findings show that there is greater autonomy among the IVO group in managing the lines compared to the SOC group as shown in **Table-2**.

In terms of mobility, both peripheral and central lines significantly restrict patient movement when connected to a catheter. Often restriction of patient mobility prevents dislodging of the catheter as lines are readily free hanging. Patients' perception and mobility were recorded with and without the IVO among the adult and

pediatric patients. The results indicated that 73.3% of children in Group-A found it easy to move around with the IV line due to the IVO, whereas 79% of children in Group-B found it difficult to move around with the IV line. Additionally, 20% of Group B reported neither difficulty nor ease of movement. A statistically significant difference was observed ( $p < 0.0001$ ).

However, 73.3% of adults in Group-A reported ease in mobility with line compared to 80% patients of with difficulty in mobility in Group-B. Additionally, a statistically significant difference was observed between the groups, with 76.3% of patients in Group-A reporting that IVOs provide less restriction in mobility compared to 26.6% in Group-B ( $p < 0.0001$ ). With an IV line mounted to the catheter, patients' performance in doing basic functional activities like walking, sitting, and standing with multiple lines was assessed. Findings show that 75% of patients in Group-A reported no

**Table-2 Comparison of autonomy outcomes in managing IV lines in Group-A and B among pediatric and adult patients**

Autonomy	Pediatric				Adults			
	Group-A n (%)	Group-B n (%)	Total n (%)	p-value <sup>#</sup>	Group-A n (%)	Group-B n (%)	Total n (%)	p-value <sup>#</sup>
<b>How confident do you feel managing the IV line by yourself?</b>								
Very Confident	17 (56.67)	0 (0)	17 (28.33)	<b>0.0001</b>	14 (46.67)	0 (0)	14 (23.33)	<b>0.0001</b>
Confident	7 (23.33)	0 (0)	7 (11.67)		11 (36.67)	0 (0)	11 (18.33)	
Neutral	6 (20)	5 (16.67)	11 (18.33)		5 (16.67)	6 (20)	11 (18.33)	
Not confident	0 (0)	14 (46.67)	14 (23.33)		0 (0)	11 (36.67)	11 (18.33)	
Not at all confident	0 (0)	11 (36.67)	11 (18.33)		0 (0)	13 (43.33)	13 (21.67)	
<b>Can you independently adjust the IV line when needed</b>								
Very Easy	13 (43.33)	0 (0)	13 (21.67)	<b>0.0001</b>	10 (33.33)	0 (0)	10 (16.67)	<b>0.0001</b>
Easy	9 (30)	0 (0)	9 (15)		12 (40)	0 (0)	12 (20)	
Natural	8 (26.67)	6 (20)	14 (23.33)		8 (26.67)	6 (20)	14 (23.33)	
Difficult	0 (0)	17 (56.67)	17 (28.33)		0 (0)	15 (50)	15 (25)	
Very Difficult	0 (0)	7 (23.33)	7 (11.67)		0 (0)	9 (30)	9 (15)	
<b>Does the IV line organizer make you feel more independent in managing your IV line?</b>								
Strongly agree	13 (43.33)	0 (0)	13 (21.67)	<b>0.0001</b>	11 (36.67)	0 (0)	11 (18.33)	<b>0.0001</b>
Agree	12 (40)	0 (0)	12 (20)		14 (46.67)	0 (0)	14 (23.33)	
Neutral	5 (16.67)	6 (20)	11 (18.33)		5 (16.67)	8 (26.67)	13 (21.67)	
Disagree	0 (0)	11 (36.67)	11 (18.33)		0 (0)	11 (36.67)	11 (18.33)	
Strongly Disagree	0 (0)	13 (43.33)	13 (21.67)		0 (0)	11 (36.67)	11 (18.33)	

n (%) – Number (percentage); <sup>#</sup> Chi-Square test for Independence was used to evaluate associations between Groups-A and B in pediatric and adult populations

difficulty compared to 16.67% of patients in Group-B, with p<0.0001 significance between the groups. The findings show that there is greater mobility in Group A with lines mounted compared to the SOC group as shown in **Table-3**.

**Clinical evaluation of medical line entanglement using the medical line entanglement severity scale (MLES-Scale) between groups A and B**

Medical line entanglement places a significant risk of unintentional injuries to the patient, the physician, and the nurse, and the patient-specific measure of entanglement provides wider insights for better outcomes. The majority of physicians (100% in children & 96.67% in adults) have reported that the IVO has no entanglement and poses no harm to the patients compared to 90% in the Group-B patients, but clinicians reported 3 (10%) potential harm (level 1), 2 (6.67%)

potential harm (level 2) and 1 (3.3%) potential harm of level 3 in the Group-B, with p<0.001 of statistically significant difference between the groups. Further, the nurse has reported the patients in Group-A showed no entanglement (no harm) (100% vs 96.67%) between the pediatric and adult groups, but Group-B had a varied outcome with no entanglement (96.67% vs 93.33%) comparing the children/adult groups. Also, there was potential entanglement of level 1 (3.33% vs 6.67%) observed in the pediatric and adult groups, with a statistically significant difference of p<0.05 as shown in **Table-4**.

Among children, there was no significant difference in entanglement, however, the adult patients reported reduced entanglement compared to Group-B (96.6% vs 86.6%), with p<0.05. The findings demonstrate an overall reduced entanglement in Group-A compared to Group-B as shown in

**Table-3 Mobility and impact of IV lines in groups-A and B among pediatric and adult patients**

Mobility	Pediatric				Adults			
	Group-A n (%)	Group-B n (%)	Total n (%)	p-value <sup>#</sup>	Group-A n (%)	Group-B n (%)	Total n (%)	p-value <sup>#</sup>
<b>How easy is it for you to move around with IV line?</b>								
Very Easy	13 (43.33)	0 (0)	13 (21.67)	<b>0.0001</b>	10 (33.33)	0 (0)	10 (16.67)	<b>0.0001</b>
Easy	9 (30)	0 (0)	9 (15)		12 (40)	0 (0)	12 (20)	
Natural	8 (26.67)	6 (20)	14 (23.33)		8 (26.67)	6 (20)	14 (23.33)	
Difficult	0 (0)	17 (56.67)	17 (28.33)		0 (0)	15 (50)	15 (25)	
Very Difficult	0 (0)	7 (23.33)	7 (11.67)		0 (0)	9 (30)	9 (15)	
<b>Does the IV line restrict your mobility compared to not using it?</b>								
Not at all	10 (33.33)	0 (0)	10 (16.67)	<b>0.0001</b>	15 (50)	0 (0)	15 (25)	<b>0.0001</b>
Slightly	13 (43.33)	0 (0)	13 (21.67)		12 (40)	0 (0)	12 (20)	
Moderately	7 (23.33)	3 (10)	10 (16.67)		3 (10)	5 (16.67)	8 (13.33)	
Significantly	0 (0)	14 (46.67)	14 (23.33)		0 (0)	10 (33.33)	10 (16.67)	
Completely	0 (0)	13 (43.33)	13 (21.67)		0 (0)	15 (50)	15 (25)	
<b>Can you perform basic activities (e.g., walking, sitting, standing) with the IV line?</b>								
Yes without any difficulty	13 (43.33)	0 (0)	13 (21.67)	<b>0.0001</b>	11 (36.67)	0 (0)	11 (18.33)	<b>0.0001</b>
Yes with some difficulty	11 (36.67)	0 (0)	11 (18.33)		10 (33.33)	0 (0)	10 (16.67)	
Neutral	6 (0)	5 (16.67)	11 (18.33)		9 (30)	5 (16.67)	14 (23.33)	
No with difficulty	0 (0)	14 (46.67)	14 (23.33)		0 (0)	15 (50)	15 (25)	
No with significant difficulty	0 (0)	11 (36.67)	11 (18.33)		0 (0)	10 (33.33)	10 (16.67)	

n (%) – Number (percentage); <sup>#</sup> Chi-Square test for Independence was used to evaluate associations between Groups-A and B in pediatric and adult populations. Significant at 5% level

**Table 4: Comfortability and Discomfort Levels with IV Lines and IV-Line Organizers among Pediatric and Adult Patients**

Comfort	Pediatric				Adults			
	Group-A n (%)	Group-B n (%)	Total n (%)	p-value <sup>#</sup>	Group-A n (%)	Group-B n (%)	Total n (%)	p-value <sup>#</sup>
<b>How comfortable do you feel using the IV line?</b>								
Very Comfortable	13 (43.33)	0 (0)	13 (21.67)	<b>0.0001</b>	12 (40)	0 (0)	12 (20)	<b>0.0001</b>
Comfortable	12 (40)	0 (0)	12 (20)		14 (46.67)	1 (3.33)	15 (25)	
Neutral	5 (16.67)	4 (13.33)	9 (15)		4 (13.33)	6 (20)	10 (16.67)	
Uncomfortable	0 (0)	14 (46.67)	14 (23.33)		0 (0)	11 (36.67)	11 (18.33)	
Very uncomfortable	0 (0)	12 (40)	12 (20)		0 (0)	12 (40)	12 (20)	
<b>Does the IV line cause any discomfort or pain?</b>								
Not at all	10 (33.33)	0 (0)	10 (16.67)	<b>0.0001</b>	15 (50)	0 (0)	15 (25)	<b>0.0001</b>
Slightly	13 (43.33)	0 (0)	13 (21.67)		12 (40)	0 (0)	12 (20)	
Moderately	7 (23.33)	3 (10)	10 (16.67)		3 (10)	5 (16.67)	8 (13.33)	
Significantly	0 (0)	14 (46.67)	14 (23.33)		0 (0)	10 (33.33)	10 (16.67)	
Completely	0 (0)	13 (43.33)	13 (21.67)		0 (0)	15 (50)	15 (25)	
<b>How satisfied are you with the design and usability of the IV-line organizer?</b>								
Very Easy	13 (43.33)	0 (0)	13 (21.67)	<b>0.0001</b>	10 (33.33)	0 (0)	10 (16.67)	<b>0.0001</b>
Easy	9 (30)	0 (0)	9 (15)		12 (40)	0 (0)	12 (20)	
Natural	8 (26.67)	6 (20)	14 (23.33)		8 (26.67)	6 (20)	14 (23.33)	
Difficult	0 (0)	17 (56.67)	17 (28.33)		0 (0)	15 (50)	15 (25)	
Very Difficult	0 (0)	7 (23.33)	7 (11.67)		0 (0)	9 (30)	9 (15)	

n (%) – Number (percentage); <sup>#</sup> Chi-square test for Independence was used to evaluate associations between Groups-A and B in pediatric and adult populations. significant at 5% level

**Table-5 Assessment of Medical Line Entanglement Severity Scale (MLME) in Group-A and Group-B**

	Pediatric			Adults		
	Group-A n (%)	Group-B n (%)	p-value <sup>#</sup>	Group-A n (%)	Group-B n (%)	p-value <sup>#</sup>
<b>Physician MLME Scale</b>						
No Harm (Level 0)	30 (100)	27 (90)	<b>0.001</b>	29 (96.67)	27 (90)	<b>0.035</b>
Potential Harm (level 1)	0 (0)	0 (0)		0 (0)	3 (10)	
Potential harm (Level 2)	0 (0)	2 (6.67)		0 (0)	0 (0)	
Potential harm (Level 3)	0 (0)	1 (3.33)		0 (0)	0 (0)	
Real Harm (Level 1)	0 (0)	0 (0)		1 (3.33)	0 (0)	
<b>Nurse MLME Scale</b>						
No Harm (Level 0)	30 (100)	29 (96.67)	0.206	29 (96.67)	28 (93.33)	<b>0.005</b>
Potential Harm (level 1)	0 (0)	1 (3.33)		0 (0)	2 (6.67)	
Potential harm (Level 5)	0 (0)	0 (0)		1 (3.33)	0 (0)	
<b>Patient MLME Scale</b>						
No Harm (Level 0)	29 (96.67)	29 (96.67)	0.201	29 (96.67)	26 (86.67)	<b>0.050</b>
Potential Harm (level 1)	1 (3.33)	1 (3.33)		0 (0)	4 (13.33)	
Potential harm (Level 3)	0 (0)	0 (0)		1 (3.33)	0 (0)	

n (%) – Number (percentage); <sup>#</sup> Chi-square test for Independence was used to evaluate associations between Groups-A and B in pediatric and adult populations. significant at 5% level

The majority of the physicians reported that the IVO was easy to use both in adults and children, with the response of easy (46.67% vs 60%) and very easy (53.3% vs 40%) between the two groups. Similarly, the nursing staff's ease of usability of the IVO was assessed, and it was found that the majority of nurses find it very easy to use in children compared to adults (63.3% vs 43.3%). However, most of the healthcare providers felt that the IVO was easy to operate and use among the patients. With regards to the safety assessment of the IVO, there was a lower incidence of erythema (6.6% vs 13.3%) and edema (23% vs 30%) among the children and adults groups. The findings show a greater acceptability and usability among healthcare providers and a lower risk of adverse incidence among the study population as shown in **Table-6**.

**Table-6 Assessment of Ease of Operability Score & Skin Irritation in Pediatric and Adult Patients under Group-A and Group B**

	Pediatric	Adults	p-value <sup>#</sup>
	Group-A n (%)	Group-A n (%)	
<b>Physician</b>			
Not Easy	0 (0)	0 (0)	0.438
Hard	0 (0)	0 (0)	
Very Hard	0 (0)	0 (0)	
Easy	14 (46.67)	18 (60)	
Very Easy	16 (53.33)	12 (40)	
<b>Nurse</b>			
Not Easy	0 (0)	0 (0)	0.195
Hard	0 (0)	0 (0)	
Very Hard	0 (0)	0 (0)	
Easy	11 (36.67)	17 (56.67)	
Very Easy	19 (63.33)	13 (43.33)	
<b>Erythema which includes dryness scaliness and wrinkles</b>			
No reaction	28 (93.3)	26 (86.67)	0.510
Very slight	2 (6.67)	0 (0)	
Slight	0 (0)	4 (13.33)	
Moderate	0 (0)	0 (0)	
Severe	0 (0)	0 (0)	
<b>Oedema</b>			
No reaction	23 (76.67)	21 (70)	0.826
Very slight	5 (16.67)	6 (20)	
Slight	2 (6.67)	3 (10)	
Moderate	0 (0)	0 (0)	
Severe	0 (0)	0 (0)	

n (%) – Number (percentage); <sup>#</sup> Chi-square test for Independence was used to evaluate associations between Groups-A and B in pediatric and adult populations. significant at 5% level



**Table 7: Mean Change in Score Comparison in Children and Adult Patients for the Usefulness Domain of the Medical Device Usability Questionnaire Between Group-A and Group-B**

Satisfaction Domain, Mean (SD)	Paediatric				Adults			
	Mean Group-A	Mean Group-B	95% of CI	p-value <sup>#</sup>	Mean Group-A	Mean Group-B	95% of CI	p-value <sup>#</sup>
Q29	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.6 (0.56)	3.63 (0.93)	(2.57 - 3.36)	<b>0.0001</b>
Q30	6.6 (0.62)	4.17 (1.29)	(1.91 - 2.96)	<b>0.0001</b>	6.53 (0.68)	4 (1.23)	(2.02 - 3.05)	<b>0.0001</b>
Q31	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q32	6.1 (0.61)	3.63 (1.19)	(1.98 - 2.95)	<b>0.0001</b>	6.23 (0.68)	3.53 (1.17)	(2.21 - 3.19)	<b>0.0001</b>
Q33	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q34	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.6 (0.56)	3.63 (0.93)	(2.57 - 3.36)	<b>0.0001</b>
Q35	6.63 (0.49)	3.7 (1.18)	(2.47 - 3.4)	<b>0.0001</b>	6.3 (0.65)	3.57 (0.94)	(2.32 - 3.15)	<b>0.0001</b>
Q36	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.4 (0.93)	3.73 (0.98)	(2.17 - 3.16)	<b>0.0001</b>
Q37	6.5 (0.68)	4.2 (1.27)	(1.77 - 2.83)	<b>0.0001</b>	6.3 (0.75)	3.63 (1.22)	(2.14 - 3.19)	<b>0.0001</b>
Q38	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q39	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.6 (0.56)	3.63 (0.93)	(2.57 - 3.36)	<b>0.0001</b>
Q40	6.1 (0.61)	3.63 (1.19)	(1.98 - 2.95)	<b>0.0001</b>	6.23 (0.68)	3.43 (1.07)	(2.34 - 3.26)	<b>0.0001</b>
Q41	6.37 (0.67)	2.67 (1.15)	(3.21 - 4.19)	<b>0.0001</b>	6.33 (0.66)	2.43 (1.1)	(3.43 - 4.37)	<b>0.0001</b>
Q42	6.33 (0.76)	2.9 (1.21)	(2.91 - 3.96)	<b>0.0001</b>	6.27 (0.74)	3.43 (1.19)	(2.32 - 3.35)	<b>0.0001</b>

SD- Standard deviation; CI- Confidence interval <sup>#</sup> Independent t-tests were conducted to assess mean differences between Groups-A and B; significant at 5% level; significant at 5% level

**Table-8 Mean Change in Score Comparison in Children and Adult Patients for the Ease- of-Use Domain of the Medical Device Usability Questionnaire Between Group-A and Group-B**

Ease of Use Domain Mean (SD)	Paediatric				Adults			
	Mean Group-A	Mean Group-B	95% of CI	p-value <sup>#</sup>	Mean Group-A	Mean Group-B	95% of CI	p-value <sup>#</sup>
Q13	6.9 (0.31)	4.1 (1.24)	(2.33 - 3.27)	<b>0.0001</b>	6.47 (0.73)	3.97 (0.96)	(2.06 - 2.94)	<b>0.0001</b>
Q14	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.4 (0.93)	3.73 (0.98)	(2.17 - 3.16)	<b>0.0001</b>
Q15	6.1 (0.61)	3.63 (1.19)	(1.98 - 2.95)	<b>0.0001</b>	6.23 (0.68)	3.53 (1.17)	(2.21 - 3.19)	<b>0.0001</b>
Q16	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q17	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.4 (0.93)	3.73 (0.98)	(2.17 - 3.16)	<b>0.0001</b>
Q18	6.8 (0.48)	4.07 (1.23)	(2.25 - 3.22)	<b>0.0001</b>	6.4 (0.77)	3.87 (1.14)	(2.03 - 3.04)	<b>0.0001</b>
Q19	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q20	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.6 (0.56)	3.63 (0.93)	(2.57 - 3.36)	<b>0.0001</b>
Q21	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q22	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.6 (0.56)	3.63 (0.93)	(2.57 - 3.36)	<b>0.0001</b>

SD – Standard Deviation; CI – Confidence Interval; <sup>#</sup>Independent Samples t – tests were conducted to assess mean differences between groups-A and B; Significant Level at 5 %

**Table-9 Mean change in Score Comparison in Children and Adult Patients for the Ease-of- Learning Domain of the Medical Device Usability Questionnaire Between Group-A and Group-B**

Ease of Learning Domain Mean (SD)	Paediatric				Adults			
	Mean Group-A	Mean Group-B	95% of CI	p-value <sup>#</sup>	Mean Group-A	Mean Group-B	95% of CI	p-value <sup>#</sup>
Q23	6.3 (0.65)	3.93 (1.17)	(1.88 - 2.86)	<b>0.0001</b>	6.3 (0.65)	3.57 (0.94)	(2.32 - 3.15)	<b>0.0001</b>
Q24	6.63 (0.56)	3.57 (1.25)	(2.57 - 3.57)	<b>0.0001</b>	6.37 (0.76)	3.7 (1.06)	(2.19 - 3.14)	<b>0.0001</b>
Q25	6.1 (0.61)	3.63 (1.19)	(1.98 - 2.95)	<b>0.0001</b>	6.23 (0.68)	3.53 (1.17)	(2.21 - 3.19)	<b>0.0001</b>
Q26	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q27	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.6 (0.56)	3.63 (0.93)	(2.57 - 3.36)	<b>0.0001</b>
Q28	6.03 (0.76)	4.1 (0.92)	(1.5 - 2.37)	<b>0.0001</b>	5.97 (0.81)	3.93 (0.74)	(1.63 - 2.43)	<b>0.0001</b>

SD- Standard deviation; CI- Confidence interval <sup>#</sup>Independent t-tests were conducted to assess mean differences between Groups-A and B; Significant at 5% level

**Table-10 Mean change in Score Comparison in Children and Adult Patients for the Satisfaction/Intention to use Domain of the Medical Device Usability Questionnaire Between Group-A and Group-B**

Satisfaction Domain, Mean (SD)	Paediatric				Adults			
	Mean Group-A	Mean Group-B	95% of CI	p-value <sup>#</sup>	Mean Group-A	Mean Group-B	95% of CI	p-value <sup>#</sup>
Q29	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.6 (0.56)	3.63 (0.93)	(2.57 - 3.36)	<b>0.0001</b>
Q30	6.6 (0.62)	4.17 (1.29)	(1.91 - 2.96)	<b>0.0001</b>	6.53 (0.68)	4 (1.23)	(2.02 - 3.05)	<b>0.0001</b>
Q31	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q32	6.1 (0.61)	3.63 (1.19)	(1.98 - 2.95)	<b>0.0001</b>	6.23 (0.68)	3.53 (1.17)	(2.21 - 3.19)	<b>0.0001</b>
Q33	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q34	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.6 (0.56)	3.63 (0.93)	(2.57 - 3.36)	<b>0.0001</b>
Q35	6.63 (0.49)	3.7 (1.18)	(2.47 - 3.4)	<b>0.0001</b>	6.3 (0.65)	3.57 (0.94)	(2.32 - 3.15)	<b>0.0001</b>
Q36	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.4 (0.93)	3.73 (0.98)	(2.17 - 3.16)	<b>0.0001</b>
Q37	6.5 (0.68)	4.2 (1.27)	(1.77 - 2.83)	<b>0.0001</b>	6.3 (0.75)	3.63 (1.22)	(2.14 - 3.19)	<b>0.0001</b>
Q38	6.33 (0.48)	4.3 (1.15)	(1.58 - 2.49)	<b>0.0001</b>	6.13 (0.51)	3.87 (1.04)	(1.84 - 2.69)	<b>0.0001</b>
Q39	6.63 (0.56)	3.63 (1.27)	(2.49 - 3.51)	<b>0.0001</b>	6.6 (0.56)	3.63 (0.93)	(2.57 - 3.36)	<b>0.0001</b>
Q40	6.1 (0.61)	3.63 (1.19)	(1.98 - 2.95)	<b>0.0001</b>	6.23 (0.68)	3.43 (1.07)	(2.34 - 3.26)	<b>0.0001</b>
Q41	6.37 (0.67)	2.67 (1.15)	(3.21 - 4.19)	<b>0.0001</b>	6.33 (0.66)	2.43 (1.1)	(3.43 - 4.37)	<b>0.0001</b>
Q42	6.33 (0.76)	2.9 (1.21)	(2.91 - 3.96)	<b>0.0001</b>	6.27 (0.74)	3.43 (1.19)	(2.32 - 3.35)	<b>0.0001</b>

SD – Standard deviation; CI – Confidence interval <sup>#</sup>Independent t-tests were conducted to assess mean differences between Groups A and B; significant at 5% level

Tables 7, 8, 9, and 10 showed the mean change in the score of medical device usability between Groups-A and B. The composite analysis of the metrics found that 87.2% of patients in the group found the device useful in their overall performance. On easy-of-use and learning domains, a significant proportion of patients (95%) in Group-A reported very easy use and learning in a shorter period. Overall satisfaction with the IVO among Group-A was significantly higher compared to the conventional IV line method (94% vs 43%) among the children and adults.

## Discussion

In recent years, many studies have highlighted the potential risk of medical line entanglement and its negative impact on the patient's outcome. However, there remains a paucity of medical devices to intervene and prevent the medical lines' entanglement. Through a problem-solving approach, we designed the IVO, which is comprised of a clamp or hook that is provided to encircle and accommodate the IV lines and other tubes. The IVO can be readily wearable on wrists and upper arms, which helps to mount and suspend the lines off the floor and entangling. [10] In this study, we evaluated the clinical performance of the IVO and its safety among children and adults.

Studies have shown that only a single line is enough to cause harm and all the patients enrolled in the study have at least one medical line. In this study, the mean age of children was 9 years. Patients from birth to toddlers, and primary school children are prone to most entanglements compared to that of other age groups. Children are naturally very active in the closed space of their cribs and have unintentional bodily movement, which poses a higher risk for line tangling, wrapping around the body, and likely incidence of ligature injuries compared to other age groups. [7] On the medical line entanglement severity scale, 3 out of 30 patients (10%) facing potential harm of levels 2 & 3 were in the standard of care group (without IVO), and almost all the patients in the IVO group did not have any entanglement among the children and adults. On ease of operability, the IVO has demonstrated better results and is very easy to learn and use, which makes it user-friendly among children and adults. [8]

Conventional IV lines and tubes require physical restrictions like sitting, standing, and walking to prevent line dislodgement and catheter failure. However, the IVO reduced such physical restrictions and allowed greater mobility among the study participants. Also, patients showed more autonomy in making any independent decisions by managing the IV line by themselves and a higher satisfaction level was found among healthcare providers in avoiding the "spaghetti syndrome" at the workspace. [11, 12]

The study paves the way for longitudinal research and explores the extent of usability, performance, and long-term safety profile at minimizing the medical line entanglement throughout the hospital stay. Our research was conducted in a controlled, clinical trial based on the pediatric and adult medical line safety model to evaluate the safety and effectiveness of innovative IVO devices in preventing entanglements and straightening the lines.

## Conclusion

The entanglement of medical lines and tubes poses a significant threat to the healthcare system causing unintentional consequences to the patients. The IVO has reduced the potential entanglement and demonstrated improvement in the patient's autonomy, mobility, and comfort in managing the IV lines. This study provides empirical evidence on the clinical performance and safety of the IVO in improving clinical outcomes.

## Acknowledgements

The authors thanked the Sapthagiri Institute of Medical Sciences and Research Centre for supporting this research. The authors thank CRO Pharexcel Consulting Private Limited. The funders had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

## Conflict of Interest – None

## Source of funding – Self funding

**Authors' Contributions:** Derryl Burke conceived the study, made the device, and drafted the manuscript. Baburao Vikram designed the statistical analysis, interpreted the results, and helped draft the manuscript. Dr Shruthi Shetty and Dr. Priyanka participated in the design and coordination of the study and helped draft the manuscript. Dr Renuka participated in the design and coordination of the study. All authors read and approved the final manuscript.

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**Data Declaration:** Data were preserved as confidential by the authors in the concern department.

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