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Assessment of Intravenous High-Risk Medication Management In A Tertiary Care Hospital

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ABSTRACT

Iatrogenic harm induced from medication occurs at a rate of more than one fourth in general wards and more than three fourth in ICUs, it estimated that during a critical care stay 1.7 medication errors per patient could be potentially life-threatening especially from drug given intravenously. We Aimed to assess the intravenous high-risk medication management in tertiary care hospital, and analyze utilization of IV high-risk medication dilution, diluent and duration. Prospective controlled study involving 250 participants evaluated the utilization patterns of intravenous high-risk medications in equal divided groups, with a focus on dilution practices, diluent selection, and duration of administration in a critical care unit over a period of six months. A researcher observed this study by reviewing all the Patient Infusion Charts, Critical Care Flow Sheet and Syringe pump/infusions. Baseline severity was assessed using APACHE II and qSOFA scores. Categorical variables were analyzed using the Chi-square test. A total of 250 participants were enrolled and equally allocated into two groups 125 intervention and 125 Control. Analyzing the baseline clinical severities parameters including APACHE II scores ($p = 0.845$) and qSofa ($p = 0.589$) were distinguished between groups. No statistically significant differences were observed in primary clinical outcomes such as mortality ($p =0.447$) or discharge status ($p = 0.609$). A researcher independent double-checking before medication administration was documented in 81 (64.8%) intervention patients compared to 79 (63.2%) control patients ($p =0.895$). In conclusion, primary outcomes were not statistically indistinct between the study groups, pharmacist-led observation and independent double-checking protocols established structured standardization in IV drug dilution, diluent selection, and infusion rate monitoring. Further research using more sensitive methods to assess key variables will provide a clearer and more comprehensive understanding of the true impact of pharmacist-led care on clinical outcomes.

Keywords: High-Risk Medications; Intensive Care Units; Infusions; Patient Safety

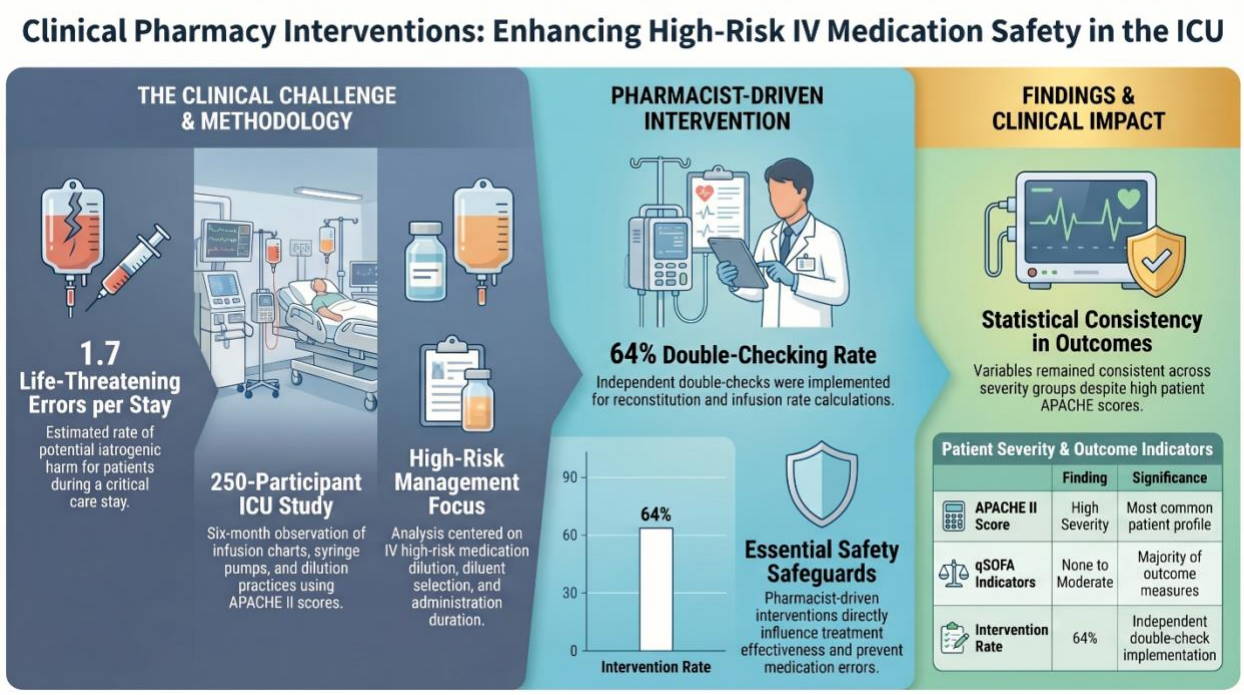
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INTRODUCTION

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Medication-related harm remains one of the most serious yet preventable challenges in healthcare worldwide. These events can range from minor incidents with no patient harm to severe, life-threatening outcomes, including death. Despite being largely avoidable, medication-related errors continue to place a substantial burden on healthcare systems, with global costs estimated at nearly $42 billion each year.[1] The Institute of Medicine (IOM) report: "To Err Is Human" unveiled that approximately 98000 patients die every year in the U.S. due to medication error. This report reinforced healthcare efforts on patient safety. [2] Medication errors occurred at different stages of the medication-use processes, including prescribing, transcribing, dispensing, administering, and monitoring [3,4]. In critical care units (CCUs), they were the most common type of medical error and accounted for 78% of serious Intervention Group, mainly due to continuous infusions [5,6]. Critical care patients often require high-risk medications, which necessitate careful use and close monitoring because of their potential to cause significant harm. These patients typically required immediate intensive care to support vital organ function during life-threatening conditions where any error could not be afforded[i].[7] The concept of high-risk medications was officially recognized by the Institute for Safe Medication Practices (ISMP) in 1990.[8] These are life-saving interventions that clinically refer to an escalating risk that causes significant patient harm. Patients require immediate intensive monitoring and treatment to support vital organ functions from a life-threatening disease.[9] Commonly used concentrated electrolytes include potassium chloride 15%, dextrose 25%, and magnesium sulfate 20%.[10] According to ISMP, administering potassium chloride at concentrations greater than 2 mmol/ml can cause fatal cardiac arrhythmias, tissue damage, and extravasation injuries, necessitating strict storage, preparation, and administration protocols.[11] Inotropic agents such as Noradrenaline, Dopamine and Dobutamine are used to regulate blood pressure. [12] However, nalbuphine, a narcotic analgesic, is used during mechanical ventilation.[13] Among high-risk medications, intravenous drugs require continuous vigilance through regular checking of infusion charts, whether administered by infusion pumps or manual IV sets. In critical care settings, error rates for high-risk intravenous medications range from 0.24 to 89.6 errors per 100 prescriptions.[14] Medication administration errors are five times more frequent with intravenous (IV) routes compared to non-IV routes.[15] Infusion pumps and syringe pumps are widely used in clinical settings, particularly for pediatric and elderly ICU patients, to maintain steady drug delivery even in small doses.[16] Nurses routinely operate these devices, which often include drug libraries to prevent infusion rates that are too high or too low.[17],[18] It is estimated that during a critical care stay, 1.7 medication errors per patient could be potentially life-threatening. [19,20] In India,

medication errors occur at a rate of 28% in general wards and 78% in ICUs, with incidence rates ranging from 8.2 to 2344 per 1000 patient days. [21] Therefore, in this study we aim to assess the intravenous high-risk medication management in tertiary care hospital, and analyze utilization of IV high-risk medication dilution, diluent and duration.



The visual abstract was created with AI-assisted support using NotebookLM, while the authors oversaw the final validation, interpretation, and presentation of the content.

MATERIALS AND METHOD

This study employed a six-month prospective non-randomized controlled study to assess the utilization of IV high-risk medication management and to analyze high-risk medication dilution, diluent, and duration in the critical care unit between the period from Nov 2025 to April 2026. This study was approved by the Institutional Ethics Committee at the Maharishi Markandeshwar Institute of Medical Sciences & Research (MMIMSR), Mullana, Ambala, India. (Project No.: IEC-3069). The study was conducted in a tertiary care hospital. Participants were selected based on the following criteria. Inclusion: patients of all ages admitted to the critical care unit who were prescribed at least one parenteral high-risk medication for their clinical condition. Exclusion: patients who were unwilling to provide informed consent, were pregnant or breastfeeding, had a mental condition affecting their ability to consent, or were receiving treatment in the outpatient department (OPD). The data were gathered through the following methods: A Pre-designed Structured Data Collection Form was used to review patient information including: Prior collecting; information from the patients, a researcher observed by

reviewing all the Patient Infusion Charts, Critical Care Flow Sheet and Syringe pump or infusions. Also, double-checking during administration were an important part during documentation. Similarly, method of preparation (dosing & diluent), ml/hr was also taken into consideration in the critical area. The baseline information was collected from the all-patients' records from admission to discharge. An investigator reviewed patient case records. Data included demographics (patient ID, age, gender, clinical presentation and diagnosis), medication details (drug name, route, dilution), and infusion data (rate, duration). Laboratory parameters included Hb, Hct, TLC, Na^+, Cl^- and serum creatinine. Arterial blood gas values included pH, $PaCO_2$, PaO_2 and HCO_3^-. Outcomes included discharge status and hospital stay duration. Severity was assessed using APACHE II and qSOFA scores. Data were entered into Microsoft Excel 2021. Categorical variables were analyzed using the chi-square test. Descriptive analysis was used to compare case and control groups and summarize the data. A p-value > 0.05 was considered not statistically significant.

RESULTS

A total of 250 participants were enrolled into two groups that equally divided into 125 participants in Intervention and control group. In line with research methodology, the study investigated specific variables, including age-gender related segregation. The interventional group included 1 patient (0.8%), 70 patients (56%) aged between 0–17 years, 18–60 years, and 54 patients (43.2%) aged above 61 years. However, the control group included 5 patients (4.0%) aged 0–17 years, 61 patients (48.8%) aged 18–60 years, and 59 patients (47.2%) aged above 61 years. the majority of participants in both groups were adults and elderly, with minimal pediatric representation. Additionally, regarding gender distribution, the control group comprised 71 males (56.8%) and 54 females (43.2%), while the intervention group comprised 69 males (55.2%) and 56 females (44.8%). The baseline demographic characteristics were comparable between the control and intervention groups.

High-risk medication

Table 3.1 distribution of High-Risk Medications among study group. Among 250 Inotropic drug receiving participants, 202(80.8%) received Noradrenaline Bitartrate, which infused intravenously by syringe pump, whereas 48 (19.2%) did not receive any infusion intravenously. In group-wise distribution, the control group (83.2 %) was received, compared to (78 %) in the intervention group. A statistical Chi-square test applied ($p>0.05$) which represent a p value = 0.422, χ^2 (p value = 0.422) between the two variables. Among 250 Neuromuscular blocker receiving agent participants; 82 (32.8%) were received Atracurium Besylate, and 168

participants (67.2%) did not receive any Atracurium Besylate. In the control group, 30.4% receive Atracurium, compared to (35.2%) in the intervention group. A Chi-Square test was applied, which exhibits (p-value > 0.05), χ^2 (p-value = 0.501). Among 250 cardiogenic blocker receiving agent participants 213 participants (85.2%) did not receive Dobutamine or Dopamine whereas 8 patients (3.2%) receive it. Moreover, group distribution possesses 7 patients 5.6 % receive intravenous infusion in Intervention group and 1 control patient (0.8) received intravenous infusion. In contrast, 13 patients (10.4%) receive Dopamine intravenously in Intervention group and 16 patient 12.8% receive intravenous infusion in control group. A Chi-Square test p-value of .088 (p >0.05). Among 250 Antidiuretics blocker receiving agent participants, 216 not receive Vasopressin infusion intravenously. In fact, in the case group (111) did not receive, while 14 patients (11.2%) received it. While, 105 Control Group (84%) did not receive any intravenous infusion, 20 Control Group (16%) received intravenous infusion Vasopressin. A Pearson Chi-Square test χ^2 (p value = .356). Among 250 opioid analgesic receiving agent participants, 203 (81.2 %) patients not receive any infusion, whereas 47 (18.8%) patients infused Nalbuphine, primarily in the intervention groups, 22 (17.6) % receive intravenous infusion and 25 (20%) control receive it. A chi-square p- value between case and opioid Analgesic is .746.

Table 1: Distribution of High-Risk Medications Among Study Groups

High-Risk Medication Category	**Medication**	**Intervention Group** *n (%)*	**Control Group** *n (%)*	**Total** *n (%)*
Inotropic Drugs	None	27	21	19.2
	Noradrenaline Bitartrate	98	104	80.8
Neuromuscular Blocking Agents	None	81	87	67.2
	Atracurium Besylate	44	38	32.8
Cardiogenic Agents	None	105	108	85.2
	Dobutamine	7	1	3.2
	Dopamine	13	16	11.6
Antidiuretics	None	111	105	86.4
	Vasopressin	14	20	13.6
Opioid Analgesics	None	103	100	81.2
	Nalbuphine	22	25	18.8

Abbreviations: SD = Standard Deviation. Data are presented as frequency distribution of high-risk medication exposure among Intervention Group and Control Group.

Table 3.2 illustrates the distribution of patients among 250 patients with each case and control group according to their duration of hospital stay in days. The predominant number of patients (n=125) experienced a hospital stay of merely 1 day (170), 2 days (33), 3 days (5), 4 days (14), 5 days (7) >5 days (20) signifying that short-term admissions were the most prevalent. A gradual

decrease in frequency was noted as the length of stay increased, with only a handful of patients remaining beyond 5 days (19). Very few patients had prolonged stays, with only 1 to 2 patients reaching 11, 12, or 15 days.

Patients with an APACHE score ranging from 25 to 100 were primarily included in the case groups (n=104), while the control group was largely represented in the moderate (15-24, n=82) and low (0-14, n=64) score categories. The primary comparison within the case group revealed that the APACHE score of 25-100 was noted in 51 Intervention Group, 15-24 in 40 Intervention Group, and 0 to 14 in 34 Intervention Group. In contrast, the control group exhibited an APACHE score of 25-100 in 53 Control Group, 15-24 in 42 Control Group, and 0-14 in 30 Control Group. Furthermore, an analysis was conducted to ascertain the relationship between Intervention Group and APACHE scores, utilizing the Chi-Square test which yielded a p-value of .845, indicating no statistically significant association ($p>0.05$). Consequently, no significant changes were observed when employing all the phenomena used to predict the mortality rate of patients based on their scores.

Outcome Measures – Predicted Mortality Table 3.2 presents the distribution of mortality rates among the case and control groups. Elevated mortality rates (55-85%) were observed in the case groups (n=51) and control groups had (51) subjects within this category. The majority of control subjects were categorized within the 15-24% (n=63) were moderate predicted mortality and 60 in Intervention Group predicted mortality, 0-14% (n=11) mild mortality ranges between control and 14 Intervention Group in Intervention Group with mild predicted mortality. This observation suggests a higher mortality association among 55-85 % then the 123 in (15-24%) as per the APACHE Scoring Criteria. 'Fisher's exact was used for 2x1 tables.

Outcome Measures - Mortality Based on sofa Score Table 3.2 provides a summary of the sofa score distribution among the case and control groups. A significant majority of patients (n=145) exhibited no sofa indicators. Mild to moderate scores (n=47) were more frequently observed in the control group whereas 40 participants were observed severity in Intervention Group. Double-checking documentation in case record file before administration of Intravenous medication were observed in 81 Intervention Group whereas 79 control were documented in Control group. However, 90 participants files were not documented double checking before administration of drug between both groups.

Table 2: Comprehensive Distribution of Clinical Severity Parameters among Intervention Group and Control Group

Clinical Parameter	Categories	Intervention Group *(n = 125)*	Control Group *(n = 125)*	Total *(n = 250)*	*p*-Value
Length of Stay (Days)	1 Day	90	80	170	Nil
	2–5 Days	15	37	52	
	>5 Days	18	7	25	
	11 Days	2	0	2	
	12 Days	0	1	1	
	15 Days	0	0	0	
Predicted Mortality (%)	55–85%	51	51	102	0.805
	15–24%	60	63	123	
	0–14%	14	11	25	
APACHE Score	25–100	51	53	104	.845
	15–24	40	42	82	
	0–14	34	30	64	
qSOFA Score	No Organ Dysfunction	77	68	145	.589
	Mild	22	22	44	
	Moderate	18	25	43	
	Severe	8	10	18	
Double-Checking Before Administration	No	44	46	90	.895
	Yes	81	79	160	

Abbreviations: APACHE = Acute Physiology and Chronic Health Evaluation; qSOFA = Quick Sequential Organ Failure Assessment. Categorical variables are presented as frequencies. Statistical significance between Intervention Group and Control Group was assessed using the Chi-square test. A *p*-value <0.05 was considered statistically significant.

Table 3: Distribution of Health Outcome Measures Among Study Groups

Health Outcome Measure	Group	Yes *n (%)*	No *n (%)*	Total *(n)*	*p*-Value
Discharge Status	Case	55	69	125	.609
	Control	51	74	125	
	Total	106	143	250	
Mortality (Death)	Case	62	63	125	.447
	Control	69	56	125	
	Total	131	119	250	

Data are presented as frequencies of clinical health outcomes among Intervention Group and Control Group. Statistical significance was evaluated using the Chi-square test. A *p*-value <0.05 was considered statistically significant.

The comparison of health outcomes between Intervention Group and Control Group demonstrated no statistically significant differences in either discharge status or mortality. Discharge outcomes were comparable between the two groups (p = .609), indicating similar recovery patterns and hospitalization trajectories. Similarly, mortality analysis had showed no significant difference between the study groups (p = .447), indicating comparable overall

survival outcomes across the study population. Although minor numerical differences were observed as small sample size, the clinical outcomes in both groups remained statistically similar throughout the study period. 'Fisher's exact was used

Table 4: Comprehensive distinction among Dilution, Diluent and Duration

Drug	Diluent	Rate of Infusion	Concentration	Intervention Group (n)	Control (n)
Noradrenaline Bitartrate	D5% and NS 0.9% 42 ml	0.75 to 7.5 ml/hr	2-20 mcg/min	98	104
Atracurium besylate	NS 0.9% 25 ml	3 to 8 ml	Loading dose 0.5 mg/kg Infusion 0.30 – 0.8 mg/kg/hr	81	87
Dobutamine	NS 40ml	0.7 to 8ml/hr	2-20 mcg/kg/min	7	1
Dopamine	NS 40 ml	1 to 10 ml/hr	4 mg/ml (2-20 mvg/kg/min)	13	16
Vasopressin	NS 38 ml	0.6 to 2.4 ml/hr	0.01 to 0.04 unit/min	14	20
Nalbuphine	NS 38 ml	4-40 ml/hr	5-15 mg/hr	22	25

DISCUSSION

The present study evaluated the utilization of high-risk medications, clinical severity indicators, and health outcomes among critically ill patients admitted to intensive care settings. Participants across all age groups were equally categorized by gender, with both male and female representation among all participants. The findings demonstrated frequent administration of high-risk medications such as noradrenaline bitartrate, atracurium besylate, vasopressin, dobutamine, and nalbuphine, reflecting the complexity of pharmacotherapeutic management in critically ill patients. Among these various drugs, noradrenaline was found most frequently utilized medication, indicating the high prevalence of hemodynamic instability and vasopressor dependence in the study population. Similar observations have been reported in previous ICU-based investigations where vasoactive medications and sedative agents constituted a substantial proportion of high-risk drug utilization in critically ill patients.[22]

Atracurium Besylate Infusions in this study were appropriately prepared using 0.9% Normal saline (NS) to achieve a concentration of 2.5 mg/mL (25). Infusion rates ranged from 3–8 mL/hr and were administered in both the case group (44) 35.2% and the control group (38), 30.4%. All patients received an appropriate loading dose ranging from 0.3 to 0.8 mg/kg/hr. No statistically significant differences were observed between the groups, and the medication was safely administered without adversely affecting Patient Outcomes. Intramuscular administration was avoided due to the risk of severe tissue irritation. Previous studies have validated that continuous

atracurium infusion at approximately 4.25 µg/kg/min achieves 90% Neuromuscular blockade with a steady-state plasma concentration of 1.13 µg/mL, while an infusion rate of 0.59 mg/kg/hr has been reported to provide adequate Neuromuscular blockade in ICU Patients.[23]

Dobutamine Dilution Practices were also performed appropriately using 42 mL of either NS or 5% dextrose in water (D5W) with two 50 mg/mL vials for all Participants. No statistically significant differences were identified between the study groups. All Preparation and Administration procedures complied with ICU hospital protocols. Intravenous Dobutamine Administration was observed in Intervention Group (7) 5.6% and Control Group (1), 0.8%, with infusion doses ranging from 2–20 µg/kg/min and titration up to 40 µg/kg/min at infusion rates of 0.7–8 mL/hr. Supporting Evidence from the European Journal of Hospital Pharmacy demonstrated that 10 mg/mL dobutamine solutions prepared with NS or D5 remained chemically and physically stable for up to 12 months when stored in cyclic-olefin copolymer (COC) vials. -[24]

Although double-checking before medication administration was performed that has shown no statistically significant association with the outcome measure was observed (Pearson Chi-square, $p = 0.895$), likely due to the limited sample size. However, Wheeler et al. (2005) highlighted that protocols alone may not adequately prevent medication errors without independent double-checking. Failure to perform this verification step can lead to unnoticed mistakes in drug reconstitution, infusion rate calculations, and diluent selection, potentially compromising patient safety.[25]

Although the outcome measures showed no significant differences between the groups, previous studies have consistently demonstrated that higher APACHE $p = 0.845$ and qSOFA $p=0.589$ scores are associated with poorer prognosis, longer ICU stays, and increased mortality risk.[26] In the present study, the similar severity profiles observed between Intervention Group and Control Group may explain the comparable discharge and mortality $p =0.447$ outcomes. However, the lack of a significant association in this study suggests that hospital stay is likely influenced by multiple factors beyond medication exposure alone, such as baseline comorbidities, severity of infection, degree of organ dysfunction, and the quality of supportive care provided.

High-risk medications such as vasoactive agents and neuromuscular blockers require close monitoring because of their narrow therapeutic index and potential for serious adverse effects. The present study highlights the considerable use of these medications and emphasizes the importance of assessing clinical severity in critically ill patients. Although no significant differences in outcomes were observed between Intervention Group and Control Group, the

findings reinforce the need for strong medication safety practices, multidisciplinary collaboration, and evidence-based critical care approaches to optimize outcomes and reduce preventable medication-related harm.

CONCLUSION

This study examined the parenteral use of high-risk medications in critically ill patients within an intensive care setting. However, key clinical findings including overall mortality ($p = 0.447$) and length of hospital stay, APACHE II scores $p = 0.845$), and Qsofa scores ($p = 0.589$) did not describe statistically significant difference between the intervention and control groups, the implementation of clinical pharmacy oversight supported the standardization of medication administration practices. evaluated interventions aimed at ensuring safe and appropriate infusion practices. clinical pharmacist involvement helped identify and correct inappropriate practices in the preparation and administration of several critical medications, including inotropes, muscle relaxants, cardiogenic agents, opioid analgesics, antidiuretics, and other high-risk drugs. The study also highlights the need for a clearer categorization of high-risk medications, including those requiring close monitoring, to further enhance medication safety. These interventions were particularly important in optimizing dilution methods and infusion durations, both of which are essential for safe and effective therapy in critically ill patients.

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