

Original Article

Albumin Utilization Evaluation in a Teaching University Hospital in Iran



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ABSTRACT

Background: Human albumin solution (HAS) is an expensive colloidal preparation that is commonly used in clinical practice. Given the high cost of albumin and its rising worldwide use, it is imperative to establish a practical protocol to improve the rational use of albumin products. This study aimed to identify albumin utilization patterns in a teaching hospital and to demonstrate the importance of revisiting strategies for albumin administration.

Objectives: This study aimed to identify albumin utilization patterns in a teaching hospital and to demonstrate the importance of revisiting strategies for albumin administration.

Methods: This retrospective study was conducted between March 20, 2023, and March 19, 2024, at Imam Khomeini Educational Hospital, an affiliated hospital of Mazandaran University of Medical Sciences, Sari City, Iran. All albumin forms completed during the study period were enrolled for appropriateness evaluation in accordance with the protocol developed by the Iranian Food and Drug Administration.

Results: In 82 patients (32.1%), serum albumin levels were greater than 2.5 g/dL at the time of albumin administration, of which 56% were above the recommended cut-off for the indication. Among 313 albumin prescriptions, in 7 cases (2.3%), albumin administration was not based on any official indication listed in the protocol. Albumin level less than 2.5 g/dL for 3 days (25.4%), ascites or generalized edema (24.4%), and hepatorenal syndrome (HRS) (13%) were the most common reasons for albumin administration. The daily albumin dose ranged from 1 vial of 20% to 5 vials, averaging 19 g/d. Only one patient (0.3%) had the duration of albumin treatment stated, and no patient had their albumin levels rechecked 72 hours after administration.

Conclusion: This study showed significant deviations from the albumin prescription protocol. Some aspects of albumin prescribing, including the minimum cut-off for starting albumin, the duration of use, and rechecking the albumin level, were not adequately considered by physicians. These findings highlight a more sophisticated focus on albumin prescribing in an attempt to minimize the irrational prescription of this expensive and valuable drug.

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Introduction

Drug utilization evaluation (DUE) studies assess the appropriateness of a particular prescribed drug indication, the drug's dosage, the length of treatment, and drug-related monitoring [1]. The clinical needs of patients and reliable guidelines should be the basis for prescribing medications [2]. Recently, DUE studies have gained popularity as a useful technique for determining if drug use is appropriate in the course of treatment [3].

The [World Health Organization \(WHO\)](#) defines drug utilization as the marketing, distribution, prescription, and use of drugs in society, considering medical, social, and economic consequences [4]. DUE research holds particular importance for expensive drugs and those with a narrow therapeutic index, given their larger clinical impact and financial burden on healthcare systems [5].

Albumin is the most abundant protein in the blood and makes up approximately 50% of all plasma proteins. It is synthesized by the liver, secreted immediately without storage, and is physiologically regulated by nutritional status and colloid osmotic pressure. Normal blood plasma concentrations range from 3.5 to 5 g, and 60% of total albumin is found in the interstitial space [6].

Human albumin solution (HAS) is a colloidal preparation with a high cost and is commonly used clinically. HAS comes in 5%, 20%, and 25% formulations, each with unique physiologic properties that should not be used interchangeably. The applications of 5% solutions with osmotic pressure equal to that of normal plasma differ significantly from those of the hyperosmotic 20% and 25% solutions [7]. It is essential to establish a workable protocol for using albumin products and limit their use due to their high cost, the rise in inappropriate use, the difficulty of their production, the risk of disease transmission, and the availability of other affordable alternatives with the same effectiveness [7]. Misuse of albumin places an excessive financial burden on health systems and is a significant pharmacoeconomic issue, especially during periodic shortages in Iran and globally, alongside limited supply resources [8, 9].

Albumin, as a colloid solution, offers greater benefits than non-protein colloids in both efficacy and safety [7-11]. Nonetheless, albumin is misused in several clinical conditions: Pancreatitis, ascites that responds to diuretic therapy, nephrotic syndrome that is not linked to hypovolemia and or pulmonary edema, and the treatment of

malnutrition in critically ill patients [1, 7, 12]. Several studies have reported albumin misuse in the literature, showing its negative clinical and economic impacts [9, 10, 11, 13, 14]. According to a study conducted in Brazil, about 55.1% of cases were inappropriate for albumin request [14]. This misuse could be attributed to the absence of collective protocols defining appropriate albumin indications to guide healthcare providers, as well as the lack of restrictive strategies for prescribing and dispensing albumin [15]. Following clinical guidelines minimizes inappropriate albumin use. Clinical pharmacists and PharmDs play a critical role in improving albumin usage, optimizing medication management, enhancing patient outcomes, and reducing unnecessary drug use or hospital stays [16, 17]. A small number of studies examined the effects of clinical pharmacist interventions on albumin use in intensive care units (ICUs) and found that these interventions resulted in both favorable clinical and financial outcomes [11, 15]. This study aimed to assess albumin use and evaluate compliance with FDA-approved guidelines in hospitalized patients.

Materials and Methods

This research was a retrospective study of patients receiving albumin at [Imam Khomeini Educational Hospital](#), affiliated with [Mazandaran University of Medical Sciences](#), Sari City, Iran. The recruitment period was from March 20, 2023, to March 19, 2024. Data were collected from the albumin request form completed by various departments and sent to the Pharmaceutical Care Department.

The reason for choosing this time was that the hospital mainly supplied albumin and had no significant restrictions on its supply, so patients did not need to visit pharmacies outside the hospital to obtain it.

We gathered information on albumin utilization using a standardized albumin prescribing form, developed by the [Iranian Food and Drug Organization](#) and based on validated references [18, 19], and made it available to hospitals to promote rational albumin prescribing.

Since there is no comprehensive international guideline available regarding the rational indications of albumin usage, the appropriateness of albumin prescription was evaluated using the latest evidence-based studies and guidelines [7-12]. The appropriate and inappropriate indications are shown in [Table 1](#).

The quantitative variables examined in this study were age, weight, initial albumin level, total protein level, prescribed albumin dose, and duration of albumin administration. The qualitative variables examined included gender, hospitalization department, and indication for albumin administration. Blood serum albumin levels were measured before administering albumin and rechecked 72 hours after the first dose.

Data were transferred to SPSS software, version 20 for statistical analysis. The Shapiro-Wilk test was used to assess the data distribution. The descriptive assessment was reported as Mean±SD for numerical variables and as median for numerical variables; numbers and percentages were reported for nominal variables.

Results

Demographic features of patients were presented in Table 2. Of the 313 included patients, 55% were male. The patient age range was 11 to 98 years, with an average age of 61 years. Approximately 60% of the patients were older than 60 years.

The departments that prescribed albumin the most were ICUs (43%, total of 4 departments); hematology, oncology, and oncosurgery (26.9%); and internal medicine departments (16.4%) (Figure 1).

Table 3 presents the indications for albumin administration based on the items mentioned in the albumin request form. Albumin level less than 2.5 g/dL for 3 days (25.4%), ascites or generalized edema (24.4%), and hepatorenal syndrome (HRS) (13%) were the most common reasons for albumin administration. In 7 cases (2.3%), albumin administration was not based on any of the official indications mentioned in the form.

The patients' minimum albumin level at the start of albumin therapy was 1.2 g/dL, and the maximum was 5.5 g/dL. The daily dose of 20% albumin solution (10 g) was a minimum of 1 vial (50 mL) and a maximum of 5 vials (250 mL), with an average of 19 g daily (approximately 2 vials) (Table 4). In 82 patients (32.1%), serum albumin levels were greater than 2.5 g/dL at the time of albumin administration, of whom 46(56%) were above the recommended cut-off for the indication.

According to the protocol defined by the Iranian Food and Drug Administration (FDA Iran), the duration of albumin treatment should be stated on the albumin request form. In this study, only 1 patient (0.3%) had the duration of albumin treatment stated.

Another item on the albumin request form is the measurement of serum albumin levels 72 hours after starting albumin, which was not recorded for any of the 313 patients.

Discussion

The WHO uses a variety of intervention techniques, such as administrative, training, and monitoring measures, to encourage the prudent use of medications and enhance drug management programs. It is acknowledged that these strategies make medications more readily accessible within public health organizations, thereby helping low-income patients financially [8].

If medications are prescribed and used appropriately, more patients could be served and supported while keeping the limited medical budget in mind. As a result, it is critical to identify the costly but often prescribed drug productions and establish appropriate consumption patterns. DUE is a time-consuming process, but it has been

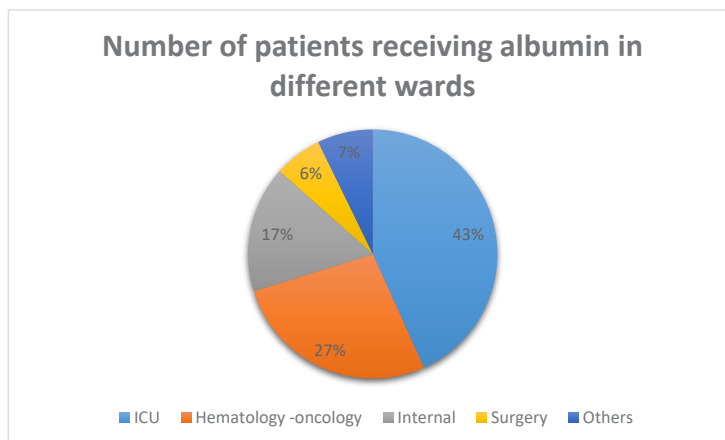


Figure 1. The number of enrolled patients in different wards

Table 1. Appropriate indications for albumin use

	Indication	Dosing Recommendation	
	Large volume paracentesis in patients with cirrhosis	Defined as >4 L removed with documented cirrhosis (or any amount removed if creatinine is >1.5 mg/dL)	Albumin 25%, 6-8 g/L of ascitic fluid removed
	Plasmapheresis	-	Albumin 5% as per plasmapheresis protocol (based on plasma volume and serum fibrinogen level)
	Postoperative volume resuscitation after cardiac surgery	-	Albumin 5% may only be used if ≥ 3 L of crystalloid has been administered within a given 24-h period without an adequate hemodynamic response.
	For the diagnosis of suspected HRS	Defined as acute renal dysfunction (serum creatinine >1.5 mg/dL) in the presence of cirrhosis	Albumin 25%, 1 g/kg/d for 2 days (dose up to a maximum of 100 g per day).
	HRS	Defined as: 1) Serum creatinine >1.5 mg/dL in the presence of cirrhosis; 2) Absence of shock, ongoing bacterial infection, and or current treatment with nephrotoxic drugs; 3) Absence of sustained improvement in renal function after discontinuation of diuretics and a trial of albumin 1 g/kg; 4) Absence of proteinuria (< 500 mg/d) or hematuria (<50 red cells per high-power field); 5) Absence of ultrasonographic evidence of obstructive uropathy or parenchymal renal disease.	1) Albumin 25%, 25-50 g daily for a total of 72 hours (starting 1-2 days after initial diagnostic trial of albumin, if applicable), and consult nephrology and hepatology services to determine whether to continue; 2) Should be used in addition to midodrine and octreotide
	SBP and cirrhosis	Defined as patients with ascitic fluid PMN counts ≥ 250 cells/mm ³ plus at least one of the following: 1) serum creatinine >1 mg/dL; 2) Blood urea nitrogen >30 mg/dL; 3) Total bilirubin >4 mg/dL	Albumin 25%, 1.5 g/kg within 6 hours of detection (day 1) and 1 g/kg on day 3
	Postoperative heart transplant	It may be useful to treat anasarca in patients with albumin ≤ 3 gm/dL.	1) Albumin 25%, 25 g IV BID x2 doses (or 12.5 g IV q6h x4 doses) may be used in combination with diuretics. 2) Monitor urine output and volume status and assess daily. If successful at achieving diuresis, may reorder albumin until serum albumin is >3 g/dL, but must be renewed each day after daily assessment.
	Postoperative lung transplant	Grade 2 or higher primary graft dysfunction	Albumin 25%, 25 g IV BID x2 doses (or 12.5 g IV q6h x4 doses) may be used in combination with diuretics to improve oxygenation for up to 48 hours.
	Postoperative liver transplant	May be useful for the control of ascites and peripheral edema if serum albumin is <2.5 g/dL	Albumin 25%, 25 g/d until albumin is ≥ 2.5 g/dL. If serum albumin remains <2.5, may continue albumin dosing up to 4 days; consult liver surgeons thereafter for consideration of continued use.
	Major hepatic resection (> 40% resected)	It may be useful after liver resection in patients with serum albumin <2.5 g/dL if crystalloids alone fail to achieve adequate intravascular volume.	Albumin 25%, 25 g/d until albumin is ≥ 2.5 g/dL. If serum albumin remains <2.5, may continue albumin dosing up to 4 days; consult liver surgeons thereafter for consideration of continued use.
	Severe nephrotic syndrome (e.g. with anasarca or pulmonary edema)	May be used in demonstrated nephrotic syndrome (>3 g/d of urinary protein excretion [or spot protein equivalent] + hypercholesterolemia + hypoalbuminemia) and loop diuretic resistance (defined as an "insufficient response" to an intravenous bolus dose of ≥ 160 mg furosemide or 4 mg bumetanide followed by ≥ 8 -hour infusion of ≥ 20 mg/h furosemide or ≥ 0.5 mg/hour bumetanide)	Albumin 25%, 25 g in combination with diuretics to effect adequate diuresis. Additional dosing must be approved by the nephrology attending.
	Burns	In the case of burns of >30% body Surface area, after the first 24 hours.	Albumin 25%, 25 g/d until albumin is ≥ 2.5 g/dL.

Table 2. Demographic characteristics of patients

Patients' Characteristics*		Mean±SD (Min-max)/No. (%)
Age (y) (n=313)		61±17.9 (11-98)
Age range (y)	≤8	8(2.6)
	19–40	41(13.1)
	41–60	81(25.9)
	≥61	183(58.5)
Sex (n=311)	Male	170(54.7)
	Female	141(45.3)
Weight (kg) (n=177)		69.2±10.5 (30–98)

*Including urology, neurosurgery, vascular surgery, infertility, and orthopedics departments.

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effective in starting a discussion between physicians and pharmacists to achieve high standards for drug use in hospitals. It aids in revealing the drug administration patterns in the institutions under investigation [9].

Despite its high cost, albumin remains a commonly used medication. According to the most recent evidence-based research and recommendations [18], we assessed the appropriateness of albumin use.

In the present study, we evaluated the administration of albumin based on rational-use protocols, which provide an evidence-based assessment of prescribing by health-care practitioners. Our study showed that albumin was used appropriately in 292 of 313 patients (93.2%).

Improper use of albumin results in significant resource waste and increases the likelihood of undesirable effects. DUEs can be used to identify patterns of albumin use in facilities, and the results could help physicians change their practices.

Because albumin and colloidal oncotic pressure are closely related, hypoalbuminemia may lead to or be the cause of edema [20]. Furthermore, a normal albumin level maintains a balance between the hydrostatic and colloid osmotic pressures inside vessels, preventing the development of edema [18]. Consequently, it is thought that albumin, which has diuretic and water-retention properties, can be used to treat edema caused by hypoalbuminemia [21, 22]. In our study, 2.3% of patients used the medication off-label during the research period.

Hypoalbuminemia was one of the most common reasons for albumin treatment in this analysis, accounting for 76 prescriptions (25.4%). A serum albumin concentration of less than 3.5–4 g/dL is known as hypoalbuminemia, and it is linked to several different clinical disorders [19]. Hypoalbuminemia has been linked to poor

outcomes in different critical conditions [12, 20]. However, several studies have shown no discernible impact of albumin administration on mortality or morbidity in hypoalbuminemic patients [7]. Reduced serum albumin concentration alone is therefore not regarded as a good enough rationale for albumin replacement in several guidelines. Finding and treating the underlying causes of the hypoalbuminemia is a helpful practice for these patients.

On the other hand, some recommendations state that albumin should be administered only when the serum albumin level is less than 2.5 g/dL [22, 23]. In this study, 76 patients with an albumin level below 2.5 were candidates for receiving albumin vials. Approximately one-third of patients had serum albumin levels above the guideline cut-off (2.5 g/dL) at the time of albumin initiation, and in 3.6% of patients, this level was above 3.5 g/dL.

As noted above, the duration of albumin treatment should be stated on the albumin request form. In this study, only 1 patient (0.3%) had the duration of albumin treatment stated.

The measurement of serum albumin levels 72 hours after starting albumin is another item on the albumin request form, but none of the 313 patients had this information documented. It is crucial to monitor patients receiving albumin for 72 hours after the start of administration to assess ongoing need. Regrettably, this study found that no patients had this evaluation done after 72 hours. Patient monitoring and re-evaluation at least 72 hours after administration can minimize irrational drug administration and the associated financial burden, as the duration of albumin administration and the need for ongoing treatment vary by indication and patient factors [24].

Table 3. Indications for albumin administration based on the contents of the albumin form

Indications	No. (%)	P
Albumin <2.5 for 3 days	76(25.4)	0.99*
Ascites or generalized Edema	73(24.4)	
HRS	40(13)	
Major surgery	26(8.7)	
Nephrotic syndrome	17(5.7)	
Paracentesis	15(5)	
Transplant	12(4)	
Severe diarrhea	9(3)	
Retroperitoneal surgery	6(2)	
Hemorrhagic shock	5(1.7)	
ARDS	5(1.7)	
Volume expansion after CABG	3(1)	
Plasmapheresis	3(1)	
SBP	2(0.7)	
Burns	0	
Others*	7(2.3)	

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Abbreviations: ARDS: Acute respiratory distress syndrome; CABG: Coronary artery bypass grafting; HRS: Hepatorenal syndrome; SBP: Spontaneous bacterial peritonitis.

*Out of albumin indication form, †The chi-square test.

In contrast to other studies, the most common improper use of albumin was observed after cardiac surgery in the studies by Jahangard-Rafsanjani et al. [25] and Kazemi et al. [5] at Shariati and Shaheed Rajaei hospitals in Tehran City, Iran. In addition, as in our investigation of irrational albumin utilization at Imam Reza Hospital in Tabriz City, Iran, Shafiee et al. [26] identified hypoalbuminemia and nutritional support as the most common causes.

A small number of studies examined the role of clinical pharmacists in optimizing albumin use, though most focused on developing albumin protocols [13, 27]. In addition to developing an approved protocol, Buckley et al. noted that clinical pharmacists assessed all albumin orders for appropriateness and intervened when necessary. In their report, inappropriate albumin consumption has significantly decreased by 72.9% [15]. According to Lyu et al. and Buckley et al. using established techniques

Table 4. Baseline albumin level and prescribed daily dose

Variables	Mean±SD (Min-Max)/No. (%)	
Baseline albumin level (g)	2.47±0.51 (1.2 – 5.5)	
Baseline albumin level	<2.5	173(55.3)
	2.6-3.5	73(23.3)
	3.6-4.5	8(2.6)
	≥4.6	1(0.3)
Dose of albumin (g)	19±7.3 (10–50)	

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resulted in an absolute decrease in albumin misuse of 50.9% and 36%, respectively [13, 15]. According to another study conducted in critically ill patients, the clinical pharmacists' actions greatly improved the appropriateness of albumin usage in the ICU from 16.3% in the retrospective phase to 84.1% in the implementation phase [28]. Our study showed that the presence of an albumin prescription form in wards and pharmacist supervision were able to minimize irrational albumin prescriptions, at least in terms of inappropriate indications. However, the duration and need for continued treatment were not in compliance with the guideline, and we believe that the pharmacist's attendance in the clinical wards could help minimize these errors. Given the financial burden and the local and even global shortage of albumin, greater pharmacist supervision of albumin request forms and compliance with guidelines can improve the rational prescribing and use of albumin.

This study represents a single teaching hospital site, and further research is needed to determine if these trends are present in other community hospital settings. The limitations of this study include the lack of investigation into the duration of albumin consumption and the total grams of albumin received by each patient, which should be examined more closely in future studies.

Conclusion

Hypoalbuminemia and ascites were the most common reasons for the administration of albumin. On the other hand, our study showed that the presence of an albumin prescription form in hospital wards and the presence of a pharmacist could minimize the irrational prescription of this drug. This study showed significant deviations from the albumin prescription protocol. Some aspects of albumin prescribing, including the minimum cut-off for starting albumin, the duration of use, and rechecking the albumin level, were not adequately considered by physicians. These findings emphasize a more sophisticated focus on the albumin prescribing in an attempt to minimize the irrational prescription of this expensive and valuable drug.

Ethical Considerations

Compliance with ethical guidelines

There were no ethical considerations to be considered in this research.

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Authors' contributions

Conceptualization, study design, and Final approval: All authors; Data collection and clinical studies: Ebrahim Salehifar, Zahra Bagherzadegan, and Shahram Ala; Data analysis and statistical analysis: Ebrahim Salehifar; Investigation and data acquisition: Sima Ramezaninejad; Writing the original draft: Sima Ramezaninejad; Review and editing: All authors; Supervision: Sima Ramezaninejad.

Conflict of interest

The authors declared no conflict of interest.

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