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Validation of Albumin Prescription in Vali Asr and Ayatollah Musavi Zanjan Hospitals

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ABSTRACT

Background: Human serum albumin (HSA) is a versatile protein exclusively produced by hepatocyte cells in the liver, constantly released into the bloodstream. Substantial quantities of HSA are employed to ameliorate a variety of clinical conditions. The purpose of this study was to assess the accuracy of albumin serum administration as recorded in the patient files of Valiasr and Ayatollah Mousavi Hospitals in Zanjan, Iran.

Methods: his study aimed to assess the accuracy of albumin prescriptions in adult departments of Ayatollah Mousavi and Valiasr hospitals from March 2013 to March 2019. Data on albumin consumption and patient information were collected by reviewing the medical records of patients, resulting in a selection of 316 cases. The study developed a reference framework for assessing albumin administration accuracy. A scoring mechanism was used to categorize prescriptions into appropriate, inappropriate, questionable, and ambiguous classes. Statistical analysis was conducted using SPSS software.

Results: The findings indicated that the average patient age was 62.2 years. Among 316 patients, 60.4% were male. The mean serum albumin level was measured at 3.14 g/dL. The collective volume of albumin administered to patients across both hospitals was 5016 units, averaging 15.77 units per patient, and this was utilized over a total of 2253 days. Among the studied patients, 197 passed away during treatment, 110 were discharged, and nine were transferred to other wards. Based on the established reference, it was observed that 5.5% of prescriptions were accurate, 51.9% were inaccurate, 26.4% were debatable, and

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0.6% were undetermined. The total cost of prescribing this quantity of albumin in both hospitals amounted to 9,274,584,000 Rials, distributed as 8,347,125,600 Rials and 927,458,400 Rials in their respective proportions.

Conclusion: Ultimately, the study highlighted that physician-prescribed albumin, guided by provided instructions, contained numerous errors necessitating vigilant and ongoing oversight. After a comprehensive review of all the data presented, it is apparent that there is no conclusive evidence supporting the existence of a formalized strategy for a consistent reduction in albumin consumption within the hospitals.

Keywords: Albumin - Prescription - Consumption - Human Serum

Introduction

Albumin, a vital human protein weighing 66.5 kilo Daltons, constitutes approximately half of the plasma proteins, with its molecular structure and concentration contributing significantly to 80% of intravascular colloid osmotic pressure [1, 2]. It plays a key role in transporting internal elements and external substances, with normal levels ranging from 4 to 5.4 g/Kg in the extracellular space and about 30% to 40% residing intravascularly to support plasma colloid osmotic pressure. Though lacking a precise threshold, maintaining serum albumin levels above two g/dL and total protein levels above 3.5 g/dL is suggested for proper function. Injection of albumin rapidly shifts fluids, limited in dehydrated patients until rehydration, while distribution between intravascular (40%) and extravascular (60%) compartments maintains steady flow. In declining intravascular albumin, extravascular migration sustains colloid osmotic pressure. The serum albumin concentration is regulated intravascularly, and blood albumin's 12 to 16-hour half-life decreases with heightened vascular permeability [1, 3-5].

Albumin's synthesis and metabolism underscore its vital role in human physiology. Adult livers, driven by neuroendocrine signals and intravascular colloid osmotic pressure, generate approximately 10 to 12 grams of albumin daily. This albumin is released directly into the intravascular space, bypassing cellular storage. Synthesis and secretion of albumin occur swiftly, lasting about 30 minutes. Once within the intravascular space, around 2 grams per hour traverse to the interstitial space through "transcapillary filtration." While inactive in endothelial gaps, albumin filtration is active in gap-free regions facilitated by the albumin-binding protein receptor. Lymphatic function regulates continuous albumin movement between intravascular and interstitial spaces. Eventually, albumin degradation prevails, with synthesis and degradation rates controlled at various levels [6, 7].

In critically ill patients, albumin's three key structural elements are noteworthy: cysteine amino acid residues, domains I and II, and imidazole amino acid residues. Cysteine at position 34 features a thiol radical group, acting as a vital extracellular antioxidant. Administering albumin to such patients in acute pathological states elevates plasma thiol levels, while the thiol groups can bind to nitric oxide, creating S-nitrophenols that counteract conditions like sepsis. Domains I and II of albumin play a pivotal role in transporting a diverse range of internal and external molecules, predominantly facilitated by albumin [8-10].

Clinical evidence robustly supports albumin's application in acute scenarios demanding volume expansion and hemodynamic support. Additionally, it proves beneficial in specific chronic conditions marked by diminished serum albumin levels. Definitive indications exist for human albumin utilization. In cases where colloids are unsuitable, albumin serves as a viable alternative. Urgent situations meriting albumin administration encompass hemorrhagic shock, major surgeries, burns, cardiac surgery, tissue grafting, and plasmapheresis. For chronic ailments like cirrhosis with unyielding ascites (including extensive paracentesis), hepatorenal syndrome, spontaneous bacterial peritonitis, and diuretic-resistant ascites, albumin administration is crucial [11-14].

Conversely, certain contexts do not warrant albumin infusion. These include serum albumin levels surpassing 2.5 g/dL (with exceptions as mentioned earlier), low serum albumin without edema and acute hypotension, severe anemia, heart failure, malnutrition, wound healing, non-hemorrhagic shock, diuretic-responsive ascites, acute and chronic pancreatitis, hemodialysis, protein-losing enteropathies, malabsorption, and burns within the initial 24 hours. These scenarios do not necessitate albumin infusion due to capillary leakage [15].

Hence, this study aimed to evaluate albumin prescriptions in Valiasr and Ayatollah Mousavi hospitals in Zanjan, Iran. In summary, the

evaluation of albumin prescription practices in Valiasr and Ayatollah Mousavi hospitals in Zanjan serves as a foundation for improving patient care, resource allocation, adherence to guidelines, and the overall quality of healthcare delivery. This study's outcomes have the potential to influence clinical decision-making, healthcare policies, and patient outcomes, making it a necessary and valuable endeavor.

Materials and Methods

Study Design

The present investigation encompassed a cross-sectional and retrospective approach, aiming to quantitatively assess albumin prescriptions within all adult departments of Ayatollah Mousavi and Valiasr hospitals from March 2013 to March 2019. Moreover, the study delved into the precision of albumin prescriptions, specifically in the year 2019, constituting the primary focus of this research. Notably, the objective of this study was to verify the accuracy of albumin prescriptions within the adult intensive care units (ICUs) of both Ayatollah Mousavi and Valiasr hospitals. The present study has been ethically approved by the Iran National Committee for Ethics in Biomedical Research IR.ZUMS.REC.1398.128.

To achieve a comprehensive understanding of albumin consumption trends, an initial quantitative analysis was conducted. Through collaboration with the Health Information System (HIS), data regarding albumin consumption quantities and patient counts were methodically collected from March 2013 to March 2019 across all departments of both hospitals. This initial phase sought to establish a broad overview of albumin utilization within the healthcare institutions under study. Subsequently, the study shifted its focus to the meticulous evaluation of albumin prescription accuracy.

In order to rigorously assess the correctness of albumin prescriptions, the complete medical records of all patients aged 18 and above who were admitted to the adult special care departments of Valiasr and Mousavi hospitals during the year 2019 were meticulously reviewed. The data retrieval process was executed in close collaboration with the Archive Department and the Information Technology Department of both hospitals. This comprehensive effort culminated in the meticulous selection of 316 cases for detailed examination. The necessary dataset was meticulously compiled, adhering to the parameters specified in the researcher-designed albumin prescription accuracy assessment form, which is available in the appendices section of the thesis.

The examination process encompassed the scrutiny of patients admitted to ICUA, ICUB, ICUOH, and Neurological ICU of Ayatollah Mousavi Hospital, as well as the ICU and Neurological ICU departments of Valiasr Hospital. The amalgamation of data acquisition strategies and precision assessment methodologies was driven by the aim of gaining a holistic understanding of albumin consumption trends and prescription accuracy within the studied healthcare settings.

Development of References Pertaining to Assessment of Albumin Administration Accuracy

In the pursuit of standardizing the assessment of the appropriateness of prescribed albumin administration, a comprehensive reference framework was meticulously crafted, integrating insights from both internal and external studies and established protocols. A meticulous evaluation of a total of seven distinct references was conducted to meticulously curate this framework. These encompassed pivotal references such as ASHP and UHC, with specific reference identification numbers 95 and 96, respectively. Additionally, a range of other references, notably encompassing diverse hospital guidelines [2, 16-21], significantly contributed to the formulation of this reference guide for evaluating the appropriateness of albumin administration (Supplementary Table 1).

In the subsequent phases, a systematic approach was adopted to allocate affirmative and adverse points in correspondence with the endorsements or disapprovals outlined within the distinct guidelines of the healthcare institutions. Notably, substantial emphasis was accorded to ASHP and UHC references, warranting a distinctive weightage in the scoring mechanism. Specifically, each diagnosis endorsed by these authoritative sources garnered a positive score of two, while those not sanctioned were assigned a negative score of two.

Upon meticulous computation of the cumulative scores attributed to each clinical indication, the prescriptions underwent categorization into four distinct classes:

Appropriate Prescriptions: This category pertains to prescriptions demonstrating an aggregate score exceeding zero.

Inappropriate Prescriptions: Denoting prescriptions tallying a cumulative score falling below zero. This class also encompasses specific prescriptions lacking confirmation or repudiation within the ambit of the seven considered references.

Questionable Prescriptions: Refers to prescriptions yielding an equilibrium sum of points, resulting in a net score of zero.

Ambiguous Prescriptions: Pertaining to prescriptions characterized by obscured rationales for albumin administration, rendering the reasons inconclusive based on the available patient records.

Statistical Analysis

Given the nature of this investigation as a descriptive study, the outcomes are presented through the depiction of key statistical measures such as the mean, standard deviation, and median, as well as numerical counts and corresponding percentages. The dataset, sourced from pertinent medical records of eligible subjects, was meticulously characterized employing the SPSS version 22 software, encapsulating the comprehensive analysis of pertinent variables.

Results

Albumin consumption in patients by year

The peak number of patients receiving albumin in Vali Asr and Ayatollah Mousavi hospitals occurred during the periods March 2016 - March 2017 and March 2014 - March 2015, respectively. In Vali Asr hospital, the highest and lowest albumin reception rates per patient were 11.11 vials and 8.87 vials, respectively, during the periods March 2016 - March 2017 and March 2018 - March 2019. Similarly, in Ayatollah Mousavi Hospital, the highest and lowest rates of albumin reception per patient were 18.61 vials and 9.71 vials, respectively, in the periods March 2016 - March 2017 and March 2013 - March 2014 (Table 3).

Demographic and prognosis

The mean ± SD age of the patients under study at Valiasr Hospital was determined to be 66.5 ± 19.2 years, ranging between 19 and 98 years, while the corresponding mean age for patients at Mousavi Hospital was 55.5 ± 22.5 years, spanning from 22 to 95 years. Ultimately, the overall mean age of all patients included in the study amounted to 62.2 ± 21.2 years. Among the study participants, a total of 191 individuals, accounting for 60.4% of the cohort, were identified as male, while 125 individuals (39.6%) were female. Notably, 58.1% of patients at Valiasr Hospital and 60% of patients at Mousavi Hospital were male. In the specific context of Ayatollah Mousavi Hospital, out of the total of 124 patients assessed, 36.8% (46 individuals) experienced mortality, 6.4% (8 individuals) were transferred to other hospital departments, and the remaining patients were discharged. Similarly, at Valiasr Hospital, a notable 83.3% (151 individuals) faced mortality, 0.5% (1 individual) were transferred to other departments, and the remaining cases were discharged.

Serum Albumin and administration

In accordance with the data collected, baseline albumin levels were typically assessed prior to administration in most cases, with the outcomes presented in Table 1. Among the 316 patients examined, 83 lacked baseline albumin measurements. Among the remaining patients, it was observed that 82.8% exhibited albumin levels exceeding 2.5 g/dL, while 17.2% displayed levels below 2.5 g/dL. The minimal albumin consumption amounted to 1 vial over a 1-day period, whereas the maximum recorded consumption reached 174 vials within a 58-day timeframe. Mean ± SD of albumin consumption per day for Valiasr Hospital, Ayatollah Mousavi Hospital and in total were 1.9 ± 1.2 (median (range): 1.7 (0.2 – 10)), 2.2 ± 0.9 (median (range): 2.00 (0.2 – 6)), 2.00 ± 1.1 (median (range): 1.8 (0.2 – 10)) respectively.

The consumption frequencies exhibited significant variability, with 37.8% of cases involving a daily intake of 1 vial (equivalent to 1 vial every 24 hours) and 4.1% entailing the highest frequency of 6 vials per day (equivalent to 1 vial every 4 hours) (Table 2).

Validity of Albumin prescription during March 2018 – March 2019

In this study, the accuracy of albumin prescription was evaluated based on the patient's diagnosis (as presented in Supplementary Tables 2 and 3). The results are shown in Table 5. According to the results, among all the patients examined in Ayatollah Mousavi and Valiasr hospitals, 51.7% of the diagnoses were accurate, 44.1% were incorrect, 3.8% were subject to debate, and albumin was prescribed to 0.3% of the patients with an unspecified index.

Imposed costs

Based on the financial burden and the cost of albumin usage, the total expenditure for

prescribed albumin among the 316 patients examined in this study amounted to 9,274,584,000 Rials (nine billion, two hundred and seventy-four million, five hundred and eighty-four thousand Rials). Of this total cost, 90% was covered by insurance, and the remaining 10% was the patient's responsibility, resulting in 8,347,125,600 Rials (eight billion, three hundred and forty-seven million, one hundred and twenty-five thousand and six hundred Rials) covered by insurance and 927,458,400 Rials (nine hundred and twenty-seven million Rials and four hundred and fifty-eight thousand and four hundred Rials) paid by the patients themselves (Table 6).

Discussion

The results of this study provide valuable insights into albumin prescription practices in Valiasr and Ayatollah Mousavi hospitals. One of the notable findings is the substantial use of albumin, with an average of 15.77 units per patient over 2253 days. This highlights a significant resource allocation to albumin therapy within these hospitals. However, a critical observation arises from the assessment of prescription accuracy. The scientific basis for these results lies in the clinical indications and guidelines surrounding albumin usage. Albumin, a major plasma protein, plays a vital role in maintaining oncotic pressure, regulating fluid balance, and transporting various molecules. Its administration is typically recommended in conditions such as hypoalbuminemia or certain types of shock [22-24].

The average age of hospitalized patients in both Valiasr and Ayatollah Mousavi hospitals was approximately 62 years, indicating that most patients are not significantly elderly. The average baseline serum albumin level for patients was about 3.1 g/dL, while the minimum recommended level was 2.5 g/dL. This raises questions about whether cheaper alternatives like crystalloids or non-protein colloids should be considered before albumin, as recommended by some references like UHC and ASHP. However, hospital guidelines did not mention these alternatives before albumin in any indications.

Additionally, there was significant variation in albumin prescription frequency among patients with similar indications and baseline albumin levels, suggesting that the decision was often at the discretion of individual doctors rather than following global guidelines. Overall, 62% of patients studied ultimately passed away, with this statistic reaching 80% in Valiasr Hospital. The study raises questions about the positive impact of albumin administration on patient mortality and whether following guidelines or conducting local studies might lead to better outcomes.

Finally, the study reveals a significant number of ambiguous and incorrect prescriptions, accounting for 70% of the total prescriptions, which not only result in high costs but also potential harm to patients. The financial cost of incorrect prescriptions is approximately 412 million tomans, while the cost of correct albumin prescriptions, covered by insurance and patients, is about 490 million tomans. When including the cost of unclear prescriptions, such as those for stroke and septic shock, the total cost of unclear and incorrect albumin prescriptions reaches 550 million tomans, highlighting the need for better prescription practices.

This study highlights the critical need for a thorough assessment of albumin drug administration practices. It found that a significant majority of albumin prescriptions, around 55.89% of them, were deemed inappropriate. Given the substantial cost associated with albumin, this raises concerns about prescription management and review [25]. These findings align with similar studies, such as one in a Tehran hospital, which found that over 90% of albumin prescriptions were incorrect, imposing a heavy financial burden [25, 26]. Interestingly, the study showed that cerebrovascular accident (CVA) cases accounted for the most albumin prescriptions, with Ayatollah Mousavi Hospital having a higher percentage of incorrect prescriptions than Valiasr Hospital. This variation may be due to factors like the diagnosed disease or physician expertise.

What sets this study apart is the creation of a reference that includes "discussed" and "unknown" categories in addition to "correct" and "incorrect" prescriptions. Defining precise clinical scenarios for albumin use is challenging due to the lack of clear indicators in existing guidelines from Europe and the United States. By amalgamating various studies, this research aimed to establish a comprehensive reference.

The study found that 51.9% of albumin administrations were inappropriate, consistent with most published data. A threshold value of 0.2 g/dL is a good cutoff for defining hypoalbuminemia [14, 27-29], although few studies show a definitive cutoff for baseline

albumin [30]. Inappropriate use often resulted from using albumin as the first-line solution for volume depletion without considering other options [27, 28, 31]. These findings emphasize the importance of careful evaluation before albumin administration, especially considering its cost and potential for misuse.

In this study, it was found that albumin levels in patients were often not measured before starting albumin injections. This practice contradicts recommendations that suggest albumin should only be used after administering synthetic colloids in cases of suspected hypovolemia or shock. Several studies, including one conducted at Ghaemshahr Teaching Hospital [32] and another at Sina Tabriz Hospital [33], revealed similar issues with albumin prescriptions. These studies showed that a significant percentage of patients received albumin without proper assessment, leading to incorrect prescriptions and financial waste.

Conclusion

After a comprehensive review of all the data presented, it is apparent that there is no conclusive evidence supporting the existence of a formalized strategy for consistent reduction in albumin consumption within the hospitals. This conclusion is drawn from the absence of a discernible pattern indicating a consistent downward trend in albumin usage over time. Overall, the findings emphasize the need for better adherence to guidelines and more accurate assessment before prescribing albumin to patients, especially considering its high cost and potential financial burden on healthcare systems.

Ethical Considerations

The study was confirmed by the Ethics Committee of Zanjan University of Medical Sciences.

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This study was pat of Rasool Markazi PharmD thesis registered in Zanjan University of Medical Sciences.

Authors' contributions

All authors contributed to obtaining final approval.

Conflict of interest

There are no possible conflicts of interest.

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