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Effect of hospital-wide interventions to optimize albumin use in a tertiary hospital

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Summary

What is known and objective: Albumin has been frequently used as a therapeutic agent based on previous recommendations that are mostly controversial. Considering limited evidence-based indications, common inappropriate albumin use in many hospitals necessitates prompt educational and regulatory interventions. We performed this study to assess the effect of a hospital-wide programme to optimize albumin use in a tertiary referral university-affiliated hospital.

Methods: This study was conducted in three 45-day phases, separated by two sequential interventions: guideline implementation and albumin order-sheet consideration. We evaluated albumin use and assessed its appropriateness in each phase at baseline, after guideline implementation and after order-sheet consideration.

Results: We recorded 100, 93 and 71 albumin orders for 100, 84 and 66 patients during the first, second and third phases, respectively. The adjusted number of albumin orders (used albumin vials) was 94.9 (1481.7 vials), 80.8 (1037.6 vials) and 66 (1219 vials) in the first, second and third phases of the study, respectively. Albumin orders with appropriate indication increased significantly over the three phases of the study (OR=1.5, P=.008). The frequency of inappropriate orders reduced significantly from the first phase to the third phase (58%-27%, P=.007).

What is new and conclusion: The pattern and amount of albumin use changed following guideline implementation and order-sheet consideration, and inappropriate albumin use was reduced in our hospital. There was still room for improvement, particularly for indications that were not included in the guideline. Hence, a more comprehensive guideline, frequent audit, feedback and interactive educational approaches might be necessary to achieve results that are of a greater magnitude.

KEYWORDS
albumin, appropriate use, drug utilization evaluation, guideline, order entry sheet

1 | WHAT IS KNOWN AND OBJECTIVE

Albumin is one of the most important blood proteins, which has various physiological functions[1]. Human albumin solution has been used as a therapeutic agent for various indications since its introduction to the market more than 40 years ago.[2,3] Several studies have evaluated clinical and economical endpoints of albumin use.[4] In spite of theoretical advantages, evidence-based albumin indications are limited and controversies exist regarding most of the previously recommended uses.[3,5]

Human albumin is expensive and is relatively scarce. The cost-effectiveness of treatment with albumin has been only established in a few indications.[6] Moreover, major risks and potential adverse reactions associated with the use of this blood product (eg transmission of infections, allergic reaction and volume overload) should be considered.[3,7]

According to albumin utilization evaluations, unjustified and inappropriate albumin use is common all around the world.[4,8-11] In order to improve the rational use of albumin, different strategies have been designed, implemented and studied in hospitals. Among them, educational and administrative interventions, such as institutional and local guidelines, have reduced inappropriate albumin use.[12-16]

Albumin utilization studies in our country have revealed that albumin is used inappropriately in 26%-95% of cases. National audits and studies have shown the economic burden of the irrational use of albumin. Some studies aimed at albumin use optimization have shown that interventions reduce the costs. Following previous albumin use reviews in our institution, feedback was given to the heads of the wards where inappropriate use was frequent.[17] In addition, clinical pharmacists discussed the available evidence for albumin use with the head attending physicians. These sporadic interventions reduced irrational albumin use in some hospital wards. However, with respect to the necessity of a hospital-wide intervention, we aimed to design and implement a local evidence-based guideline for human albumin use. The main objective of the present study was to assess the effect of a hospital-wide programme to optimize human albumin use in a tertiary referral university-affiliated hospital in Iran.

2 | METHODS

This study was conducted in three phases separated by two sequential hospital-wide interventions in Shariati Hospital, affiliated to Tehran University of Medical Sciences. We evaluated albumin use and assessed its appropriateness in each 45-day phase according to a locally developed evidence-based guideline (Table 1).

In order to develop and approve the guideline in our hospital, we took following steps. Initially, we performed a literature review to collect

TABLE 1 Institutional guideline for albumin use

Indication	Criteria and dosing
Large-volume paracentesis	Post-paracentesis if >4-5 L of ascitic fluid removed. Dose: 6-8 g of albumin for each litre removed[30-32]
Spontaneous bacterial peritonitis (SBP)	If one of the following conditions exists (clinical suspicion of SBP): • a serum creatinine >1 mg/dL • blood urea nitrogen >30 mg/dL, or • total bilirubin >4 mg/dL Dose: 1.5 g albumin/kg (up to 150 g) within 6 h of detection and 1.0 g/kg on third day (up to 100 g)[5,28,31-33]
Hepatorenal syndrome (HRS)	Diagnosis of HRS: lack of serum creatinine decreasing below 1.5 mg/dL after discontinuation of diuretics for at least two continuing days and initiation of volume expansion with an albumin infusion[5,28,34] Dose: 1 g/kg (up to 100 g) daily for two consecutive days Treatment of Type I HRS: Albumin infusion plus administration of vasoactive drugs such as octreotide and midodrine[5,28,31,32,34,35] Dose: 1 g/kg (up to 100 g) daily for two consecutive days followed by 25-50 g/d until vasoactive discontinuation
Plasmapheresis	Large-volume plasma exchange (greater than 20 mL/kg in one session, or greater than 20 mL kg^{-1} wk^{-1} in repeated sessions)[2,5,28,36] Dose: 15%-20% of 1-1.5 total plasma volume with albumin and the remaining with normal saline 0.9%.
Post-operative cardiac surgery	For post-operative volume expansion, in cases of inadequate response to crystalloids and non-protein colloids[2,3,5,28] Dose: 50 mL albumin 20% in 150-200 mL crystalloid solution in first 3 h after surgery
Major gastrointestinal surgery and liver transplantation	After major surgery (as indicated by >40% of liver resection or extensive intestinal resection) if one of the following conditions exists[3]: • Crystalloid refractory haemodynamic compromise (mean arterial pressure <60, central venous pressure <8 despite maximum 40 mL/kg crystalloid as 500 mL doses every 30 min in the setting of hypoalbuminaemia (serum albumin ≤2.5 g/dL) Dose: single dose intravenous infusion of 100 mL (20 g) of albumin 20%, in addition to 300 mL appropriate crystalloid solution • Clinical instability: Mesenteric ischaemia, allograft function in the setting of hypoalbuminaemia (serum albumin ≤2.5 g/dL) Dose: Intravenous infusion of 100 mL albumin 20% every 8 h up to three doses
Nutritional intervention	In patients with diarrhoea associated with enteral feeding intolerance if all the following conditions are met[3]: • Significant diarrhoea (>2 L/d) occurs • Serum albumin is <2.0 g/dL • Continued diarrhoea occurs despite trial of short-chain peptide and elemental formulas • Other causes of diarrhoea have been considered and ruled out

up-to-date evidence and previously published institutional guidelines. Then, we drafted the guideline and asked 20 attending physicians of the hospital, from different specialties, to review the initially developed version. After we made final revisions according to the experts' comments, the hospital's Drug and Therapeutics Committee approved the guideline. It should be noted that the available albumin dosage form during the study was 50-mL vials containing 20% albumin solution.

The first phase was performed to evaluate the baseline albumin use from 6 December 2014 to 20 January 2015. For each new albumin order, data including indication, dose and treatment duration, as well as the patient's demographic and relevant clinical information, were collected from the patient's medical record, nursing files and pharmacy database. We did not count repeated physicians' orders as a separate order and the total albumin use (number of vials) for all such orders was recorded for the first new order. If a new order was registered for a patient, it was included in the study with a new code.

After completion of the baseline evaluation, the approved guideline was sent to all hospital wards and we held sessions to present the guideline to physicians, including postgraduate medical students (residents and fellows). The second phase was started when the presentation sessions were completed on 29 June 2015 and continued until 13 August 2015. In this phase, the previously mentioned approach was considered for data collection.

Following the second phase, an order entry sheet for albumin was designed based on the aforementioned guideline. In this stage, the physicians were required to fill the order sheet and specify the indication before hospital pharmacy provided albumin for the patient.

The third phase of the study started 2 weeks after albumin order-sheet implementation from 6 December 2015 to 20 January 2016. All received order sheets by the pharmacy were examined to evaluate albumin use and relevant data were collected accordingly.

Appropriateness of orders was summarized and compared in each period between different wards using chi-square test. Two-by-two comparison of phases was also performed by chi-square test. The trend of changes of appropriate orders was analysed using logistic regression model. Adjusted albumin use in each ward was calculated using the number of albumin vials used divided by the occupation rate of the ward. Adding the adjusted number of albumin orders in different wards together yielded the total adjusted number of albumin orders.

3 | RESULTS AND DISCUSSION

We recorded 100 and 93 albumin orders during the first and second phases for 100 and 84 patients, respectively. In the third phase of the study, 71 albumin order sheets were recorded for 66 patients. Demographic and clinical characteristics of the patients are described in Table 2. The adjusted number of albumin orders (and the corresponding used albumin vials) considering hospital ward bed occupancy rates in the first, second and third phases of the study were 94.9 (1481.7 vials), 80.8 (1037.6 vials) and 66 (1219 vials), respectively. The highest frequency of albumin orders was seen in the Hematology, Oncology and Hematopoietic Stem Cell Transplantation (HSCT) wards in all of the phases. However, the Neurology Ward used the highest amount of albumin in all phases of the study.

As illustrated in Figure 1, albumin orders with appropriate indication showed a significant increasing trend over the three phases of the study (OR=1.5, *P*=.008). Two-by-two comparison of phases revealed that the frequency of inappropriate orders reduced significantly from the first to the third phase of the study (58%-27%, *P*=.007).

Reasons for albumin use and related indications during the three phases of the study are summarized in Table 3. In the first and second phases of the study, the most common use in terms of orders was hypoalbuminaemia, followed by plasmapheresis and paracentesis. Paracentesis (14%) and plasmapheresis (39%), which are among appropriate indications for albumin, were two frequent uses in the last phase. Inappropriate use of albumin for nutritional interventions and treatment of oedema decreased significantly in the third phase, accounting for a major relative decline in albumin use. In spite of the

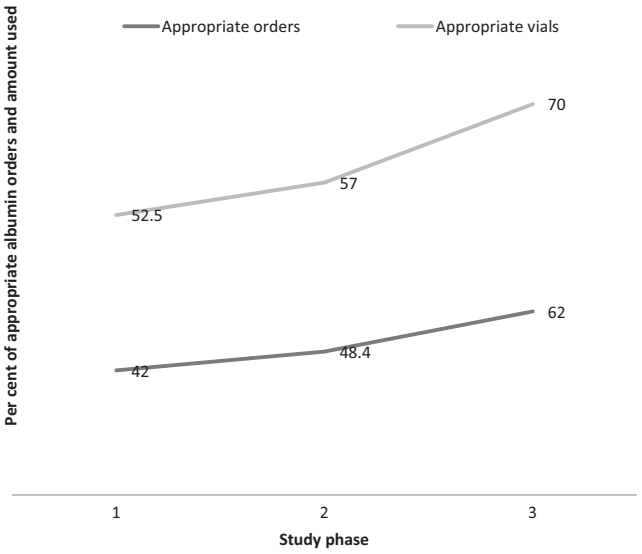

FIGURE 1 Changes of appropriate albumin use over three phases of study

TABLE 2 Patients' demographic and clinical characteristics in the three study phases

Characteristics	Phase 1 (n=100)	Phase 2 (n=84)	Phase 3 (n=66)
Age (y), mean (SD)	48.0 (19.0)	46.2 (21.0)	39.5 (20.4)
Serum albumin (g/dL), mean (SD)	2.8 (0.7)	2.6 (0.6)	2.7 (1.0)
Male sex, N (%)	62 (62.0)	41 (48.8)	30 (45.4)

TABLE 3 Frequency of appropriate and inappropriate albumin uses during three phases of study

Indication		Phase 1: Before guideline		Phase 2: After guideline		Phase 3: After order sheet	
		Order N (%)	Amount (vial) N (%)	Order N (%)	Amount (vial) N (%)	Order N (%)	Amount (vial) N (%)
Inappropriate	Ascites	2 (2.0)	22 (1.6)	1 (1.1)	3 (0.3)	0 (0.0)	0 (0.0)
	Cirrhosis	0 (0.0)	0 (0.0)	3 (3.2)	55 (5.1)	1 (1.4)	14 (1.1)
	Donor HSCT cell preparation	4 (4.0)	4 (0.3)	3 (3.2)	3 (0.3)	4 (5.6)	4 (0.3)
	Diuretic resistant/intolerant oedema	9 (9.0)	185 (13.1)	10 (10.7)	141 (13.1)	9 (12.7)	149 (11.9)
	Oedema	9 (9.0)	64 (4.5)	11 (11.8)	78 (7.2)	2 (2.8)	15 (1.2)
	Nutritional intervention	6 (6.0)	106 (7.5)	3 (3.2)	13 (1.2)	0 (0.0)	0 (0.0)
	Hypoalbuminaemia	26 (26.0)	271 (19.2)	17 (18.3)	170 (15.8)	10 (14.1)	172 (13.7)
	Hypocalcaemia	2 (2.0)	18 (1.3)	0 (0.0)	0 (0.0)	1 (1.4)	23 (1.8)
	All (%)	58 (58.0)	670 (47.5)	48 (51.6)	463 (42.9)	27 (38.0)	377 (30.0)
Appropriate	Hepatorenal diagnosis	2 (2.0)	7 (0.5)	3 (3.2)	16 (1.4)	0 (0.0)	0 (0.0)
	Hepatorenal treatment	4 (4.0)	117 (8.3)	2 (2.1)	35 (3.2)	3 (4.2)	38 (3.0)
	Paracentesis	13 (13.0)	110 (7.8)	22 (23.6)	86 (8.0)	10 (14.1)	39 (3.1)
	Plasmapheresis	22 (22.0)	501 (35.5)	16 (17.2)	463 (42.9)	28 (39.4)	776 (61.9)
	Spontaneous bacterial peritonitis	0 (0.0)	0 (0.00)	2 (2.1)	15 (1.4)	3 (4.2)	24 (1.9)
	Major GI surgery	1 (1.0)	4 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	All (%)	42 (42.0)	739 (52.4)	45 (48.4)	615 (57.0)	44 (62)	877 (69.9)

observed decreasing trend in the frequency of hypoalbuminaemia as an indication during three phases of the study, this use of albumin remained the second common indication in the last phase. Among patients who received albumin for hypoalbuminaemia in the first, second and third phases, 46%, 35% and 40% had a serum albumin level below 2.5 g/dL, respectively.

Previous albumin use evaluations revealed a substantial need for educational, administrative or regulatory actions to address common inappropriate uses of albumin.[17-22] In spite of uncertainty regarding the effectiveness of the approaches to optimize medication use in the hospitals, a combination of interventions is assumed to be more effective.[23] In this study, we assessed the effect of two sequential interventions (institutional albumin guideline followed by albumin order sheet) on albumin use in our hospital.

The pattern of albumin use changed following each step of the intervention. The total adjusted number of albumin orders decreased from each phase to the other. Lyu et al.[24] showed that a sequential multifaceted intervention resulted in significant declines in ICU albumin use. Considering two components of their intervention, that is the institutional albumin guideline and changed computerized ordering process, they achieved a significant reduction in the proportion of patients with albumin orders.[24] Likewise, we observed a reduced number of patients for whom albumin was prescribed following order-sheet implementation.

In a study by Mahmoudi et al.,[25] several strategies were incorporated to optimize the use of three costly medications, including albumin. Guideline implementation, in conjunction with computer decision support programme, audit and feedback, and educational meetings reduced albumin use by 36% in the intervention group compared with the control group.[25] However, similar to our study, the long-term effect of the strategies was not evaluated.

The total amount of albumin used did not show a steady and statistically significant decreasing trend throughout all phases of our study. A 30% reduction in albumin use was seen from the first to the second phase. However, it increased in the third phase in comparison with the second phase. This could be attributed to the increased relative frequency of plasmapheresis in the third phase, an indication for which significant amounts of albumin are needed according to the guideline. Considering the number of used vials, plasmapheresis accounted for the greatest amount of albumin use in all study phases.

Appropriate albumin use showed an increasing trend during the study phases. Accordingly, the frequency of inappropriate orders reduced significantly from the first phase to the third phase. Mahmoudi et al.[25] also reported less inappropriate albumin use in the intervention group, although they did not describe the underlying indications.

Inappropriate albumin use for nutritional interventions and treatment of oedema decreased significantly in the third phase, which accounted for a major decrease in albumin use. In spite of the observed decreasing trend in the frequency of hypoalbuminaemia during three phases of the study, this indication remained the top inappropriate use and the second common indication in the last phase. It is in contrast to the results of a study performed by King et al.,[14] in which an implemented provincial guideline reduced albumin use for hypoalbuminaemia significantly.

Considering previous and current study results, hypoalbuminaemia as an indication was more frequent in the Hematology, Oncology and Hematopoietic Stem Cell Transplantation (HSCT) wards.[17,20] Nejad et al.[20] reported hypoalbuminaemia as the most common indication for albumin use in our HSCT wards whereas only 5.6% of the patients who received albumin for this reason had albumin levels ≤2.5 g/dL. Similarly, less than half of the patients who received albumin for hypoalbuminaemia in all phases of our study had a serum albumin level <2.5 g/dL.

Our guideline included only appropriate indications of albumin use and considered detailed rigid criteria for them. Evidence does not support the use of albumin in many clinical conditions manifested with hypoalbuminaemia and it is recommended to find and treat the main reason.[26-28] However, controversies exist regarding the management of complicated patients with very low serum albumin levels and some guidelines consider it as an occasionally appropriate indication with different cut-off levels ranging from 1.5 to 2.5 g/dL.[2,3,8] Occasionally appropriate indications were not included in our guideline.

The observed significant decline in the albumin inappropriate use from the first to the third phase supports the more pronounced effect that was expected from combinational interventions. Although it seems that the order sheet had a more significant effect, any conclusion in this regard should be made with caution considering the study design and limitations. On the other hand, the Hawthorne effect should be considered in interpretation of the effect of interventions because the attending physicians were aware of the guideline implementation process in the first phase of the study.[29]

4 | WHAT IS NEW AND CONCLUSION

The hospital-wide sequential interventions decreased inappropriate albumin use in our study. However, we did not observe the expected changes considering occasionally appropriate indications that were not included in the guideline. Hence, a more comprehensive guideline, frequent audit and feedback, and interactive educational approaches might be necessary to further reduce inappropriate use of albumin. Although we expected the intervention to modify the practice of attending physicians,[13] it is important to focus on new postgraduate medical residents that are added to the treatment team every year.

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