MA-1

報道発表資料 緊急情報 HOME

平成１０年１０月１５日

# 医薬品等安全性情報１５０号（概要）

## ４．アルブミン製剤の適正使用について





今般、英国コクラン研究所から、既存の無作為抽出比較試験２４報を系統的な総合評価を行った結果、重篤な循環血流量減少、熱傷、低アルブミン血症等の患者で、アルブミンを投与した群と投与していない群とで比較検討したところ、投与群で死亡率が高かったとの論文が報告されたので紹介する。

このコクラン研究所の報告を受け、現在、我が国においては、中央薬事審議会において専門家による検討が行われているところであるが、各国においてもアルブミンの適正使用に関して注意喚起がなされているところである。今後ともアルブミンの使用にあたっては使用基準を踏まえ、適用を十分に検討するとともに患者の状態を十分に観察する等、慎重に行うことが必要である。

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ı on time to death. If a report did not mbers of deaths in each group, we ata from the authors. Two reviewers extracted the data, and any disagree- lved by discussion.

### ıd statistical methods

[antel-Haenszel method to calculate sk differences, and 95% confidence h for each trial on an intention to treat vMan (Review Manager) statistical here are no events in one group the 5 to each cell of the 2×2 table. We eity between trials using $\chi^2$ tests, with g significant heterogeneity. As long as eneity did not exist, we used a fixed calculate summary relative risks and ıtervals.

ıe extent to which the results of the y have been biased as a result of the ı of randomised trials with positive on and other selection bias), we pre- ɔt and used the regression approach l plot asymmetry proposed by Egger e log odds ratio in the funnel plot he measure that is used in the unnel plot asymmetry as described Using simple unweighted linear essed the standard normal deviate odds ratio divided by its standard estimate's precision (defined as the ard error). The larger the deviation the regression line from zero, the try and the more likely it is that the ield biased estimates of effect. As et al, we considered $P < 0.1$ to indi- ımetry.

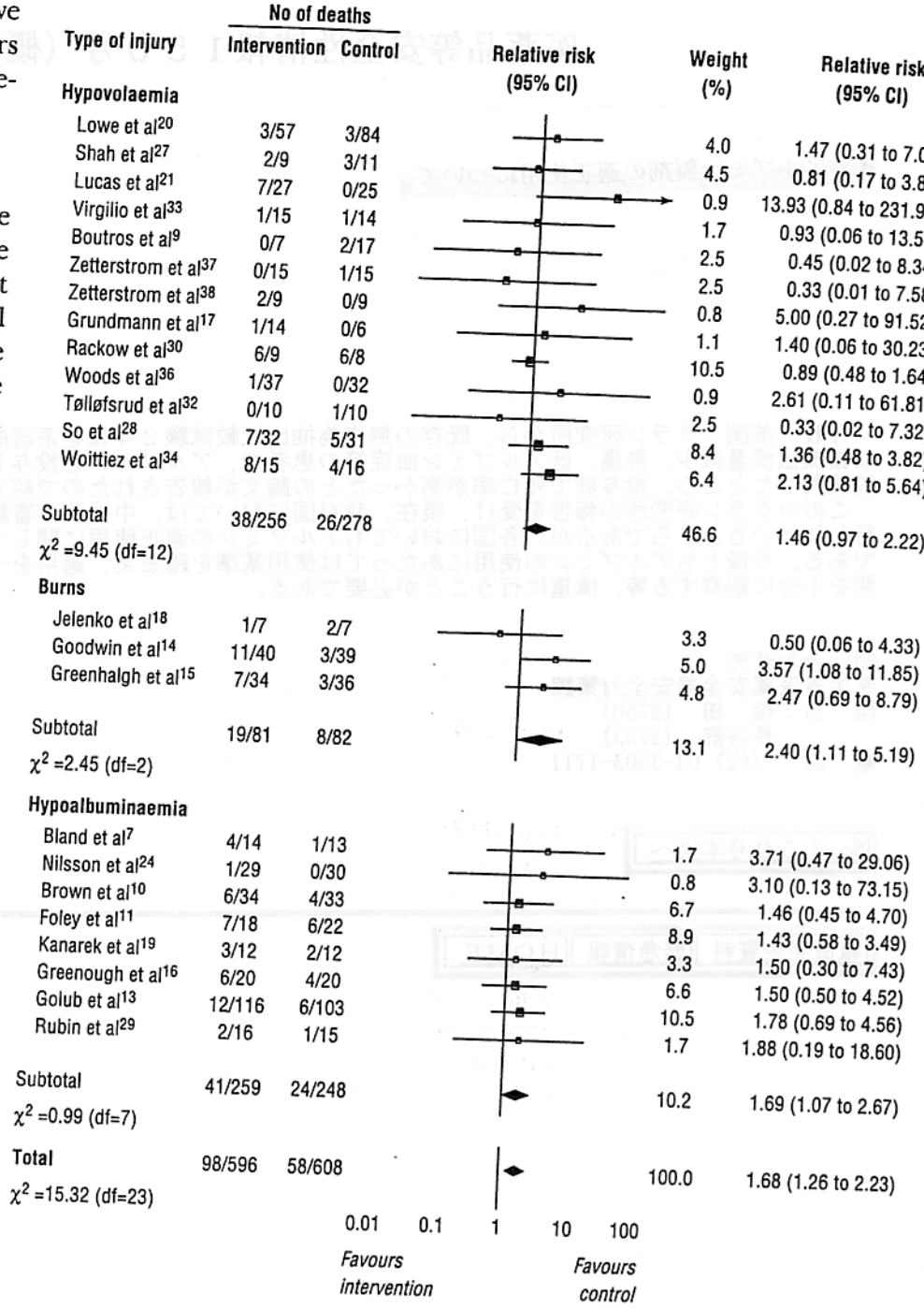


**Fig 1** Fixed effects model of relative risks (95% confidence interval) of death associated with intervention (fluid resuscitation with albumin or plasma protein fraction) compared with control (no albumin or plasma protein fraction or resuscitation with a crystalloid solution) in critically ill patients

of 32 randomised controlled trials s inclusion criteria.[7-38] The table ıese trials. Mortality data were m the published report or on ıors in 30 of these trials. The two tality data could not be obtained randomised patients, comprising ber of randomised patients in all ıclusion criteria.[22 31] One of the hed trial registered in the Medical y, and we obtained further details, rtality, directly from the trialist. In ) deaths in either the intervention s.[8 12 23 25 26 35]

:as et al was reported in five early report gave the

13 included a method of allocation concealment that would be expected to reduce the risk of foreknowledge of treatment allocation (pharmacy controlled randomisation or serially numbered sealed opaque envelopes). In seven trials this was unclear, and in four trials concealment was inadequate (table).

In each of the patient categories the risk of death in the albumin treated group was higher than in the comparison group (fig 1). For hypovolaemia the relative risk of death after albumin administration was 1.46