**PREPRINT: Instruments for assessing the risk of falls in acute hospitalized patients: a systematic review protocol**

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**Abstract**

Aim. The purpose of this article is to present the research protocol of a systematic review about fall risk assessment tools in acute hospitalized patients.

Background. Various risk assessment tools for falls have been developed, but with uncertainties derived from validation in heterogeneous environments and variations in their sensitivity, specificity and predictive validity.

Design. Systematic review and meta-analysis.

Methods. Two independent reviewers will extract data in a blinded process. Quality of studies will be assessed using various standardized instruments. A meta-analysis will be performed if applicable. For all studies, sensitivity, specificity, positive and negative predictive values, together with the positive and negative likelihood ratios and Youden index will be calculated. The diagnostic odds ratio of the studies and the hierarchical summary Relative Operating

Characteristic curve and bivariate model will be applied. Calculations will be made from random effects models. Forest-plot diagrams for sensitivity and specificity and likelihood ratios, in addition to Cochrane's Q test and the I2 statistic, will be calculated. Funding of the review was confirmed in December 2010.

Discussion. The results of this review will help to clarify some uncertainties provoked by earlier research findings and enable informed choice of a validated, reproducible instrument for assessing the risk of falls by hospital patients, so that preventive action may be taken to minimize this risk.

Falls are the leading cause of injuries among people aged 65 years or older, followed by traffic accidents, burns and fires, drowning and food poisoning. One of the largest stud- ies on the subject conducted in Europe estimated that from 13·3–164·5 deaths per 100,000 inhabitants aged over 65 years in the European Union are due to falls (Petridou et al. 2007).

Rates of falls recorded vary depending on the case-mix, environment and health practices, but over 84% of all adverse events among hospital patients are associated with falls. Approximately 30% of hospitalized patients who fall suffer injuries, of which, 4–6% are severe, such as fractures, subdural haematomas, bleeding and even death (Hitcho et al. 2004). The highest costs are caused by hip fractures, followed by skull fractures and lower extremity injuries, although it is difficult to obtain accurate values because most studies include only the costs arising from patients hospital- ized for an injury, without taking into account those who fall in the hospital itself (Polinder et al. 2005). The British NHS has estimated that annual hospital costs of around 15 mil- lion pounds are incurred as a result of falls (about 92,000 pounds a year for an 800-bed hospital) (Healey et al. 2007). The scale of this problem among hospital patients is such that it ranked sixth in the rating of sentinel events published by the Joint Commission (2010). The consequences of falls are not only physical but also psychological, producing fear of a recurrence and loss of self esteem and independence, which can adversely affect the patient's lifestyle and also impact on carers in the family.

The causes of falls in hospitals have traditionally been analysed in the field, with investigations taking place at the scene of the accident, trying to identify the circumstances where they occurred and to determine the most prevalent risk factors. Among those identified are advanced age, ner- vousness, confusion or disorientation, generalized weakness of the muscles and/or lower limbs, instability of gait, the existence of urinary incontinence, a history of previous falls, visual deficiency or the use of certain medications (hypnotics, sedatives, vasodilators, diuretics, antidepres- antidepressants, etc.) (Perell et al. 2001, Oliver et al. 2004, Polinder et al. 2005). Among factors extrinsic to the person, related to falls in hospitals and institutions, the absence of handrails, the height and stability of seating (including the toilet) and obstacles in the form of hospital appliances have been mentioned (Connell 1996).

In view of these considerations, various risk assessment tools for falls have been developed. The European Prevention of Falls Network defines this measurement as

a diagnostic process for determining a person's risk of suffering afall, to plan coordinated treatment and long-term follow-up (Prevention of Falls Network Europe, 2007). These instrumentsinclude the Downton scale (Downton 1993), the St. Thomas risk assessment tool in falling elderly inpatients (STRATIFY) (Oliver et al. 1997), the Morse Falls Scale (MFS) (Morse et al. 1989), the Tinetti Mobility Test (Tinetti et al. 1986) and the Hendrich II Fall Risk Model (HFRMII) (Hendrich et al. 2003), among many others. Some of the above instruments have been tested in environments other than those for which they were originally developed (Nyberg & Gustafson 1996, O'Connell & Myers 2002, Myers 2003, Papaioannou et al. 2004, Schwendimann et al. 2006, Smith et al. 2006) and in some cases difficulties have been encountered, regarding variations in their sensitivity, specificity and predictive validity. During the last decade, several reviews have been made of risk evaluation

methods for falls by hospital patients, the most recent being in 2007 and all have confirmed these inconsistencies with respect to validity and reliability (Perell et al. 2001, Myers 2003, Papaioannou et al. 2004, Haines et al. 2007). Other factors, too, may affect the validity of the results obtained, such as the sampling losses excluded from some studies, but incorporated into others; moreover, in some studies, action was taken on the basis of the results derived from the screening process, but not in others, where the clinical staff were blinded to these results. These variations increase the heterogeneity of the data, which should be taken into account when considering the validity of the overall results (Haines et al. 2007). The significance of these methodological weaknesses was tested in a recent clinical trial, comparing the use of evaluation instruments, on the one hand and the clinical judgemen of nurses, on the other, in predicting the risk of falls by elderly hospital patients. In fact, the results obtained with the instruments were no better than the clinical prediction

made by nurses (Meyer et al. 2009), as had been reported in an earlier study (Nordin et al. 2008). A meta-analysis conducted in 2007 showed that of the instruments with multiple prospective evaluations and highest numbers of participants STRATIFY and the Morse Falls Scale obtained similar levels of efficacy, comparable those of nurses' judgement in the clinical trial (Haines et al. 2007). everal authors suggest that some adjustments to the scales are needed (Perell et al. 2001, Myers 2003, Papaioannou et al. 2004, Smith et al. 2006); moreover, scalescould be specifically adapted to the environment where they are applied (Nyberg & Gustafson 1996). Nevertheless,many studies conducted in the community or in institutions caring for the elders (Scott et al. 2007, Gillespie et al. 2009) have failed to detect the need for such changes, with respect to the care of severely affected elderly patients. This

is due not only in part to the increased number of trials in both contexts, but also to the characteristics of participants,to the nature of interventions among several environments and to differences in skill-mix (Gillespie et al. 2009). Hospitalized

patients in the acute phase of their disease have specific characteristics, requiring a special assessment in this setting to prevent falls. The same patient can have different risk factors depending on the context: home care, institutionalization or acute care. Furthermore, as observed above, systematic reviews focused on this area have not been carried out since 2007 and some of the studies on risk factors

are now considerably outdated. If currently available instruments are under or overestimating patients at risk of falling, their routine use could provoke a dangerous diversion of attention and resources towards patients who would, in fact, least benefit from preventive measures, or ignore those who really need them. From the standpoint of taking preventive action, it is necessary to compare the factors comprising the different instruments to initiate a suitable plan of care for these patients, since only the factors that are modifiable offer scope for action and thus, for reducing the incidence of adverse events among hospital patients. In addition, the mere use of such an evaluation instrument regardless of its validity to detect the risk of falls is no guarantee that they will actually be prevented. A register of risk could even become an end in itself, rather than a means of targeting treatment and preventive care (Healey et al. 2007). Nevertheless, a recent Cochrane review showed that multifactorial interventions in hospital do reduce the rate of falls (rate 069; 95% CI 049–096), although many other factors must also be taken intoaccount in evaluating this risk, making it difficult to isolate the specific effect (Cameron et al. 2010). The criteria considered in adopting one or other evaluation

instrument should be, essentially, that the scales have been validated prospectively and their sensitivity and specificity analysed, for more than a single population; the instrument should present good predictive value, inter-observer. reliability, be readily complied with by nursing staff and be traightforward to calculate (Perell et al. 2001). A prospective, observational study, published in 2005, compared the results from the simultaneous application of four fall risk assessment tools among hospital patients (Vasallo et al.2005) and highlighted the differences between these scales with respect to the time needed for their completion, together with their sensitivity, specificity and predictive value. Although the STRATIFY scale has shown to be the best predictor of falls, and requiring least time to complete, it also presents the poorest sensitivity among the scales studied. A similar study, published in 2007 (Kim et al. 2007), compared three scales applied in acute care units and concluded

that the HFRM has better predictive validity, reproducibility and feasibility than the STRATIFY and Morse scales. The diversity of results achieved reflects the considerable inconsistencies involved in this question. The importance of this problem has led to specific strategies being developed in many health services, some of them recommending the explicit use of risk assessment tools for falls by hospital patients; this is the case of the Andalusian Public Health System Strategy

for Patient Safety, which sets out detailed measures to be taken to detect and counter the risk of falls. In particular, it includes the assessment of the risk of falls as part of the comprehensive assessment of patients, made during their first 24 hours in hospital (Junta de Andalucı´a. Consejeráa de Salud 2006). Regarding the prevention of falls in hospitals, the Andalusian Health Ministry specifically recomendó the use of one of the above scales. Nevertheless, as remarked previously, considerable uncertainty remains (Junta de Andalucía. Consejería de Salud 2009). A systematic review in this context would contribute to the implementation of best practices related to preventing falls in an acute care hospital setting. Therefore, this review seeks to clarify some of these uncertainties provoked by earlier research findings and to enable informed choice of a validated, reproducible instrument for assessing the risk of falls by hospital patients, so that preventive action may be taken to minimize this risk. For this purpose, a detailed review and analysis are needed of relevant publications.

Aim

The aim of this review is to determine the accuracy of instruments for detecting fall risk and predicting falls in acute hospitalized patients.

Specific objectives:

1 To analyse the diagnostic validity of the various risk assessment tools for predicting falls in acute hospitalized patients.

2 To determine the psychometric properties of the risk bassessment tools for falls in acute hospitalized patients.

3 To compare the effectiveness of risk assessment instruments for falls and its impact on the incidence of falls by acute hospitalized patients.

Accordingly to the Cochrane Manual for Diagnostic Test Accuracy (Higgins & Green 2011), this systematic review seeks to answer the question about the accuracy of instruments, scales or questionnaires (index) developed for detecting or predicting falls (target condition) in acute hospitalized patients, aged 16 or over (patients).In this sense, the review will have to determine what instruments are available for assessing the risk of falls by acute hospitalized patients, the differences among them in terms of diagnostic accuracy and/or psychometric properties and their potential impact on preventing falls when implemented into the clinical context.

**Methodology**

**Study design**

Systematic review, performed according to the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green 2011). This

review Will be focused on three types of research papers: those which develop diagnostic validity (DV), those which accomplish psychometric validity (PV) and those which evaluate the effectiveness of fall risk assessment instruments (EFRA).

Inclusion/exclusion criterio:

Types of studies.

• For DV, diagnostic validation studies of falls risk assessment tools.

• For PV, observational studies that compare the validity and reliability of falls risk assessment tools.

• For EFRA, experimental studies, randomized or not, with a control group, including the use of a falls risk assessment tool and including comparison data for sensitivity,

specificity, predictive values and/or likelihood ratios with respect to other instruments or professional clinical judgement (nurses, doctors, physiotherapists, etc.).

• Systematic reviews of either of these types of studies, if they agree with the inclusion criteria for participants, interventions and outcomes.

Types of participants. For any of the three types of studies, only adult patients in acute hospitals will be included.In this sense, hospitals are institutions with an organized medical staff which guarantees medical care to patients in the acute phase of illness. This includes the following:

• Adults (aged over 16 years) admitted to acute care hospitals.

• Studies focusing on patients admitted to acute psychiatric units or to paediatric units will be excluded from this review.

Types of intervention. In DV and PV studies the types of intervention criterion is not applicable.

In EFRA studies, experimental studies involving the use of a falls risk assessment tool, either as a sole intervention or in conjunction with others, will be accepted.

Types of outcome measure. In DV studies, any measure of diagnostic validity: sensitivity, specificity, predictive values, likelihood ratios, diagnostic odds ratios, area under the curve (AUC) and frequency and distribution of risk factors.

In PV studies, any psychometric outcome such as reliability,internal consistency, face, criterion or construct validity and frequency and distribution of risk factors.

In EFRA studies: frequency of falls during patients' stay in hospital or falls predicted, complications resulting from falls, frequency and distribution of risk factors identified.

Search methods

The following databases will be searched: MEDLINE, CINAHL, EMBASE, WEB OF SCIENCE, SCOPUS, COCHRANE, CRD, IME, CUIDEN, ENFISPO, DIALNET, SCIELO,

together with these related websites: IMSERSO, PRoFaNE (Prevention of Falls Network Europe), NSW Falls Prevention Network, Cochrane Bone, Joint and Muscle Trauma Group and Google Scholar. The search languages will be English, Spanish and Portuguese and the periods covered, from the date of the first study indexed in the corresponding database, up to and including 2010. In addition, linked searches will be made in the references for the studies found. For the searches, we will use specific methodological filters developed by the Health Information Research Unit at McMaster University for studies of diagnostic tools and clinical prediction rules (Wong et al. 2003, Kastner et al. 2009). Initially, the following terms will be used: accidental; falls; fallers; risk assessment; assessment tool; balance; gait; validation studies; prevention; prediction; hospital units; hospitals; acute care. In addition, we will apply theterms needed to adjust the criteria for exclusion from the review, with the logical operator NOT (exclusion of studies in the community and those focusing on psychiatric, paediatric and other such institutions).

**Review method**

The first stage of our review will include a detailed assessment of the titles and abstracts to determine whether each article meets the requirements for inclusion. If there is any doubt, the full text of the article will be assessed to decide whether it meets these criteria. To ensure the quality of the process, all records will be doubly evaluated, by two blinded reviewers.

After this initial process, all the references identified as potentially eligible will be evaluated to see if they meet the inclusion criteria for the review. This process will again be carried out in parallel by two blinded reviewers. Any discrepancias that might arise in the process will be resolved by discussion between the two evaluators, assisted by the intervention of a third expert, not otherwise involved in the project. In addition, a pilot exercise will be performed with the reviewers, for application of the inclusion criteria, on a sample of 15 items to reduce the risk of bias. Figure 1 provides a diagram of the ‘phases of the study’.

**Quality appraisal**

The evaluation will use the checklist included in the application RevMan 5_0_24, for assessing the quality of DV studies. In addition, we will make use of the STARD

publication guidelines (Bossuyt et al. 2003), QUADAS (Whiting et al. 2003) and QAREL (Lucas et al. 2010) on studies of diagnostic tests, to resolve those cases where doubts may arise. For PV studies the assessment will be based on the quality

criteria identified for health questionnaires (Terwee et al. 2007). These quality criteria addressed the content validity, internal consistency, criterion validity, construct validity, reproducibility, longitudinal validity, responsiveness, floor and ceiling effects and interpretability. For EFRA studies, both diagnostic accuracy and intervention studies instruments will be used. For this, the Critical Appraisal Skills Programme (CASP) for intervention studies will be the tool selected. And to reduce the risk of bias before conducting the evaluation, pilot tests will be run among the reviewers, with selected articles and the methodological advice from an expert in the methodology of systematic reviews on Health Sciences.

**Data abstraction**

An electronic form will be used to input the results of the studies included and evaluated, supported by the application RevMan 5_0_24 and will include the following items: clinical characteristics and context of the study, participants

(number, selection, age, sex, type of disease or condition), design, reference standard and target process, test and comparisons, monitoring and observations. In addition, and to obtain data for PV and EFRA studies, the information included will be the following: number of ítems comprising the assessment tool, number of subscales (if applicable), type of questions (dichotomous, Likert, semantic differences, etc.), cut-off points (if any), recommendations on training for use, recommended frequency of administration, time required for administration, reliability data, results from factorial analysis or concurrent validity. Also included on this form will be the RevMan 5_0_24 check-list items for assessing the quality of diagnostic studies and, if applicable, those arising from the STARD-QUADAS-QAREL regulations for publication. Furthermore, for EFRA studies, data on intervention, randomization, group allocation, follow-up and end-points will be collected.

Prior agreement will be reached on possible codes to describe the standard outcome routines for these studies.

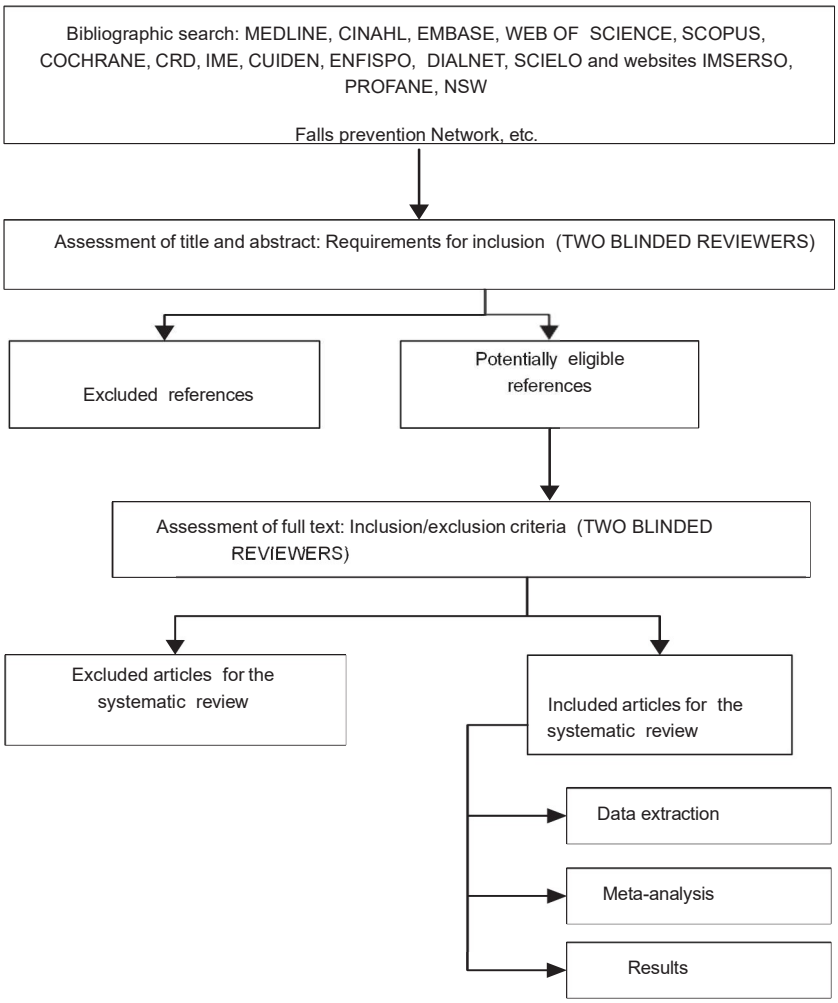


Figure 1 Phases of the study.

What is already known about this topic

- Over 84% of all adverse events among hospital patients are associated with falls.
- Various risk assessment tools for falls have been developed.
- Some of these instruments have been tested in different environments and inconsistencies with respect to validity and reliability have been confirmed What this paper adds
- We seek to clarify some of these uncertainties provoked by earlier research findings.
- To analyse the possible effects of using these instruments on the incidence of falls by hospital patients.
- Implications for practice and/or policy

- The results of the systematic review will allow the informed choice of a validated, reproducible instrument for assessing the risk of falls by hospital patients.
- Some preventive action will be taken to minimize this risk of falling for inpatients and to increase the clinical safety.

When the original studies do not clearly provide the data necessary for analysis, the authors will be contacted directly for clarification or for the exact data, if possible.

**Synthesis**

Depending on the degree of heterogeneity and comparability of studies, a meta-analysis of the results will be conducted.To this end, we shall define in advance the comparisons to be made, the outcome variables to be used and the most appropriate summary measure. Initially, for every study we shall report the sensitivity, specificity and positive and negative predictive values and calculate the positive and negative likelihood ratios and the Youden and correct classification indexes. If there is found to be excessive heterogeneity, no meta-analysis will be carried out and only a narrative review of the different studies will be made.

For the meta-analysis, the diagnostic odds ratio for the included studies will be calculated and the hierarchical summary ROC (HSROC) and the bivariate model. Nevertheless at least four studies will be necessary for this purpose. The calculations will be made from random effects models.

Heterogeneity among studies will be addressed using forest- plot diagrams for sensitivity and specificity and the likelihood ratio test for these two dimensions. In addition, Cochrane's Q statistic will be calculated for the positive and negative probability ratios, using as weights the reciprocals of the variances and the I2 statistic. The latter value will be calculated from the Q statistic (the standardized measure of the observed heterogeneity, which is not affected by effect size units):

$$Q = \sum_{i=1}^{k} W_i(Y_i - M)^2$$

where: W = weight of each study (reciprocal of the variance); Y = effect size of the study; M = global effect; K = number of studies. Thus, we calculate the ratio between the excess variance and the dispersion:

$$I^2 = \frac{(Q^2 - gl)}{Q} \times 100$$

_ 100where: gl = degrees of freedom __ k_1 (k = number of studies included in the meta-analysis).

The heterogeneity will be stratified into three levels, following the criteria of Higgins et al. (2003):

<25%: Low heterogeneity

25–50% : Moderate heterogeneity

>50% : High heterogeneity

For EFRA studies, only if indicated, meta-analysis of incidence of falls in intervention and control groups and estimation of the effect size through risk measurements (OR,RR, NNT) and their 95% confidence intervals will be developed. Moreover, sensitivity and heterogeneity analyses will be performed.

**Ethical considerations**

This study deals with secondary data from original studies and therefore is not subject to the usual criteria for original research. Nevertheless, the review participants will sign an explicit statement that there is no conflict of interest.

**Validity and reliability**

To control the potential extra source of variability among studies resulting from potential differences among them about the thresholds for defining positive and negative results (threshold effect), we will calculate Spearman's correlation coefficient between sensitivity and specificity. If there is a threshold effect, the combination of results, instead of averaging the sensitivity and specificity or the likelihood ratios, will be achieved by adjusting the pointon a ROC curve. Prior to this, we will determine whether or not the diagnostic odds ratio, using the Moses-Shapiro-

Littemberg method to decide whether the points on a ROC curve should be adjusted symmetrically or asymmetrically, respectively. If there is no threshold effect, the global sensitivity and specificity will be calculated. A funnel plot analysis will be performed to determine potential publication bias. In addition, a concordance analysis among reviewers will be carried out during the different phases of the process and this will subsequently be incorporated into the results of the review, using a Kappa index. For the different phases of analysis, the applications RevMan 5_0_24, MetaDiSc 1_1_1 and PASW 18 will be used.

**Discussion**

Systematic reviews of diagnostic studies and psychometric research are less frequent in evidence-based literature. One of the main cornerstones along these types of reviews is the assessment of quality of studies. In our study we will include,

the recommendations of the Cochrane Manual for Diagnostic Test Accuracy, combined with the STARD reporting guidelines (Bossuyt et al. 2003), QUADAS (Whiting et al. 2003) and QAREL (Lucas et al. 2010) on studies of diagnostic tests and according to guidelines described by Terwee et al. (2007) for the assessment of psychometric studies. Depending on the demands found along the process and the type of data, these tools will acquire different prominence, but it will improve a common shortfall in these reviews.

**Limitations**

During the search phase, relevant studies might be omitted if appropriate terms or search strategies are not employed. To avoid this, several consecutive searches will be performed and the results combined, and to design and perfec the final search. In turn, this will be updated by the activation of the alerts available in various bibliographical databases. In addition, specific methodological filters, as mentioned above, will be used. In the selection phase of items relevant to the study, peer selection will minimize the risks arising from inadequate individual assessment. Similarly, the double-blinded peer review of the studies included will enable greater consistency in the conclusions reached by the reviewers. Discrepancie may occur between pairs of evaluators, which Will be resolved by discussion between them and by the intervention of a third reviewer if necessary, and by a concordance analysis between the reviewers at various stages of the process, using the Kappa index.

Furthermore, during this stage, the data required fo review and statistical analysis of different studies may bemissing. This could be overcome by contacting the original authors of the study in question. For EFRA studies a limitation to consider is the possibility of contamination relative to the effectiveness of the fall risk assessment instrumentsdue to the simultaneous implementation of other interventions and a possible Hawthorne effect.

**Conclusion**

The results of this review will help to clarify some uncertainties provoked by earlier research findings and to enable informed choice of a validated, reproducible instrument for assessing the risk of falls by hospital patients, so that preventive action may be taken to minimize this risk. Because of these actions, clinical practice could be improved in varioussettings and it will directly affect patient safety.

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**Conflict of interest**

No conflict of interest has been declared by the authors.

**Author contributions**

All authors meet at least one of the following criteria (recommended by the ICMJE: http://www.icmje.org/ethical_1author.html) and have agreed on the final version:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

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