Enteral nutritional support in prevention and treatment of pressure ulcers: a systematic review and meta-analysis

CRD summary
This well-conducted review examined whether enteral nutritional support was beneficial in preventing and treating pressure ulcers. The authors concluded that enteral nutritional support, particularly with high-protein oral nutritional supplements, can reduce the development of pressure ulcers in high-risk patients. However, the studies were generally of poor quality and further research is required. The authors' cautious conclusions are likely to be reliable.

Authors' objectives
To evaluate the effects of enteral nutritional support for the prevention and treatment of pressure ulcers.

Searching
PubMed, the Cochrane Library, TRIP, Clinical Evidence, National Electronic Library for Health guidelines finder and National Service Frameworks were searched in August 2004 using the reported terms. Studies published in any language were eligible provided an English abstract was available. Reference lists were screened and experts in the field were contacted. Two studies that were identified as potentially relevant were not included (one was unobtainable and the other had no English language abstract).

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), non-randomised controlled trials, before-and-after clinical trials, prospective and retrospective cohort studies, and case studies were eligible for inclusion. In all of the included studies, the minimum duration of follow-up was 2 weeks (the maximum duration was 2 years).

Specific interventions included in the review
Studies that evaluated oral nutritional supplements (ONS) or enteral tube feeding (ETF) containing at least two macronutrients in addition to micronutrients were eligible for inclusion. The interventions could provide either part or the entire daily requirement of energy and could be nutritionally complete or incomplete. Studies could also use concurrent parenteral nutrition or dietary advice, but studies using only these interventions were excluded. The studies could use any type of control intervention. The included studies evaluated standard formula, standard high-protein and disease-specific high-protein supplements. The review compared nutritional support (ONS or ETF) versus routine care; different formulas given orally (ONS) or by tube (ETF); and ETF versus parenteral nutrition.

Participants included in the review
Studies of adults (aged over 18 years) of any nutritional status, with or at risk of pressure ulcers, were eligible for inclusion. The participants could be based in hospital, out-patients, or at home. Most of the participants in the included studies were elderly; concomitant illnesses included cognitive impairment, critical illness, fracture neck of femur and diabetes.

Outcomes assessed in the review
The primary review outcomes were pressure ulcer incidence and healing. The secondary outcomes were quality of life, complications, mortality, dietary intake and nutritional status.

How were decisions on the relevance of primary studies made?
One reviewer screened the full papers of identified potentially relevant studies and a second reviewer verified the inclusion and exclusion of studies.
Assessment of study quality
One reviewer performed the validity assessment and a second reviewer checked it. Validity was assessed and scored using the Jadad scale, which considers the reporting and handling of randomisation, blinding and handling of withdrawals. The maximum possible score was 5 points. The level of evidence was also assessed using a 6-point scale adapted from Quality of Evidence Quality Assessment scale (developed by the U.S. Agency for Health Care Policy and Research). Scores ranged from the highest grade of 1 for RCTs to 6 for inadequate evidence.

Data extraction
The data were extracted onto a pre-designed form, but the authors did not state how many reviewers extracted the data. Outcomes data were extracted from each study, based on definitions reported in the study. Log odds ratios (ORs) and 95% confidence intervals (CIs) for pressure ulcer incidence were calculated for each study. The absolute risk reductions and numbers-needed-to-treat (NNT) were also calculated.

Methods of synthesis
How were the studies combined?
The studies were grouped by intervention and outcome. Where two or more RCTs reported the same outcome measure, the studies were combined in fixed-effect meta-analyses. Pooled weighted absolute risk reductions, pooled weighted log OR and the NNT were calculated; studies were weighted by the inverse of the variance. Otherwise, studies were combined in a narrative. The authors considered that there were too few studies to assess publication bias using a funnel plot.

How were differences between studies investigated?
Statistical heterogeneity was assessed using the Q statistic. Where possible, studies of the prevention and treatment of ulcers were analysed separately. There were insufficient data to examine the effects of study duration, different concentrations of specific nutrients and nutritional status.

Results of the review
Fifteen studies (n=3,216) were included: eight RCTs (n=1,485), one CCT (n=28), one before-and-after clinical trial (n=39) and five cohort studies (n=1,664). Five RCTs (n=1,430) were included in meta-analyses.

All eight RCTs were graded 1 (the highest Quality of Evidence scale grade). One RCT scored 5 points on the Jadad scale, one RCT scored 4 and one RCT scored 3; the other five RCTs scored 2. One of the five RCTs included in the meta-analysis scored 4 points, one scored 3 and three scored 2. The studies were generally poorly reported with respect to methods of randomisation, blinding and description of drop-outs.

Nutritional support versus routine care.
Pressure ulcer prevention: the meta-analysis showed that ONS (mainly high-protein) significantly reduced the risk of pressure ulcers developing in patients with no ulcers at baseline compared with routine care (OR 0.75, 95% CI: 0.62, 0.89; based on four RCTs, n=1,224). The results were similar after including one RCT of ETF in a mixed group of patients (with and without pressure ulcers at baseline) (OR 0.74, 95% CI: 0.62, 0.88). No significant heterogeneity was found for either meta-analysis (p=0.813 and p=916, respectively). The NNT (based on five RCTs) was 19.25. The four non-randomised studies were difficult to interpret.

Healing of existing pressure ulcers: three studies (two RCTs and one before-and-after clinical trial) reported non significant trends towards increased healing with enteral nutrition compared with control, but meta-analysis was not possible.

Different enteral formulas.
Healing of existing pressure ulcers: meta-analysis was not possible. One RCT reported a non significant reduction in the surface area of ulcers in patients receiving a high-protein ETF compared with standard formula. One RCT reported that pressure ulcers healed more rapidly in patients receiving a specially formulated supplement compared with the standard
supplement, but no statistics were presented. One CCT reported a significant reduction in ulcer surface area in patients receiving a high-protein formula compared with a standard enteral formula.

ETF versus parenteral feeding: no studies were identified.

Results for the secondary outcomes were also reported.

**Authors' conclusions**

Enteral nutritional support, particularly with high-protein ONS, can reduce the development of pressure ulcers in high-risk patients. However, the studies were generally of poor quality and further research is required to confirm these findings.

**CRD commentary**

The review question and inclusion criteria were clear in terms of the study design, participants, intervention and outcomes. Several relevant sources were searched and attempts were made to minimise publication bias, although language restrictions might have increased the possibility that some relevant studies were not included in the review. Methods were used to minimise reviewer errors and bias in the study selection and validity assessment processes, but it was unclear whether similar steps were taken in the data extraction. Validity was assessed using specified criteria, and adequate details of the interventions and participants were provided. Only RCTs were combined in meta-analyses and statistical heterogeneity was assessed. Study quality was taken into account when considering the strength of the evidence. Overall, this was a well-conducted review and the authors' cautious conclusions are likely to be reliable.

**Implications of the review for practice and research**

Practice: The authors did not state any implications for practice. Research: The authors stated that adequately powered, well-conducted RCTs are needed to confirm the review findings, to determine the mechanisms underlying effects, and to identify optimal nutritional interventions.

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