**Authors' objectives**
To examine the efficacy of somatostatin and octreotide in refractory diarrhoea and to determine whether efficacy is independent of aetiology.

**Searching**
MEDLINE (from 1968 to 2000) and the Cochrane Library (1996 to 2000) were searched for English language studies using the MeSH terms (‘diarrhoea’) AND (‘somatostatin’ OR ‘octreotide’) AND (‘AIDS’ OR ‘post-chemotherapy’ OR ‘cisplatin’ OR ‘5-fluorouracil’). Review articles and their references were also checked for further additional studies.

**Study selection**
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and case series with at least five patients were eligible for inclusion.

Specific interventions included in the review
Studies of octreotide or somatostatin versus either placebo or other antidiarrhoeals were eligible for inclusion. The doses of octreotide ranged from 50 to 5,000 microg, while the doses of somatostatin ranged from 50 to 2,400 microg.

Participants included in the review
Participants with refractory diarrhoea associated with acquired immune deficiency syndrome, post-chemotherapy, graft versus host disease, post-gastrectomy, short-bowel syndrome, ileostomy output, or cholera were included. Participants with diarrhoea associated with endocrine tumours were excluded.

Outcomes assessed in the review
No inclusion criteria for the outcomes to be included were stated. The outcome of primary interest was response. This was assessed either descriptively, such as absence or lack of diarrhoea, or measured as the mean stool volume, ileostomy output or net fluid absorption.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

**Assessment of study quality**
The authors did not state that they assessed validity.

**Data extraction**
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. Data on the patient indication, number of patients, intervention (including dose and route of administration), duration of the intervention and the number of responders were extracted.

**Methods of synthesis**
How were the studies combined?
The percentage response in the case series was compared with the overall percentage of patients who responded in the RCTs. The relative risk (RR) was pooled using a random-effects model. The results were presented as the RR with 95% confidence intervals (CIs).

How were differences between studies investigated?
The authors applied a formal statistical test of heterogeneity, but did not state which specific test was used. They further explored differences in response rates by aetiology.

**Results of the review**

Thirty studies were included in the review: 8 RCTs (n=354), 4 randomised crossover trials (n=34) and 18 case series (n=324). Data from 9 randomised trials (RCTs and crossover trials) were included in a meta-analysis (n=378).

A rough estimate of mean response to somatostatin or octreotide, based on group level data, was 71% in 15 case series and 68% in 9 randomised trials. These were not significantly different.

The meta-analysis of 9 randomised trials gave an RR of 0.5 (95% CI: 0.27, 0.91) with significant heterogeneity between studies. A subgroup analysis of the largest aetiological groups showed that AIDS studies were statistically homogeneous and there were no significant differences between somatostatin and octreotide (RR 0.86, 95% CI: 0.62, 1.19). Post- chemotherapy studies were statistically heterogeneous.

**Authors’ conclusions**

The results of the review lend support to the beneficial effect of somatostatin or octreotide as therapy for refractory diarrhoea, but the magnitude of the benefit remains in question.

**CRD commentary**

The review question was only loosely defined, as no explicit inclusion criteria were stated in terms of the participants, interventions and outcome measures. Only two databases were searched and the search was restricted to English language publications. No measures were therefore taken to limit publication or language bias. The authors did not appear to undertake a validity assessment, thus it is impossible to comment on the quality of the studies included in the review. The authors also failed to report how the data extraction process was undertaken.

Adequate extracted information was presented in tabular format; this allows the reader to fully interpret the results presented. The statistical analysis was appropriate, with a heterogeneity assessment and subgroup analysis being undertaken. The authors also explored how differences in study design might have influenced the results of the primary studies. Overall, the evidence base reviewed was limited and many aspects of the review methodology were not reported. Therefore, the authors’ conclusions, that the results lend support to the beneficial effect of somatostatin or octreotide as therapy for refractory diarrhoea, may be overstated.

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

Practice: The authors stated that, despite the need for further research, the favourable responses reported in most of the reviewed studies cannot be ignored and, as such, support and strengthen consensus guidelines on the use of somatostatin or octreotide in refractory diarrhoea.

Research: The authors stated that further RCTs that focus upon patients with similar aetiology, and use a similar dose and duration of treatment, are needed to assess the efficacy of somatostatin or octreotide in different patient subgroups.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.