Effect of pharmaceutical care programs on glycemic control in patients with diabetes mellitus: a meta-analysis of randomized controlled trials

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CRD summary
The authors concluded that pharmaceutical care programmes, compared to usual care, can significantly improve glycaemic control in patients with diabetes mellitus. Given the differences between studies in patients and interventions with potentially differing levels of effectiveness, the authors’ caution is warranted.

Authors’ objectives
To evaluate the impact of pharmaceutical care programmes on glycaemic control in patients with diabetes mellitus.

Searching
MEDLINE, EMBASE, The Cochrane Library, Elsevier (databases unspecified), Chinese Biomedicine Database and Chinese Journal Full-Text Database were searched for articles published between January 1996 and February 2010. Search terms were reported. Bibliographies of identified studies were handsearched.

Study selection
Randomised controlled trials (RCTs) that compared the effect of pharmaceutical care delivered primarily by a pharmacist with non-pharmaceutical care treatment on haemoglobin A1c in patients with diabetes mellitus were eligible for inclusion. Studies needed to report changes in mean and standard deviation (SD) A1c from baseline to end point or mean and SD A1c at baseline and endpoint to be eligible for inclusion. Studies without adequate description of the pharmaceutical care intervention were excluded. The components of pharmaceutical care intervention varied between studies and most commonly included counselling, training in self-monitoring of blood glucose, drug therapy management, dietary education, self management and exercise education. All interventions involved a pharmacist and had face to face contact. Three trials also had telephone contact. The frequency of interventions ranged from two a week to three a month. Interventions lasted from four months to 18 months. Studies included patients with type1, type 2 or gestational diabetes. One study was of children and adolescents only and one was of males only. Studies were conducted in community pharmacies, hospitals and outpatient clinics. Studies were conducted in USA, Australia, Thailand, Spain, France, China and United Arab Emirates.

Titles were reviewed by one of three reviewers to determine eligibility. Abstracts were assessed independently by two reviewers. Disagreements were resolved by consensus among three reviewers.

Assessment of study quality
Study quality was assessed using the Jadad scale of randomisation, allocation concealment and withdrawals/drop-outs to give a maximum score of 5. Studies that scored 3 or more were deemed high quality. Studies that scored 2 or less were considered low quality.

It appeared that the validity assessment was carried out by two reviewers independently. Disagreements were resolved by consensus.

Data extraction
Mean and standard deviation changes in haemoglobin A1c from baseline to endpoint were extracted for each group. Where this was not reported, mean and SD A1c were extracted at baseline and endpoint and used to calculate the mean and standard deviation change in A1c using methods from the Cochrane handbook.

Two reviewers independently extracted data. Disagreements were resolved by consensus.
Methods of synthesis
Weighted mean differences (WMD) and their corresponding 95% confidence intervals (CI) were used to combine the studies. Random-effects models were used in the presence of significant statistical heterogeneity. Fixed-effect models were used where no significant statistical heterogeneity was detected. Statistical heterogeneity was assessed using $\chi^2$. Sensitivity analyses removed each study in turn. Publication bias was assessed using visual inspection of funnel plots and Egger's test.

Results of the review
Fourteen RCTs were included for review (1,770 participants). Six studies were deemed high quality and eight were considered low quality. Because of the nature of the intervention, allocation concealment was not possible in any study.

Haemoglobin A1c significantly reduced in pharmaceutical care groups compared to usual care groups, (WMD -0.68, 95% CI -1.03 to -0.34, p=0.000). There was evidence of significant statistical heterogeneity ($\chi^2=129.84$, df=13, p=0.000). Sensitivity analysis that removed each study individually did not significantly alter the results.

There was no evidence of publication bias.

Authors' conclusions
Pharmaceutical care programmes, compared to usual care, can lead to improved glycaemic control in patients with diabetes mellitus. The results should be treated with caution due to the presence of statistical heterogeneity.

CRD commentary
The review addressed a clear question. Inclusion criteria were well defined but broad for patients and interventions, which resulted in clinical heterogeneity between included studies. An appropriate search was conducted. It was unclear whether any language restrictions were applied and so language bias could not be ruled out. It appeared that no attempts were made to identify unpublished studies. Publication bias was assessed and ruled out. It appeared that suitable steps were taken to minimise reviewer error and bias. A validity assessment was carried out and most of the included studies were of low quality. There was significant statistical heterogeneity and high levels of clinical heterogeneity between the included studies and so it was unclear whether the decision to combine the studies was appropriate.

Given the presence of heterogeneity between studies, the authors' caution is warranted.

Implications of the review for practice and research
Practice: The authors stated that it would be beneficial for pharmacists to give advice on diet, exercise and self-monitoring to patients with diabetes. Pharmaceutical care programmes should include a strong medication management component. Pharmaceutical care programmes for diabetes should be considered by policy makers in developing countries.

Research: The authors stated that further research was needed on the role of pharmacy technicians in pharmaceutical care programmes with patients with diabetes. Further research was needed into the cost effectiveness of pharmaceutical care programmes.

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