Metformin combined with acarbose vs. single medicine in the treatment of type 2 diabetes: A meta-analysis

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Received August 4, 2015; Accepted January 6, 2017

DOI: 10.3892/etm.2017.4333

Abstract. The present meta-analysis aimed to evaluate metformin combined with acarbose compared with mono-therapy with either of the two drugs for type 2 diabetes (T2DM). Relevant trials were retrieved through searching PubMed, Embase, Cochrane library, China National Knowledge Infrastructure, Wanfang and Chongqing VIP information network databases. Heterogeneous and homogeneous data were statistically combined using a random- and fixed-effects model, respectively. For dichotomous and continuous data, the merged effect size was presented as the risk ratio (RR) and weighted mean differences (WMD), respectively, with 95% confidence interval (CI). All included studies were divided into subgroups. A Funnel plot was used to detect publication bias. Review Manager 5.2 software was applied to perform the statistical analyses. Meta-analysis revealed that compared with metformin monotherapy, combined therapy was significantly more efficacious regarding indexes including the total effective rate, fasting blood glucose (FBG), blood glucose levels at two post-prandial hours (2HPG) and hemoglobin A1C (HbA1C). Similarly, combined therapy showed advantages on indexes including FBG, 2HPG and HbA1C over acarbose therapy after 4 months of treatment. In conclusion, the findings of the present meta-analysis suggested that combined therapy of metformin and acarbose appears to be more efficacious than metformin or acarbose monotherapy.

Introduction

Type 2 diabetes (T2DM), also known as non-insulin-dependent diabetes mellitus, is a chronic metabolic disorder caused by the body’s inadequate production or use of insulin and results in excessive amounts of glucose in the blood and urine (1,2). T2DM may have various complications affecting the nervous system, the eye and the kidneys (3-5). Various health indicators, including total effective rate (%=[excellence+improvement]/total cases x 100), fasting blood glucose (FBG) and blood glucose levels at two post-prandial hours (2HPG) give information on the efficacy of medications for T2DM. Not all studies indicated a total effective rate. In addition, blood lipid indexes, including hemoglobin A1C (HbA1c), triglyceride (TG), total cholesterol (TC), high-density lipoprotein (HDL) and low-density lipoprotein (LDL) may be used as health indicators. Various medicines have been assessed for the treatment of T2DM, including sulfonylureas, glinides, biguanides and α-glycosidase inhibitor (6-9); however, no final conclusion has yet been reached on the best treatment of T2DM.

Acarbose and metformin treatment has been reported to have a beneficial effect on patients with T2DM (10,11). Metformin, which is the most frequently prescribed oral hypoglycemic agent, targets insulin resistance and excessive glucose (12,13). However, β-cell function continues to deteriorate in patients with T2DM, accompanied with progressive failure of insulin secretion (14). The development of T2DM has been shown to be delayed by acarbose by impairing glucose intolerance (15). However, acarbose has common gastrointestinal adverse effects, including abdominal pain, diarrhea and bloating (16). With the increasing promotion of medicine combinations, various studies have provided gradually increasing evidence that acarbose combined with metformin treatment has a higher efficacy than monotherapy (17-19). It has also been indicated that combined medicines have higher efficacy with regard to HbA1c, FBG and 2HPG as well as insulin levels (19). At the same time, this therapy method is safe and well tolerated. However, the results of these studies were not statistically significant. Particularly in China, the inconsistencies of results are more obvious due to various factors, including heredity, immune system, environment, region and ethnicity. In addition, the low number of samples assessed by individual clinical trials has represented a limitation.

Therefore, the aim of the present meta-analysis was to assess and compare the advantageous effects of acarbose combined with metformin treatment over monotherapy using either drug in the treatment of T2DM. By retrieving relevant
studies using Chinese Han populations and performing a meta-analysis, evidence-based results on a large number of samples were provided.

Materials and methods


Inclusion and exclusion criteria. Studies included in the present meta-analysis were selected using the following criteria: i) Chinese Han populations with T2DM as the subjects; ii) randomized clinical trials designed to compare the effects of combined metformin and acarbose vs. monotherapy for T2DM; iii) T2DM diagnosed according to the standards of the World Health Organization (WHO) (20); iv) inclusion of at least one of the following evaluation indexes: Total effective rate, FBS, 2HPG and HbA1c; v) sufficient information for calculation of merged effect size; and vi) among various studies with duplicate data, the study with the higher quality and number of indexes assessed was selected.

Studies were excluded for the following reasons: i) No specific description of treatment course included in the study; ii) literature reviews, meeting reports and letters.

Data extraction and quality assessment. Two evaluators assessed the quality of all studies and extracted relevant data independently. For each article retrieved, the following data were extracted: Name of first author, year of publication, region where the study was performed, the number of patients, age of the experimental and control groups, treatment course of diabetes, dosage regimen, evaluation index (total effective rate, FBG, 2HPG, HbA1c; the mean ± standard deviation was calculated). Any disagreement was resolved by discussion with a third investigator. The Cochrane quality evaluation system was used to assess the quality of the included studies (21).

Statistical analysis. Review Manager 5.2 software (Cochrane Collaboration, Oxford, UK) was used for meta-analysis in this study. χ²-based Q test (22) and I² statistics were chosen for heterogeneity test. α=0.05 was set as a testing standard. The fixed-effects model (Mantel-Haenszel method) was used for meta-analysis when the heterogeneity inspection results were P>0.05 and I²<50%. Otherwise, the random-effects model (Dersimonian-Laird method) was used. For dichotomous data, the merged effect size was presented as the risk ratio (RR) with 95% confidence interval (CI). For continuous data, the merged effect size was shown as weighted mean differences (WMD) with 95% CI. All included studies were divided into subgroups for further analysis based on different treatment courses. Funnel plots were used to detect publication bias. Sensitivity analysis was applied to test the stability of results by eliminating low-quality studies and combing other studies.

Results

Characteristics of studies included. Initially, a total of 1,417 studies were retrieved (290 with pubmed, 232 with Embase, 78 with the Cochrane, 347 with the NCKI, 364 with the Wanfang and 106 with the VIP database) based on the key words. Among them, 1,057 studies were duplicates or not focused on Chinese Han populations. After screening of the abstracts, the full-text versions of 41 studies were then retrieved. Among these, a total of 17 studies were excluded, including 12 studies lacking the required data, 3 studies with the different rule of classification, 1 study with duplicate data and 1 retrospective study. Finally, a total of 24 relevant studies were selected for meta-analysis (23-46) (Fig. 1). The included studies contained 1 English language study and 23 Chinese language studies comprising 2,337 patients. As shown in Table I, these patients were treated for durations of 2 weeks, 2, 3, 4 and 6 months. And the treatment duration of the majority of patients was 3 months. For most patients, the regimen for acarbose was 50 mg three times a day during meals, while that for metformin was 500 mg three times a day after meals. After the studies included were assessed by the Cochrane quality evaluation system, the study by Wang et al (36) was confirmed to be a high-quality study with a low risk of bias.
Table I. Characteristics of the studies included in the present meta-analysis.

### A, A+M vs. A

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Region</th>
<th>Study duration</th>
<th>Patient number (male/female)</th>
<th>Age (years)</th>
<th>History of disease, (years)</th>
<th>Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chen, 2013</td>
<td>Jiangsu</td>
<td>3 months</td>
<td>32 (22/10)</td>
<td>60±11.2</td>
<td>NA</td>
<td>A, 50 mg t.i.d.; M, 0.25 g/0.5 g b.i.d.</td>
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<tr>
<td>Guo and Guo, 2011</td>
<td>Jiangsu</td>
<td>3 months</td>
<td>25 (13/12)</td>
<td>65.4±4.8</td>
<td>5.2±1.8</td>
<td>A, 50 mg t.i.d.; M, 500 mg b.i.d</td>
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<tr>
<td>Wang et al, 2013</td>
<td>Taiwan</td>
<td>16 weeks</td>
<td>117 (60/57)</td>
<td>55.9±9.5</td>
<td>4.1±4.3</td>
<td>A, 50 mg t.i.d.; M, 0.25 g/0.5 g t.i.d.</td>
</tr>
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</table>

### B, A+M vs. M

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<th>Author, year</th>
<th>Region</th>
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<th>Age (years)</th>
<th>History of disease, (years)</th>
<th>Regimen</th>
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<tbody>
<tr>
<td>Bian, 2014</td>
<td>Shandong</td>
<td>3 months</td>
<td>32 (18/14)</td>
<td>52.1±8.2</td>
<td>6.4±1.3</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<tr>
<td>Ding, 2012</td>
<td>Zhejiang</td>
<td>3 months</td>
<td>50 (29/21)</td>
<td>53.1±9.4</td>
<td>3-11</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
</tr>
<tr>
<td>Huang et al, 2015</td>
<td>Beijing</td>
<td>3 months</td>
<td>57 (33/24)</td>
<td>52.15±1.25</td>
<td>5.7±1.4</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
</tr>
<tr>
<td>Li, 2013</td>
<td>Hunan</td>
<td>3 months</td>
<td>98 (56/42)</td>
<td>46.3±12.4</td>
<td>6.2±2.6</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<tr>
<td>Ni, 2014</td>
<td>Zhejiang</td>
<td>3 months</td>
<td>36 (21/15)</td>
<td>53.6±8.2</td>
<td>2-9</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<tr>
<td>Wang, 2013</td>
<td>Shanghai</td>
<td>3 months</td>
<td>80 (41/39)</td>
<td>60.5±9.5</td>
<td>7.5±2.0</td>
<td>M, 0.25 g t.i.d.; A, 50 mg t.i.d.</td>
</tr>
<tr>
<td>Wu, 2014</td>
<td>Jiangsu</td>
<td>3 months</td>
<td>40 (27/13)</td>
<td>51.1±8.9</td>
<td>5.5±1.4</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<tr>
<td>Yang, 2015</td>
<td>Shenyang</td>
<td>3 months</td>
<td>40 (23/17)</td>
<td>51.2±4.1</td>
<td>NA</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<td>Zhou et al, 2013</td>
<td>Zhejiang</td>
<td>3 months</td>
<td>40 (25/15)</td>
<td>50.8±10.2</td>
<td>6.3±1.8</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<td>Chen, 2014</td>
<td>Henan</td>
<td>2 months</td>
<td>35 (24/11)</td>
<td>61.7±8.1</td>
<td>7.1</td>
<td>M, 0.25-0.5 g t.i.d.; 0.25-0.5 g t.i.d.</td>
</tr>
<tr>
<td>Ren et al, 2014</td>
<td>Beijing</td>
<td>2 months</td>
<td>56 (30/26)</td>
<td>56.4±6.5</td>
<td>NA</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<tr>
<td>Wu, 2013</td>
<td>Zhejiang</td>
<td>2 months</td>
<td>210 (112/98)</td>
<td>57.4±6.2</td>
<td>NA</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
</tr>
<tr>
<td>Chen, 2014</td>
<td>Guangdong</td>
<td>2 weeks</td>
<td>60 (31/29)</td>
<td>54.8±13.8</td>
<td>NA</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<tr>
<td>Gao, 2013</td>
<td>Tianjin</td>
<td>2 weeks</td>
<td>60 (32/28)</td>
<td>57.9</td>
<td>NA</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<tr>
<td>Liu and Li, 2010</td>
<td>Guangdong</td>
<td>2 weeks</td>
<td>68 (36/32)</td>
<td>40-68</td>
<td>NA</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
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<tr>
<td>Zhang, 2014</td>
<td>Henan</td>
<td>2 weeks</td>
<td>60 (33/27)</td>
<td>41.40±1.40</td>
<td>NA</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.</td>
</tr>
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</table>
Table I. Continued.

### B, A+M vs. M

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Region</th>
<th>Study duration</th>
<th>Patient number (male/female)</th>
<th>Age (years)</th>
<th>History of disease, (years)</th>
<th>Regimen</th>
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<tr>
<td>Zhang et al., 2014</td>
<td>Henan</td>
<td>2 weeks</td>
<td>60 (30/30)</td>
<td>42-80</td>
<td>NA</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.; 0.5 g t.i.d. (43)</td>
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<td>Zheng et al., 2014</td>
<td>Zhejiang</td>
<td>6 months</td>
<td>92 (52/40)</td>
<td>60.79±7.02</td>
<td>8.39±4.02</td>
<td>M, 0.5 g t.i.d.; A, 50 mg t.i.d.; 0.5 g t.i.d. (44)</td>
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</tbody>
</table>

### C, A+M vs. A vs. M

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<th>Author, year</th>
<th>Region</th>
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<th>Patient number (male/female)</th>
<th>Age (years)</th>
<th>History of disease, (years)</th>
<th>Regimen</th>
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<tbody>
<tr>
<td>Zhang, 2011</td>
<td>Beijing</td>
<td>3 months</td>
<td>30</td>
<td>35-60</td>
<td>NA</td>
<td>A, 50 mg t.i.d.; M, 500 mg b.i.d. (42)</td>
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<tr>
<td>Zhu et al., 2011</td>
<td>Jiangsu</td>
<td>6 months</td>
<td>31 (18/13)</td>
<td>52±10</td>
<td>NA</td>
<td>A, 50 mg t.i.d.; M, 500 mg b.i.d. (46)</td>
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</table>

Values are expressed as the mean ± standard deviation, range or number as applicable. M, metformin; A, acarbose; Once: once a day; b.i.d., twice a day; t.i.d., three times a day; NA, not available. Whenever there are no entries for patient number and age in the monotherapy groups, it means that the values for the combined therapy groups include the monotherapy groups.
However, unclear risk of bias was determined for the other studies (Fig. 2A and B).

**Meta-analysis of combined therapy compared with metformin monotherapy for T2DM.** A total of 21 studies including 1,968 patients (983 receiving combined therapy and 985 receiving monotherapy) reported on combined therapy vs. metformin monotherapy for T2DM patients (23-25, 27, 28, 30-35, 37-46).

**Total effective rate.** The heterogeneity test showed no significant differences between studies regarding the total effective rate (P>0.05, I²<50%). Therefore, the fixed-effects model was applied to calculate the merged effect size. Regarding the total effective rates for combined therapy vs. metformin monotherapy for T2DM patients for 6 months, 3 months, 2 months and 2 weeks, the RRs were 1.19 (95% CI: 1.07, 1.33; P=0.002), 1.22 (95% CI: 1.14, 1.30; P<0.01), 1.26 (95% CI: 1.14, 1.38; P<0.01) and 1.44 (95% CI: 1.20, 1.73; P<0.01), respectively. As all differences were statistically significant, the combined therapy was shown to be a more effective treatment for T2DM than metformin monotherapy. In addition, the total effective rate was not significantly affected by the treatment duration as there was no significant difference between the total effective rate among different treatment durations (P>0.05; Fig. 3A).

**Blood glucose.** The indexes associated with blood glucose included FBG, 2HPG and HbA1c. The heterogeneity test indicated significant differences in FBG levels between studies (P<0.05, I²>50%; Fig. 3B). Therefore, the random-effects model was applied to calculate the merged effect size. The WMDs for combined therapy vs. metformin monotherapy for T2DM patients treated for 6 months, 3 months, 2 months and 2 weeks were -0.47 (95% CI: 1.43, 0.49; P=0.34), -1.46 (95% CI: -2.41, -0.52; P<0.01), -0.97 (95% CI: -1.38, -0.56; P<0.01) and -2.97 (95% CI: -3.86, -2.08; P<0.01), respectively. The results showed that except for the 6-months group, the differences at were statistically significant for all other treatment durations. Heterogeneity tests revealed significant differences in 2HPG among the studies (P<0.05, I²>50%; Fig. 3C). Therefore, the random-effects model was applied to calculate the merged effect size. The WMDs for combined therapy vs. metformin monotherapy for T2DM patients treated for 6 months, 3 months, 2 months and 2 weeks were -1.71 (95% CI: -3.39, -0.02; P=0.05), -1.62 (95% CI: -2.91, -0.33; P=0.01), -1.12 (95% CI: -2.06, -0.18; P=0.02) and -2.37 (95% CI: -3.38, -1.36; P<0.01), respectively. The differences were not statistically significant with the exception of the 2-week group.

Heterogeneity tests revealed significant differences in HbA1c among the studies (P<0.05, I²>50%; Fig. 3D). Therefore, the random-effects model was applied to calculate the merged effect size. The WMDs for combined therapy vs. metformin monotherapy for T2DM patients treated for 6, 3 and 2 months was -0.13 (95% CI: -0.61, 0.35; P=0.65), -0.80 (95% CI: -2.16, 0.56; P=0.25) and -0.63 (95% CI: -1.07, -0.18; P=0.006), respectively. The differences were statistically significant after two months, but not after three or six months of treatment.

**Meta-analysis of combined therapy compared with acarbose monotherapy for T2DM.** A total of 5 studies including 470 patients (235 receiving combined therapy and 235 receiving monotherapy) reported on the combined therapy vs. acarbose
monotherapy for T2DM patients (26,29,36,42,46). Based on the treatment course, only one study was available for each subgroup. Therefore, no meta-analysis was performed here for the included studies (Fig. 4A-D). The RR regarding the total effective rate of combined therapy vs. acarbose monotherapy for T2DM patients treated for 3 months was 1.29 (95% CI: 1.05, 1.59) and there was no statistically significant difference between the two groups. However, FBG, 2HPG and HbA1C at four months of treatment were significantly different between the two groups with WMDs of -1.61 (95% CI: -2.23, -0.99), -2.08 (95% CI: -3.21, -0.95) and -1.36 (95% CI: -1.66, -1.06), respectively.

**Evaluation of publication bias.** In the present study, funnel plots were used to identify publication bias. Symmetric funnel plots on the total effective rate of FBG showed that there was no publication bias in the studies included (Fig. 5A and B).

**Sensitivity analysis.** By eliminating low-quality studies (38,43,45) in turn and combing other studies, it was confirmed that the results of the sensitivity analysis were reliable and stable.

**Discussion**

The present meta-analysis showed for the first time, to the best of our knowledge, that metformin combined with acarbose treatment of T2DM patients of a Chinese Han population had a greater beneficial effect than monotherapy with either drug. Acarbose is the first-line medication for the treatment of T2DM, which delays carbohydrate absorption by inhibiting α-glycosidase enzymes on the surface of intestinal epithelial cells to effectively lower post-prandial hyperglycemia (47). Similarly, metformin enhances insulin sensitivity and decreases insulin resistance by increasing glucose uptake and utilization of peripheral tissue, accelerating anaerobic

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**Figure 3.** Forest plots of various indexes compared between combined therapy and metformin monotherapy. (A) Total effective rate; (B) fasting blood glucose; (C) blood glucose levels at two post-prandial hours; and (D) hemoglobin A1C. CI, confidence interval; df, degrees of freedom; M-H, Mantel-Haenszel; SD, standard deviation.
glycolysis to inhibit glycogenosis, and reduce the output of hepatic glycogen (48). Therefore, metformin is considered to have various effects in metabolic regulation through activating the protein kinase signaling system (49). The actions of metformin and acarbose are complementary, and combined therapy may therefore achieve improved effects. Through reducing gluconeogenesis, metformin lowers the rate of glucose production (50). However, the results of the present

<table>
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<th>Study or Subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
<th>Risk Ratio M-H, Fixed, 95% CI</th>
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<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
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<td></td>
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<td>Total</td>
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![Forest plots of various indexes compared between combined therapy and acarbose monotherapy. (A) Total effective rate; (B) fasting blood glucose; (C) blood glucose levels at two post-prandial hours; and (D) hemoglobin A1C. CI, confidence interval; SD, standard deviation.](image)

![Funnel plot for (A) total effective rate and (B) fasting blood glucose. SE, standard error; RR, risk ratio; MD, mean difference.](image)

Figure 4. Forest plots of various indexes compared between combined therapy and acarbose monotherapy. (A) Total effective rate; (B) fasting blood glucose; (C) blood glucose levels at two post-prandial hours; and (D) hemoglobin A1C. CI, confidence interval; SD, standard deviation.

Figure 5. Funnel plot for (A) total effective rate and (B) fasting blood glucose. SE, standard error; RR, risk ratio; MD, mean difference.
study showed that the efficacy of this treatment method was lower than that of combined treatment after three months.

In the present meta-analysis, differences in indexes, including the total effective rate, fasting blood glucose, 2HPG and HbA1c were found between combined and monotherapy groups. The results were in accordance with the finding of most individual studies. In the study by Zhang (42), the combined treatment confirmed to be effective than single medicine treatment on various indexes such as FPG, 2HPG and BMR. A variety of previous meta-analyses on different therapy methods for T2DM patients are available. Boulé et al (51) confirmed that exercise therapy is an important constituent of diabetes treatment, which was able to reduce HbA1c as well as the risk of diabetic complications. Their meta-analysis study showed that physical therapy was beneficial for T2DM patients, while the efficacy of anti-diabetic drugs, particularly combined regimens, was demonstrated in the present study. Furthermore, a meta-analysis study by Amori et al (52) showed that incretin can be applied for T2DM with a favorable weight-change profile and modest efficacy. However, the present study did not perform any meta-analyses for indexes including lipid profile, postprandial glycemia and antibody development due to insufficient data provided by the studies included. Due to the selection criteria applied after the literature search, the studies included in the present meta-analysis contained comprehensive data on indexes including total effective rate, fasting blood-glucose, 2HPG and HbA1c.

Of note, the present meta-analysis had certain limitations. After the studies included were assessed using the Cochrane quality evaluation system, the study by Wang et al (36) was confirmed to be a high-quality study with low risk of bias. However, other studies (38,43,45) had an unclear risk of bias and are therefore a lower standard. Furthermore, Fig. 5 indicated that there may have been bias for each individual time-point. In addition, only one study on combined vs. acarbose monotherapy was available for each subgroup based on the treatment course; therefore, the studies on combined therapy vs. acarbose monotherapy were not subjected to meta-analysis.

The present meta-analysis indicated that combined treatment with metformin and acarbose is more efficacious in T2DM patients than monotherapy with metformin or acarbose. In addition, with increasing treatment time (2 weeks, 2, 3 and 6 months), the differences in the efficacy between combined therapy and metformin monotherapy decreased. For clinical application, specific conditions of individual patients should be taken into account. In order to improve the therapeutic efficacy, combined therapy of metformin and acarbose is a better treatment method than monotherapy if it is matched to the individual patient.

References


