Author’s response to reviews

Title: Effectiveness of monthly and bimonthly follow-up of patients with well-controlled type 2 diabetes: a propensity score matched cohort study

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Author’s response to reviews:

Dear Dr. Saisho

Thank you for consideration of our manuscript for publication in the BMC Endocrine Disorders and spending time reviewing our article. We believe the revised manuscript is improved and look forward to your editorial decision. Below, we addressed the reviewers’ comments.

Sincerely,

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Responses to reviewers’ comments

Reviewer 1

The study compares the effectiveness of monthly vs bimonthly follow up of Japanese patients with well controlled type 2 diabetes and shows that outcomes are equivalent at one year. The study is clearly presented. There are a few points for clarification.

Background- second last paragraph - suggest change "but the difference was not clinically relevant" to "...not of clinical significance."

—Thank you for your suggestion. We changed the sentence as you suggested. (Background section, line 9, page 7)

Methods -

Opt out recruitment. I understand the need for this. How was it actually done? Do patients routinely agree to use of their data?

—We appreciate your suggestion about our insufficient description of opt-out. Patients did not routinely agree to use of the data, but they were informed of our research plan and could decline the use of their data if they wanted. We added detailed information. (Methods section, line 9, page 7)

Aging rate - can you please explain this briefly

—We removed the term “aging rate” and instead described it as “people aged 65 years or more”. (Methods section, line 7, page 7)

Results

Table 3 - please include n= at top of columns of results.

—We included “n=” as advised. (Table 3)

Please check annual costs as text and table 3 are different
We are sorry for the mistake and thank you for pointing it out. (Table 3)

Table 3 shows minimal differences in lipids and BP so please note this in text and reconcile this, especially for BP, with your comments on figure 1 in the text.

—Thank you for your suggestion. The figure shows equivalence was not met between monthly and bimonthly groups, but they were not significantly different. Therefore, we changed the sentence as in Results section, line 11, page 12.

Reviewer 2

The authors have asked and addressed an important question with regards to the necessity of frequent follow-up in patients with well controlled diabetes. Although many international guidelines have suggested f/u duration of 3-6 months with well controlled diabetes, frequent followup (1 month or bimonthly) has not been looked at, as it is generally not practised in most other countries. This however is still an important question, particularly for the local practice whereby the follow-up frequency appears to be unnecessarily frequent and a costly exercise.

—We appreciate your constructive feedback.

There are a few issues for the authors to address,

Is there a clinical explanation / or otherwise, why physicians may choose to have bimonthly follow-up (f/u) with patients, compared to monthly? As the reader may not be aware of the practice in Japan, and it appears that physicians may not be remunerated if the patient is not seen monthly, then is there another non-medical / medical reason why some patients may have different follow-ups? Since this will affect how some patients may be selected to be in one group and not the other, and may confound results.

—We do not fully understand how physicians decide visit intervals. However, previous studies have shown that physicians/population rations are associated with visit frequency. The visit frequency increased as physicians/population rations increased. Therefore, we assume physicians decide visit intervals from financial incentives but they also take other factors, such as the number of patients they can manage, into account. Since we do not have information on physician-side factors, we mentioned it in the limitation section. (Discussion section, line 8, page 16)
It was good that the authors matched both groups at baseline for other parameters eg lipid and BP levels, as follow-up may have been different if these other risk factors were not controlled. However, as they mentioned in the discussion, due to the matching, subjects with monthly f/u with poor control were excluded entirely. Since more patients on monthly f/u were using more antihypertensive, or oral blood glucose lowering drugs and lipid lowering drugs, more of these patients were excluded and these findings cannot be extrapolated to all the patients.

—We selected only well-controlled diabetes patients because our interest was about how we could shorten the visit interval for already well-controlled patients. As you suggested, this possess a question of generalizability. We mentioned it in Discussion section, line 15, page 16.

In the abstract background, they have mentioned that the objective was to look at cardio-metabolic outcomes. This can be misleading as it suggests hard cardiovascular endpoints (eg AMI / CVA).

—We removed the misleading term. Thank you for pointing it out.

In the methods, it is unclear what an opt-out recruitment approach is.

——We appreciate your suggestion about our insufficient description of opt-out. Patients did not routinely agree to use of the data, but they were informed of our research plan and could decline the use of their data if they wanted. We added detailed information. (Methods section, line 9, page 7)

Does it mean that this study only uses National Health Insurance dat which consists only of the self-employed?

—The National Health Insurance covers self-employed, retired and employees who are not provided health insurance by the company. We added the description. (Methods section, line 11, page 7)

Would recommend a consort diagram to explain to the readers the selection of subjects in the study.

—We add the diagram as you recommended (Figure 1).
In the results, it is confusing when the authors mentioned 'blood pressure and all three outcomes', as it is not clear which three outcomes they are. Furthermore, the following line has again, 'all other secondary health related outcomes.'

— We changed the confusing terms for clarity. (Results section, line 10, page 12)

It is unclear why the authors chose absolute SD in table 1 and 2 instead of a paired t test.

— Thank you for your suggestion. We put absolute SD so readers can understand how well monthly follow-up group and bimonthly follow-up group were matched by comparing the value of absolute SD between table 1 and table 2. However, we also added the p-value of t-test as you suggested.

In table 3, they mention that a few variables are different between the two groups (eg BP, cost, and all three outcomes). However, in this table only annual cost appears to be statistically significant?

— From figure 2, in which we used binary scales, we can say that the clinical outcomes for diabetic control and cholesterol control are equivalent between monthly and bimonthly groups. We cannot say that the clinical outcomes for blood pressure control and all three (blood sugar level, cholesterol level, and blood pressure) are equivalent. Since the 95% CI includes zero, we cannot say whether monthly follow-up is better than the bimonthly follow-up, either. We think our description was confusing so we changed the text.

In table 3, we used the continuous scale, not binary scale. In contrast with binary scale, equivalence was meet for blood pressure.