**Anticoagulation-related quality-of-life associated with extended-interval monitoring: A pre-specified analysis of the FADE-OUT study**

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**Purposes**

- The CHEST 2012 Guideline included an option to extend the interval of warfarin monitoring up to every 12 weeks (vs. the previous 4 weeks).
- Reduced anticoagulation follow-up burden has been proposed to improve quality of life (QoL); but, to our knowledge, this question has not been explicitly studied.
- We aimed to assess the impact of a real-world extended-interval warfarin monitoring on QoL, and to identify patient characteristics associated with changes in QoL.

**Methods**

- FADE-OUT was a prospective single-arm intervention pilot study of extended-interval warfarin monitoring in patients recruited from 5 UF ACR Network clinics; patient enrollment criteria are summarized in Table 1.
- Study visits were performed at baseline and weeks 6, 14, and 26, and every 12 weeks thereafter to a maximum of 68 weeks of follow-up, or until no longer suitable for extended follow-up.
- Patients were removed from the study if they required a warfarin dose change, or were otherwise deemed no longer appropriate for extended-interval monitoring.
- The validated 25-question Duke Anticoagulation Satisfaction Scale (DASS) was used to assess QoL at baseline and end of study.
- Possible score range: Best QoL = 25 – Worst QoL = 18.

**Results**

- Baseline patient characteristics are summarized in Table 2.
- The primary outcome was change in total DASS score; secondary outcomes were change in sub-scale score (limitations, time points; however, QoL on the psychological impact sub-scale was significantly worse after extended-interval monitoring (Table 3).
- No significant change was observed in total DASS score comparing baseline and post-extended-interval monitoring time points, though, QoL on the psychological impact sub-scale was significantly worse after extended-interval monitoring (Table 3).
- Sensitivity analyses demonstrated no significant association between total DASS score (or any sub-scale score) and whether or not a patient completed the -week extended interval monitoring intervention.
- Individual survey questions demonstrating the greatest adverse effect on QoL (mean change ≥ 2.5).
- 4b: how much do you feel reassured because of your anti-clot treatment (+0.5 psychological impact sub-scale)
- 4a: overall, how much has anti-clot treatment had a positive impact on your life (+0.67 psychological impact sub-scale)
- No significant association was found between change in total DASS score and sex, employment, or taking the DASS survey.
- No significant change was observed in total DASS score and sex, employment, or taking the DASS survey.
- Increasing years taking warfarin at baseline trended toward an association with decreased hassles sub-scale score.
- Greater number of medications may be associated with greater adverse psychological impact.

**Conclusions**

- Extended-interval follow-up resulted in substantial variation in DASS score change (Figure 2).
- Total DASS score trended toward an adverse change in QoL.
- In particular, adverse changes were most pronounced in the psychological impact sub-scale.
- One plausible reason for the potential decrement is that extended-interval follow-up fosters patient disengagement from self-management activities due to less frequent feedback and patient-provider interaction.
- No characteristics were significantly associated with a favorable change in QoL after the extended-interval monitoring intervention.
- Study limitations include a relatively small sample size and incomplete data in a minority of patients; due to these limitations and no adjustment for multiple comparisons, these results should be considered hypothesis-generating.
- Additional research is needed to identify who extended interval monitoring may benefit or impair with regards to QoL.
- Additionally, QoL should be clarified with clinical factors and shared-decision making when implementing extended-interval warfarin monitoring.

**References**