Predicting Quality of Life through Changes in Menstrual Blood Loss in Patients with Uterine Fibroids

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Background & Objective

- Uterine fibroids (UF) are common benign tumors that grow within the uterine wall. Heavy menstrual bleeding is the main symptom of UF, significantly affecting quality of life (QoL) of women with UF. Menstrual blood loss (MBL) is measured in most clinical trials involving UF patients.
- The objective was to develop a predictive utility function based on incremental changes in MBL to predict QoL in patients with symptomatic UF for use in health economic models.

Methods

- **Population:** Adult women with UF included in the LIBERTY 1-3 clinical trials (1,2).
- **Variables:** QoL was assessed through EQ-5D, previously estimated from Uterine Fibroid Symptom and Quality of Life (UFS-QoL) measures (3). Other variables of interest: MBL in mL and age in years.
- **The model:** An ordinary least squares (OLS) regression was parameterized on patient-level data, defined as:

$$EQ\text{-}5D = \alpha + \beta_1 \text{ MBL volume} + \beta_2 \text{ Age} + \varepsilon$$

α: intercept, $\beta_{1/2}$: linear change in EQ-5D for one unit change in MBL/age, ε: error term

A parsimonious regression model was used to promote replicability and transparency. Within-patient correlations were not accounted for, as the prediction of individual EQ-5D scores was based on point estimates.

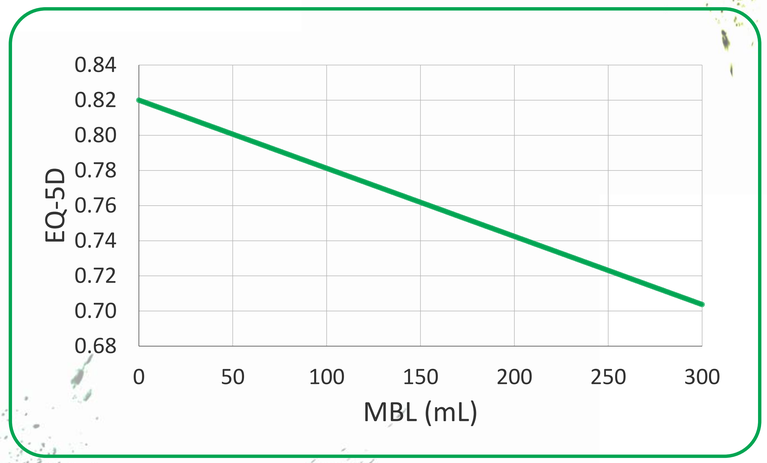

Figure 1. Modelled linear association between EQ-5D and MBL (green line) at constant age of 42 years (population mean age).

Results

The OLS model was fitted using 1,706 observations. Results for each regression coefficient are listed in Table 1. The model predicts that a 100 mL decrease in MBL volume increases EQ-5D index value by 0.04 (Figure 1) and a one-year increase in age corresponds to a 0.003 increase in EQ-5D. However, the EQ-5D increase with age (3% in 10 years) was negligibly small and should therefore be interpreted with caution.

Table 1. OLS results

Coefficient	Point estimate
Intercept (α)	0.6957
MBL volume in mL (β_1)	-0.0004
Age at baseline in years (β_2)	0.0030

Conclusions

In women with UF, symptomatic improvements in MBL were associated with proportional improvements in overall quality of life. This prediction model offers a replicable, accessible, and transparent way to estimate quality of life based on changes in MBL for direct use in health economic modelling.

Limitations

It should be noted that age should be used as a constant at baseline and should not be varied over time when used in health economic modelling. Multiple patient observations were included, and a within-patient correlation was not modelled. Hence, standard errors may be biased, and the model should not be used for inference. However, it may still produce accurate coefficient-based EQ-5D predictions.

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