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Commentary on the cost-utility analysis of the FEMME trial Dikshyanta Rana, Research Assistant, HEHTA, University of Glasgow

BJOG: An International Journal of Obstetrics & Gynaecology recently published the results of an economic evaluation¹ of the FEMME² randomised controlled trial (RCT) along with an accompanying mini commentary³. The economic evaluation included a cost-utility analysis (CUA) which compared uterine artery embolisation (UAE) and myomectomy for women with symptomatic uterine fibroids wishing to avoid hysterectomy. CUA is a form of economic evaluation which allows estimation of cost per preference-based valuation of outcome.

The CUA was performed from the perspective of the UK national health service (NHS) at two-years and four-years follow up. It included 254 women who were randomised to UAE (n=127) and myomectomy (n=127) arm. Direct medical costs were estimated. Quality-adjusted life-years (QALYs), which is a summary measure that quantifies the quality and quantity of life-years gained from a treatment, were used to express the health-related quality of life outcome. It was calculated using the utility score obtained from a preference-based quality of life instrument, EuroQoL 5D 3L.

Rana et al. (2021) explain, "The results indicate UAE as not a cost-effective alternative to displace myomectomy. We observed that UAE patients had higher costs and lower QALYs compared to myomectomy patients. Our analysis also showed that at a willingness-to-pay (WTP) threshold of £20,000, myomectomy had a 98% and 96% probability of being cost-effective at two-and four-years follow-up. In the UK, the National Institute for Health and Care Excellence (NICE) has specified a maximum WTP threshold of £20,000-£30,000 per QALY. Any treatment which is over this threshold are judged as not cost-effective and are not recommended for adoption by the NHS."

The authors also state, "Initially, treatment costs were lower for UAE patients as the procedure itself is cheaper and requires a shorter stay in the hospital for recovery compared to myomectomy. However, UAE patients started accumulating higher costs after discharge. The reason behind this was an increased utilisation of healthcare resources in form of GP visits, outpatient appointments and inpatient admissions during the follow-ups. The increase was also associated with re-interventions for fibroid removal. Related to the QALYs, both treatments led to an improvement in the quality of life of women. A closer look at the EQ-5D domains showed that women who underwent myomectomy experienced a greater improvement in terms of pain/discomfort and anxiety/depression".

The study emphasises that the differences in costs and QALY between the two procedures were small and statistically insignificant. The cost difference over two years and four years was £645 and £352, respectively. QALY difference was -0.09 for both years.

The authors remarked, "Converting the QALY difference between the two treatments to days in perfect health shows that myomectomy added only 33 days on average compared to UAE. Interestingly, it is difficult to establish if 33 days creates a meaningful difference in women's lives or not. Though QALYs are a valid and reliable measure for expressing health outcomes, they may not always be sufficiently sensitive to capture non-health related preferences of individual patients for various treatment processes. Thus, CUA framework is restrictive here".

The authors add, "our trial design did try to capture women's preferences for non-health outcomes by asking questions like 'would you have your operation again?' and 'would you recommend the operation to a friend?' to women at various follow-up time points. The results were favourable to both treatments, albeit myomectomy was viewed more favourably. Nevertheless, an inclusion of more formal quantitative methods for elicitating patient preferences, such as a discrete choice experiment

(DCE) would have added value. But it may be difficult to streamline such methods into the framework of cost-effectiveness/cost-utility analyses and its decision rules".

The authors share that "The comparison of non-invasive, non-surgical treatment UAE and invasive, surgical treatment myomectomy for women with symptomatic uterine fibroids is long overdue. There are few existing RCTs which compare both treatments, however, they have small samples and together provide inconclusive results. Our trial has overcome this hurdle of recruitment and successfully achieved its aims. Relatedly, the current economic literature includes studies based on inconclusive clinical evidence and do not directly compare UAE and myomectomy. We hope that our economic evaluation will fill this gap by using robust data obtained from the largest, multicentre trial of its kind".

They conclude, "Above all, we must remember that symptomatic uterine fibroids are a genuine issue for women of reproductive age as it impacts their quality of life. Therefore, it is crucial that the preferences of well-informed patients are considered when choosing between UAE and myomectomy. All women should have the option to choose between the two procedures". The authors recommend future research to explore methods like DCE to elicit patient preferences and incorporate other treatments (such as magnetic resonance-guided high-intensity focused ultrasound (MRgHIFU)) in an economic evaluation.

The conclusion derived from the economic evaluation is analogous to the two-year trial results published in the NEJM² and covered previously by *Interventional News* ⁴. The four-year clinical result is awaiting publication and will be available in the National Institute for Health Research (NIHR) Journals Library.

Hyperlinks:

- 1. Rana, D, Wu, O, Cheed, V, Middleton, LJ, Moss, J, Lumsden, M-A, McKinnon, W, Daniels, J, Sirkeci, F, Manyonda, I, Belli, A-M, McPherson, K; the FEMME Trial Collaborative Group. Uterine artery embolisation or myomectomy for women with uterine fibroids wishing to avoid hysterectomy: a cost—utility analysis of the FEMME trial. *BJOG*. 2021; https://doi.org/10.1111/1471-0528.16781.00: 1–10.
- 2. Manyonda, I., Belli, A. M., Lumsden, M. A., Moss, J., McKinnon, W., Middleton, L. J., ... & McPherson, K. (2020). Uterine-artery embolization or myomectomy for uterine fibroids. *New England Journal of Medicine*, 383(5), 440-451.
- 3. Hooker A. B. (2021). Is the patient's choice the best choice? *BJOG*: an international journal of obstetrics and gynaecology, 10.1111/1471-0528.16814. Advance online publication. https://doi.org/10.1111/1471-0528.16814
- 4. https://interventionalnews.com/femme-trial-myomectomy-superior-uae/