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Epidemiology of uterine myomas and clinical practice in Spain: An observational study

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ABSTRACT

Objective: Characterization of the clinical features of symptomatic uterine myomas in Spanish women visiting the gynaecologist, including impact on quality of life and possible risk factors, description of main therapeutic approaches, and evaluation of symptom and quality of life progression 6 months after inclusion in the study.

Study design: This was an observational, epidemiological, non-interventional, multicentre study performed between June 2015 and March 2016. Data were collected at baseline and follow-up visits 6 months apart from women with a diagnosis of uterine myomas and visiting a participating gynaecologist in outpatient units of private clinics or public hospitals in Spain. Data consisted of a gynaecological clinical inspection, an interview with open questions to the patients, and self-administered generic questionnaires. The main outcome measures were socio-demographic data, clinical history, myoma clinical features, symptomatology, data on surgical choices, patient satisfaction, and risk factors associated to myomas.

Results: Data were collected from 569 patients (1,022 myomas) at 56 hospitals and private gynaecological offices in Spain. Most patients (85%) presented between 1 and 3 myomas, predominantly intramural and subserosal. Most common symptoms reported heavy menstrual bleeding and pelvic pain, and the mean (±SD) symptom severity score in the UFS-QoL questionnaire (range 0–100) was 50.89 ± 20.85. Up to 60.5% of patients had an indication of surgery (55.8% myomectomies, 40.4% hysterectomies) to treat their uterine myomas and 39.5% followed other therapies, mainly pharmacological. After six months of treatment, all patients had experienced significant reduction in symptoms and improvement of quality of life.

Conclusions: The most frequent symptoms reported by women diagnosed with uterine myomas were heavy menstrual bleeding, pelvic or abdominal pain and dysmenorrhea; QoL was impaired reflecting high symptom distress. We found that surgery was the main therapeutic approach to manage uterine myomas in Spain. Both surgical and non-surgical treatments achieve relevant improvements in symptom severity and quality of life.

Introduction

Uterine myomas represent 20% of all benign tumours in women of childbearing age and, according to some estimates, they can affect up to 70–80% of women [1–3]. In addition to this high prevalence, it is estimated that 25–40% of myomas generate symptoms that ultimately impact on the quality of life and the daily activities of the affected women, or become so severe as to require specific treatment [3–5]. Myomas can cause heavy menstrual bleeding, anaemia [6], bowel and bladder dysfunction,

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urinary incontinence, infertility and recurrent miscarriage [7]. Risk factors include genetics, ethnicity, age, early menarche, caffeine and alcohol intake, and obesity [3,8,9].

The incidence rates and prevalence of uterine myomas are likely underestimated as they only take into account those women who have symptoms or consult a healthcare professional [1,3]. The choice of treatment requires knowledge of the clinical features (myoma size, localization and number) for optimal outcomes, and also of the patient's symptomatology and preferences (i.e. desire to preserve fertility or avoid 'radical' surgery) [8,10]. Although hysterectomy was long considered the only therapeutic option for the treatment of severe myomatosis, other techniques are currently available now which allow for a more individualized approach and preservation of the uterus [8].

Multiple studies have highlighted the importance of symptoms in the quality of life of the patient [7,11,12]. In spite of this, in many cases the time between the onset of symptoms and the beginning of a medical treatment can be long. Indeed, a study of myomatosis in five large European countries revealed that between 9.0% and 32.5% of women waited $\geq$5 years before seeking treatment [13]. Spain had the highest proportion of diagnosed but untreated myomas (57.4%) [13].

The primary aim of this observational epidemiological study (EME Study: Spanish for 'Epidemiological Study on Uterine Myomas in Spain') was to describe the clinical features of uterine myomas and their progress in diagnosed women in Spain. Secondarily, we evaluated the quality of life of women suffering from this condition and possible risk factors. We also described the different therapeutic approaches and evaluated symptom progression and quality of life 6 months after inclusion in the study.

Methods

This is a non-interventional, epidemiological, multicentre study performed between June 2015 and March 2016 in Spain. The primary objective was the clinical characterization of symptomatic myomas in women visiting a gynaecologist in Spain. Other objectives included the assessment of the impact of the symptoms on patient's quality of life; the average time between programming and surgical intervention of the myomas; estimation of the fraction and characteristics of myomas subjected to surgery; the determination of the frequency of different risk factors typically associated with presence of uterine myomas; and, finally, the assessment of the level of acceptance of the patient regarding the need for surgery. The protocol and all study materials were approved by the Clinical Research Ethics Committee of Teknon Medical Center - Quirón Hospital Group on June 2, 2015. The EME study reference number is GR-OB-02-2015.

Participation in the study did not imply any risk for the patients nor did it involve the modification of usual therapeutic guidelines. It did not require the prescription of any particular drug. The study was carried out in accordance with the principles adopted by the 18th World Medical Assembly (Helsinki, 1964).

Study population and procedure

A total of 57 gynaecologists working at gynaecologic units at public hospitals (80.0%) and private consultation offices (20.0%) accepted to participate. Each gynaecologist collected data for 10 patients. The gynaecologists had a mean 26.6 ± 8.3 years of experience in clinical practice and the participating centres attended between 30 and 1,400 patients weekly.

To be included in the study patients had to be older than 18 years with a confirmed diagnosis of single or multiple uterine symptomatic myomas. In addition, they had to agree to participate in the study and provide their informed consent. Pregnant women were excluded from the study.

Data were collected in consultations according to usual clinical practice in two sequential visits: the baseline visit and the follow-up visit. In the baseline visit, the patient was informed of the study and signed the informed consent. The gynaecologist completed all sections of the data collection notebook, which included gynaecological and obstetric history of the patient and assessment of the current episode: characteristics of the myomas (according to ultrasound (US)), current symptoms and previous treatments. Consecutively the patient filled a form in which specific symptoms and an assessment of general health status, habits and quality of life was recorded. In addition, the therapeutic approach was also recorded by the gynaecologist, confirming (or not) the need of surgical intervention, as well as the selected procedure and the estimated date of surgery.

At the follow-up visit (6 months $\pm$2 weeks after the baseline visit) the gynaecologist recorded data on the overall patient's progress, as well as the treatment followed and whether or not surgery had been carried out; characteristics of the myomas in patients not undergoing surgery were re-assessed. The patient again provided data on the associated symptomatology, general health status and quality of life.

Measurement instruments

Socio-demographic data, medical record, risk factors and other variables were obtained by the gynaecologist based on the clinical interview and examination, and using both from generic questionnaires and open questions to the patients. Transvaginal sonography (TVS) provided information on the number of myomas and their location, as well as their relation to the myometrium (submucosal, intramural, subserosal) using the classification system proposed by the Working Group on Menstrual Disorders of the International Federation of Gynaecology and Obstetrics (FIGO) [14]. The symptom intensity was assessed by the patient with a Visual Analogue Scale (VAS) with a score of 0–10 where a higher value denotes greater severity. Health-related quality of life was assessed with the Spanish version of the EuroQoL-5D [15], (ranging from 0–having concerns- to 1–no concerns) and the Uterine Fibroids Symptom and Health-related Quality of Life Questionnaire (UFS-QoL) [7], in which scores for symptom severity range from 0 to 100, with higher scores indicating increased severity. Total scores for health-related quality of life range from 0 to 100, with higher scores indicating a better quality of life.

Statistical analysis

Categorical variables were presented as lists of frequencies and proportions. Quantitative variables were described as means and standard deviations or as medians with maximum and minimal values. All tables, figures or graphs were calculated from the number of valid cases (N). Categorical variables were analysed by Pearson's Chi-Square Tests and the effect size was measured by Odds Ratio). In case of continuous variables, analysis was carried out by One-way ANOVA and effect size measured by Cohen's d. In case of non-normally distributed or ordinal data, *U*-Mann Whitney test were performed. Multivariate methods were used in order to study the independence of the factors detected. Paired tests (McNemar and Wilcoxon test) were used to assess the evolution of quality of life, patient symptomatology, and tumour volume. Statistical analysis was performed using SPSS 22.0 statistical software for Windows.

Results

In this observational study we collected data on 569 women diagnosed with uterine myomas. The sociodemographic