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The incidence of hysterectomy, uterus-preserving procedures and recurrent treatment in the management of uterine fibroids

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ABSTRACT

Objective: To determine the incidence of hysterectomy and uterus-preserving procedures (UPPs) among women with uterine fibroids (UFs) and the incidence of further procedures after a UPP.
Study design: This was an observational study using a primary care database, The Health Improvement Network (THIN). Women in THIN with UFs aged 15–54 years between January 2000 and December 2009 were eligible for study. The UPPs examined were myomectomy, endometrial ablation (EA) and uterine artery embolization (UAE). Using Read codes, women were followed up until one of the following was met: there was a record of hysterectomy or UPPs, they died or the study ended (end of 2010).
Results: The cumulative incidence of hysterectomy or UPPs was 23.6% at 1 year, and 40.9% after the follow-up period (median 3.6 years). At the end of the follow-up period, the cumulative incidences of hysterectomy, myomectomy, EA and UAE were 33.0%, 3.9%, 6.4% and 1.9%, respectively. For women initially treated with a UPP, the cumulative incidence of second procedures was 11.5% at 1 year. At the end of the follow-up period (median 2.7 years), the cumulative incidence of further procedures was 26.1%, and the cumulative incidences of women undergoing hysterectomy, myomectomy, EA and UAE were 19.0%, 4.3%, 3.4% and 1.4%, respectively.
Conclusions: Women considering UPPs for the management of UFs should be made aware that the incidence of further treatments is high, with hysterectomy being the most frequent procedure undergone.

Introduction

Uterine fibroids (UFs) are the most common benign tumors in women. In an international, Internet-based survey, the self-reported prevalence of UFs ranged from 4.5% in the UK to 9.8% in Italy [1]. However, ultrasound screening and the assessment of medical records of randomly selected members of a US urban health plan showed that 70–80% of women developed UFs before the menopause [2]. Many women with UFs experience heavy menstrual bleeding, and may also suffer from pelvic pressure and pain resulting from the presence of UFs [3]. Hysterectomy is the definitive treatment for UFs, but results from the vaginal abdominal or laparoscopic uterine excision (VALUE) study showed that severe operative complications occur in 4.4% of women [4]. The VALUE study also showed that the risk of severe complications was higher in women with fibroids than in those undergoing hysterectomy for other indications.

Patients who do not wish to undergo hysterectomy may seek uterus-preserving procedures (UPPs), such as myomectomy, endometrial ablation (EA) or uterine artery embolization (UAE) [5]. EA is most commonly used in the treatment of heavy menstrual bleeding, but may also be used to treat submucosal fibroids [6]. Fibroid recurrence (i.e. regrowth and/or the development of additional fibroids) is common after UPPs, and some women undergo further procedures, including hysterectomy [7–9]. In fact, ultrasound examination showed fibroid recurrence in 46% of women 2 years after abdominal myomectomy, and in 84.4% of women 8 years after laparoscopic myomectomy, although the majority of women who experienced fibroid recurrence did not

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[1] This manuscript is dedicated to Dr Susan Andersson, who passed away suddenly on 3 February 2013. Susan was a passionate researcher and fully contributed to all stages of this project.

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undergo further procedures [10,11]. In a detailed histological study of 100 consecutive hysterectomy samples, most fibroids that were found measured no more than a few millimeters in diameter [12]. Therefore, complete eradication of fibroids by UPPs is unlikely to be achieved.

The objectives of this study were to determine (1) the incidence of hysterectomy and UPPs among women with UFs and (2) the incidence of further procedures after UPPs, using data from a primary care database, The Health Improvement Network (THIN).

Materials and methods

Data source

THIN is a medical research database that contains anonymized data for over 3 million patients. Participating primary care physicians (PCPs) record information on diagnoses, procedures and symptoms using Read codes [13]. The patient data in THIN is representative of the UK population and has been validated for pharmaco-epidemiological research [14]. THIN data collection scheme has been approved by the UK Multicentre Research Ethics Committee (reference number: 07H1102103) and the study protocol was reviewed and approved by an independent scientific review committee (reference number 12-014).

Study design

Women in THIN aged 15–54 years between January 2000 and December 2009 who had UFs were identified [15]. To be eligible for inclusion in the study, women had to have been enrolled with PCP for at least 5 years, have a computerized prescription history of at least 3 years and have had at least one consultation with their PCP in the past 3 years. Women with a record of surgery of the uterus on or before the date of diagnosis of UFs were excluded. Using Read codes, women were followed up from the date of first diagnosis until one of the following criteria was met: there was a record of hysterectomy or a UPP, they died or the study period ended (end of 2010).

The UPPs studied were myomectomy, EA and UAE. UFs can also be treated using magnetic-resonance-guided focused ultrasound, but the routine use of this technique was not approved by the National Institute for Health and Care Excellence until 2011, so was outside the scope of the current study [16]. The cumulative incidence of procedures was calculated using the Kaplan–Meier method. Overall incidence per 100 woman-years was also estimated.

In a subsequent analysis, women who underwent a UPP (including those who had undergone a UPP before or on the UF diagnosis date) were followed up until there was a record of further procedures, they died or the follow-up period ended (end of 2010). A further follow-up was conducted to identify those who underwent hysterectomy following a UPP. Data on parity status were collected on the date of UF diagnosis. The hazard ratio (HR) of procedures according to age, parity status and type of first procedure was calculated by Cox regression methods.

Results

Cumulative incidence of treatment following diagnosis of UFs

In total, 9260 women with UFs were identified. Of these, 561 had undergone surgery of the uterus on or before the recorded date of UF diagnosis and were excluded. Of the remaining cohort of 8699 women, 2992 underwent hysterectomy or a UPP. An incidence of 9.7 procedures per 100 woman-years (95% confidence interval (CI): 9.3–10.0 procedures per 100 woman-years) was determined. When stratified by age group, the incidence peaked at 14.9 procedures per 100 woman-years for women aged 40–44 years at diagnosis of UFs (Fig. 1).

Following a recorded diagnosis of UFs, 23.6% ($n = 2035$) of women underwent hysterectomy or a UPP within 1 year (Fig. 2 and Table 1). Among those at risk, the proportions of women who underwent hysterectomy, myomectomy, EA or UAE were 18.8%, 2.1%, 3.1% and 0.7%, respectively (Table 1). Over the follow-up period (a maximum of 11 years, median follow-up 3.6 years), 40.9% of women underwent hysterectomy or UPPs. The cumulative incidences of hysterectomy, myomectomy, EA and UAE were 33.0%, 3.9%, 6.4% and 1.9%, respectively.

Risk factors for undergoing invasive procedures following a diagnosis of UFs

Adjusting for age and parity status, women aged 34 years or under at diagnosis of UFs were at a reduced risk of undergoing invasive procedures compared with women aged 35–49 years (adjusted HR: 0.57; 95% CI: 0.47–0.70). Similarly, women aged 50 years or over at diagnosis were at a reduced risk of undergoing invasive procedures compared with women aged 35–49 years (HR: 0.61; 95% CI: 0.56–0.68). At the time of diagnosis of UFs, women who were parous were at a similar risk of invasive procedures as women who were non-parous (HR: 0.95; 95% CI: 0.88–1.02).

Cumulative incidences of further procedures following a UPP

For women initially treated with a UPP ($n = 1033$), the cumulative incidence of subsequent UPPs and hysterectomy was 11.5% ($n = 112$) within 1 year and 26.1% ($n = 182$) over the study period (median follow-up of 2.7 years) (Fig. 3). The cumulative incidences of second procedures after a UPP were: 19.0% ($n = 112$) for hysterectomy, 4.3% ($n = 34$) for myomectomy, 3.4% ($n = 26$) for EA and 1.4% ($n = 10$) for UAE.

The proportion of women requiring a second procedure during the first 6 months after the initial UPP was higher for women having undergone myomectomy (7.0%; $n = 36$) or UAE (7.0%; $n = 7$) than for women who underwent EA (4.9%, $n = 19$) (Fig. 4a). At the end of the follow-up period, the proportion of women requiring second procedures was higher in those who initially underwent UAE (30.8%) than in those undergoing EA (25.8%) or myomectomy

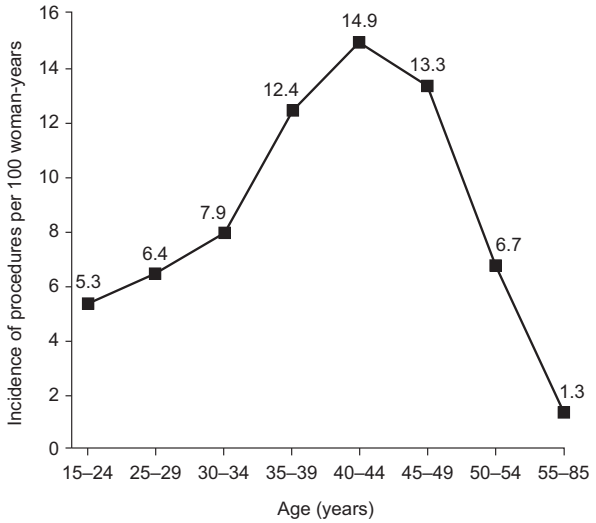

Fig. 1. Incidence of hysterectomy and uterus-preserving procedures per 100 woman-years among women with uterine fibroids, stratified by age group.