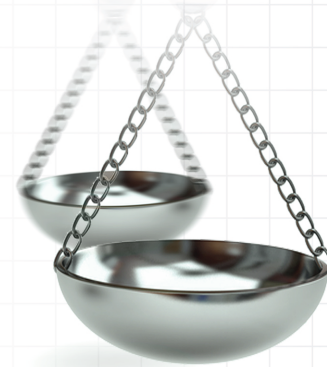




The health-related quality of life of patients with a benign gynecological condition: a 2-year follow-up

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Kristiina Pynnä*,¹ , Pirjo Räsänen² , Harri Sintonen³ , Risto P Roine^{4,5}  & Piia Vuorela^{6,7} 

¹Department of Obstetrics & Gynecology, University of Helsinki & Helsinki University Hospital, PB 140 FI-00029 HUS, Finland

²External Evaluation Unit, Hospital District of Helsinki & Uusimaa, PB 780 FI-00029 HUS, Finland

³Department of Public Health, University of Helsinki, P.O. Box 20, University of Helsinki FI-00014, Finland

⁴Department of Health & Social Management, University of Eastern Finland, PB 1627, Kuopio FI-70211, Finland

⁵Group Administration, University of Helsinki & Helsinki University Hospital, PB 705 FI-00029 HUS, Finland

⁶Department of Obstetrics & Gynecology, University of Helsinki & Helsinki University Hospital, Biomedicum Helsinki, Helsinki 00029, Finland

⁷Department of Health & Social Welfare, City of Vantaa, Peltolantie 2D, Vantaa 01300, Finland

*Author for correspondence: Tel.: +35 850 428 7393; kristiina.pynna@hus.fi

Aim: To assess health-related quality of life (HRQoL) of patients with benign gynecological disorders. **Materials & methods:** Prospective 2-year follow-up with the 15D HRQoL-instrument of 311 women treated in Helsinki-area hospitals in 2012–2013. **Results:** The initially impaired HRQoL regarding excretion, discomfort and symptoms, and vitality and sexual activity improved after treatment. However, only sexual activity reached similar levels as in the general population. Treatment of endometriosis, fibroids and polyps resulted in best and that of unspecific pelvic pain and bleeding disorders in worst HRQoL scores. Results were independent of hospital size. **Conclusion:** The impaired HRQoL dimensions were improved by treatment but HRQoL still remained poorer than in the general female population. Treatment of unspecific pelvic pain and bleeding disorders needs further evaluation.

Tweetable abstract: Benign gynecological conditions markedly impact women's quality of life including physical, sexual and mental well-being. Two-year follow-up of patients in this new study found quality of life to be partly improved by treatment, but was still lower than in the general female population.

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Keywords: benign • gynecology • health-related quality of life • patient-reported outcomes • women's health

The impact of seemingly simple common benign gynecological conditions on the quality of life (QoL) of women [1] and on the costs for the society is high [2,3]. Half of fertile aged women suffer from a benign gynecological condition [4]. Nearly 80% of these women see a doctor annually and a third spends one or more days in bed every year due to their condition [1]. Physical, sexual and mental well-being is impaired in these women [1,5,6]. Women with chronic pelvic pain and conditions associated with it (endometriosis) have been reported to have worse health-related QoL (HRQoL) than women with other benign gynecological conditions [1]. However, it is not only the endometriosis and pelvic pain patients that suffer from diminished HRQoL as for example two-thirds of uterine fibroid patients report moderate to severe symptoms and diminished HRQoL [7]. Even more concerning than this is the fact that, for example, only a third of women treated for a gynecological bleeding disorder were satisfied with the treatment regarding symptoms and HRQoL 1 year after treatment [8]. Nevertheless, limited data on patient reported outcomes have hindered the establishment of new, better patient satisfaction yielding treatment protocols [9]. Another challenge in the field of benign gynecology is how to assess whether surgery yields more benefit than conservative treatment and whether this benefit will last. For example, studies have not been able to

answer whether surgical treatment of pelvic organ prolapse improves HRQoL at all, and if it does, will the benefit last in the long term [10–12].

During the recent years, there has been a shift among healthcare professionals toward a more patient-centered healthcare system. Patient-reported outcomes have gained importance when assessing treatments and can now-a-days even outweigh clinical and caregiver-reported outcomes during therapy selection [13]. In order to assess the HRQoL results of treatment, various generic instruments (such as EQ-5D, 15D, SF-36 or HUI-3) can be used.

The aim of this study is to provide new, original, and short- and long-term data on the HRQoL of patients with a common benign gynecological condition. The study perspective is that of patients in a typical outpatient gynecological clinic in a real-world setting. The long-term follow-up enables better recognition of patient groups whose treatment protocols need further development.

Materials & methods

A prospective observational HRQoL and cost study was conducted in the Department of Obstetrics and Gynecology in the hospitals of the Helsinki and Uusimaa Hospital District: the Helsinki University Hospital (comprising the Women's Hospital, the Kätilöopisto Maternity Hospital and the Jorvi Hospital in the Helsinki metropolitan area) and four smaller community hospitals (Hyvinkää Hospital, Lohja Hospital, Porvoo Hospital and Raasepori Hospital [former Länsi-Uusimaa Hospital] outside of the Helsinki metropolitan area). The cost data will be reported separately. All women treated for a benign gynecological condition in the general gynecological outpatient department in these hospitals between 1 June 2012 and 31 August 2013 were invited to participate in the study. Patients with uterine fibroids or other benign uterine neoplasm, endometriosis, adenomyosis, a uterine prolapse, endometrial or cervical polyps, a gynecological bleeding disorder, dysmenorrhea or lower abdominal/pelvic pain, or some other benign uterine finding were included in the study. No other inclusion or exclusion criteria were used apart from the above-mentioned diagnosis groups. The ICD-10 classification codes were used to group the patients according to the clinician's assessment. If a specific reason for the condition was found (for example a uterine fibroid or a uterine polyp causing abnormal uterine bleeding), this specific disease was the primary diagnosis and the patient fell into that patient group. If no apparent reason for the condition was found, the patient was categorized into the group reflecting the symptom (for example, idiopathic menorrhagia in the bleeding disorder group).

Patients were treated according to typical clinical practice. They filled in the 15D HRQoL questionnaire before treatment (before/when attending the first outpatient clinic appointment and baseline) and 6 months and 2 years after treatment initiation. If no answer to the follow-up survey was received in 3 weeks, one reminder was sent. The results were compared with the HRQoL of age-standardized general female population of the same geographical area (urban Southern Finland). The population data came from the Health 2011 Health Examination Survey which covers a representative sample of the general Finnish population [14].

The 15D is a standardized, generic and self-administered HRQoL instrument validated in the Finnish population that provides a HRQoL profile and a single index score. The patient is asked to evaluate its 15 dimensions (mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity) on a scale of 1–5 (1 = no problems and 5 = worst possible state). Population-based preference weights are used to calculate dimension level values and the single index score representing overall HRQoL (the 15D score) on a 0–1 scale (1 = full health and 0 = being dead). Thus, the higher the score is, the better the QoL of the patient is. Up to three missing answers can be imputed by predictions from linear regression analysis based on the other dimensions, with age and gender as independent variables [15,16]. The minimum clinically important change or difference in the 15D score has been established to be ± 0.015 [17].

Paired samples t-test was used to test the statistical significance of the change in HRQoL during follow-up. Statistical significance of the differences in means between groups was tested using Student's t-test. A two-way p-value of <0.05 was considered statistically significant. All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Ethics Committee of the Helsinki University Central Hospital, registration number 538/E0/02) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed written consent was obtained from all individual study participants. This included consent to include material pertaining to themselves and an acknowledgement that patients cannot be identified via the published article.

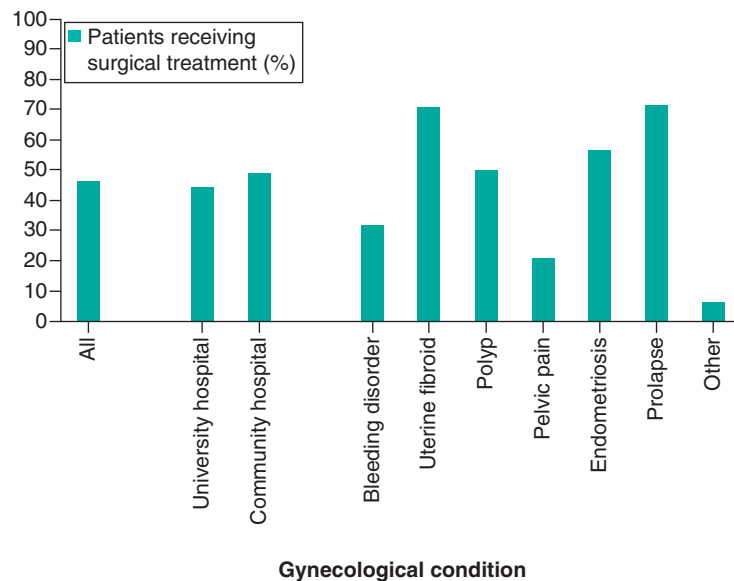


Figure 1. Percentage of patients receiving treatment in the operation theatre according to hospital & diagnosis group.

Results

Of the 1173 women who were invited to participate in the study, 543 women answered the baseline questionnaire. Of them 389 (71.6% of the women who decided to participate in the study) women fulfilling the inclusion criteria (concerning the reason of treatment and had answered at least 12 of the 15D dimensions in all three follow-up questionnaires) answered the 6-month follow-up and 311 (57.3%) women the 2-year follow-up. The mean age of the included patients at baseline was 49.6 years (standard deviation [SD] ± 12.8 , range 19–98). Of them 178 (57.2%) were treated in a university hospital and 133 (42.8%) in a community hospital. Patients were treated due to bleeding disorders ($n = 94$), uterine fibroids ($n = 79$), polyps ($n = 68$), dysmenorrhea/pelvic pain ($n = 24$), endometriosis ($n = 23$), uterine prolapse ($n = 7$) or some other benign uterine disorder ($n = 16$). The mean long-term follow-up time was 24 months 11 days (SD ± 12 days).

Of all patients 167 (46.3%) were treated operatively: 44.4% ($n = 79$) of university hospital patients and 48.9% ($n = 65$) of community hospital patients. The percentage of patients operated on varied depending on the patient's disorder (Figure 1). The only statistically significant difference in operative treatment between university hospitals and community hospitals was the higher frequency of polyp treatment in the surgical theatre in community hospitals (66.7 vs 36.8%, $p < 0.05$).

HRQoL

The total HRQoL score improved in a clinically important manner (15D score change of ≥ 0.015) in 41.5% ($n = 129$) of the study patients by the 6-month follow-up and 46.3% ($n = 144$) by the 2-year follow-up. The mean 15D score had improved statistically significantly compared with baseline (mean 0.901, SD ± 0.084) at the 6-month (0.909, SD ± 0.092 , $p < 0.05$) and the 2-year follow-ups (0.909, SD ± 0.087 , $p < 0.05$) but it did not improve statistically significantly between the 6-month and 2-year measurement points. The dimensions of excretion, discomfort and symptoms, and vitality and sexual activity improved statistically significantly ($p < 0.05$) in the whole study group from baseline compared with both the 6-month and the 2-year follow-up. Of these dimensions, only sexual activity improved statistically significantly also between the 6-month and the 2-year follow-up. No dimensions deteriorated during the follow-up.

When compared with the age-standardized general female population of the same geographical area, patients in our study had poorer mean 15D scores both at baseline (0.901, SD ± 0.084 vs 0.927, SD ± 0.020) and at the follow-up points (0.909, SD ± 0.092 vs 0.927, SD ± 0.020 and 0.909, SD ± 0.087 vs 0.924, SD ± 0.024). The differences were both statistically significant ($p < 0.05$) and clinically important (≥ 0.015). At baseline, the study patients were statistically significantly worse off on the dimensions of vision, sleeping, excretion, usual activities, discomfort and symptoms, distress, and vitality and sexual activity than the general female population. Of the dimensions impaired at baseline, treatment effectively improved only sexual activity to a similar level as observed in

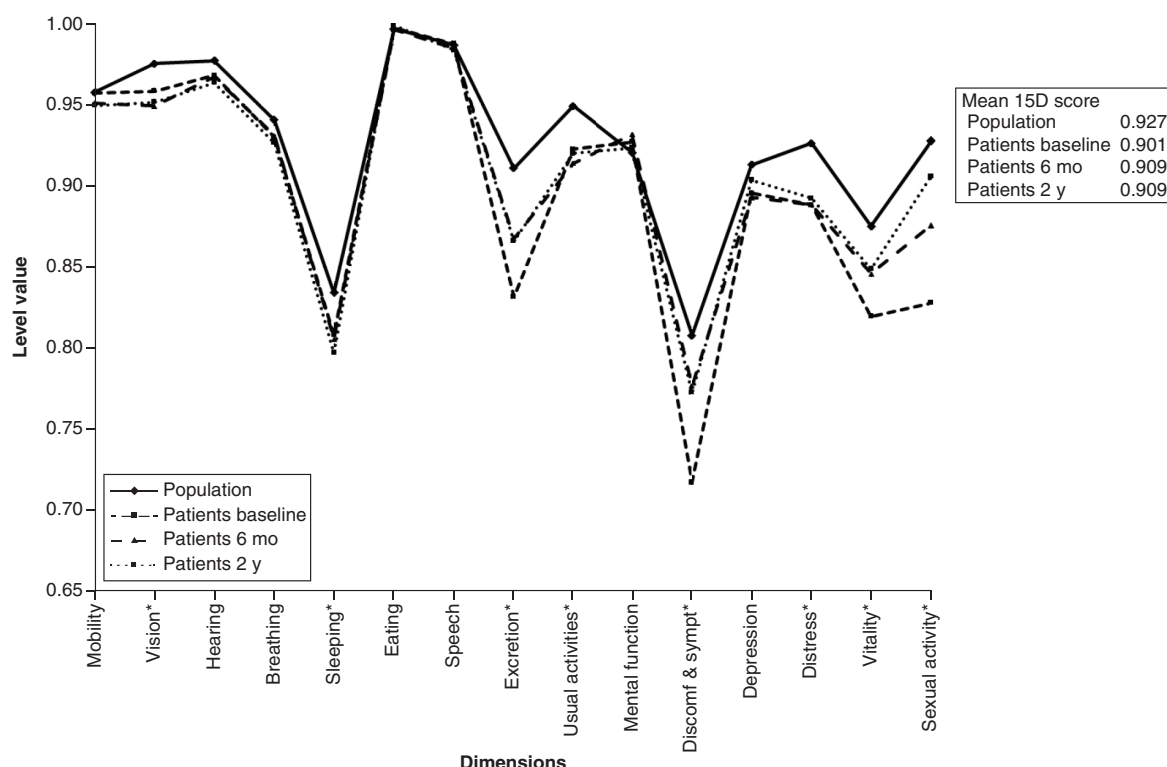


Figure 2. Health-related quality of life profile & 15D scores of age-standardized general female population compared with study patients at baseline, 6 months & 2 years.

*Statistically significant difference when comparing study patients and the general female population.

the general population during the 2-year follow-up. All other dimensions impaired at baseline remained impaired during the whole follow-up (Figure 2).

Both at baseline and at the short-term follow-up, patients with a uterine fibroid or polyp were better off regarding total HRQoL than those with pelvic pain ($p < 0.05$). At the 2-year follow-up the only significant difference in total HRQoL was seen between patients with fibroids and bleeding disorders in favor of the fibroid patient group. The total HRQoL score did not differ significantly when comparing the other patient groups to each other at the different follow-up points (Table 1).

The percentage of patients who had a clinically important improvement (≥ 0.015) in the 15D score was largest in endometriosis patients at the long-term follow-up (65.2%) and in endometriosis and prolapse patients at the short-term follow-up (56.5 and 57.1%, respectively). Only 33.0% of patients suffering from bleeding disorders and 37.5% of those with pelvic pain received clinically important symptom alleviation by 6 months. HRQoL improvement remained poor for pelvic pain patients even at the 2-year follow-up, as only 33.3% of patients showed a clinically important improvement. Some of the bleeding disorder patients, however, benefited from treatment later on as by the long-term follow-up 43.6% of patients had clinically important improvement in HRQoL, more in line with the other diagnosis groups (Table 2).

Prolapse patients seemed to benefit from operative treatment as the percentage of patients with improved HRQoL at the 6-month follow-up was higher in those treated operatively than in those treated conservatively ($p \leq 0.0005$). Also the mean HRQoL scores at the 6-month and 2-year follow-ups were higher in operatively treated patients. Also patients with uterine fibroids reported significantly higher mean 2-year HRQoL scores in the patient group treated surgically.

The only statistically significant and clinically important change in the mean HRQoL score in the different diagnosis groups during the whole follow-up was seen in fibroid patients as their score improved from the baseline 0.911 to 0.926 at 2 years ($p < 0.05$). Treatment had a significant impact most often on the sexual activity of the study patients. Also the dimensions of discomfort and symptoms, excretion and vitality improved statistically significantly ($p < 0.05$) in more than one of the diagnosis groups (Table 3). When comparing the different

Table 1. Health-related quality of life (total 15D score) according to hospital, diagnosis and treatment group.

	15D baseline	15D 6 months	15D 2 years
All	0.901 (SD ± 0.08) [†]	0.909 (SD ± 0.09) [†]	0.909 (SD ± 0.09) [†]
University hospitals	0.898 (SD ± 0.09)	0.905 (SD ± 0.09)	0.902 (SD ± 0.09)
Community hospitals	0.905 (SD ± 0.08)	0.914 (SD ± 0.09)	0.919 (SD ± 0.08)
Bleeding disorder	0.895 (SD ± 0.10)	0.900 (SD ± 0.10)	0.898 (SD ± 0.10)
Fibroid	0.911 (SD ± 0.07) [†]	0.917 (SD ± 0.09)	0.926 (SD ± 0.07) [†]
Polyp	0.910 (SD ± 0.08)	0.921 (SD ± 0.08)	0.915 (SD ± 0.08)
Pelvic pain/dysmenorrhea	0.872 (SD ± 0.10)	0.875 (SD ± 0.10)	0.881 (SD ± 0.10)
Endometriosis	0.894 (SD ± 0.07)	0.914 (SD ± 0.09)	0.906 (SD ± 0.09)
Prolapse	0.883 (SD ± 0.09)	0.911 (SD ± 0.12)	0.886 (SD ± 0.15)
Other	0.915 (SD ± 0.08)	0.919 (SD ± 0.07)	0.921 (SD ± 0.04)
All – oper	0.915 (SD ± 0.06) [†]	0.926 (SD ± 0.08) [†]	0.927 (SD ± 0.07) [†]
All – nonoper	0.889 (SD ± 0.10) [†]	0.895 (SD ± 0.10) [†]	0.894 (SD ± 0.09) [†]
Bleeding disorder – oper	0.877 (SD ± 0.19)	0.923 (SD ± 0.19)	0.914 (SD ± 0.08)
Bleeding disorder – nonoper	0.888 (SD ± 0.11)	0.888 (SD ± 0.11)	0.891 (SD ± 0.10)
Fibroid – oper	0.925 (SD ± 0.05) [†]	0.925 (SD ± 0.09)	0.944 (SD ± 0.05) [†]
Fibroid – nonoper	0.876 (SD ± 0.10) [†]	0.898 (SD ± 0.08)	0.880 (SD ± 0.09) [†]
Polyp –oper	0.920 (SD ± 0.06)	0.938 (SD ± 0.06)	0.925 (SD ± 0.07)
Polyp – nonoper	0.899 (SD ± 0.09)	0.903 (SD ± 0.10)	0.905 (SD ± 0.08)
Pelvic pain – oper	0.913 (SD ± 0.08)	0.894 (SD ± 0.09)	0.889 (SD ± 0.15)
Pelvic pain – nonoper	0.861 (SD ± 0.10)	0.870 (SD ± 0.10)	0.879 (SD ± 0.09)
Endometriosis – oper	0.872 (SD ± 0.07)	0.894 (SD ± 0.10)	0.894 (SD ± 0.10)
Endometriosis – nonoper	0.923 (SD ± 0.06)	0.940 (SD ± 0.06)	0.921 (SD ± 0.08)
Prolapse – oper	0.908 (SD ± 0.04)	0.976 (SD ± 0.03) [†]	0.954 (SD ± 0.03) [†]
Prolapse – nonoper	0.822 (SD ± 0.14)	0.750 (SD ± 0.12) [†]	0.715 (SD ± 0.21) [†]
Other – oper (n = 1)	0.917 (–)	0.879 (–)	0.876 (–)
Other – nonoper	0.915 (SD ± 0.08)	0.922 (SD ± 0.07)	0.924 (SD ± 0.04)

[†]Significant differences (p < 0.05).

All: baseline vs 6 months, baseline vs 2 years

Fibroid: baseline vs 2 years

All oper vs all nonoper: baseline, 6 months, 2 years

Fibroid oper vs fibroid nonoper: baseline, 2 years

Prolapse oper vs prolapse nonoper: 6 months, 2 years

Non-oper: Non-operative treatment; Oper: Operative treatment; SD: Standard deviation.

Table 2. The percentage of patients experiencing a clinically important improvement in health-related quality of life (15D score changed ≥ 0.015) or deterioration (15D score changed ≤ -0.015) from baseline to 6 months and from baseline to 2 years according to hospital and diagnosis group.

Patient groups	Change in HRQoL from baseline to 6 months		Change in HRQoL from baseline to 2 years	
	HRQoL improved	HRQoL deteriorated	HRQoL improved	HRQoL deteriorated
All	41.5	26.4	46.3	28.0
Bleeding disorder	33.0	31.9	43.6	27.7
Fibroid	44.3	21.5	54.4	25.3
Polyp	48.5	20.6	44.1	27.9
Pelvic pain	37.5	33.3	33.3	37.5
Endometriosis	56.5	21.7	65.2	17.4
Prolapse	57.1	42.9	42.9	42.9
Other	25.0	31.2	25.0	37.5
University hospitals	42.1	29.2	43.3	32.6
Community hospitals	40.6	22.6	50.4	21.8

HRQoL: Health-related quality of life.

Table 3. Statistically significant changes ($p < 0.05$) in the mean dimension level values of the 15D in different patient groups.

	From baseline to 6 months		From baseline to 2 years		From 6 months to 2 years
	Improvement	Deterioration	Improvement	Deterioration	Improvement deterioration
All	Discomfort and symptoms	–	Discomfort and symptoms	–	Sexual activity
	Excretion		Excretion		
	Vitality		Vitality		
	Sexual activity		Sexual activity		
Bleeding disorder	Discomfort and symptoms	–	Sexual activity	–	–
	Vitality				
Uterine fibroid	Discomfort and symptoms	–	Discomfort and symptoms	–	Discomfort and symptoms
			Excretion		Vitality
			Vitality		Sexual activity
			Sexual activity		
Polyp	Excretion	–	Vitality	Mobility	–
	Sexual activity		Sexual activity		
Pelvic pain	Sexual activity	–	Discomfort and symptoms	Sleep	–
			Sexual activity		
Endometriosis	Discomfort and symptoms	–	Discomfort and symptoms	–	–
	Excretion		Excretion		
Prolapse	–	–	–	–	–
Other	–	–	–	–	–

dimensions along the follow-up between the different disorder groups it was noted that as a whole, patients with pelvic pain or bleeding disorders seemed to have more HRQoL concerns than patients with polyps or fibroids (Figure 3).

There were no statistically significant differences on either follow-up point and in any of the diagnosis groups in the mean 15D scores between patients treated in university hospitals and those treated in community hospitals. A total of 42.1 and 43.3% of patients treated in a university hospital, and 40.6 and 50.4% of patients treated in community hospitals showed a clinically important improvement (≥ 0.015) in the mean 15D score at the 6-month and 2-year follow-ups, respectively.

As only 57.3% of the 542 women, who answered the baseline questionnaire in the end, met the inclusion criteria concerning diagnosis and answered all of the follow-up questionnaires, we analyzed the HRQoL results of those lost-to-follow-ups as well. One could suppose that patients with more distress caused by the condition at hand would more eagerly answer study questionnaires. However, when comparing the baseline mean HRQoL score of the patients, who did not answer the follow-up questionnaires to those who did, it turned out that the mean baseline 15D score was higher in those who continued to participate in the study (0.901 [$SD \pm 0.084$] vs 0.872 [$SD \pm 0.123$], $p < 0.001$). It remains out of reach of this study to determine whether the HRQoL of these patients improved so well due to treatment that they did not feel inclined to answer the follow-up questionnaires, or whether these patients were already so tired of their symptoms that answering the study questionnaires did not seem relevant.

Discussion

Even though the impact of benign gynecological conditions on the HRQoL of women is significant, relatively little has been published on HRQoL results of typical treatment protocols in an every-day clinical environment [1,3]. As a whole, our study revealed that the present clinical practice of treatment of benign uterine disorders yields mostly rather good HRQoL results. However, HRQoL remains inferior compared with the general female population and the degree of improvement after treatment varies from one condition to another.

As nearly 80% of women suffering from a benign gynecological disorder see a doctor annually [4] and up to two-thirds of patients may report moderate to severe impact on QoL [7], the HRQoL results in our study were surprisingly good already at baseline. However, the significance of these seemingly minor common disorders is

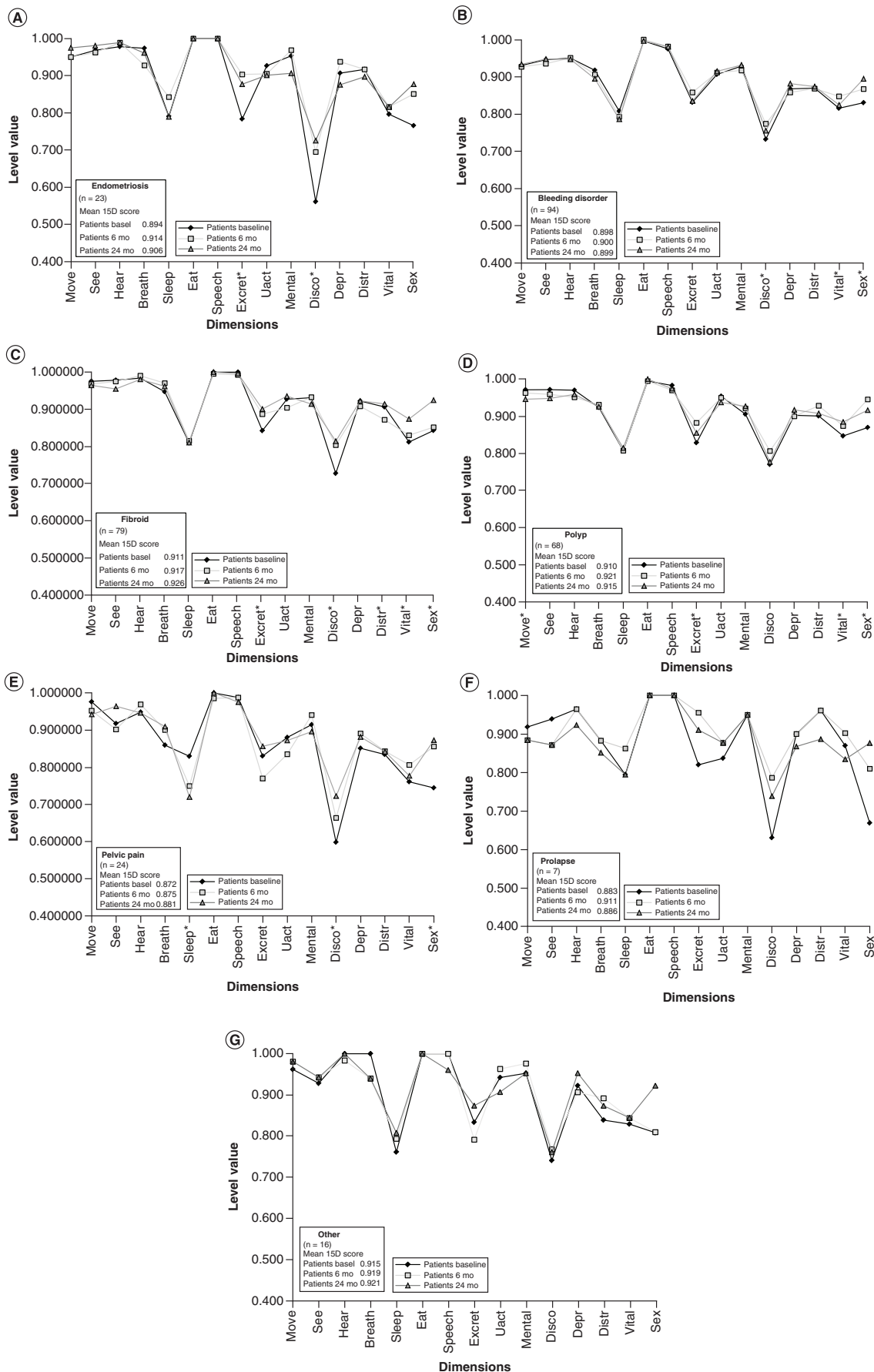


Figure 3. The mean 15D profiles of patients in the different diagnosis groups (A–G).

evident also in our study as HRQoL of the women suffering from them does not reach the level of that of the general female population even after treatment. A wide spectrum of HRQoL dimensions is impaired but it is noteworthy that treatment allows women to regain sexual activity over time.

It has been reported previously that the impaired physical, sexual and also mental well-being in women with a benign gynecological condition improves after treatment [1,5–7,18–21]. Our study showed that the benefits of treatment appear fairly rapidly and were evident already at the short-term follow-up in the whole study group and in most of the specific diagnosis groups. The benefits were also relatively well sustained throughout the long-term follow-up. The physical QoL (dimensions of excretion, discomfort and symptoms, and vitality) and the mean 15D score improved statistically significantly from the baseline to the 6-month follow-up and remained at the improved level also at the 2-year follow-up. Sexual activity kept improving significantly throughout the study period, even from the 6-month follow-up to the 2-year follow-up.

Only a third of the bleeding disorder patients reported improved HRQoL during 6 months after treatment initiation. However, some of these patients benefited from treatment later on, as by the 2-year follow-up 43.6% of patients had improved HRQoL compared with baseline, quite well in line with the other diagnosis groups. The mean total HRQoL score did not improve and patients with bleeding disorders had more concerns in the different areas of QoL when compared with several other diagnosis groups. Thus, it seems that bleeding disorders affect the QoL of women suffering from them and treatment is not always easy. Hysterectomy has traditionally been thought to be the most effective treatment strategy of heavy menstrual bleeding [22–27]. However, literature has more recently also shown HRQoL results to be similar after less invasive treatments such as endometrial ablation and levonorgestrel-releasing intrauterine system (IUS) [23–27]. Furthermore, the IUS has been found to be the most cost-effective treatment [28,29] even though nearly 50% of patients initially treated with IUS may need to undergo hysterectomy later on [28]. Our study showed no difference in total HRQoL independent of whether bleeding disorder patients were treated conservatively or operatively. However, the 6-month results were not encouraging which could be due to conservative treatment failing in some patients. A larger proportion of patients had received symptom alleviation by the 2-year follow-up. In order to improve HRQoL of patients with bleeding disorders, a possibility for a second assessment of symptoms after 6 months of primary treatment should be maintained to be able to intervene if burdensome symptoms persist.

Like the systematic review of Jones *et al.*, our study also found dysmenorrhea and pelvic pain patients to have impaired HRQoL. However, opposed to findings of the systematic review, virtually no improvement was seen in the HRQoL of our study patients during the 6-month or the 2-year follow-up [1]. Thus, our study suggests that the treatment conventions of pelvic pain and dysmenorrhea patients should be re-evaluated as healthcare resources are used for very little HRQoL benefit.

The QoL of endometriosis patients has been reported to affect all areas of QoL [30]. However, in our patient material, endometriosis patients were not significantly worse off at baseline than the other patient groups, but the patients with diagnosed endometriosis stood out from the other diagnostic groups with the biggest proportion of patients benefiting from treatment. Compared with treatment of other benign indications, hysterectomy has been found to be especially cost-effective in the treatment of endometriosis [2]. However, as a primary treatment of endometriosis drug treatment has been reported to be more cost-effective than surgery [31,32]. Even though laparoscopic excision of endometriosis has been shown to improve all domains (pain, control and powerlessness, emotional well-being, social support, and self-image) of QoL [33], our study patients with endometriosis had similar mean 15D scores irrespective of whether surgery or conservative treatment was used. This could, however, also be an indication of successful selection of the treatment modality for the patients at hand.

Treatment in the operation theatre is associated with high healthcare resource use and often places the patient under a higher complication risk. Thus, decisions for surgical treatment should always be justifiable. A study setting of comparison of the subjective patient outcome between operative and conservative treatment of a certain gynecological condition is rare. In our study, patients with uterine fibroids and prolapses benefited from operative treatment with better HRQoL results after surgery than after conservative treatment. Patients treated for polyps with an operational hysteroscopic polypectomy or in an outpatient setting did not differ regarding HRQoL results suggesting that outpatient hysteroscopic polypectomy should be preferred, as resource use in an outpatient setting tends to be smaller. Similar results concerning polypectomy have been reported earlier but the accessibility of outpatient polypectomies has been thought to be a restricting factor [34,35].

Strengths & limitations

HRQoL data of the variety of common benign gynecological disorders in usual clinical practice in a real-life setting are rare. The aim of this study was to produce such data on the HRQoL and treatment results of the whole entity of gynecological patients treated in a typical public outpatient clinic. A consequence was a fairly heterogeneous patient material with many different conditions. Yet, the patient material of a typical gynecological outpatient clinic is broad and the precise aim of the study was to reflect the actual real-life situation of gynecological patients. This heterogeneity of the patient material can be regarded as strength of the study but at the same time also as a limitation as some of the diagnosis groups were rather small. In a real-life setting some overlapping of diagnoses may always exist. Therefore, the HRQoL may have been reported by some women while suffering from two separate medical conditions simultaneously. In this study they have, however, been grouped to only one group according to their primary diagnoses. Even though this might disturb the HRQoL comparisons between groups, the authors find this to be acceptable when gaining knowledge from a real-life setting. The authors consider this is strength of the study. Even though the study cohort is from a few years back, the patient material in outpatient gynecological clinics has remained the same and treatment protocols have not changed since the IUS gained ground before the study time period. Millions of women worldwide suffer from these common gynecological conditions. Thus our study setting and cohort is valid and still timely.

Conclusion

As a whole, the HRQoL of patients with benign gynecological disorders is good but still inferior to that of the general female population. The treatment improved especially the patients' excretion functions, decreased discomfort and symptoms, and enhanced vitality and sexual activity. However, of these dimensions only sexual activity did not deviate statistically significantly from that in the general population at 2 years. Treatment of endometriosis, fibroids and polyps resulted in best HRQoL scores but the treatment protocols of unspecific pelvic pain and bleeding disorders need further evaluation. No differences in the HRQoL results were seen between smaller community hospitals and university hospitals.

Future perspective

Millions of women worldwide suffer from common gynecological conditions. These conditions have a marked effect on the HRQoL of the women affected by them. Thus, the impact of these seemingly minor disorders, without clear objective parameters to follow in healthcare, is vast on our population. In healthcare, more weight has generally started to be placed on subjective patient reported outcomes. In the future, especially in the field of common benign gynecological disorders, it is important to evaluate the outcome of treatment, the need for further treatment and the appropriate allocation of healthcare funds according to patient reported outcomes. Based on the research trend of recent years, we suspect that clinical practice could very well be evolving toward this direction in the upcoming years.

Summary points

- Health-related quality of life (HRQoL) data on the variety of common benign gynecological disorders in real-life clinical practice are rare.
- The impact of benign gynecological conditions on the HRQoL of women is significant.
- The impaired HRQoL of women with gynecological disorders is improved by treatment but still remains poorer than in the age-standardized general female population.
- Treatment especially improved the patients' excretion functions, decreased discomfort and symptoms, and enhanced vitality and sexual activity.
- Treatment of endometriosis, fibroids and polyps resulted in best HRQoL scores, but the treatment conventions of unspecific pelvic pain and bleeding disorders need further evaluation.

Author contributions

All the authors participated in planning the study. K Pynnä gathered the data. K Pynnä and H Sintonen were responsible for data analysis and K Pynnä for most of the interpretation of the data and for drafting the manuscript. P Räsänen, H Sintonen, RP Roine and P Vuorela acted as senior authors and consultants throughout the writing process and were responsible for revising the manuscript. All authors have approved the final version to be published.

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Financial & competing interests disclosure

H Sintonen is the developer of the 15D and receives royalties from its electronic versions. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Ethical conduct of research

The study protocol was approved by the Ethics Committee of the Helsinki University Central Hospital (registration number 538/E0/02) and, thus, the study was performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed written consent was obtained from all individual study participants. This included consent to include material pertaining to themselves, an acknowledgement that patients cannot be identified via the paper and that full anonymization was performed.

Data sharing statement

The authors certify that this manuscript reports original clinical trial data. Individual, de-identified participant data that underlie the results reported in this article (text, tables, figures and appendices) are available from the corresponding author following publication if needed.

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