

# The efficacy of Implanon for the treatment of chronic pelvic pain associated with pelvic congestion: 1-year randomized controlled pilot study

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## Abstract

**Objective** To evaluate the beneficial effects of Implanon on pelvic pain in women with pelvic congestion syndrome (PCS). The efficacy of pain control, amount and frequency of menstrual loss, degree of patient's satisfaction and objective pelvic venography scores were investigated.

**Methods** In a prospective open-labelled study, 25 consecutive women complaining of chronic pelvic pain were recruited. Pretreatment objective peruterine venography and diagnostic laparoscopy of pure PCS together with subjective pelvic pain scores, prefilled questionnaire of Hospital Anxiety and Depression Scale (HADS), visual analogue scale (VAS), verbal rating scale (VRS) and quantified menstrual loss using the pictorial blood loss chart were documented in all cases. After identification, 23 subjects with pure PCS were randomly assigned to have either Implanon inserted subcutaneously (12 cases) or no treatment (11 cases). Patients

were followed up at 1, 3, 6, 9 and 12 months. A symptom diary for side effects, VAS, VRS and menstrual scores were used to assess the subjective response to treatment. At the end of the study, all patients underwent repeat venography to assess the long-term objective response. After 12 months, subjects having Implanon inserted were requested to rate their overall degree of satisfaction with therapy.

**Results** All 25 women recruited in the study completed follow-up. Two cases were excluded from the study and referred to the psychiatry department after a negative evaluation for disease and HADS scores relevant for depression. An improvement in symptoms was observed throughout the 12 months amongst the Implanon group versus no treatment. The greatest changes in pain assessed using either the VAS or VRS were between the pretreatment scores and those after 6 months ( $7.7 \pm 1.3$  vs.  $4.6 \pm 3.0$  for VAS,  $P < 0.001$ ; and  $25 \pm 13.8$  vs.  $19 \pm 18.9$  for VRS,  $P < 0.002$ ). The monthly quantified blood loss fell from 204 (196) pretreatment to 90 (157) at 6 months ( $P < 0.001$ ) and then to 64 (32) at 9 months ( $P < 0.002$ ). Objective repeat venography score was reduced significantly at 1 year after treatment compared with the baseline evaluation as well as with the control group ( $4.5 \pm 1.2$  vs.  $8.6 \pm 0.5$ ;  $P = 0.001$  and  $4.2 \pm 0.9$  vs.  $8.5 \pm 0.6$ ;  $P = 0.0002$ , respectively). At final satisfaction assessment, 2 (17%) women were very satisfied 8 (66%) were satisfied, and 2 (17%) were uncertain. The implant was retained by all women at the end of the study.

**Conclusion** Implanon seems to be an effective hormonal alternative for long-term treatment of properly selected patients with pure PCS-related pelvic pain.

**Keywords** Implanon · Pelvic congestion syndrome · Pelvic pain · Treatment

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## Introduction

In many women with chronic pelvic pain no clearly defined pathological cause will be found. Such 'unexplained' pain may well be associated with pure pelvic congestion due to venous stasis which produces a clinical picture that has become known as the pelvic pain or pelvic congestion syndrome (PCS) [1, 2].

One hallmark of PCS is its disappearance after the menopause [3]. As induced hypo-oestrogenic stages, venoconstriction and/or occlusion of varicose veins (by medical or surgical as well as interventional radiological treatment) results in amelioration of symptoms, this syndrome is suspected to occur as a result of gonadal dysfunction, cooperative with mechanical factors [2–4].

Medical treatment of PCS includes progestins [5], danazol [2], combined oral hormonal contraceptives [3], phlebotonics [6], non-steroidal anti-inflammatory drugs [7] and gonadotropin-releasing hormone (GnRH) agonists [8]. Although these drugs are effective, their systemic side effects commonly affect compliance or long-term use. The need for regular follow-up may further result in poor compliance. At a time, progestins (oral and depot forms) were considered as the first choice for the treatment of PCS because they are as effective as danazol or GnRH analogues and have a lower cost and a lower incidence of side effects [1, 8–10].

The synthetic steroid Implanon is a single-rod, progestogen only, non-biodegradable implant containing and releasing the desogestrel metabolite etonogestrel (ENG, 3-keto-desogestrel), which has been used for long-term contraception. It inhibits FSH activity resulting in ovulation inhibition. The implant provides long-term contraceptive efficacy during the period of 3 years. The earlier studies have shown that Implanon suppress follicular development and steroid production, producing a state of hypoestrogenism [11, 12]. Thus, patients with pure PCS due to venous stasis may benefit from this kind of treatment.

Several studies on Implanon as a contraceptive method have demonstrated that it was well tolerated and had excellent, reversible, contraceptive efficacy [13]. Furthermore, it has been reported that over 85% of women with dysmenorrhoea at baseline noted an improvement at the end of treatment [14].

Implanon has been extensively evaluated for contraceptive purposes, but never formally evaluated for the treatment of pelvic pain in women with PCS. Given this background, we set out to investigate the effectiveness and tolerability of Implanon in the treatment of women with symptomatic PCS presented with chronic pelvic pain. The objectives of this pilot study were to determine degree of symptoms relief and assess patient's satisfaction during the 1-year period of Implanon treatment for unexplained pelvic pain amongst women with symptomatic PCS.

## Materials and methods

This prospective open-labelled study was conducted at Fertility Care Unit, Mansoura University Hospital (Mansoura, Egypt) from July 2006 to June 2007. The protocol was approved by the local ethics committee of the institution. Each subject signed an informed consent to partake in this study.

During this period, 70 women complaining of chronic pelvic pain for more than 6 months were included in this trial. The exclusion criteria were age <18 years or >45 years, any hormonal therapy in preceding 3 months, a desire to conceive within 1 year, unwillingness to tolerate expected menstrual changes or other adverse effects of Implanon and unable to follow-up. Cases with proved non-gynaecologic causes of chronic pelvic pain (intestinal, urinary and/or musculoskeletal) were also excluded from the study.

All patients in this trial underwent pelvic examination, peruterine pelvic venography, high-resolution transvaginal and/or transabdominal ultrasonography, diagnostic laparoscopy and questionnaires to determine the psychological status. Basic work-up investigations including, mid-stream urine analysis, stool analysis, plain X-ray of lumbo-sacral spine and hip joints, intravenous urogram, full blood count and/or barium enema were done whenever indicated.

In all cases, outpatient peruterine venography as described by Beard et al. [5] was performed before diagnostic laparoscopy in the first week after menses. Fluoroscopic screening was performed to observe the spread of contrast material into myometrial, uterine and ovarian venous plexuses. Routine films were taken at the end of injection, and 20 and 40 s later. Peruterine venographies were assessed by a pelvic venogram scoring system described by Beard et al. [7], according to that ovarian vein dilatation, dye disappearance and congestion are considered as three variables. Each variable is assigned a value of 1–3, depending on the degree of abnormality. Ovarian vein diameter was measured at the point of maximum diameter of the segment of the vein that could be clearly visualised. If the diameter was <4 mm, it was assigned a value of 1, 5–8 mm a value of 2, and >8 mm a value of 3. The disappearance interval was determined from the films taken at the end of injection, and at 20 and 40 s after injection. When the dye disappeared at the end of injection, it was assigned a value of 1; when the time was >20 s it was valued as 2, while a time >40 s was valued as 3. Congestion was assessed from the caliber and the tortuous appearance of individual pelvic veins. Normally, the veins are small, straight, similar in calibre, and easily visualised. Such an appearance was assigned a value of 1. In moderate congestion, the veins were of variable calibre and tortuous, and difficult to discern individually (value of 2). In extensive congestion, the veins

were wide, obscured by a pool of contrast medium around the ovarian plexus, showed great variation in calibre, and appeared highly tortuous (value of 3). Thus, a total score of 3 indicated a normal venogram while a score of 9 indicated the most abnormal venogram. A venogram score of  $\geq 5$  was found to be an objective measure of pelvic congestion with a high sensitivity (91%) and specificity (89%) [5, 7]. In this trial, all patients were assessed according to the above-mentioned scoring system. A venography score of  $\geq 5$  was accepted as a threshold to diagnose pelvic congestion.

For the month preceding the Implanon insertion, each patient completed a diary for the generation of baseline variables, which were used for the assessment of the response to treatment. Response to treatment was assessed subjectively by changes in the variables, which included the patient's perception of pelvic pain severity using a visual analogue scale (VAS), her rating of both types of pelvic pain (dysmenorrhoea and/or non-cyclical pelvic pain) on a verbal rating scale (VRS), a monthly pelvic pain and bleeding score.

The VAS was a subjective assessment of the pain on a scale of 0 (no pain) to 10 (most severe pain). It was recorded on a 10 cm ruler in the diary at each follow-up visit and reflected the severity of this symptom as perceived by the patient in the preceding month. A 4-point scale (0–3; where 0, no pain; 1, mild pain; 2, moderate pain; 3, severe pain) was used to rate dysmenorrhoea and/or non-cyclical pain on a daily basis (daily VAS). A monthly score (VRS) was then generated from the summation of the daily VAS over a 28-day period (0, no pain; 96, maximum pain). Once again, this VRSmonthly was only determined for the 28 days prior to the follow-up visit. Menstrual loss was quantified using the pictorial blood loss assessment chart (PBAC) described by Higham et al. [15]. A score of  $>100$  was used to define menorrhagia. Only the loss in the month prior to a follow-up visit was quantified.

Furthermore, all patients were asked to complete the submitted forms of the Hospital Anxiety and Depression Scale (HADS) [16]. The HADS is a self-assessment mood scale designed specifically for use in non-psychiatric hospital outpatients to determine states of anxiety and depression. The scale is composed of 14 items, seven for the anxiety and seven for the depression subscales. Five mutually exclusive answers, rated from 0 to 4 according to increasing psychiatric severity, are provided for each of the questions. The points are then summed to give anxiety and depression subtotals, and a total score. For the subscales, a score of  $\leq 7$  indicates non-psychiatric cases, whereas a score of 8–10 indicates doubtful cases, and a score  $>11$  indicate definitive psychiatric cases. In the present study, HADS was used to diagnose, and to assess the states of anxiety and depression. The submitted HADS forms for our

patients were interpreted by a specialist psychiatric physician blinded to the patients and treatment, and was unaware of other pelvic symptom scores.

High-resolution ultrasound examinations were carried out using commercially available instruments. The investigators were aware of the physical changes in the pelvic organs (uterine and endometrial changes, cystic ovaries) of women with pelvic congestion as stated by Adams et al. [17]. Further, in this study, the aim of the sonography was to determine the detailed internal consistency of the uterus and adnexa in order to detect, suspect or exclude organic pathology such as myoma, adenomyosis, endometrioma, pelvic endometriosis and hydrosalpinx. General endotracheal anaesthesia was used in all cases for multiple puncture diagnostic laparoscopy. Patients with organic pathology other than pure PCS confirmed by demonstration of large, prominent pelvic and/or ovarian varices while limiting the head-down tilt and the amount of  $\text{CO}_2$  peritoneal insufflation had no additional surgical procedure undertaken at the laparoscopy.

Thus, at the time recruitment in the study; all patients with newly diagnosed pure pelvic congestion due to venous stasis had pretreatment objective peruterine venography and diagnostic laparoscopy demonstrating large, prominent pelvic and/or ovarian varices, subjective pelvic pain scores, and prefilled questionnaire of HADS, VAS, VRS and menstrual scores. They were randomized in a ratio of 1:1 that was performed in accordance with a computer-generated randomization sequence using numbered, sealed envelopes to have either Implanon therapy or no treatment (control group).

The Implanon implant was inserted subcutaneously into the medial aspect of upper forearm within 5 days of onset of menstruation. The insertion technique was the same as described by the manufacturer (Organon, The Netherlands). None of the patients with pure PCS had psychotherapy as an adjunct to medications. None of them used oral contraceptives after the original treatment as an adjunctive measure. Patients in the control group were instructed to rely on both condoms and periodic abstinence withdrawal methods for contraception during the time of the study.

Follow-up visits after Implanon insertions were after 1, 3, 6, 9 and 12 months. A month before each visit, the patients completed a diary of their pain score and menstrual loss. These were collected at the follow-up visit and new diaries given for the next visits. Grading of symptoms and physical findings were assessed at each clinic visit. The duration of treatment was completed in 12 months.

At the end of the study, all patients repeat peruterine pelvic venography to assess the long-term objective response to therapy. Further, those having Implanon inserted were requested to rate their overall degree of satisfaction with treatment, which was assessed using a 4-point

VRS (very satisfied, satisfied, uncertain, dissatisfied). At this point, those who requested the discontinuation had the implant removed.

#### Data analysis

SPSS version 11.0 was used to record and statistically analyse the data. Values at the time of the insertion of the implant (i.e., time 0) were compared with those at different time points after insertion using the paired *t* test, Mann–Whitney *U* test, Wilcoxon and Friedman two-way ANOVA tests as appropriate. In addition, perception by the patient of the efficacy of the implant in pain control was evaluated at 1,3,6,9 and 12 months using a VAS, as well as overall satisfaction with the treatment (taking into account the undesirable side effects) as indicated on a 4-point VRS.

#### Results

By strict adherence to the protocol for diagnostic evaluation of chronic pelvic pain, organic pathology was detected in 45 of 70 patients (64.3%). The most common organic pathology detected was endometriosis ( $n = 25$ , 36%), chronic pelvic inflammatory disease (PID) ( $n = 7$ , 10%), postoperative adhesions ( $n = 6$ , 9%), uterine disease (myoma,  $n = 8$ , 11.4%; adenomyosis,  $n = 4$ , 5.7%), Allen–Master syndrome ( $n = 1$ , 1.4%) and ovarian mass ( $n = 10$ , 14.3%).

In 23 patients (33%), pure PCS due to venous stasis was the only detected abnormality. All had dull pelvic pain of variable intensity that persisted for more than 6 months, increased with prolonged standing and coupled with ovarian point tenderness on pelvic examination. All patients were married and had children. In the remaining two patients (3%), referral to the psychiatry department was offered after a negative evaluation for disease (ultrasonography, venography and laparoscopy were all normal in this

subset of patients) and HADS scores relevant for depression (HADS depression subscale was  $\geq 12$ ). These two cases were excluded from the study.

The baseline clinical characteristics, mean pelvic venography scores, mean pelvic pain, and HADS scores of all patients are listed in Table 1. The parity (mean  $\pm$  SD) of patients with pure PCS was higher than the parity of those with organic pathology ( $3.4 \pm 1.3$  vs.  $2.8 \pm 1.3$ ;  $P = 0.0001$ ). Even though patients with organic pathology had venography scores significantly lower than those with pure PCS ( $4.6 \pm 1.5$  vs.  $8.6 \pm 0.5$ ;  $P = 0.00001$ ). Pelvic symptom scores were significantly higher in those patients with pure PCS as compared with those patients with organic pathology ( $10.5 \pm 1.3$  vs.  $6.7 \pm 1.8$ ;  $P = 0.0001$ ). HADS scores of patients with pure PCS were significantly higher amongst all patients. Significantly higher total HADS scores of  $13.7 \pm 1.4$  were noted for patients with pure PCS as compared to total HADS scores of  $10.6 \pm 2.1$  for patients with organic pathology ( $P = 0.0001$ ); the significantly elevated scores were also observed in anxiety and depression subscales scores (anxiety subscale score  $7.4 \pm 0.9$  vs.  $5.7 \pm 1.4$ ;  $P = 0.0001$ ; depression subscale score  $6.3 \pm 1.02$  vs.  $4.9 \pm 1.3$ ;  $P = 0.0001$  for patients with pure PCS as compared to those patients with organic pathology, respectively).

After identification, 23 patients with pure PCS (study group) were randomized to receive either Implanon (12 cases) or no treatment (11 cases). The baseline clinical characteristics of the pure PCS group by allocated treatment are listed in Table 2. Both groups were comparable in terms of age, parity, venography scores, pelvic symptom scores and HADS scores. All patients were cycling regularly, suggesting a normal hormonal milieu. None of them was using oral contraception, and none used oral contraceptives after the implant insertion as an adjunctive measure.

The changes in the VAS over the 1 year after insertion at different time intervals are shown in Table 3. Amongst the Implanon group, there was a marked improvement in the

**Table 1** Baseline clinical characteristics of patients with chronic pelvic pain

Parameter	Chronic pelvic pain patients ( $n = 70$ )		
	Organic pathology ( $n = 45$ )	Pure pelvic congestion ( $n = 23$ )	Referral to psychiatry ( $n = 2$ )
Age (years)	$32.9 \pm 5.1$	$32 \pm 2.8$	$34.3 \pm 2.4$
Parity ( $n$ )	$2.8 \pm 1.3$	$3.4 \pm 1.2$	$3.2 \pm 1.3$
Venography score	$4.6 \pm 1.5$	$8.6 \pm 0.5$	$3.1 \pm 0.7$
Pelvic symptom score	$6.7 \pm 1.8$	$10.5 \pm 1.3$	$9.5 \pm 1.3$
HADS score			
Anxiety	$5.7 \pm 1.4$	$7.4 \pm 0.9$	$8.3 \pm 1.7$
Depression	$4.9 \pm 1.3$	$6.3 \pm 1.02$	$15.6 \pm 2.1$
Total	$10.6 \pm 2.1$	$13.7 \pm 1.4$	$23.0 \pm 1.9$

Values are mean  $\pm$  SD  
HADS Hospital Anxiety and Depression Scale

**Table 2** Clinical characteristics of Implanon group compared with no treatment group

Parameter	Implanon group ( <i>n</i> = 12)	Control group	<i>P</i> value
Age (years)	32.3 ± 3.0	33.1 ± 3.3	NS
Parity ( <i>n</i> )	3.4 ± 1.2	3.4 ± 1.3	NS
Venography score	8.6 ± 0.5	8.5 ± 0.6	NS
Pelvic symptom score	10.9 ± 1.0	10.2 ± 1.4	NS
HADS score			
Anxiety	7.2 ± 0.9	7.5 ± 0.9	NS
Depression	6.4 ± 0.8	6.2 ± 1.1	NS
Total	13.6 ± 1.3	13.8 ± 1.4	NS

Values are mean ± SD

HADS Hospital Anxiety and Depression Scale, NS not significant

VAS throughout the 12 months after treatment compared with control group. This fell continuously from a pre-insertion and 1 month score of 7.7 (1.3) to a nadir of 2.4 (1.3) at 12 months. The differences between VAS 1 month after insertion and subsequent follow-up scores after 3 months were all statistically significant ( $P < 0.05$ ) when compared with the control. The VAS for dysmenorrhoea fell throughout the 1 year on Implanon. The greatest change in VAS was achieved during the first 9 months on Implanon (Table 3). Of the 10 patients experiencing moderate to severe dysmenorrhoea pre-insertion, 7 (70%) continued to have similar pains at 3 months ( $P = 0.001$ ), 5 (50%) at 6 months ( $P < 0.001$ ) and only 2 (20%) at 11 months ( $P < 0.0001$ ). At 12 months, only one patient continued to experience moderate, rather than severe, dysmenorrhoea, which she found acceptable and hence retained the implant.

The total number of days of pain experienced during a 28-day period was determined from the diaries retained at the follow-up visits. Similarly, Implanon was shown statistically to be more effective in reducing pelvic pain score than no treatment at different time intervals. This fell from a mean of 15.0 days (6.9) to 10.7 days (8.7) after 6 months therapy ( $P < 0.05$ ) and to 6 days (3.4) after 12 months ( $P < 0.001$ ). Further, the VRS or the mean score for pain

per month (out of a total 84) dropped from 25 (13.8) pre-insertion and 1 month after insertion to 19 (18.9) 6 months later; this change was not statistically significant ( $P = 0.076$ ). However, after 9 months, the mean score per month had dropped to 14 (9.4) and this change was statistically significant compared with control group values ( $P < 0.05$ ). There was a further statistically significant ( $P < 0.001$ ) fall to 11 (5.2) after 12 months (Table 3).

The changes in the quantified menstrual loss from the PBAC chart at different time intervals are shown in Table 3. Implanon proved to be statistically more efficient in decreasing the quantified menstrual loss compared with no treatment. This fell from 204 (196) pre-insertion and 1 month after insertion to 90 (157) after 6 months of treatment ( $P < 0.001$ ). There was further statistically significant ( $P < 0.05$ ) reduction in the total blood loss after 9 months. Although this number did not change significantly over the remaining 1 year, most of them were reported as spotting rather than heavy bleeding.

Repeat peruterine venography evaluation at 12 months from the end of the treatment demonstrated a statistically significant reduction in pelvic venography score compared with baseline evaluation as well as with the control group ( $4.5 \pm 1.2$  vs.  $8.6 \pm 0.5$ ;  $P = 0.001$  and  $4.2 \pm 0.9$  vs.  $8.5 \pm 0.6$ ;  $P = 0.0002$ , respectively).

The side effects from Implanon reported by the patients during the study period were well tolerated. The most common were irregular vaginal bleeding (36%), amenorrhoea (28%) and weight gain (16%). There were two patients (17%) with acne and another two cases (17%) complaining of occasional migraine headaches. Two cases of simple functional ovarian cysts were diagnosed on ultrasound follow-up scan. One of them presented with mild one-sided abdominal discomfort. Both cases were monitored with serial ultrasound scan only and improved spontaneously.

At final evaluation for satisfaction with treatment, 2 (17%) women were very satisfied, 8 (66%) were satisfied, 2 (17%) were uncertain. All cases were willing to continue treatment with the implant after the end of the study.

**Table 3** Changes in the VAS, VRSmonthly pain, and menstrual scores during 1 year on Implanon at different time intervals compared with no treatment

Parameter	Implanon group ( <i>n</i> = 12)					Control group ( <i>n</i> = 11)					<i>P</i> value*
	Duration in months					Duration in months					
	0/1	3	6	9	12	0/1	3	6	9	12	
VAS	7.7 (1.3)	6.1 (2.4)	4.6 (3.0)	3.5 (1.8)	2.4 (1.3)	7.9 (1.2)	7.7 (1.3)	7.5 (1.2)	7.7 (1.3)	7.6 (1.2)	<0.05
VRSmonthly	24 (13.8)	22 (15.7)	19 (18.9)	14 (9.4)	11 (5.2)	25 (13.8)	24 (13.5)	24 (13.5)	25 (13.8)	24 (13.5)	<0.05
QMLmonthly	201 (193)	129 (273)	90 (157)	60 (50)	64 (32)	204 (196)	200 (190)	204 (196)	203 (191)	204 (196)	<0.05

VAS visual analogue scale, VRS verbal rating scale, QML Quantified Menstrual Loss

\* Friedman two-way ANOVA test

## Discussion

In the present study, the efficacy of Implanon compared with no treatment was tested in a prospective, randomized manner. The results presented in this preliminary trial provide the first probable evidence to support the long-term use of Implanon therapy in women with pure PCS presented with chronic pelvic pain.

Our preliminary results confirm that Implanon as a subcutaneous implant seems to be effective in terms of both objective and subjective improvement for at least 1 year in selected patients with pure PCS-related pain compared with no treatment. The symptoms continued to improve, albeit more dramatically after the first 6 months on the implant. Although a few of our patients experienced the typical systemic side effects of progestogens, these were mild and tolerable. These results provide ample support for the use of Implanon in those women who are not immediately desirous of pregnancy. The benefits of using Implanon on even a short-term basis significantly outweigh the cost of a 6 months course of a GnRH agonist as reported by Soysal et al. [8]. The continuation rate after 1 year was 100%, similar to that in women using Implanon for contraception [11]. It is, however, difficult to compare this with other medical treatment options, as these often involve a much shorter duration. An advantage of Implanon over other medical treatment options available for women with PCS, which are usually short-term, is obviation of the need for repeated treatment (often with alternative regimens) where symptoms recur (in up to 75% of patients) [18] and the lack of need for additional contraception.

The most dramatic improvements in symptoms as determined by the VAS, VRS and quantified blood loss occurred during the first 6 months of therapy compared with control group. Thereafter, there were no marked significant changes in the variables used to assess the response to treatment over the remaining 12 months. However, a noteworthy observation is that amongst the Implanon group an improvement was observed throughout the 12 months in the mean scores of pelvic pain, VAS, VRS and quantified menstrual blood loss compared with pre-insertion values. Whether these improvements in symptoms will persist for the entire 3 years (i.e., duration of action of Implanon) remains to be determined.

In our series, although small, patients with pure PCS had higher HADS scores than any other pathology. It was stated that psychological disturbances may co-exist in this syndrome [19]; even psychotherapy was recommended and tested in a prospective randomized manner [9, 20]. Although a high score of anxiety and depression was noted in the present PCS patients, it is believed that the chronic pelvic pain of the condition is the result of varicosities, while the greater anxiety and depression of the patient is a

natural human response to an undiagnosed, unclear aetiology of debilitating chronic pain. In the present study, although psychotherapy was not used instead of any proposed treatment for aetiology, a significant reduction of HADS scores was noted (data not shown). In agreement with our results; it has been shown that surgical, interventional radiological treatment, vasoconstrictors and medroxyprogesterone acetate (MPA) all reduce the diameter of veins ameliorate symptoms, irrespective of the psychological status of the patient [1, 4, 10, 21].

It is believed that the cause of pelvic congestion is speculative; it may be either be oestrogen-dependent or simply mechanical, but it is most probably cooperative [1, 2]. Currently, it is known that in order to overcome the symptomatology, an effective treatment should reduce the diameter of veins and improve venous drainage of the pelvis [1–3]. Long-term benefits of MPA and/or GnRH agonists have been demonstrated previously [9, 10, 18] and the authors of these studies have been used MPA and/or goserline to produce a hormonal milieu of hypo-estrogenism and a reduced end-organ response to oestrogen. These authors were successful in reducing both venogram scores and pain using such medications. However, it is unlikely that a temporary artificial menopause of 6 months will achieve permanent cure of the syndrome. Hence, we postulated that the most effective suppression of ovarian function would have a longlasting effect on the syndrome and this was the reason for choosing an arbitrary 1-year interval for assessment after treatment with Implanon.

In fact, long-term therapy with progestin appears to be more favourable than with GnRH analogues. The limitation of GnRH agonists were side effects, costs and could not be used in long-term course due to risk of menopausal symptoms and osteoporosis. One of the advantages from Implanon comparing to MPA is that the patients return their fertility function more rapidly after discontinuation, since the ENG levels decreased to level less than the detection limit of the assay (20 pg/ml) within 1 week [11, 13].

Various local mechanisms can be proposed for the action of Implanon in women with pure PCS, but an exact understanding of these mechanisms remains unclear. In addition, it is known that the local effect of progestogen on the endometrium resulting in hypomenorrhoea or amenorrhoea significantly improves the pain of dysmenorrhoea [2]. Whatever the case, it is likely that the implant is effective through a combination of systemic and local mechanisms.

It is well known that blinding of treatment both to provider and patient is critical to know if the treatment or some other factors is causing the observed effect. In fact, it would be difficult to blind patients to Implanon. Furthermore, although it is perhaps not unreasonable to adduce from these findings that the improvement in symptoms was primarily a result of the Implanon implant inserted subcutaneously,

the placebo effect of the diagnostic laparoscopy cannot be eliminated. The only way to answer this question will be a randomized trial where one group receives the Implanon and another group a placebo implant. Since such a placebo implant is currently not available, we cannot draw a definite conclusion regarding this issue.

Although irregular vaginal bleeding and spotting were common adverse effects, no patients discontinued the treatment. The menstrual problems were predominantly during the first 6 months on the implant. These findings are not dissimilar to those women using the implant for contraception. If this information with proper selection is provided to patients during counselling and at follow-up visits, we would anticipate the continuation rates to remain high. Although there have been anecdotal approaches to manage irregular bleeding in such women, such as short-term use of combined oral contraceptive pills, there are no studies on the best approach to treatment [11, 13]. Until this evidence is available, we would advocate a careful selection of patients, pre-insertion counselling supported by information leaflets and regular re-assuring follow-up visit during the first 6 months.

In conclusion, Implanon seems to offer good results in pelvic pain alleviation with tolerable side effects in selected patients with symptomatic pure PCS. Overall, nearly 80% of the women were satisfied after 3 months of treatment. Implanon probably is an option for long-term medical treatment and should be more extensively evaluated for this indication in comparison with other medical treatments. A long-term larger study should also be conducted to evaluate the effectiveness and recurrence of the disease after Implanon removal.

**Conflict of interest statement** There is no actual or potential conflict of interest in relation to this article.

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