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## Is helium thermal coagulator therapy for the treatment of women with minimal to moderate endometriosis cost-effective? A prospective randomised controlled trial

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**Abstract** This study compared the cost and time involved of helium thermal coagulator (HTC) treatment with medical therapy using gonadotrophin-releasing hormone analogues in women with minimal to moderate endometriosis. In a prospective randomised controlled trial, 35 women with history of pain were, upon confirmation of minimal to moderate endometriosis at diagnostic laparoscopy, randomised to immediate surgical or medical treatment. They were asked to complete analogue pain score sheets, and their symptoms were reviewed before treatment and at 3, 6, and 12 months after treatment. The cost of the medical or surgical treatment was evaluated from the time of diagnosis to the time of cure or symptom relief. The average cost per Helica probe is £111.81 with the machine on free loan, and the total cost of a 6-month course of injectable Zoladex with add-back therapy is £811.92. The costs involved in the two treatment modalities were analysed using the Mann–Whitney test; a *p*-value <0.05 was considered significant. In the medical group, three women out of 18 were symptom-free, 11 required surgical treatment of endometriosis, one had a laparoscopically-assisted vaginal hysterectomy, and three became pregnant before their final reviews. In the surgical group, nine women

were symptom-free at the end of 12 months, four required Zoladex therapy, one required oral contraceptive pills, and three required repeat surgical treatment. The average cost per patient in the surgical arm was £323.29 and in the medical arm was £918.12 (*p* < 0.0001). Mean operating times in the surgical and medical arms were 32.35 min and 20.83 min, respectively. This suggests that when facilities and expertise are available, it is better to see and treat mild to moderate endometriosis. There were no surgical complications in our series. Surgical treatment with HTC therapy is safe and is a cheaper and more effective therapy. This is the first study that has looked at the cost-effectiveness of HTC therapy in managing mild to moderate endometriosis.

**Keywords** Endometriosis · Helium thermal coagulator · Cost-effectiveness

### Introduction

Endometriosis, characterised histologically by the presence and growth of endometrial glands and stroma outside the uterine cavity, is a chronic recurring disease commonly encountered in women of reproductive age [1]. It is found in 71% of laparoscopies for pelvic pain and in 84% of cases in which pain and infertility are complaints [2]. Its frequent occurrence seen at laparoscopy in asymptomatic women has led to the suggestion that this may be a normal physiological process that becomes a disease only when the patient is symptomatic [3]. However, once symptomatic, it can be an extremely debilitating condition, causing chronic pelvic pain, dysmenorrhoea, dyspareunia, and infertility, and its management is often frustrating for both the patient and the gynaecologist [4]. The diagnosis of endometriosis can be elusive and confirmed only by visualisation, i.e. laparoscopy, which is considered to be the gold standard for diagnosing the disease [5]. Treatment for the condition is either medical or surgical.

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Several medical strategies are available for treating endometriosis. These include combined oral contraceptive pills, progestogens, Danazol, gestrinone, and gonadotrophin-releasing hormone analogue (GnRH-a) with or without add-back therapy. Of these, the two main drugs used are GnRH-a and, until recently, Danazol. Both have been shown to decrease symptoms when compared with placebo [6, 7]. A large Cochrane metaanalysis of 26 randomised controlled trials confirmed GnRH-a to be effective in relieving pain [8, 9]. However, long-term follow-up studies show a high recurrence rate following medical treatment [10, 11].

Surgical treatment for endometriosis is now usually performed laparoscopically. By this minimally invasive method, the endometriotic lesions are either excised or ablated using laser, monopolar, or bipolar diathermy or newer methods such as helium thermal coagulator (HTC) therapy.

Although both medical and surgical therapy have been shown to satisfactorily treat endometriosis, no published studies have compared the cost or the operating time involved in the two treatment modalities, considering that a diagnostic laparoscopy will be involved in making a diagnosis before commencing medical therapy. Direct and indirect medical costs associated with this condition are estimated to be more than \$3 billion in the United States annually before factoring in the costs of diagnostic testing [12]. Thus, it is important to make an appropriate choice for an optimal treatment.

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## Methods

All women presenting to the gynaecology outpatient clinic with a history of pelvic pain, dysmenorrhoea, dyspareunia, and dyschesia suggestive of endometriosis or who had previously been diagnosed as having the disease were asked to enter the trial. All women who were less than 16 years of age, pregnant, or subfertile were excluded from the study. Power studies were performed prior to the study, and 25 patients were required in each arm. However, only one in three women who were asked to enter the trial agreed because two in three wished to have surgical therapy if they were diagnosed with endometriosis. A total of 35 women between September 1999 and March 2001 were recruited for this study.

All the women with suspected endometriosis were subjected to a diagnostic laparoscopy as a day-case procedure, and any endometriosis found was staged according to the American Fertility Society classification [13]. Randomisation into either HTC or GnRH-a therapy was done at the time of diagnostic laparoscopy. All women were given visual analogue pain scores preoperatively and 3, 6, and 12 months postoperatively, and their symptoms were taken into consideration. Women in the surgical arm had either ablation or excision of all endometriotic lesions with HTC therapy. Women who had diagnostic laparoscopy had only a proper staging of the disease.

All women in the medical arm were given six injections of GnRH-a with add-back hormone replacement therapy (HRT) every 28 days. These women were seen in the outpatient clinic 3, 6, and 12 months after the end of treatment.

## Mechanism of action of HTC therapy and GnRH-a

### *HTC generator*

An HTC generator is a device capable of producing low operating powers. It has a high-output impedance circuit that limits the flow of energy. It operates at power levels lower than 5 W but still produces a satisfactory cauterising effect. Combining helium within the Helica generator produces an ionised plasma beam/corona-type flame at very low levels of energy. The energy is delivered to the target tissue via a probe. The discharged beam has a high molecular temperature typically of the order of 800°C; the beam takes place within the plasma provided by the flowing inert gas (helium). The power emission can be regulated to emit levels from 1 to 33 W. For coagulation purposes only, the discharged plasma on 4-s bursts will achieve a maximum level of tissue penetration of 1.1 mm. In our trial, the same coagulating probe was also used for cutting (energy can be concentrated by the probe with tension on the tissues). However, we are aware that the company has manufactured probes with a coagulating and cutting component in the same probe.

Our hospital negotiated with the company to have the machine on loan and buy more than 10 probes per month. Various financial arrangements can be made with the company. In the free loan option, the machine is free, and the average cost per probe is £111.81. In the machine purchase option, the machine costs £17,192, and the average cost per probe is £63.63. One probe is used per patient.

### *GnRH-a therapy*

GnRH-a acts continuously on the GnRH receptors, resulting in the downregulation and desensitisation of the pituitary gonadotroph. This results in the chronic suppression of gonadotrophin secretion, luteinising hormone, and follicle-stimulating hormone and the cessation of ovarian activity and, consequently, a decrease in circulating oestradiol levels, creating a pseudomenopausal state. This causes predictable side effects, namely those symptoms experienced by women at menopause. The other problem associated with a 6-month course of GnRH-a is a reduction in vertebral bone mineral density (BMD) of approximately 3–4%. This concern has therefore limited its use to a 6-month duration [8, 9]. In a multicentre randomised double-blinded trial using a 12-month course of GnRH alone, women experienced a BMD loss in the lumbar spine of 3.2% at 6 months and 6.3% at 12 months and com-

plained of hot flashes, which were dramatically suppressed in the add-back HRT groups, whereas women receiving add-back HRT for 12 months had a significantly negligible (< 1%) BMD loss [14].

| Cost                                  |         |
|---------------------------------------|---------|
| Injectable Zoladex (goserelin) 3.6 mg | £122.27 |
| Livial (tibolone; add-back), 28-pack  | £13.05  |
| Total cost for 6 months               | £811.92 |

### Main outcome measures and statistics

The main outcome measures were the costs and operating times involved in the two treatment modalities. Analysis of costs was performed using the Mann–Whitney test. Analysis was undertaken using the Statistics Package for Social Sciences (SPSS) for Windows. A *p*-value < 0.05 was considered significant.

## Results

A total of 35 women were included in the study. Eighteen women received medical and 17 received surgical treatment of endometriosis. Their mean age was 32.8 years (range 20–45 years), and mean parity was 1 (range 1–3). The mean revised American Fertility Society scores were 5 (range 2–12) for the medical group and 6 (range 2–12) for the surgical group.

All 35 women underwent diagnostic laparoscopy before being randomised into the two treatment modalities. Therefore, the basic cost incurred for diagnostic laparoscopy was the same for all patients. There were no surgical complications reported in this series.

All of the women were reviewed at 3, 6, and 12 months following their treatment. In the medical group, three women out of 18 were symptom-free (17%), 11 required surgical treatment of endometriosis, one had a laparoscopically-assisted vaginal hysterectomy, and three became pregnant before their final reviews.

In the surgical group, nine women out of 17 were symptom-free at the end of 12 months (53%), four required Zoladex therapy, one required oral contraceptive pills, and three required repeat surgical treatment.

The costs involved were significantly higher in the medical group (Tables 1, 2; Mann–Whitney test *p*-value of 0.0001).

**Table 1** Treatment outcomes in the two groups

| Group    | Further treatment  | Number of cases | Cost per patient |
|----------|--------------------|-----------------|------------------|
| Medical  | None               | 6               | £811.92          |
| Medical  | Surgical           | 11              | £923.73          |
| Medical  | Hysterectomy       | 1               | £1,493.63        |
| Surgical | None               | 9               | £111.81          |
| Surgical | Medical            | 4               | £923.73          |
| Surgical | Oral contraceptive | 1               | £123.81          |
| Surgical | Surgical (repeat)  | 3               | £223.62          |

**Table 2** Cost

| Mean total cost per patient ( <i>p</i> < 0.0001) |         |
|--------------------------------------------------|---------|
| Surgical arm                                     | £323.29 |
| Medical arm                                      | £918.12 |

**Table 3** Operating time

| Mean operating time                  |                         |
|--------------------------------------|-------------------------|
| Surgical arm                         | 32.35 min (range 20–50) |
| Medical arm (diagnostic laparoscopy) | 20.83 min (range 15–35) |
| Difference                           | 11.52 min               |

An extra 11.5 min was required to surgically treat mild to moderate endometriosis in 17 patients who were allocated to the surgical group (Table 3).

Analysis of the pain scores (using the Wilcoxon nonparametric test) and of the success rates of the two treatment modalities (using the chi-square test) will be discussed in our second paper comparing the effectiveness of medical versus surgical treatment.

## Discussion

Women with endometriosis have a symptom complex of pelvic pain, dysmenorrhoea, dyspareunia, and dyschezia, which can cause profound ill health and reduced quality of life. Various studies have looked at different medical and surgical treatment options. Additional complexity has been added to the healthcare decision-making process by the socioeconomic constraints of the industry and by a population that is increasingly educated about healthcare. As a result, decisions balanced on the basis of outcomes and economic realities are needed. This modelling of surgical versus medical treatment costs for chronic pelvic pain and endometriosis factors in the large number of women with chronic pelvic pain, direct and indirect costs of the condition, and the clinical benefits, projected costs, and savings of the therapies. This process of calculation becomes an aid for decision-making in the current healthcare system [15].

There has been debate about 3- versus 6-month GnRH-a therapy. Heinrichs and Henzl have suggested that GnRH-a administration for 3 months is a cost-effective approach. In their series, reduction in endometriosis symptoms and signs was similar at the end of 3 and 6 months [16]. Notably, various side effects are associated with GnRH-a therapy.

Winkel suggested that medical treatment is cheaper and safer than surgical treatment [17]. In our study group, surgical treatment with HTC appeared to be a safer, cheaper, and more effective therapy. There were no surgical complications in our series, and patients had prompt relief of symptoms without the possible side effects of medical treatment. In our series, 12 out of 18

patients in the medical group underwent subsequent surgical treatment, adding to the cost of already expensive treatment.

Apart from the cost-effectiveness of surgical treatment, another important point shown in our study is that by spending only an extra 11.5 min in the operating theatre, 53% of the patients with minimal to moderate endometriosis were successfully treated.

To our knowledge, this is the first study that has looked at the cost-effectiveness of HTC therapy in managing mild to moderate endometriosis.

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## References

1. Thomas E (1999) The clinician's view of endometriosis. *Int J Gynaecol Obstet* 4(Suppl 1):S1–S3
2. Koninckx PR, Meuleman C, Demeyere S, Lesffre E, Cornillie FJ (1991) Suggestive evidence that pelvic endometriosis is a progressive disease, whereas deeply infiltrating endometriosis is associated with pelvic pain. *Fertil Steril* 55:759–765
3. Tierney R, Prentice A (2002) The medical management of endometriosis. *Rev Gynaecol Pract* 2:91–98
4. Brosens IA (1999) Symptomatic endometriosis: focus on recurrent ectopic bleeding as a defining feature of endometriosis and a therapeutic target. *Hormonal Ther Obstet Gynaecol* 5:4–11 [Biomedis]
5. Rice VM (2002) Conventional medical therapies for endometriosis. *Ann N Y Acad Sci* 955:343–352
6. Telimaa S, Puolakka J, Ronnberg L, Kauppila A (1987) Placebo-controlled comparison of danazol and high-dose medroxyprogesterone acetate in the treatment of endometriosis. *Gynecol Endocrinol* 1(1):13–23
7. Dlugi AM, Miller JD, Knittle J (1990) Lupron depot (leuprolide acetate for depot suspension) in the treatment of endometriosis: a randomized, placebo-controlled, double-blind study. *Lupron Study Group. Fertil Steril* 54:419–427
8. Prentice A, Deary AJ, Goldbeck-Wood S, Farquhar C, Smith SK (2000) Gonadotrophin-releasing hormone analogues for pain associated with endometriosis. *Cochrane Database Syst Rev* 2:CD000346
9. Wright S, Valdes CT, Dunn RC, Franklin RR (1995) Short-term lupron or Danazol therapy for pelvic endometriosis. *Fertil Steril* 63:504–507
10. Minjarez DA, Chaff WD (2000) Update on the medical treatment of endometriosis. *Obstet Gynecol Clin North Am* 7(3):641–651
11. Wellbery C (1999) Diagnosis and treatment of endometriosis. *Am Fam Physician* 60(6):1753–1762, 1767–1768
12. Barbieri RL (1997) Primary gonadotropin-releasing hormone agonist therapy for suspected endometriosis: a nonsurgical approach to the diagnosis and treatment of chronic pelvic pain. *Am J Manag Care* 3(2):285–290
13. The American Fertility Society (1985) Revised American Fertility Society classification of endometriosis. *Fertil Steril* 43:351–352
14. Hornstein MD, Surrey ES, Weisberg GW, Casino LA (1998) Leuprolide acetate depot and hormonal add-back in endometriosis: a 12-month study. *Lupron Add-Back Study Group. Obstet Gynecol* 91(1):16–24
15. Winkel CA (1999) Modelling of medical and surgical treatment costs of chronic pelvic pain: new paradigms for making clinical decisions. *Am J Manag Care* 5(Suppl 5):S276–S290
16. Heinrichs WL, Henzl MR (1998) Human issues and medical economics of endometriosis. Three versus 6-month GnRH-agonist therapy. *J Reprod Med* 43(Suppl 3):299–308
17. Winkel CA (2000) A cost-effective approach to the management of endometriosis. *Curr Opin Obstet Gynaecol* 12(4):317–320