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ORIGINAL ARTICLE

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Over one thousand patients with early stage endometriosis treated with the Helica Thermal Coagulator (HELICA): safety aspects

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Abstract *Study objective*: To assess the safety of the Helica Thermal Coagulator in the laparoscopic treatment of early stage endometriosis. *Design*: Retrospective, observational. *Settings*: The Princess Royal University Hospital, The Sloane and Chelsfield Park Hospitals, Kent, UK. *Patients*: One thousand and sixty patients with early stage endometriosis. *Results*: All patients were treated laparoscopically with the Helica Thermal Coagulator; a new laparoscopic device that combines electrical energy with helium for the treatment of endometriosis. No major bladder, ureteric or bowel injuries occurred. The only complication was a perforated vagina from the cutting probe during dissection of the cul-de-sac in a patient with a vaginal endometriotic nodule. *Conclusion*: The Helica Thermal Coagulator is a safe device for the laparoscopic treatment of endometriosis.

Keywords Endometriosis · Helica · Treatment · Laparoscopy · Safety

Introduction

Endometriosis is one of the most common gynaecological causes associated with chronic pelvic pain [14, 18]. Laparoscopy is the gold standard in both diagnosis and management of early stage (mild and moderate) endometriosis. However, the optimal method for surgical destruction of endometriotic implants remains the subject of ongoing debate [4, 5].

The Helica Thermal Coagulator (Helica Instruments Ltd., Riccarton, Edinburgh, UK) is an instrument that combines low-pressure helium gas with low-voltage electrical power for the laparoscopic treatment of endometriosis. It was introduced into clinical practice in Scotland in 1993 [12]. To date over 14,000 probes have been used in the United Kingdom and the device has been licensed in many countries.

This study aims to assess the safety of the Helica Thermal Coagulator and combines the prospective study of the first 250 patients treated with the Helica device at the Princess Royal University Hospital [7] with a retrospective review of a further 810 patients treated in three different hospitals.

Materials and methods

Between March 2001 and April 2005, 1,060 women complaining of chronic pelvic pain of longer than 6 months duration had their early-stage (i.e. stage I and II) endometriosis treated laparoscopically with the Helica Thermal Coagulator. Patients were all treated by a team of consultant gynaecologists in three hospitals: The Princess Royal University Hospital (335 patients); The Sloane Hospital (100 patients) and Chelsfield Park Hospital (625 patients). The study was approved by the appropriate committees in the three hospitals. All patients gave written informed consent prior to surgery.

Pre-operative evaluation consisted of a complete history, physical examination and if appropriate a vaginal ultrasound. The severity of endometriosis was determined according to the revised American Fertility Classification [1] and only patients with stage I or II were included in this study.

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Surgical technique

The procedure was performed under general anaesthetic. All patients were operated upon in the modified Trendelenberg (semi-lithotomy) position. The abdomen and vagina were prepared with povidine–iodine solution and a catheter was used to empty the bladder. Laparoscopic examination of the pelvis and lower abdomen was performed to assess the degree and stage of the endometriosis. The laparoscopic approach was limited to one 5 mm infaumbilical and two 5 mm suprapubic cannula punctures. The lower portals were inserted under direct vision just medial to the obliterated umbilical artery to avoid damage to the inferior epigastric vessels. A non-disposable laparoscopic grasping forceps was inserted through one of the lower portals, which was used to retract bowel or move the ovaries to allow room for Helica to be used. The Helica works by combining low-pressure helium gas with low AC electrical power, which passes along a single insulated probe. Prior to insertion of the probe, the beam was assessed visually outside the abdomen by advancing the instrument to approximately 5 mm from a metal object and the foot pedal activated to fire the device. For destruction of endometriosis, the machine was set to low power. Medium power was used for cutting adhesions or for treatment of endometriomas.

Once tested outside the abdomen, the Helica device was introduced through the other lower portal and directed towards the affected tissue to be treated maintaining an angle of 90°. Once the tip of the Helica was approximately 5 mm from the endometriosis the instrument was activated using the foot pedal and the endometriosis was vapourised using a paintbrush technique. Using this technique, large areas of endometriosis and surrounding tissue can be rapidly treated. If the endometriosis is located at the back of the broad ligament or over the bladder then an area of at least 5 cm is treated. However, if the endometriosis is in the cul-de-sac then the entire cul-de-sac is treated. The power setting for treatment in these areas is 6 W using the low power setting of the machine. The tissue affect will depend on the duration of treatment and the distance of the probe from the endometriosis. For treatment of bowel endometriosis or endometriosis over the ureter, 4 W of energy was again used.

Outcome measures and follow up

The primary outcome of the study was occurrence of major complications which were defined as haematoma requiring surgical drainage, bleeding requiring transfusion, bowel or urinary tract injury, conversion to laparotomy, return to theatre and thrombosis [6]. Secondary outcome measures included hospital re-admission or general practitioner referral before the 3 months follow-up visit. All patients were reviewed 3 months after surgery when any late complications were noted.

Results

During the study period 1,060 consecutive women were included. All were treated laparoscopically for early stage endometriosis using the Helica Thermal Coagulator. No major complication occurred in the patients treated with the probe without the cutting end. One patient (0.1%) had a vaginal perforation from the cutting probe. This patient had a vaginal vault endometriotic nodule and vaginal perforation occurred during excision of the nodule. The problem was immediately identified when gas escaped from the vagina and the defect was sutured vaginally. The patient made an uneventful recovery. None of the patients required blood transfusion, returned to theatre, or developed venous thrombosis. No bladder, ureteric or bowel damage occurred despite the Helica being used regularly over these structures. No patients were re-admitted following hospital discharge.

When seen for follow up 3 months later no further major complications were reported. In the first cohort series of 250 patients 71% of patients had obtained symptomatic improvement.

Discussion

Endometriosis is a common gynaecological condition, affecting up to 10% of women in the reproductive age group [16]. This is reflected in the large number of patients included in this study, which report almost 10% of the whole United Kingdom experience with the use of the Helica Thermal Coagulator. The prime aim of laparoscopic treatment of endometriosis is to destroy the ectopic implants on the peritoneal surface and restore normal anatomy where possible. Simple destructive techniques such as provided by the Helica Thermal Coagulator can provide symptomatic improvement [8, 10]. In our series of 250 women, the rate of resolution of symptoms 3 month after surgery was 71% [7]. Nardo et al. [12] subsequently reported a study of 79 women in which 75% of patients reported either resolution or satisfactory improvement of symptoms at 3 months and this figure increased to 87% at 6 months.

The present series highlights the safety of the Helica Thermal Coagulator as a treatment modality for early stage endometriosis and a complication rate of only 0.1% is testament to this safety. No major complications occurred using the conventional non-cutting probe and no patient required conversion to laparotomy or blood transfusion. In addition, the combination of low pressure helium gas and low AC current (4–6 W) is used to deliver energy to tissue in a non-touch mode providing highly selective tissue coagulation and haemostasis with no risk of thermal tissue injury since the operational power is much lower than conventional diathermy [13, 15]. Furthermore, as coagulation only occurs within the helium beam and no carbonisation or smoke is

generated during treatment, the operating surgeon is able to maintain a clear view throughout the entire process of endometriosis destruction.

The operating power of the device and the distance of the Helica probe from the endometriotic lesion can also be modified in order to vary the depth of penetration of the beam. Using low power settings and a 5 mm distance from tissue, the depth of tissue penetration has been reported to be less than 1.5 mm [3]. This makes the Helica Thermal Coagulator an ideal choice when treating endometriotic implants around vulnerable structures such as bowel, bladder or ureter. In addition, using a paint brush technique whole peritoneal fields can be treated rapidly, allowing for treatment of both the endometriotic implants as well as the surrounding abnormal vasculature. Destruction of this vasculature may be important in decreasing recurrence rates of the disease particularly as macroscopically normal peritoneum may contain ectopic endometrium when examined microscopically [2, 9, 11].

The Helica Thermal Coagulator offers a versatile surgical tool, particularly when dealing with the various forms of endometriotic implants often encountered [17]. Our experience has shown that for mild disease the best results are achieved using 6 W on the low power setting, unless delicate structures are being treated in which case the power is reduced to 4 W. If deeper destruction of an endometriotic plaque is required then deeper penetration can be achieved either by putting the helica probe nearer the tissue; activating the device for a longer period until visualisation of total destruction of the endometriotic plaque has occurred; or by using a higher power setting. If endometriomas need to be treated then the ovary is opened conventionally and the cyst base destroyed using the medium power setting.

Conclusion

The Helica Thermal Coagulator provides a safe alternative treatment modality in the laparoscopic management of early stage endometriosis and has a very low complication rate. The use of the technique requires further evaluation as part of a randomised control trial against more conventional treatment modalities such as laser or diathermy.

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