Journal of Obstetncs and Gynaecology, January 2005*;* 25(1): 52-54

Taylor & Francis
Taylor & Francis Group

GYNAECOLOGY

Safety of the Helica Thermal Coagulator in treatment of early stage endometriosis

N. C. W. HILL, T EL-TOUKHY, S. CHANDAKAS, T. GRIGORIADES and J. ERIAN

Minimal Access Unit, Department of Obstetrics and Gynaecology, The Princes Royal University Hospital, Kent, UK

Summary
The objective of this prospective study was to assess the safety and short-term outcome of the Helica Thermal Coagulator in the laparoscopic treatment of early stage endometriosis. Two hundred and fifty consecutive women with chronic pelvic pain and stage I and II endometriosis (r-AFS classification) were treated laparoscopically with the Helica Thermal Coagulator. No bladder, ureteric or bowel injuries occurred. None of the procedures was converted to laparotomy and there were no major peri-operative complications. The only complication was a vaginal perforation during dissection of the cul-de-sac in a patient with a vaginal vault endometriotic nodule, We conclude that the Helica Thermal Coagulator is a safe alternative for the treatment of mild to moderate endometriosis. Long-term efficacy studies are required to better assess the role of the device in laparoscopic management of endometriosis.

Introduction

Endometriosis can affect up to 10% of women in the reproductive age group and 35% of infertile women (Vigano *et al.,* 2004*)*. The main clinical manifestations are dysmenorrhoea, dyspareunia and chronic pelvic pain with or without infertility. Traditionally, therapeutic options include surgery via laparoscopy, medical treatment or a combination of both, In spite of significant development in surgical and medical approaches, the optimal therapy for endometriosis--associated pelvic pain has yet to be established (Valle and Sciarra, 2003),

The Helica Thermal Coagulator (Helica Instruments Ltd. Riccarton, Edinburgh, UK) is a new instrument that combines low-pressure helium gas with low AC electrical power and can be used for the laparoscopic treatment of endometriosis. The operational power is much lower than conventional diathermy yet sufficient to ionise a jet of helium gas, thereby allowing tissue fulguration and producing an effect similar to the argon beam coagulator (Sutton. 1995).

The aim of the present study was to assess the safety and Helica Thermal Coagulator in the laparoscopic treatment of mild to moderate endometriosis.

Materials and methods

Between March 2001 and June 2003, women (mean age 29.4 years, range 18 - 47 years) complaining of chronic pelvic pain no longer than 6 months duration had laparoscopic treatment of endometriosis with the Helica Thermal Coagulator. All patients gave written informed consent prior to surgery. Pre-operative evaluation consisted of a thorough history, physical examination and if indicated a transvaginal ultrasound scan, The severity of endometriosis was determined laparoscopically according to the revised American Society of Reproductive Medicine classification (Canis *et a.,* 1997), Only symptomatic patients who were found to have stage I and II endometriosis were included, All patients were seen for follow up three months after surgery.

Instrument

The Helica machine and an attached small tank of helium (sufficient for approximately 200 cases) weighs 20 pounds. When used, it only has to be plugged into an AC current source and a foot pedal be put in place, An insulated sterile Helica probe is plugged into the machine ready for use.

Surgical technique

The procedure was performed under a general anaesthetic with the patients in a modified Trendelenberg 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 abdomen was performed to stage the severity of endometriosis, The laparoscopic approach was limited to one 5 mm infraumbilical 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

Correspondence Mr Nicholas C. W. Hill, MD FRCOG, Consultant Obstetrician and Gynaecologist, Administration I, Level 3, South Wing, The Princess Royal University Hospital, Farnborough Common, Orpington, Kent, BR6 8ND. E-mail: denise.Dalton@bromleyhospitals.nhs.uk

ISSN 0144-3615 print ISSN 1364-6893 online
DOI 10.10800144361040002490 6

portals to retract bowel or move the ovaries to allow room for the Helica probe 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 activating the foot pedal to fire the device. For destruction of peritoneal and/or ovarian endometriotic implants, the machine was set to low power. Medium power was used for cutting adhesions or dissection of the cul-de-sac using a special probe with a metal point ending. Although the device has a high power setting, this was not used in the study.

Once tested outside the abdomen, the Helica probe 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 vaporised using a paintbrush technique, which allowed the endometriotic implants and approximately one inch of surrounding peritoneum to be rapidly treated. For treatment of endometriosis on bowel surface or over the ureter, the same power setting (4-6 watts) was again used.

Outcome measures

The primary outcome of the study was occurrence of major complications. These were defined as haemorrhage requiring transfusion, haematoma requiring surgical drainage or transfusion, bowel or urinary tract injury, conversion to laparotomy, return to theatre and venous thromboembolism (Garry et *al., 2004).* Secondary outcomes included hospital re-admission or general practitioner (GP) referral before the 3-months follow up visit and short-term symptom relief.

FollowUp

Patients were reviewed in the outpatient clinic 3 months following hospital discharge. At follow up, symptoms review was conducted and any complications were noted.

Results

During the study period, 250 consecutive women were included. All were treated laparoscopically for early stage endometriosis using the Helica Thermal Coagulator as day-cases. No major perioperative complications occurred in patients treated with the probe without the cutting end. None of the procedures required conversion to open surgery. No bladder, ureteric or bowel damage occurred in this series despite the Helica device being used regularly over these structures. None of the patients required blood transfusion, returned to theatre, developed venous thrombosis or was re-admitted following hospital discharge. One patient (0.4%) had a vaginal perforation from the cutting probe. Incidentally, this patient was found to have a vaginal vault endometriotic nodule. Perforation occurred during attempted excision of the nodule. The problem was immediately identified and the defect was sutured vaginally. The patient made an uneventful recovery. No GP referrals were received for the study population within three months after surgery. When seen for follow up at three months, no complications were reported and 71% of patients *(179/250)* had obtained symptomatic relief.

Discussion

Mild to moderate endometriosis is a common condition and is associated with pelvic pain and/or subfertility (Porpora et *al.,* 1999; Valle and Sciarra, *2003),* The prime aim of laparoscopic surgery is to destroy the ectopic implants on the peritoneal surface, divide adhesions and restore normal anatomy (Donnez et *al*., 2004). Achievement of those goals is likely to provide relief of symptoms without the possible side effects of medical treatment (Howard, *2000;* Milingos *et al., 2003)* The optimum method of treatment, however, remains a source of ongoing controversy. Some surgeons advocate excision of the lesion (Redwine, 1991); others coagulate endometriotic implants electrosurgically or using laser (Adamson et *al.*, 1988). Only few randomised control trials have been performed (Howard, 2000) and technology is continuing to advance as new devices are developed. Furthermore, endometriosis is a recurrent disease, a fact which often complicates long-term follow-up efficacy studies. In one study of patients treated laparoscopically by laser for mild to moderate endometriosis, symptoms of pelvic pain recurred in 74% within 7 years of treatment (Jones *et al.,* 2001).

The Helica Thermal Coagulator represents an alternative energy source that is simple to use and can be utilised in the laparoscopic treatment of endometriosis. A combination of low pressure helium gas and low AC electric current (4 - 6 watts) is used to deliver energy to tissue in a non-touch mode allowing coagulation and haemostasis at the same time, The operating power of the device and the distance of the Helica probe *from* the endometriotic lesion can be altered in order to vary the depth of penetration of the beam. Using low power setting and a 5 mm distance from tissue, the depth of tissue penetration has been reported to be less than 1,5 mm making the instrument valuable in treating endometriosis around vulnerable structures such as the ureter or bowel surface (Donaldson and Hawthorn, 1995). Moreover, because of the low levels of power used, the risk of arcing to surrounding tissue is reduced (Nduka *et al.,* 1994), rendering the technique intrinsically safer than other fulguration methods.

Using a paint-brush technique, wide peritoneal held (including the endometriotic plaque and surrounding peritoneum) can be rapidly and safely treated. This is particularly relevant in light of the current awareness that_ macroscopically normal peritoneum may contain ectopic endometrium when examined under the microscope (Demco, 1998; Muzzi *et aI.,* 2000; Howard *et al.,* 2000). Furthermore, because tissue coagulation occurs within a helium environment, the operating surgeon maintains clear view of the destruction process as no carbonisation or smoke is generated during activation of the device. Finally the cost of the Helica Thermal Coagulator is considerably cheaper than conventional fulguration devices (such as laser, electro-surgery or Argon Beam Coagulator) and the instrument is easy to maintain.

This large series is the first to highlight the safety of the Helica device and to report a satisfactory short-term rate of symptom relief in the treatment of early stage endometriosis. In order to further assess efficacy of the device, a

randomised controlled study of the Helica Thermal Coagulator versus the Y AG laser is planned.

Conclusion

The Helica Thermal Coagulator represents an alternative treatment modality in the laparoscopic management of early stage endometriosis. It is safe, relatively cheap to maintain, uses low power energy levels and allows a large surface area to be treated including deposits over vulnerable structures. Comparative studies against more traditional treatment modalities are required to determine the role of the Helica device in management of endometriosis.

References

Adamson G., Lu J. and Subak L., (1988) Laparoscopic carbon dioxide laser vaporisation of endometriosis compared with traditional treatments. *Fertility and Sterility, 50,* 704-710.

The Revised American Society of Reproductive Medicine classification of endometriosis (1997) *Fertility and Sterility,* 67, 817-821.

Demco L., (1998) Mapping the source and character of pain due to endometriosis by patient-assisted laparoscopy, *Journal of the American Association of Gynecological Laparoscopists,* 5, 241-245.

Donaldson K. and Hawthorn R, (1995) Laparoscopic use of the Helica Thermal Coagulator. *Helica Thermal Coagulator Medical Reports* http://www.helica.co.uk/medicalRepons,html, pp, 1- 3.

Donnez J., Pirard C., Smets M., Jadoul P. and Squifflet J. (2004) Surgical Management of endometriosis. *Best Practice and Research in Clinical Obstetrics and Gynaecology,* **18**, 329 – 348.

Garry R. Fountain J., Mason S.U., Hawe J., Napp V., Abbolt J., Clayton R., Phillips G., Whittaker M., Lilford R., Bridgman S. and Brown J. (2004) The eVALuate study: two parallel randomised trails, one comparing laparoscopic with vaginal hysterectomy. *British Medical Journal,* 17,**328**,129.

Howard F. (2000) An evidence-based medicine approach to the treatment of endometriosis-associated chronic pelvic pain: placebo-controlled studies. *Journal of the American Association of Gynecological Laparoscopists,* 7, 477-488.

Howard F, EI-Minawi A. and Sanchez R (2000) Conscious pain mapping by laparoscopy in women with chronic pelvic pain, *Obstetrics and Gynecology,* 96, 934 – 939.

Jones KD., Haines p, and Sultan *C.J.G.* (2001) Long-term follow-up of a controlled trial of laser laparoscopy for pelvic pain, *Journal of the Society of Laparoscopic Surgeons,* 5, 111-115.

Milingos S., Protopapas A., Drakakis 1., Liapi A., Loutradis D., Kallipo G., Milingos D. and Michalas S, (2003) Laparoscopic management of patients with endometriosis and chronic pelvic pain. *Annals of the New York Academy of Science,* 997, 269 - 273.

Muzii I., Marana R, Brunelti I., Orlando G., Michelolto B., Benedelti P. and Panici P. (2000) Atypical endometriosis revisited: clinical and biochemical evaluation of the different forms of superficial implants, *Fertility and Sterility,* 74, 739 - 742,

Nduka C, Super P., Monson J, and Darzi A, (1994) Cause and prevention of electrosurgical injuries in laparoscopy, *Journal of the American College of Surgeons,* 179, 161-170.

Porpora M., Koninckx P., Piazze J., Natili M., Colagrande S. and Cosmi E, V, (1999) Correlation between _dometriosis and pelvic pain. *Journal of* the *American Association of Gynecological Laparoscopists,* 6, 429 - 434.

Redwine D.B. (1991) Conservative laparoscopic excision of endometriosis by sharp dissection: life table analysis of re-operation and persistence *or* recurrent disease. *Fertility and Sterility,* 56, 628 - 634.

Sulton C.J.G., Ewen S.P., Whitelaw N. and Haines P. (1994) Prospective randomised, double blind, controlled trial of laser laparoscopy in the treatment of pelvic pain associated with minimal, mild and moderate endometriosis. *Fertility and Sterility,* **62**, 696 - 700.

Sulton C.J.G., (1995) Power sources in endoscopic surgery, *Current Opinion in Obstetrics and Gynaecology,* 7,248 – 256.

Valle R, and Sciarra J. (2003) Endometriosis: treatment strategies. *Annals of the New York Academy of Science,* **997**, 229 - 239.

Vigano P., Parazzini F., Somigliana E. and Vercellini P.(2004) Endometriosis: epidemiology and aetiological factors, *Best Practice and Research in Clinical Obstetrics and Gynaecology,* **18**,177-200.