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REPORT

SECOND GENERATION ENDOMETRIAL ABLATION

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EXECUTIVE SUMMARY

INTRODUCTION

Menorrhagia is a common clinical problem and makes a large contribution to the workload of gynaecologists. Dysfunctional uterine bleeding (DUB) affects 20-30% of women and accounts for 12% of gynaecological referrals. Sixty percent of these women will have undergone hysterectomy within 5 years of referral, making it the commonest major gynaecological operation. A survey of over 36 000 hysterectomies reported a mortality rate of 0.38 per 1 000 operations, and serious morbidity rate of 3% (return to theatre to stop bleeding, visceral injury and other complications).

The first generation endometrial ablation techniques, the transcervical resection of the endometrium (TCRE) as well as roller ball electro coagulation (RBE), have been proven to be effective but the complication rate has been reported higher for TCRE. There is still a need to improve training in hysteroscopic surgery and to develop ablative techniques that allow the endometrium to be easily and safely destroyed to reduce the menstrual blood loss. Second generation ablative techniques that are minimally invasive, have a low risk profile, and are technically simple to operate have, therefore, been developed with the aim of improving on these existing minimal access techniques, all aimed at treating DUB, effectively, safely, quickly and preferably in the ambulatory setting. These include balloon heating, intrauterine instillation of heated saline, endometrial laser intrauterine thermal therapy, global 3-D ablation, punctual vaporation, photodynamic endometrial ablation, microwave endometrial ablation, radiofrequency and cryotherapy.

OBJECTIVE

To determine the safety, effectiveness, organizational implications and cost-effectiveness of various (nine modalities) second generation endometrial ablation techniques in the management of menorrhagia.

RESULTS

ENDOMETRIAL LASER INTRA-UTERINE THERMOTHERAPY - The clinical data is sparse. Studies have insufficient patient numbers or lengths of follow-up on which to fully evaluate the long-term efficacy, safety or cost effectiveness.

INTRA-UTERINE SURGERY USING A COAXIAL BIPOLAR ELECTRODE - The clinical data is insufficient. There are inadequate patient numbers or lengths of follow-up in which to fully evaluate the long-term efficacy, safety or cost effectiveness.

INTRAUTERINE INSTILLATION OF HEATED SALINE - Studies on intrauterine instillation of heated saline are prospective, observational studies involving small number of patients and short follow-up. More studies are needed to further address the long term effectiveness.

MICROWAVE ENDOMETRIAL ABLATION - There is some evidence that microwave endometrial ablation is safe and effective.

ENDOMETRIAL CRYOABLATION - There is some evidence that endometrial cryoablation is a safe and effective procedure in the treatment of dysfunctional uterine bleeding.

PUNCTUAL VAPORATION - There is evidence that endometrial ablation with a vaporizing electrode is safe and effective.

PHOTODYNAMIC ENDOMETRIAL ABLATION - Photodynamic endometrial ablation is selective and does not cause endometrial fibrosis or adhesions. There is evidence of effectiveness of photodynamic endometrial ablation.

THERMAL BALLOON ENDOMETRIAL ABLATION - There is sufficient evidence that thermal balloon endometrial ablation is easy to perform and compares favourably with first-generation endometrial ablation, in terms of effectiveness (reduced menstrual bleeding, dysmenorrhoea and premenstrual symptoms with concomitant improvement in quality of life), patient satisfaction and safety profile. It can be undertaken using local anesthesia on an ambulatory basis.

RADIOFREQUENCY ENDOMETRIAL ABLATION - There is evidence that radiofrequency endometrial ablation is safe and effective.

RECOMMENDATIONS

Vaporizing electrode, photodynamic endometrial ablation, thermal balloon endometrial ablation and radiofrequency endometrial ablation are recommended for use in endometrial ablation. Further evidence is required before endometrial laser intra-uterine thermotherapy, coaxial bipolar electrode, intrauterine instillation of heated saline, microwave endometrial ablation and endometrial cryoablation can be recommended.

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1. BACKGROUND

The conventional treatment for heavy menstrual loss or menorrhagia (a form of dysfunctional uterine bleeding) has been hysterectomy. Hysterectomy is a common and effective treatment, but is associated with a substantial post-operative convalescence period and morbidity.

The evolution of the surgical treatment of dysfunctional uterine bleeding has resulted in the design and manufacture of instrumentation that is minimally invasive, has a low risk profile, and is technically simple to operate. Although endometrial ablation has been accepted for more than 20 years, it continues to be a source of research, controversy and speculation. In the early 1990s, transcervical resections of the endometrium (TCRE) as well as roller ball electro coagulation (RBE), recognized as first generation endometrial ablation techniques, have proven to be effective for the treatment of menorrhagia. These became well-established day-care alternatives for the surgical treatment of menorrhagia. However, in the past two decades, various new hysteroscopic endometrial ablation techniques for the treatment of menorrhagia have emerged. These include balloon heating, intrauterine instillation or heated saline, endometrial laser intrauterine thermal therapy, global 3-D ablation, punctual vaporation, photodynamic endometrial ablation, microwave endometrial ablation, radiofrequency and cryotherapy. One of the important determinants of success of treatment is complete endometrial removal or destruction.

Both endometrial resection and ablation require general anesthesia, a high level of skill, and may be time-consuming. The various new techniques of second-generation endometrial ablation can be carried out under local anesthesia and potentially as a day-care procedure. However, the safety and effectiveness of most of these technologies have not been confirmed.

2. INTRODUCTION

Menorrhagia is a common clinical problem and makes a large contribution to the workload of gynaecologists. Dysfunctional uterine bleeding (DUB) affects 20-30% of women (Cooper et al, 1997) and accounts for 12% of gynaecological referrals (Cooke et al, 1999). Sixty percent of these women will have undergone hysterectomy within 5 years of referral (Coulter et al, 1991), making it the commonest major gynaecological operation (Vessey, 1992). The recent VALUE survey of over 36,000 hysterectomies reported a mortality rate of 0.38 per 1 000 operations, and serious morbidity rate of 3% (return to theatre to stop bleeding, visceral injury and other complications (Maresh, 2002).

Recently, several ablative techniques have been described to treat menorrhagia in order to reduce hysterectomy rates. Because the majority of women with menorrhagia have a normal sized uterus with no obvious pathology, hysteroscopic ablative techniques are increasingly performed. With the development of minimal access techniques, it has become possible to destroy the endometrium *in-situ*, in a short, day-care operation. These techniques include endometrium ablation with a Nd:YAG laser (Goldrath et al, 1981) and

resection of the endometrium with the operative hysteroscope (Magoes et al, 1988). Unfortunately, these techniques require considerable surgical skill and a long learning curve. It has been suggested that a surgeon learning the technique of resection, should treat 200 cases. Although resection is considered to be safe, it is still associated with a mortality of 2 per 10 000 and a serious complication rate of 2.1-6.4% (Overten et al, 1997).

The first generation endometrial ablation techniques have been proven to be effective but the complication rate has been reported higher for TCRE. There is still a need to improve training in hysteroscopic surgery and to develop ablative techniques that allow the endometrium to be easily and safely destroyed to reduce the menstrual blood loss.

Second generation ablative techniques have, therefore, been developed with the aim of improving on these existing minimal access techniques. In the past 10 years, there has been an explosion of research in the field and it has yielded a plethora of devices all aimed at treating DUB, effectively, safely, quickly and preferably in the ambulatory setting.

3. OBJECTIVE

To determine the safety, effectiveness, organizational implications and cost-effectiveness of various second generation endometrial ablation techniques in the management of menorrhagia.

4. METHODOLOGY

The electronic databases of Medline, PubMed, OBGYN net, Medscape, Ovid, Google, were searched from 1990 until 2003. The following were the keywords used, either singly or in combination - *second generation endometrial ablation, endometrial laser intra-uterine thermotherapy, intra-uterine surgery, coaxial bipolar electrode, punctal vaporation, photodynamic endometrial ablation, thermal balloon, heated saline, microwave endometrial ablation, radiofrequency endometrial ablation, cryotherapy, safety, effectiveness, cost, cost-effectiveness, menorrhagia and heavy menstrual blood loss*. The searches were limited to studies on human subjects only and abstracts presented in English.

All evidence retrieved was graded according to the modified Catalonian Agency of HealthTechnology Assessment (CAHTA) scale.

5. RESULTS

5.1. ENDOMETRIAL LASER INTRA-UTERINE THERMOTHERAPY

5.1.1. TECHNICAL FEATURES

The endometrial laser intra-uterine thermotherapy (ELITT) uses a diode laser powered by a 20W source, and a disposable handset. The laser light is emitted from three integrated optical-light diffusers designed to conform to the shape of the cavity. This allows a uniform distribution of laser light, which is then absorbed by haemoglobin in the uterine wall, resulting in coagulation. The laser, therefore, does not need to be in contact with the endometrium, nor does the technique require fluid distension of the cavity. The cervix is dilated to 7 mm and the handset is inserted into the cavity in a blind manner. The laser is then activated for a 7-minute pre-programmed cycle.

5.1.2. SAFETY

Currently, the clinical data on ELITT is sparse. Jones et al (2001) conducted a multi-center prospective study on 40 patients with 12 months follow-up, in which no uterine perforation or major complication was noted. Another prospective study on 100 post-menopausal women with DUB by Donnez et al (2000) found no perforation of the uterus.

5.1.3. EFFECTIVENESS

Jones et al (2001) in a multi-center prospective study on 40 patients, concluded that the average menstrual score reduction was 88%, and most patients were satisfied with the treatment. However, at 1 year, 12.5% had undergone hysterectomy due to treatment failure. Similarly, Donnez et al (2000) found that the rate of amenorrhea/severe hypomenorrhea was less than 90% at 1 year after treatment. A cohort study by Donnez et al (1999) noticed a 63% amenorrhea rate in 88 women.

5.1.4. CONCLUSIONS

The clinical data on ELITT is sparse. Studies have insufficient patient numbers or lengths of follow-up on which to fully evaluate the long-term efficacy, safety or cost effectiveness.

5.2. INTRA-UTERINE SURGERY USING A COAXIAL BIPOLAR ELECTRODE

5.2.1. TECHNICAL FEATURES

The system has an electrode of 1.6 mm diameter, that is inserted into the operative channel of a 55 mm continuous-flow hysteroscope. In use, the electrode does not extend more than 8 mm beyond the hysteroscope. The electrosurgical generator provides power settings from 1-200 W. The system requires uterine distension, achieved using normal

saline. When activated in the normal saline, a high resistance air pocket is created that effectively insulates the active electrode. It is only when contact is made with the tissue that the circuit is completed and cutting occurs.

5.2.2. SAFETY

Data on the safety of the system is scarce. All series reported had small sample sizes. In the series of Marwah and Bhandari (2003), 5 patients underwent endometrial ablation with no complications reported. In the preliminary experience by Loffer (2000), one patient underwent endometrial ablation, and no complication was reported. A similar result was reported by Vilos (1999). However, the depth of tissue destruction was not determined in both series.

5.2.3. EFFECTIVENESS

As with safety, data on the efficacy of the system is also scarce, and all series reported had small sizes. In both the series of Marwah and Bhandari (2003) and Vilos (1999), it was concluded that the system is an effective alternative, though the duration of follow-up was not mentioned. In the interim report of the American Vests Trial of Endometrial Ablation by Carson Slet al (1999), a 31.8% amenorrhea rate was reported. However, long term results are not available.

5.2.4. CONCLUSION

The clinical data on Coaxial Bipolar electrode is insufficient. There is inadequate patient numbers or lengths of follow-up in which to fully evaluate the long-term efficacy, safety or cost effectiveness.

5.3. PHOTODYNAMIC ENDOMETRIAL ABLATION

5.3.1. TECHNICAL FEATURES

Ganon et al reported that photosensitization of the endometrium with topical 5-aminolevulinic acid was preferentially taken up by the endometrium, reaching a level providing a sufficient degree of photosensitization for ablation. The deepest extent of ablation is the basal layer, which is the level required for therapeutic endometrial ablation. Incomplete uptake throughout the endometrium may limit the clinical usefulness of topical photosensitization. No regeneration of the endometrium was evident 10 days after the treatment. Therefore endometrial destruction can be achieved by direct ablation combined with local toxicity from photoablated tissue.

5.3.2. SAFETY

There were no studies to evaluate the safety issues in photodynamic endometrial ablation. It is a minimally invasive procedure, may not require anaesthesia and can be performed

in an ambulatory setting. Since the photodynamic endometrial ablation concentrates the photosensitizer in the endometrium, it minimizes systemic risks such as skin photosensitivity.

The Pius Wyss Morphological Study found that necrosis including the full thickness of the endometrium 3 days after the procedure. Follow up after 35 and 152 days did not exhibit fibrosis or adhesions. Foci of preserved endometrium were detected in all patients. Therefore photodynamic endometrial ablation is very selective and does not cause endometrial fibrosis or adhesions. Fehr et al also supported this in their study.

5.3.3. EFFECTIVENESS

The Pius Wyss Morphological Study found necrosis including the full thickness of the endometrium 3 days after the procedure. The Fehr study concluded that photodynamic endometrial ablation is effective if a sufficient light dose can be delivered to the entire endometrium with an appropriate intrauterine light delivery device.

5.3.4. CONCLUSION

Photodynamic endometrial ablation is selective and does not cause endometrial fibrosis or adhesions. There is evidence of effectiveness of photodynamic endometrial ablation.

5.4. PUNCTUAL VAPORATION

5.4.1. TECHNICAL FEATURES

The vaporizing electrode seems to combine the benefits of the cutting loop (speed, efficacy and possibility of removing myomas) and the roller ball electrode (safety and limited fluid absorption) while avoiding their respective disadvantages (Vercellini et al, 1997).

5.4.2. SAFETY

Vercellini et al (1997) reported that all procedures in her study were completed without complications.

5.4.3. EFFECTIVENESS

Punctual vaporation has been suggested to be an alternative to the hysteroscopic treatment of menorrhagia, since it is as rapid and effective as the loop and as simple as the roller ball (Vercellini et al, 1997).

5.4.4. CONCLUSION

There is evidence that endometrial ablation with a vaporizing electrode is safe and effective.

5.5. THERMAL BALLOON ENDOMETRIAL ABLATION

5.5.1. TECHNICAL FEATURES

This system utilises a 16 cm long, 5 mm diameter catheter with a heating element contained in a latex balloon on the treatment end. This apparatus is connected to a control unit that can monitor display and adjust pre-set intrauterine balloon pressure, temperature and duration of treatment. The deflated balloon and a 5 mm catheter are introduced transcervically into the uterine cavity and once in place, 5 % dextrose solution is used to inflate the balloon. A minimum pressure of 150 mm Hg must be achieved for the device to activate. The fluid is then heated to approximately 87°C and treatment is undertaken for 8 min. The balloon is then deflated and removed from the cavity.

5.5.2. SAFETY

Anderson et al (1998) assessed the safety aspects of thermal balloon therapy, and found that that up to 16 minutes of therapy can destroy the endometrium and the submucosal layers. The myometrium is only coagulated to a depth where full thickness necrosis or injury is unlikely.

A randomized controlled trial comparing the Cavaterm endometrial ablation system with the Nd:YAG laser for the treatment of dysfunctional uterine bleeding found no major complications in either group (Hawe et al, 2003). Lok et al (2002) performed thermal balloon endometrial ablation on 30 women with menorrhagia in an outpatient setting and did not encounter any intra-operative complication. Another prospective randomized trial on thermal destruction versus hysteroscopic transcervical endometrial resection for menorrhagia found less intra-operative blood loss and shorter operating time in the thermal destruction group (Pellicano et al, 2002). A multicenter, prospective, randomized study comparing thermal balloon ablation with endometrial resection for the treatment of abnormal uterine bleeding by Gervaise et al (1999), found no intraoperative complications and minimal postoperative morbidities.

Mangeshikar et al (2003), Alaily et al (2003), Alestebi et al (1999), Amso et al (1998) and Buckshee et al (1998) also did not encounter any complications when performing endometrial ablation using the thermal balloon. .

Ulmsten et al (2001) evaluated the safety of MenoTreat, a new balloon device for thermal endometrial ablation, and did not have any intra-operative complications while post-operative morbidities were similar to that reported for other similar treatment methods.

A review by Barrow et al (1999) concluded that thermal balloon is the safest of all endometrial ablation methods on an outpatient basis.

5.5.3. EFFECTIVENESS

A randomized controlled trial comparing the Cavaterm endometrial ablation system with the Nd:YAG laser for the treatment of dysfunctional uterine bleeding concluded that Cavaterm endometrial ablation system is as good as Nd:YAG laser when used for the treatment of dysfunctional bleeding (Hawe et al, 2003).

Patient satisfaction rate has been shown to be significantly higher in thermal destruction compared to hysteroscopy transcervical endometrial resection for menorrhagia (Pellicano et al 2000). The operative time was significantly shorter with thermal destruction and there was no significant difference in postoperative pain between both groups..

Gervaise et al (1999) found no significant difference comparing thermal balloon ablation with endometrial resection for the treatment of abnormal uterine bleeding and found that thermal balloon therapy was much easier to perform.

Corson et al (2001) compared endometrial ablation by Hydro-Therm Ablator (HTA) and rollerball for treatment of menorrhagia and found roller ball to be superior. A similar study by Grainger et al (2000) found that patient satisfaction with both treatments was consistently high, but more patients in the roller ball group needed hysterectomy at the end of 2 years. A 5-year follow-up of this study reported normal or less bleeding in most of the women, with high patient satisfaction and nearly seven out of 10 women were cured of menorrhagia without additional intervention (Loffer FD et al, 2002).

Lok et al (2002) reported an overall success rate of 85% for treating menorrhagia with thermal balloon endometrial ablation. A study Nazar et al (2003) on using uterine endometrial thermal balloon therapy for the treatment of menorrhagia found to be very effective Amso et al (1998) reported a success rate of 88-91% in terms of reduction in menstrual bleeding and severity of pain.

Mangeshikar et al (2003) reported amenorrhoea in 50% of patients and 38% of patients became hypomenorrhoeic after thermal balloon on women with menorrhagia. However this is a small study with a follow up period of 6 months only. Jarell et al (2003) had only 57% of women reporting overall satisfaction with thermal balloon endometrial ablation. However, this study involved only 28 patients

Bongers et al (2002) showed 81% of patients were satisfied with the result of treatment with thermal balloon after 2 years. Alaily et al (2003) reported an overall patient satisfaction of 90% with treatment of dysfunctional uterine bleeding using thermal balloon.

Mettler et al (2002) looked at long-term results in the treatment of menorrhagia and hypermenorrhoea with a thermal balloon endometrial ablation technique. This study reported 58% patients had amenorrhoea, 33 % hypomenorrhoea and 9 % eumenorrhoeic. Buckshee et al; (1998) reported a 92.3% reduction in bleeding. Aletebi et al (1999) had a 77% overall success rate.

Ulmsten et al (2001) evaluated the efficacy of MenoTreat, a new balloon device for thermal endometrial ablation, and reported an overall success rate of 43%.

A review by Brun et al (2000) concluded that success rate for balloon therapy is 90% in selected patients up to a follow up period of 12-24 months. Another review by Barrow et al (1999) concluded that thermal balloon has resulted in reduction in menstrual flow in 70-90% of patients.

5.5.4. CONCLUSION

There is sufficient evidence that thermal balloon endometrial ablation is easy to perform and compares favorably with first-generation endometrial ablation, in terms of effectiveness (reduced menstrual bleeding, dysmenorrhoea, and premenstrual symptoms with concomitant improvement in quality of life), patient satisfaction and safety profile. It can be undertaken using local anesthesia on an ambulatory basis.

5.6. INTRAUTERINE INSTILLATION OF HEATED SALINE

5.6.1. TECHNICAL FEATURES

The system consists of a controller, computer and a disposable flexible probe that provides *in-situ* heating and circulation of the saline while maintaining a tight seal at the internal os of the cervix. Endometrial ablation is performed with controlled intrauterine instillation and circulation of heated saline (at approximately 90°C) for about 10 minutes under hysteroscopic control.

5.6.2. SAFETY

A study by Perlitz et al (2001) on 14 patients found no intraoperative or procedure related complications. Similarly, no complications were encountered by Weisberg et al (2000) Das Dores et al (1999), Richart et al (1999), Bustos-Lopez et al (1998) after performing endometrial ablation using heated saline for the treatment of menorrhagia.

5.6.3. EFFECTIVENESS

Perlitz et al (2001) Weisberg et al (2000) in their study of endometrial ablation using hysteroscopic instillation of hot saline solution into the uterus obtained good results. Das Dores et al (1999) treated 26 women with uncontrolled menorrhagia, resulting in 87.5 % women being amenorrhic at 18 months.

5.6.4. CONCLUSIONS

Studies on intrauterine instillation of heated saline are prospective, observational studies involving small number of patients and short follow-up. More studies are needed to further address the long term effectiveness.

5.7. MICROWAVE ENDOMETRIAL ABLATION

5.7.1. TECHNICAL FEATURES

Microwave energy at 9.2 GHz is propagated through an applicator known as microwave 'waveguide'. When the device is inserted into uterine cavity, the microwave energy produces a tissue temperature of 95°C at a depth of 6 mm. In order to treat the entire uterine cavity, the surgeon moves the probe cornu to cornu and across the lower uterine segment until the entire endometrium has reached the desired temperature. The total treatment time is 1-4 minutes. The probe is reusable and can be sterilized in an autoclave or by other sterilization methods. The disadvantage of this is that the probe is too large for office use without the use of either general or regional anesthesia.

5.7.2. SAFETY

A study of 1364 microwave endometrial ablation (MEA) procedures in 13 units by 25 different surgeons found a low incidence of complications. Possible complications were bowel injury and endometritis. No emergency hysterectomies were required, compared to 11 out of 1 000 transcervical resections of the endometrium (TCRE) (Downes et al, 2000).

5.7.3. EFFECTIVENESS

A randomized controlled trial comparing MEA and TCRE involving 263 women with menorrhagia, followed up for a year showed shorter mean operating time for MEA Cooper et al (1999). A pilot study in 1994 involving 23 patients showed a success rate of 83% with an operating time of 2 minutes.

5.7.4. CONCLUSION

There is some evidence that MEA is safe and effective.

5.8. RADIOFREQUENCY ENDOMETRIAL ABLATION

5.8.1. TECHNICAL FEATURES

Radiofrequency ablation heats the whole of the endometrial cavity of the uterus. The device consists of a silicone-inflatable electrode carrier probe to be inserted into the uterine cavity and a controller to monitor and distribute current to matched

electrosurgical generator. The probe at 27.12 MHz causes the temperature of the basalis layer to be raised to approximately 50 -55°C destroying 4-5 mm of the myometrium to reduce the bleeding.

5.8.2. SAFETY

A study by Thijssen et al (1997) for 4 years in 6 countries involving 1 280 women. found Radiofrequency Endometrial Ablation to be safe as long as the strict protocols are maintained.

5.8.3. EFFECTIVENESS

A small study using radiofrequency treatment found reduction in the menstrual blood loss (Phipps et al, 1992). A study by Thijssen et al reported a 80% success rate in reducing blood loss.

Cooper's study on 267 women who underwent thermal radiofrequency endometrial ablation showed 91% had reduction in the menstrual flow to normal levels at 12 months and amenorrhea rate of 41%.

A comparison of thermal radiofrequency endometrial ablation, hydrothermal ablation, balloon and cryogen, showed that radiofrequency endometrial ablation produced the highest rate of success, ammenorrhea and patient satisfaction.

5.8.4. CONCLUSION

There is evidence that radiofrequency endometrial ablation is safe and effective.

5.9. ENDOMETRIAL CRYOABLATION

5.9.1. TECHNICAL FEATURES

The device consists of a compact compressor housed in a portable console containing a digital display and user interface. The cryoprobe applicator is attached to the console with insulated flexible tubing. A disposable sheath (control unit) fits over the cryoprobe and has a metallic tip for thermal conduction. There is an initial 3–5 minutes pre-cool cycle, followed by heating to 37°C. A small amount of saline is then flushed through the device to clear any air. The uterus is sounded and if necessary, the cervical canal is dilated to accommodate the probe. A 5.5 mm cryoprobe is inserted through the cervix and into the uterine cavity. The probe is cooled by either liquid nitrogen or by differential gas exchange. When the probe is cooled to the temperature of less than -90°C, an elliptical ice ball forms around the probe. The freezing of the tissue causes less pain because of cryoanesthesia and patients experience minimal cramps during the procedure.

5.9.2. SAFETY

Dobak et al (2000) monitored the serosal surface temperature, and reported that it was safe. A study by Duleba et al (2003) found less usage of general anaesthesia in Cryotherapy as well as avoidance of potential complications related to distension media.

A review by Kelly et al reported that the procedure is safe since ultrasound monitoring allows for individualized treatment and permits the operator to stop the freeze cycle if the iceball approaches the serosal surface of the uterus, while freezing will automatically terminate after 10 minutes.

5.9.3. EFFECTIVENESS

Duleba et al from a prospective randomized study reported significant improvement in broad range of symptoms including menses related pain, mood and overall improvement in quality of life.

A multicentre clinical trial showed a 67.4% success rate with an amenorrhoea rate of 22.2%, and 86% satisfaction rate. Another study of 222 patients with up to 1 year follow-up reported that 75% of patients had a greater than 90% reduction in their patient bleeding assessment card score.

5.9.4. CONCLUSION

There is some evidence that endometrial cryoablation is a safe and effective procedure in the treatment of dysfunctional uterine bleeding.

6. COST IMPLICATIONS

All 3 techniques - microwave endometrial ablation, radiofrequency endometrial ablation, endometrial cryoablation - were reported as inexpensive and quick based on the operating time, the usage of anaesthesia and distension media. The newer techniques were also found to take less time to perform compared to conventional techniques, and more likely performed under local anaesthesia. (Cochrane Review, 2002).

A randomized prospective study of endometrial ablation versus hysterectomy estimated the overall mean cost is lower in ablation than hysterectomy when assessed after 4 years. Cryotherapy and radiofrequency ablation have been described as being prohibitively costly at present.

The cost for device disposables are similar - \$650.00 for ThermaChoice and Hydro ThermAblator, \$850.00 for the Novasure and \$1250.00 for HerOption. The non-disposable controllers range from approximately \$10,000 to \$30,000 depending on the device.

The cost-effectiveness and long-term safety and efficacy of microwave, radiofrequency and cryoablation remain to be studied, as these techniques are not widely available as compared to first generation endometrial ablation. The data available involved a small sample and only MEA was widely evaluated.

7. CONCLUSIONS

There is inadequate evidence on the safety and effectiveness of endometrial laser intra-uterine thermotherapy, coaxial bipolar electrode and intrauterine instillation of heated saline. There is some evidence of safety and effectiveness of photodynamic endometrial ablation, microwave endometrial ablation and endometrial cryoablation. There is sufficient evidence that vaporizing electrode, photodynamic endometrial ablation, thermal balloon endometrial ablation and radiofrequency endometrial ablation is safe and effective.

8. RECOMMENDATIONS

Vaporizing electrode, photodynamic endometrial ablation, thermal balloon endometrial ablation and radiofrequency endometrial ablation are recommended for use in endometrial ablation. Further evidence is required before endometrial laser intra-uterine thermotherapy, coaxial bipolar electrode, intrauterine instillation of heated saline, microwave endometrial ablation and endometrial cryoablation can be recommended.

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