

Appendix 2

Characteristics of studies included in the systematic review of randomised trials comparing hysterectomy, endometrial ablation and Mirena for heavy menstrual bleeding

Paper/number of women randomised	Patients	Intervention	Stated key outcome measures	Patient satisfaction and how it was measured	IPD received?
Hysterectomy vs first-generation EA					
Dickersin <i>et al.</i> , 2007 ⁹² (design and methods paper also published ¹⁴⁷) Raw data available <i>n</i> =237	Women with DUB. Up to 3 fibroids allowed, must each be smaller than 3 cm	EA vs hysterectomy	Major problem solved (primary outcome) Resolution of problem Bleeding Pain Fatigue QoL Adverse events Reoperation rate Follow-up reported at 12 months, 2 and 5 years; IPD at 6 months, 3 and 4 years also received	Women were asked if their major problem was solved from baseline Answers were given using the following scale: Yes No	Yes
Zupi <i>et al.</i> , 2003 ⁷⁸ Raw data available <i>n</i> =203	Women with HMB. Fibroids excluded	TCRE vs laparoscopic supracervical hysterectomy	Primary outcome unclear Duration of hospitalisation Period of convalescence Perioperative complications Resumption of usual activities QoL Follow-up reported at 3 months, 1 and 2 years	No comparable measure	Yes
Crosgnani <i>et al.</i> , 1997 ⁴⁵ <i>n</i> =92	Women with HMB < 50 years old with a mobile uterus smaller than a 12-week pregnancy. Fibroids excluded if > 3 cm	TCRE vs vaginal hysterectomy	Satisfaction (primary outcome) Improvement in menstrual blood loss Operating time Complications Postoperative hospital stay Resumption of usual activities Resumption of work activities QoL Follow-up reported at 2 years	Women were asked how satisfied they were with their operation Answers were given using the following scale: Very satisfied Satisfied Uncertain Dissatisfied Very dissatisfied	No

continued

Paper/number of women randomised	Patients	Intervention	Stated key outcome measures	Patient satisfaction and how it was measured	IPD received?
O'Connor <i>et al.</i> , 1997 ⁴⁴ Raw data available <i>n</i> = 202	Women with symptomatic HMB. Fibroids excluded if larger than 5 cm	TCRE vs abdominal + vaginal hysterectomy	Satisfaction (primary outcome) Need for further surgery QoL Duration of surgery Duration of hospital stay Operative and postoperative complications Resumption of work activities Resumption of usual activities Resumption of sexual activities Follow-up reported at 3 months, then 1, 2 and 3 years	Women were asked how satisfied they were with their treatment Answers were given using the following scale: Very satisfied Satisfied Not sure Dissatisfied Very dissatisfied	Yes
Pinion <i>et al.</i> , 1994 ⁴³ Raw data available <i>n</i> = 204	Women who would have otherwise had a hysterectomy for HMB. IPD showed that fibroids were included; exact eligibility details regarding this parameter not given in paper	TCRE + laser vs abdominal hysterectomy	Satisfaction (primary outcome) Operative complications Postoperative recovery Relief of menstrual symptoms Relief of other symptoms Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with their treatment Answers were given using the following scale: Very satisfied Moderately satisfied Dissatisfied Very dissatisfied	Yes
Dwyer <i>et al.</i> , 1993 ⁴² (health economics papers also published ^{132,146}) Raw data available <i>n</i> = 200	Women needing surgical treatment for HMB. IPD showed that fibroids were included; exact eligibility details regarding this parameter not given in paper	TCRE vs abdominal hysterectomy	Satisfaction (primary outcome) Postoperative complications Duration of operation Length of hospital stay Resumption of work activities Resumption of usual activities Resumption of sexual activities Changes in pre-menstrual symptoms QoL Need for further surgery Total health service resource cost Follow-up reported at 4 months and 2 years	Women were asked how satisfied they were with their operation Answers were given using the following scale: Very satisfied Quite satisfied Not very satisfied Dissatisfied	Yes
Gannon <i>et al.</i> , 1991 ⁴¹ Raw data available <i>n</i> = 54	Women with HMB. Fibroids excluded	TCRE vs abdominal hysterectomy	Primary outcome unclear Length of operating time Hospitalisation Recovery Cost of surgery Change in menstrual blood loss Postoperative complications Need for further surgery Resource cost of surgery Follow-up reported at 12 months	No comparable measure	Yes

Paper/number of women randomised	Patients	Intervention	Stated key outcome measures	Patient satisfaction and how it was measured	IPD received?
Hysterectomy vs Mirena					
Hurskainen <i>et al.</i> , 2001 ⁹³ (5-year follow-up study also published ²⁷) Raw data available <i>n</i> = 236	Women with HMB. Fibroids excluded	Mirena vs hysterectomy (abdominally, vaginally or laparoscopically)	QoL (EQ-5D) (primary outcome) QoL (SF-36) Cost-effectiveness Adverse events General health (visual analogue scale, VAS) Anxiety/depression Sexual functioning Follow-up reported at 12 months and 5 years; IPD at 6 months also received	No comparable measure	Yes
First- vs second-generation EA					
Brun <i>et al.</i> , 2006 ¹⁰³ Raw data available <i>n</i> = 62	Women with HMB unresponsive to medical treatment. Submucous fibroids excluded, other fibroids included (further details not given)	TCRE vs thermal balloon (Cavaterm)	Amenorrhoea rate (primary outcome) Satisfaction PBAC (Higham blood loss) score Operative time Discharge time Complication rate Resumption of normal activities Follow-up reported at 6 and 12 months; IPD at 3 months also received	Refers to 'satisfaction rate' Answers were given using the following scale: Excellent Good Moderate Bad	Yes
Cooper <i>et al.</i> , 2004 ⁹⁹ Raw data available <i>n</i> = 322	Women with documented HMB due to benign causes. Fibroids excluded if > 3 cm	RB vs microwave	Satisfaction Amenorrhoea rate Duration of procedure Anaesthesia Type of anaesthesia Device-related complications Adverse events Dysmenorrhoea QoL questionnaire (SF-36) Acceptability of treatment Follow-up reported at 3, 6 and 12 months	Women were asked how satisfied they were with their treatment Answers were given using the following scale: Very satisfied Satisfied Dissatisfied	Yes
Perino <i>et al.</i> , 2004 ¹⁰⁰ <i>n</i> = 116	Women with abnormal uterine bleeding. Not stated if fibroids were excluded	TCRE vs ELITT	Amenorrhoea rate (primary outcome) Satisfaction Bleeding status Intraoperative complication rate Duration of procedure Pain Further treatment with hysterectomy Follow-up reported at 12 months and 3 years	Refers to 'patient satisfaction' Answers were given using the following scale: Very satisfied Satisfied Dissatisfied	No

continued

Paper/number of women randomised	Patients	Intervention	Stated key outcome measures	Patient satisfaction and how it was measured	IPD received?
Duleba <i>et al.</i> , 2003 ⁹⁸ <i>n</i> =279	Women with HMB due to benign causes. Fibroids excluded if > 2 cm	RB vs endometrial cryoablation	PBAC (Higham blood loss) score (primary outcome) Satisfaction Bleeding Pain Adverse events Anaesthesia Pre-menstrual symptoms Follow-up reported at 12 months	Women were asked how satisfied they were with the outcome of the procedure Answers were given using the following scale: Very Slightly Not at all	No
Hawe <i>et al.</i> , 2003 ⁹⁴ Raw data available <i>n</i> =72	Women with DUB requesting conservative surgical management of their condition. Fibroids excluded	Nd:Yag laser vs thermal balloon (Cavaterm)	Amenorrhoea rate (primary outcome) Satisfaction Effect on blood loss QoL Sexual activity Acceptability of procedure Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with their treatment Answers were given using the following scale: Very satisfied Moderately satisfied Dissatisfied Very dissatisfied	Yes
van Zon-Rabelink <i>et al.</i> , 2004 ⁹⁵ (technical safety report also published ¹⁴⁹) Raw data available <i>n</i> =139	Women with DUB. IPD showed that fibroids were included; exact eligibility details regarding this parameter not given in paper	RB vs thermal balloon	PBAC (Higham blood loss) score (primary outcome) Satisfaction QoL Menstrual status Follow-up reported at 6 and 12 months and 2 years	Refers to 'patient satisfaction' Answers were given using the following scale: Satisfied Not satisfied	Yes
Cooper <i>et al.</i> , 2002 ⁵⁶ <i>n</i> =265	Women with symptomatic HMB. Fibroids excluded	Wire loop resection + RB vs bipolar radiofrequency (NovaSure)	PBAC (Higham blood loss) score (primary outcome) Satisfaction Procedure time Sedation Intraoperative complications Postoperative complications Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with the outcome of the procedure No precise information was given on the scale used to answer this question and IPD were not received. Percentage of women very satisfied or satisfied was quoted	No
Pellicano <i>et al.</i> , 2002 ¹⁰² <i>n</i> =82	Women with HMB unresponsive to medical treatment. Fibroids excluded	TCRE vs thermal destruction (Cavaterm)	Satisfaction (primary outcome) Operative time Discharge time Complication rate Reintervention rate Resumption of normal activities Follow-up reported at 3 and 12 months and 2 years	Women were asked about the improvement of their health state after the procedure Answers were given using the following scale: Excellent Good Moderate No improvement	No

Paper/number of women randomised	Patients	Intervention	Stated key outcome measures	Patient satisfaction and how it was measured	IPD received?
Corson, 2001 ⁷⁹ <i>n</i> =276	Women with HMB due to benign causes. Fibroids excluded if >4 cm	RB vs HA	PBAC (Higham blood loss) score (primary outcome) Amenorrhoea rate Adverse events Need for further surgery Operative complications Follow-up reported at 6 and 12 months	No comparable measure	Yes
Soysal <i>et al.</i> , 2001 ⁹⁶ <i>n</i> =96	Menorrhagic women over 40 with a mobile myomatous uterus smaller than 12-week pregnancy. Fibroids excluded if >3 cm	RB vs thermal balloon	PBAC (Higham blood loss) score (primary outcome) Satisfaction Duration of procedure Complication rates Postoperative pain scores Amenorrhoea rates Follow-up reported at 12 months	Women were asked how satisfied they were with their operation Answers were given using the following scale: Very satisfied Satisfied Dissatisfied	No
Corson <i>et al.</i> , 2000 ¹⁰¹ <i>n</i> =276	Women with HMB, without organic uterine disease, who failed or poorly tolerated medical therapy. Fibroids excluded if >2 cm	TCRE + RB vs thermal balloon (Vesta)	PBAC (Higham blood loss) score (primary outcome) Amenorrhoea Adverse events QoL Follow-up reported at 12 months and 2 years	No comparable measure.	No
Cooper <i>et al.</i> , 1999 ⁵⁴ (2-year ⁵⁵ and 5-year ¹¹⁵ follow-up study also published) Raw data available <i>n</i> =263	Women referred for EA surgery. Fibroids included; exact eligibility details regarding this parameter not given in paper	TCRE + RB vs microwave	Satisfaction (primary outcome) Acceptability of treatment Menstrual status QoL Morbidity Duration of procedure Intraoperative complications Postoperative pain relief Postoperative stay. Absence from work Follow-up reported at 12 months, 2 years, 5 years and 10 years	Women were asked how satisfied they were with their treatment Answers were given using the following scale: Totally satisfied Generally satisfied Fairly satisfied Fairly dissatisfied Generally dissatisfied Totally dissatisfied	Yes
Meyer <i>et al.</i> , 1998 ⁵³ Raw data available <i>n</i> =275	Women with HMB. Fibroids excluded	RB vs thermal balloon (ThermaChoice)	PBAC (Higham blood loss) score (primary outcome) Satisfaction Improvement in dysmenorrhoea symptoms Inability to work Complication rate Duration of procedure Requirement for additional surgery Follow-up reported at 3, 6 and 12 months	Women were asked how satisfied they were with their treatment Answers were given using the following scale: Very satisfied Satisfied Not satisfied	Yes

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Paper/number of women randomised	Patients	Intervention	Stated key outcome measures	Patient satisfaction and how it was measured	IPD received?
Romer, 1998 ⁹⁷ <i>n</i> = 20	Women with recurrent therapy for refractory HMB. Fibroids excluded (intrauterine abnormalities excluded, so assumed this included fibroids)	RB vs thermal balloon (Cavaterm)	Amenorrhoea rate (primary outcome) Hypomenorrhoea rate Follow-up reported at 12 months	No comparable measure	No
Mirena vs first-generation EA					
Malak, 2006 ¹⁰⁴ <i>n</i> = 60	Women with excessive uterine bleeding. Up to 3 fibroids allowed, must each be < 3 cm	TCRE vs Mirena	Primary outcome unclear PBAC (Higham blood loss) score LNG IUS discontinuation rate Effect of menstrual bleeding on general well-being, work performance, physical activity and sexual activity assessed using VAS Follow-up reported at 12 months	No comparable measure	No
Kittelsen and Istre, 1998 ¹⁰⁵ (long-term follow-up paper also published ¹⁵⁰) <i>n</i> = 60	Women with HMB. Fibroids excluded	TCRE vs Mirena	Primary outcome unclear QoL Additional treatments received Adverse events Follow-up reported at 12 months, 2 years and 3 years	No comparable measure	No
Croignani <i>et al.</i> , 1997 ⁸⁰ <i>n</i> = 70	Women with DUB. Fibroids excluded	TCRE vs Mirena	Primary outcome unclear Satisfaction Reduction in menstrual bleeding Health-related QoL Amenorrhoea rates Additional treatments Adverse events Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with their treatment Answers were given using the following scale: Very satisfied Satisfied Uncertain Dissatisfied	No
Mirena vs second-generation EA					
Shaw <i>et al.</i> , 2007 ¹⁰⁸ <i>n</i> = 66	Women with HMB. Fibroids excluded	Thermal balloon vs Mirena	PBAC (Higham blood loss) score (primary outcome) Satisfaction Continuation with treatment Hysterectomy rates Follow-up reported at 3, 6, 9 and 12 months, and 2 years	Women were asked for their perception of their treatment effect Answers were given using the following scale: Very good Good Poor	No

Paper/number of women randomised	Patients	Intervention	Stated key outcome measures	Patient satisfaction and how it was measured	IPD received?
Tam <i>et al.</i> , 2006 ¹⁰⁹ Raw data available <i>n</i> = 44	Women with excessive menstrual bleeding attending the outpatient gynaecology clinic. IPD showed that fibroids were included; exact eligibility details regarding this parameter not given in paper	Thermal balloon vs Mirena	Primary outcome unclear Health status function SF-36 Follow-up reported at 12 months; IPD at 6 months also received	No comparable measure	Yes
Busfield <i>et al.</i> , 2006 ¹⁰⁷ (cost-effectiveness paper carried out by Brown <i>et al.</i> , 2006 ¹¹⁴) Raw data available <i>n</i> = 79	Women with HMB. Fibroids excluded if >3 cm	Thermal balloon vs Mirena	PBAC (Higham blood loss) score (primary outcome) Satisfaction QoL Menstrual symptoms Adverse events Treatment failures Follow-up reported at 3, 6 and 12 months, and 2 years	Women were asked if the menstrual symptoms had been successfully treated Answers were given using the following scale: Definitely yes Probably yes Not sure Probably no Definitely no	Yes
Barrington <i>et al.</i> , 2003 ⁸¹ Raw data available <i>n</i> = 50	Women with HMB. Fibroids excluded	Thermal balloon vs Mirena	Primary outcome unclear PBAC (Higham blood loss) score Amenorrhoea Follow-up reported at 6 months	No comparable measure	Yes
Soysal <i>et al.</i> , 2002 ¹⁰⁶ <i>n</i> = 72	Women with dysfunctional HMB. Fibroids excluded if >2 cm	Thermal balloon vs Mirena	PBAC (Higham blood loss) score (primary outcome) Satisfaction Health-related QoL Additional treatments Adverse events Follow-up reported at 12 months	Women were asked about their degree of satisfaction/recommendation Answers were given using the following scale: Highly recommends Recommends Did not know Did not recommend	No