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PRACTICE AND POLICY

Evidence based management of patients with endometriosis undergoing assisted conception: British fertility society policy and practice recommendations

Karolina Skorupskaite[a]*, Madeleine Hardy[b]*, Harish Bhandari[b], Ephia Yasmin[c], Wael Saab[d] and Srividya Seshadri[d]

[a]Edinburgh Fertility & Reproductive Endocrine Centre, Royal Infirmary of Edinburgh, Edinburgh, UK; [b]Leeds Centre for Reproductive Medicine at Leeds Teaching Hospitals NHS Trust, Seacroft Hospital, Leeds, UK; [c]Reproductive Medicine Unit, University College London Hospital NHS Foundation Trust, London, UK; [d]The Centre for Reproductive & Genetic Health, London, UK

ABSTRACT

Endometriosis is a chronic inflammatory condition in women of reproductive age, which can lead to infertility and pelvic pain. Endometriosis associated infertility is multifactorial in nature adversely affecting each step of the natural reproductive physiology and thereby processes and outcomes of Assisted Reproductive Technology (ART) cycles. These outcomes are further complicated by the subtype of endometriosis, being peritoneal, deep infiltrating and ovarian, which bear negative effects on ovarian reserve, response to stimulation, accessibility for oocyte retrieval, intraoperative safety and endometrial receptivity. There is still a lack of clear guidance about the role of surgery for ovarian endometriosis/endometriomas. This guideline evaluates the evidence of the impact of pelvic endometriosis and endometriomas on the outcome of ART and provides recommendations for management options before and during ART including intra-uterine insemination. Recommendations are made based on the current evidence for the management of patients with endometriosis across each step of ART with the primary aim of improving ART outcomes.

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Introduction

Endometriosis, a condition characterised by the presence of tissue resembling endometrium outside the uterus, is estimated to affect 10% of the women of reproductive age (Zondervan et al., 2020). It is a chronic condition associated with significant physical, sexual, psychological and social sequelae. Endometriosis can present with broad-ranging symptoms, whilst some patients have no symptoms at all. The condition is frequently associated with infertility, and it is estimated that up to 50% of women presenting with infertility have endometriosis (Ozkan et al., 2008). Women with endometriosis take longer to conceive compared to those without the condition, with the monthly fecundability rate for women with endometriosis estimated at 2–10% compared to 20% in women in the reproductive age with no known fertility issues (Macer & Taylor, 2012; Marcoux et al., 1997).

The effects of endometriosis-associated infertility are likely to include mechanical, inflammatory, hormonal, genetic and environmental factors. Endometriosis is known to contribute to infertility via anatomical distortion with pelvic adhesions and tubal blockage. Ovarian endometriomas, which are prevalent in almost 50% of cases, are thought to damage the ovarian tissue itself, with histological studies reporting invasion of the cortex, fibrosis and irregular vascular networks (Schubert et al., 2005). Consequently, women with endometriomas have reduced ovarian reserve compared to both patients with healthy ovaries and those with other benign ovarian cysts, resulting in lower serum anti-Mullerian Hormone (AMH) levels, and lower antral follicle counts on ultrasound scan (Hamdan,

CONTACT Karolina Skorupskaite Karolina.Skorupskaite@nhslothian.scot.nhs.uk Edinburgh Fertility & Reproductive Endocrine Centre, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh, EH16 4SA, UK; Madeleine Hardy madeleinehardy@doctors.net.uk Leeds Centre for Reproductive Medicine at Leeds Teaching Hospitals NHS Trust, Seacroft Hospital, Leeds, UK.
*Joint first authors of this paper with equal contribution.

Dunselman et al., 2015). Surgical excision of endometrioma(s) is further associated with a decline in ovarian reserve with up to 38% reduction in AMH after ovarian cystectomy reported (Raffi et al., 2012). The effect of surgery on ovarian decline is greater especially if the pathology is bilateral and after repeat surgery in cases of cyst recurrence (Kwon et al., 2014). The damage inflicted by surgery to the ovarian reserve can occur as healthy ovarian tissue is inadvertently removed during ovarian stripping, as well as through vascular compromise, thermal damage, and local inflammation.

Endometriosis associated infertility is multi-factorial. Advanced maternal age, tubal blockage and failure of expectant management mean that ART procedures, such as *in-vitro* fertilization (IVF) or intracytoplasmic sperm injection (ICSI) are necessitated. The current evidence on the impact of endometriosis on pregnancy outcomes in ART is inconsistent. Data are derived from evidence comparing ART outcomes in women with endometriosis to women without this condition or to other causes of infertility such as tubal factor infertility.

Systematic reviews and meta-analyses concluded that the presence of moderate and severe endometriosis is associated with fewer oocytes retrieved, poorer implantation and lower live birth rates in women undergoing ART (Hamdan, Omar, et al., 2015; Harb et al., 2013). However, a large analysis of 347,185 fresh and frozen ART cycles from The Society of Assisted Reproductive Technologies (SART) database indicated that women with endometriosis have similar live birth rates to those with other causes of infertility, unless they have a combination of factors for infertility (Senapati et al., 2016). The latter is also echoed by a retrospective study running over 16 years and including 27,294 ART cycles, which suggested that although those with endometriosis have lower oocyte numbers, pregnancy and live birth rates are not affected by endometriosis (Murta et al., 2018). A systematic review of 8 studies addressing the implications of endometrioma on ART outcomes, showed that despite the reduced number of mature oocytes retrieved in women with endometrioma versus controls, the total number of embryos, high-quality embryos, implantation rates, clinical pregnancy and live birth rates were similar in women with and without endometrioma (Alshehre et al., 2021).

This BFS Policy and Practice guideline aims to evaluate the literature relating to endometriosis-associated infertility and to develop recommendations, based on current evidence, on the management of patients both pre-ART and during ART including IUI cycles, in order to improve outcomes of assisted conception in patients with endometriosis (Figures 1 and 2).

Materials and methods

A search of online databases (MEDLINE, EMBASE and CINAHL) was performed to identify the studies published from their inception up to March 2022 relevant to the management of endometriosis during ART. The search was carried out using MESH terms with key words including endometriosis 'AND'/'OR' endometrioma 'AND' assisted reproductive techniques (ART), *in-vitro* fertilization (IVF), intracytoplasmic sperm injection (ICSI), and intrauterine insemination (IUI). Manual screening of references of the retrieved articles was undertaken to identify other pertinent studies by two authors (KS and MH). Only papers in the English language were included. The list of topics relevant to the management of endometriosis during ART was approved by all the authors. The studies identified by the search were then subcategorized into those topics.

In this guideline, studies with a diagnosis of endometriosis by laparoscopy or by non-invasive imaging modalities were included (Nisenblat et al., 2016). The revised American Society for Reproductive Medicine (r-ASRM) classification of endometriosis from 1996 is used, which is based on the location and size of the implants and the severity of adhesions at surgery: minimal (stage I), mild (II), moderate (III) and severe (stage IV).

The recommendations made by the guideline development group (GDG) have been graded according to the GRADE approach, as either 'strong' or 'weak' recommendations, or as 'good practice points' where limited evidence exists, and the recommendation is instead based upon the expertise of the GDG members. Research recommendations are also given in this guideline.

Governance

Guideline was ratified by the society after undergoing consultation with the BFS Executive Committee and Membership (Policy & Practice - British Fertility Society | BFS) as per agreed protocol.

Management of endometriosis prior to ART

Hormonal therapies as an adjuvant/pre-treatment to IVF

There is a hypothesis that prolonged (3–6 months) ovarian suppression with GnRH analogues prior to IVF

Figure 1

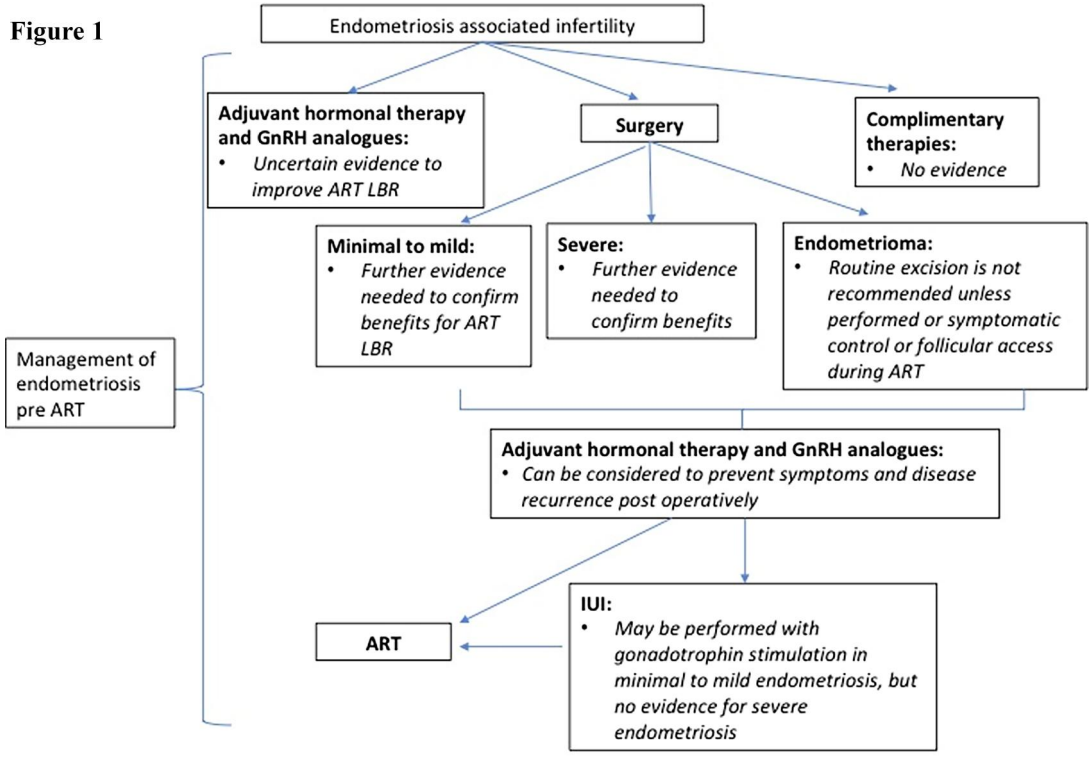
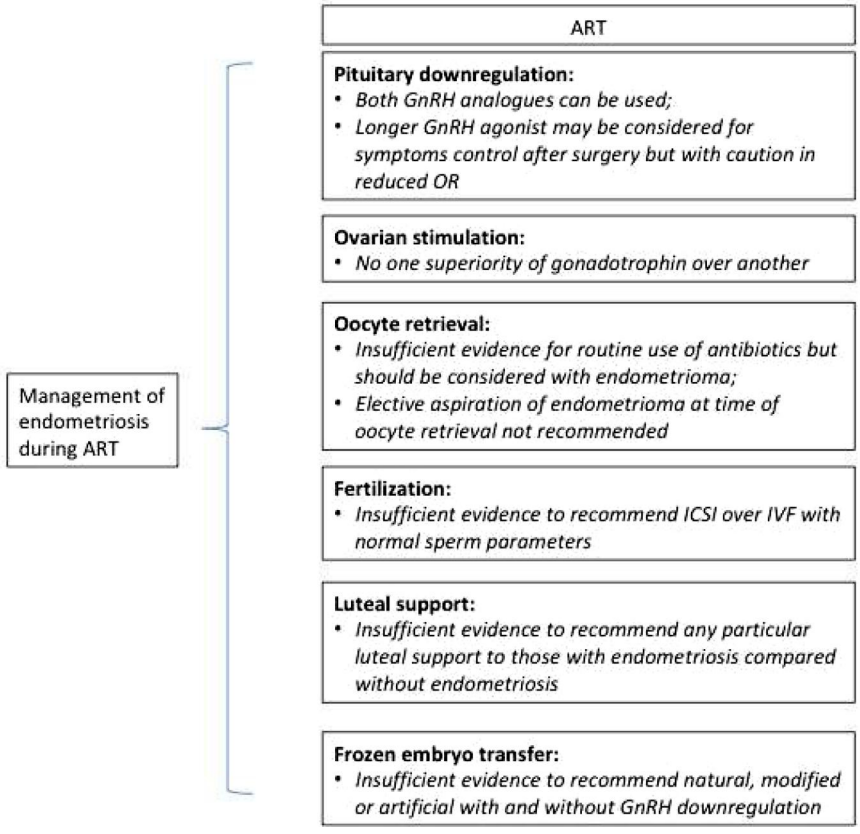


Figure 2



Figures 1 and 2. Pictorial representation summarising the management of endometriosis in patients undergoing assisted conception.

in patients with endometriosis may improve pregnancy outcomes by dampening the inflammatory effects of endometriosis on oocyte quality and endometrial receptivity (Sallam et al., 2006). A later Cochrane review, including 8 RCTs and 640 participants with any stage of endometriosis, concluded that long-term GnRH therapy (minimum 3 months) had uncertain effects on rates of clinical pregnancy, miscarriage or live birth versus no pre-treatment prior to IVF or ICSI (Georgiou et al., 2019). There is a concern that prolonged GnRH agonist use may cause pituitary oversuppression, which can lead to poor ovarian response and luteal insufficiency (Brus et al., 1997; Duan et al., 2017). The Cochrane systematic review was uncertain of the effects of long-term GnRH therapy on ART outcomes, such as mean oocyte and embryo numbers (Georgiou et al., 2019). However, those results are based on very low quality studies, with high degree of heterogeneity.

A RCT of 400 infertile women with minimal and mild endometriosis treated with GnRH agonists for 3 months following surgical cauterization of endometriosis and prior to ART showed no beneficial effect on embryo quality, implantation or clinical pregnancy rates (Kaponis et al., 2020). As GnRH agonist therapy post-endometriosis surgery minimises the risk of disease recurrence and endometrioma formation (Chen et al., 2020), its use may have a role pre-ART for women who are symptomatic and are awaiting ART.

A small RCT compared pregnancy outcomes in stimulated IUI cycles in those patients who received daily Decapeptyl 0.1 mg for 2 weeks preceding the stimulation cycle (n = 41, 'long protocol'), versus the outcomes in those patients receiving a single dose of 3.75 mg Decapeptyl and then 4 weeks later receiving daily Decapeptyl 0.1 mg daily for 2 weeks prior to ovarian stimulation (n = 39, 'ultralong protocol'). Both patient populations had endometriosis of all stages (C. H. Kim et al., 1996). There was no difference in clinical pregnancy rates between the protocols in those with minimal or mild endometriosis. In patients with moderate and severe endometriosis, the clinical pregnancy rate was significantly higher with the 'ultralong' protocol (50%, 10/20) compared to 'long' GnRH agonist protocol prior to stimulated IUI (19% 4/21) (C. H. Kim et al., 1996).

There are no studies comparing long-term GnRH agonist therapy with long-term combined oral contraceptive pill (COCP) or surgical management of endometrioma(s) prior to ART treatment. The evidence is limited and of low quality for other hormonal therapies such as long-term continuous oral contraceptive pill (de Ziegler et al., 2010) or different progestins (Barra et al., 2020; Guo et al., 2020; Khalifa et al., 2021; Tamura et al., 2019) on pregnancy outcomes prior to ART. Limited low-quality evidence exists evaluating the use of aromatase inhibitors in pre-treatment regimens with GnRH agonists (Cantor et al., 2019). This retrospective cohort study involving 126 women with endometriomas reported improved IVF outcomes in women treated with daily Letrozole alongside GnRH agonists.

Elagolix, an oral second generation GnRH receptor antagonist, has been shown to be an effective treatment for the improvement of endometriosis-related dysmenorrhoea, dyspareunia, and non-menstrual pelvic pain in several studies (Surrey et al., 2018; Taylor et al., 2017) A specific benefit of Elagolix as compared with GnRH agonists have been cited as its immediate suppression of pituitary gonadotrophins, thereby avoiding the initial flare-up effect of GnRH agonists, and providing immediate efficacy (Taylor et al., 2017). A randomised double-blinded trial comparing the effectiveness of Elagolix 200 mg twice daily versus placebo for two weeks prior to undergoing IVF in patients with endometriosis is currently underway (Taylor et al., 2022).

Recommendations

- There is insufficient evidence to recommend the use of GnRH agonist therapy or hormonal contraceptives prior to ART to improve live birth rates. ***Good practice point.***
- Suppressive hormonal therapies can be considered after endometriosis surgery to prevent endometriosis associated symptoms and disease recurrence whilst awaiting ART. ***Good practice point***.
- There is insufficient evidence to recommend aromatase inhibitors as pre-treatment prior to ART. ***Good practice point.***
- There is currently no evidence to support the use of GnRH antagonists as pre-treatment prior to ART, but results of ongoing studies will determine further. ***Research recommendation.***

Surgery as an adjuvant/pre-treatment to ART

There is only a single and retrospective cohort study thus far that compared the outcomes in women proceeding with IVF/ICSI who underwent complete surgical excision of disease (n = 399) versus diagnostic laparoscopy only (n = 262) for minimal to mild endometriosis (Opøien et al., 2011). This study reported higher implantation, pregnancy, live birth rates, and

cumulative pregnancy rates recorded in the group undergoing excision of disease compared to those who just underwent diagnostic laparoscopy, as well as shorter time to first pregnancy (Opøien et al., 2011). However, further well designed studies are needed to determine if surgery can be recommended before ART for women with minimal to mild endometriosis.

A meta-analysis (Casals et al., 2021) of four studies comparing the reproductive outcomes in women with infertility and deep infiltrating endometriosis who received IVF with or without a previous surgery found that live birth rates were 2.2 times (95% CI 1.42–3.46) higher in the operated group versus the non-operated group. They sought to analyse patients in subgroups according to whether patients had 'complete' or 'incomplete' surgery, as well as whether patients had bowel involvement or not. They also assessed surgical and IVF complications. The addition of data from the incomplete surgery groups also showed a higher pregnancy rate per patient for surgery before IVF (odds ratio [OR] 1.63; 95% CI, 1.16–2.28). The meta-analysis did not include any RCTs, and therefore all included studies have high risk of selection and allocation bias. A qualitative analysis of complications of surgery and IVF revealed lack of data and high heterogeneity. The authors note that deep infiltrating endometriosis often co-exists with endometrioma, and they included in their meta-analysis a study, which had significantly more patients with ovarian endometrioma in the IVF group with no previous surgery, which could have led to bias in results.

The clinical evidence and recommendations for surgical management of an ovarian endometrioma prior to IVF are discussed in section 'Effects of endometrioma on ART'.

Recommendations

- Further research is needed to confirm the positive benefits of routine surgery for minimal to mild endometriosis prior to IVF before this can be recommended. ***Good practice point.***
- Further research is needed before surgery prior to IVF for severe endometriosis can be recommended with the sole aim of improving IVF outcomes, given the extent of surgery required and risk of complications to treat severe endometriosis, especially when associated with bowel involvement. Care should be individualised jointly with minimal access surgeons in the multidisciplinary team setting. ***Good practice point.***

Complementary therapies, lifestyle measures and supplements

Whilst data exists to support the benefit of complementary therapies and lifestyle measures (acupuncture, yoga, electrotherapy, exercise) in the management of endometriosis-associated pain (Mira et al., 2018), there is no evidence to support the benefit of these therapies in the treatment of endometriosis-associated infertility. Despite evidence that oxidative stress plays a role in endometriosis-associated infertility (Agarwal et al., 2005), to our knowledge there are no well-conducted studies proving the benefit of antioxidants in the treatment of endometriosis-associated infertility. There is no evidence to support the benefit of Chinese medicine in the treatment of endometriosis-associated infertility (Burks-Wicks et al., 2005; Flower et al., 2012).

Recommendations

- Research into the effectiveness of complementary therapies and lifestyle interventions for the management of endometriosis-associated infertility is needed before their effectiveness either alone, or as an adjunct to ART, can be evaluated. ***Research recommendation.***

Management of endometriosis during ART

Effects of endometriosis on intrauterine insemination

There are limited studies assessing the effectiveness of intrauterine insemination with or without controlled ovarian stimulation in patients with endometriosis and especially stratifying efficacy based on the stage of the disease. The available evidence from one RCT provides some evidence as to the benefit of IUI with ovarian stimulation using gonadotropins for infertile patients with minimal to mild endometriosis, patent fallopian tubes and using partner's sperm. The live-birth rate was 5.6-times higher in the treated group (53 patients with endometriosis) when compared to expectant management (50 patients with endometriosis), although the results have a wide confidence interval (95% CI 1.18–17.4) (Tummon et al., 1997). Evidence from low quality studies in the absence of randomised controlled trials shows that IUI with controlled ovarian stimulation with gonadotropins appears to be more effective than with IUI alone in improving pregnancy rates (95% CI 1.1–22.5) (Nulsen et al., 1993) and as effective as IUI for couples with unexplained infertility, if performed within 6 months of

surgical management of minimal or mild endometriosis (Werbrouck et al., 2006).

Data on the efficacy and safety of IUI in advanced stages of endometriosis are based on low quality evidence. A retrospective study of 65 patients with surgically proven moderate to severe endometriosis, showed that IUI with ovarian stimulation significantly increased cumulative ongoing pregnancy rates compared to IUI with no ovarian stimulation in the first three cycles followed by stimulated IUI if unsuccessful (40% vs 15.6%) (van der Houwen et al., 2014). In endometriosis, pregnancy rates were significantly higher with IVF (111 patient, 139 cycles) or IVF after failed IUI with controlled ovarian stimulation (56 patients, 68 cycles) compared to stimulated IUI alone (202 patients, 648 cycles) (47% vs 44% vs 11%) (Dmowski et al., 2002). The benefit of IVF over stimulated IUI was especially pronounced in severe endometriosis and in women >38 years of age (Dmowski et al., 2002).

There are no direct studies comparing anti-oestrogenic therapy (clomiphene citrate and letrozole) versus gonadotropins for ovarian stimulation and IUI in patients with endometriosis.

Recommendations

- In infertile patients with minimal and mild endometriosis with confirmed tubal patency and normal seminal fluid parameters, IUI with ovarian stimulation using gonadotropins may be performed, especially following surgical management of minimal and mild endometriosis. ***Weak recommendation.***
- The efficacy of IUI as a treatment option for infertile patients with moderate and severe endometriosis and patent fallopian tubes remains unclear, and if there are additional risk factors, such as advancing maternal age, comparatively IVF appears to have better pregnancy rates. ***Good practice point.***

Effects of endometrioma on ART

Effects of endometrioma on ovarian stimulation

It is not surprising that the presence of an ovarian endometrioma as a space occupying lesion itself is associated with lower numbers of follicles and oocytes retrieved than from the contralateral healthy ovary during superovulation IVF/ICSI cycles (Coccia et al., 2014; Ferrero et al., 2017; Somigliana et al., 2020). When compared to simple ovarian cysts of 10–35 mm, women with endometriomas of 10–50 mm undergoing IVF required higher doses of gonadotropins, and had significantly fewer oocytes retrieved, although oocyte maturation remained unaffected (Kumbak et al., 2008). A study comparing IVF outcomes in cycles with ovarian endometrioma (n = 80 cycles) versus endometriosis without endometriotic cysts (n = 248 cycles) versus tubal disease with no endometriosis (n = 283 cycles) reported that endometriosis alone and irrespective of the volume of the endometriotic cysts was associated with retrieval of fewer oocytes (Suzuki et al., 2005). There was no difference in embryo quality and pregnancy rates between the groups (Suzuki et al., 2005).

The effects of endometrioma(s) on IVF/ICSI reproductive outcomes are summarised in a recent systematic review and meta-analysis of 8 studies, showing that the number of mature oocytes retrieved were significantly lower in women with endometrioma versus controls, but all the other outcomes, including gonadotropin dose and duration, the total number of embryos, high-quality embryos, clinical pregnancy rate and live birth rate were similar in women with and without ovarian endometrioma (Alshehre et al., 2021).

Limited data are available on the threshold at which the size of endometrioma becomes detrimental to ovarian response during stimulation. The relationship between the endometrioma size (range 15–44 mm, mean 21.8 mm) and ovarian responsiveness was evaluated in a prospective study of 64 women with unilateral endometriomas (Coccia et al., 2014). Endometrioma of 30 mm or more was shown to have a negative effect on the total number of follicles and oocytes retrieved, and although only 12 women had endometrioma >30 mm in this cohort, there was no difference in pregnancy rates (Coccia et al., 2014). Another retrospective study including 26 women with unilateral endometrioma of 5 cm or more showed reduced responsiveness to ovarian superovulation when compared to the healthy contralateral ovary (Ferrero et al., 2017). However, these studies do not extrapolate a precise threshold to discern between the size of the cysts that do and do not influence ovarian response.

To our knowledge, a publication by Somigliana et al., 2020 is the only study to retrospectively compare the endometrioma sizes of 20–29 mm (n = 23), 30–39 mm (n = 23) and 40–49 mm (n = 21) and ovarian response during controlled ovarian hyperstimulation (Somigliana et al., 2020). Women with endometrioma 40–49 mm had significantly fewer follicles recruited, and the authors concluded that the threshold to be used to distinguish between endometriomas that could and could not interfere with ovarian response is 4 cm in diameter (Somigliana et al., 2020). However,

there was no difference in the number of oocytes retrieved and the pregnancy rates. Studies comparing the effect of the size of endometrioma on ART outcomes are small and overall of poor quality, therefore leaving the debate open about the precise size of endometrioma that negatively affects ovarian response to stimulation during an ART.

Effects of endometrioma surgery on ART outcomes

The effect of endometrioma surgery on ART outcomes has been thus far assessed in two systematic reviews and meta-analysis. A systematic review concluded that ovarian cystectomy for endometrioma prior to ART does not improve live birth (5 studies, 655 women) and pregnancy (11 studies, 1,512 women) rates compared to no surgical intervention (Hamdan, Dunselman, et al., 2015). These findings were echoed by a further review of 10 studies showing no significant benefit of endometrioma surgery on pregnancy and live birth rates compared to expectant management in women undergoing ART. Similarly, there was no difference in the number of oocytes retrieved, embryos created and the dose of gonadotropins used (Nickkho-Amiry et al., 2018).

A recent retrospective study compared ART outcomes in 26 women who underwent 44 ART cycles in the presence of ovarian endometrioma versus 53 women who underwent 58 ART cycles after laparoscopic resection of endometrioma(s) (Şükür et al., 2021). The cystectomy group had a significantly higher rate of cycle cancellation due to poor ovarian response and/or failed oocyte retrieval (13.7% versus 0%) (Şükür et al., 2021). There was no significant difference in the live birth rates (23.7% versus 26.1% with surgery) (Şükür et al., 2021).

Few studies have considered different approaches to the surgical management of ovarian endometrioma prior to ART. When considering the effect of sclerotherapy, a systematic review and meta-analysis has shown that women treated with sclerotherapy had a higher number of oocytes retrieved during ART and had similar clinical pregnancy rates compared to women treated by laparoscopic cystectomy (Cohen et al., 2017). A recent prospective cross-sectional study evaluated ART outcomes after either laparoscopic cystectomy (n = 57) or ethanol sclerotherapy at the time of oocyte retrieval (n = 44) in infertile women with endometrioma, and found that there were no significant differences in ART outcomes (live birth rate, cumulative pregnancy rate), however those treated with sclerotherapy had a higher rate of endometrioma recurrence (p=.017) (Alborzi et al., 2021).

Recommendations

- Surgical management of ovarian endometriomas should not be routinely performed before ART, as current evidence shows that neither the presence of endometrioma nor the surgical excision of it have a negative or a positive effect on live birth rates, respectively, but surgery is likely to reduce ovarian reserve. ***Strong recommendation***.
- Excision or ablation of ovarian endometrioma prior to ART can be considered for endometriosis-associated symptom control or to improve follicular accessibility during oocyte retrieval, but there is insufficient evidence to recommend the threshold size of the endometrioma at which surgery is indicated. ***Good practice point***.

Pituitary downregulation protocols during ovarian stimulation

GnRH agonist versus GnRH antagonist protocols

Clinical outcomes have been evaluated in several studies comparing GnRH agonist versus GnRH antagonist downregulation protocols in patients with endometriosis undergoing ART. A RCT of 246 ICSI cycles in patients with minimal and mild endometriosis and endometrioma with and without surgical resection showed that implantation rates and clinical pregnancy rates were not different after ovarian stimulation in GnRH agonist and GnRH antagonist protocols (Pabuccu et al., 2007). Another observational, retrospective analysis of 1,180 IVF cycles found that there was no differences in clinical pregnancy rates with GnRH agonists and antagonist pituitary down-regulation protocols used in patients across all stages of endometriosis (1,180 cycles) (Rodriguez-Purata et al., 2013).

A retrospective cohort study of 386 women with endometriosis reported a tendency towards higher live birth rate (42.8% vs 26.7%) with GnRH agonist compared to GnRH antagonist in patients with minimal and mild endometriosis, whilst no difference was observed in those with moderate and severe endometriosis (Drakopoulos et al., 2018). In a retrospective study of 342 women with decreased ovarian reserve after endometrioma cystectomy, no difference was found in implantation and clinical pregnancy rates, although prolonged GnRH agonist protocols trended towards improved clinical outcomes compared to GnRH antagonist (Zhao et al., 2020). Higher clinical pregnancy rates (25% vs 12%) and live birth rates (18% vs 8%) per fresh but not frozen embryo transfer was observed with GnRH long protocols compared to GnRH antagonist protocols in a retrospective analysis

of 284 IVF cycles in patients with endometriosis (Kolanska et al., 2017). However, this did not translate into a difference in cumulative live birth rates per cycle between the two groups.

GnRH agonist protocols

Longer GnRH agonist protocols increased clinical pregnancy rates compared to shorter GnRH agonist downregulation in infertile patients with moderate and severe endometriosis (CI 1.37–3.04) in the meta-analysis of 7 RCTs (Cao et al., 2020). However, the evidence from this meta-analysis was based on studies which are of high heterogeneity and with three low quality RCTs. Subgroup analysis of GnRH agonist downregulation protocols by duration showed no significant difference in improving clinical outcomes in patients with endometriosis in 14 non-RCT studies ('short', 'long', and 'ultralong'), and the authors suggested that results from non-RCTs should not be neglected (Cao et al., 2020).

A recent meta-analysis of 9 RCTs (943 participants) showed that ultra-long GnRH agonist protocol of 3 months downregulation could improve clinical pregnancy rates (CI 1.11–1.55) in patients with endometriosis compared to long protocol (Liu et al., 2021). There was no difference in the effectiveness of ultra-long protocol between different stages of endometriosis, and there was no increase in the rates of OHSS. This meta-analysis and systematic review included RCTs only, had an overall low heterogeneity index, included two additional studies to a previous meta-analysis by Cao et al., 2020 and excluded one study in subgroup analysis due to inappropriate grouping, overall indicating good quality evidence (Liu et al., 2021).

Progestogens

Oral progestogens have been proposed as alternatives to GnRH analogues to prevent premature LH surge during controlled ovarian stimulation, with the promising advantages of oral administration and lower costs (Yu et al., 2019). However, progestogen downregulation protocol renders the endometrium unreceptive, necessitating the freezing of all the embryos and transfer in a subsequent cycle.

There are no RCTs comparing oral progestogens to GnRH analogues for pituitary suppression during controlled ovarian stimulation in ART in patients with endometriosis. A retrospective case-controlled study of 244 women with advanced endometriosis undergoing controlled ovarian stimulation IVF/ICSI and FET cycles showed no difference in oocyte, embryo and pregnancy outcomes (implantation, clinical pregnancy and ongoing pregnancy rates) in medroxyprogesterone acetate (MPA) used at a dose of either 4 or 10 mg/day from menstrual cycle day 3 versus GnRH agonist downregulation protocols (Guo et al., 2017). There is only 1 RCT comparing the efficacy of different oral progestogen co-treatment with human menopausal gonadotropin (hMG) in 450 women with severe endometriosis during ART cycles. The number of oocytes retrieved was marginally higher in the MPA group compared to dydrogesterone and progesterone groups (9.3 ± 5.7 vs. 8.0 ± 4.5 vs. 7.8 ± 5.2), but no significant difference between the three progestin protocols was observed in fertilisation and pregnancy outcomes (Guo et al., 2020). There are no studies to our knowledge evaluating progestogens as pituitary suppression agents during ART cycles in other stages than severe endometriosis.

Recommendations

- Both GnRH agonist and GnRH antagonist downregulation protocols can be offered in patients with endometriosis undergoing IVF as no difference has been demonstrated in clinical pregnancy and live birth rates. ***Strong recommendation.***
- There is insufficient data to favour either GnRH agonist or GnRH antagonist protocols in different stages of endometriosis. ***Strong recommendation.***
- If GnRH agonists are used, a longer protocol may be considered, especially if after surgical management for symptomatic endometriosis, but with caution in those with reduced ovarian reserve. ***Good practice point.***
- There is insufficient evidence to recommend oral progestogens for pituitary suppression during controlled ovarian stimulation in patients with endometriosis. ***Weak recommendation.***

Ovarian stimulation protocols

Gonadotropins

In infertile patients undergoing ART, there is overall no superiority of recombinant FSH versus urinary FSH (purified and highly purified) versus human menopausal gonadotropin (ESHRE Guideline Group on Ovarian Stimulation, Bosch et al., 2020). There are no studies directly comparing different preparations of gonadotropins or their dose effects specifically in patients with endometriosis during controlled ovarian stimulation. Patients with endometriosis undergoing ovarian stimulation during IVF cycles may have

reduced ovarian response to gonadotropins. A case control study showed that the ovarian endometriosis group (n = 40) compared to those with tubal infertility (n = 80) had a poorer ovarian response and required significantly higher doses of urinary FSH to achieve adequate stimulation during IVF/ICSI treatment, a difference that became greater with each subsequent cycle (Al-Azemi et al., 2000). Nevertheless, cumulative pregnancy (63.3% vs 62.6% by fifth cycle) and live birth rates (46.8% vs 50.9% by fifth cycle) were similar in both groups (Al-Azemi et al., 2000). Reduced response was not observed in a retrospective study of 612 IVF cycles in patients with minimal to mild endometriosis compared to 7,338 IVF cycles in those with tubal infertility, where regardless of the type of ovarian stimulation, the fertilisation and pregnancy rates were comparable (Meden-Vrtovec et al., 2000).

Letrozole

Aromatase p450 enzyme is aberrantly expressed in eutopic endometrial tissue as well as ectopic endometrial implants (Noble et al., 1996). High endometrial aromatase expression is associated with poor IVF outcomes (Brosens et al., 2004). Dual stimulation by an aromatase inhibitor with gonadotropin during ovarian stimulation may therefore improve endometrial receptivity in patients with endometriosis, increase follicular response to FSH stimulation and reduce the total gonadotropin requirement in IVF (Mitwally & Casper, 2004).

In a retrospective study of 47 women with endometriosis, who were specifically negative for endometrial integrins, higher clinical pregnancy and delivery rates were reported in those who received letrozole in addition to gonadotropins compared to women who did not receive letrozole (11/18 (61%) vs 4/29 (14%), and 9/18 (50%) vs 2/29 (7%), respectively) (Miller et al., 2012). A more recent cohort study of 64 women with endometriosis showed similar oocyte and embryo yield with and without letrozole addition to gonadotropins, whilst pregnancy outcomes were not examined (S. J. Kim et al., 2020). There is insufficient data to make recommendations for letrozole cotreatment with gonadotropins in patients with endometriosis.

Clomiphene citrate

There are no RCTs evaluating the benefit of adding clomiphene citrate to gonadotropins during ovarian stimulation in patients with endometriosis.

Natural and modified natural cycles

There are no studies comparing conventional IVF with natural cycle IVF in patients with endometriosis. A prospective cohort design compared outcomes in modified natural cycles with hCG trigger for final maturation in patients with minimal peritoneal endometriosis (n = 30) and other causes of infertility (n = 57) (Omland et al., 2001). The fertilisation rates and clinical pregnancy rates per embryo transfer in minimal endometriosis group (80% and 23.5%, respectively) were similar to tubal factor infertility patients (68.6% and 16%) but higher than that of the unexplained infertility group (62.2% and 8.7) (Omland et al., 2001).

Recommendations

- No particular type of gonadotropin is recommended over another for ovarian stimulation in patients with endometriosis. The choice of gonadotropins depends on the clinician's and patient's preferences. ***Good practice point.***
- A higher dose of gonadotropins may be required for ovarian stimulation in patients with stage III-IV endometriosis. ***Strong recommendation.***
- There is insufficient data to recommend the use of letrozole as an adjunct to gonadotrophins for ovarian stimulation in women with endometriosis. ***Good practice point.***
- There is no evidence for the use of clomiphene citrate in addition to gonadotropins for ovarian stimulation for patients with endometriosis. ***Good practice point.***
- There is no evidence to make recommendations on natural, modified natural cycles or mild stimulation protocols in women with endometriosis undergoing ART. ***Good practice point.***

Prophylactic antibiotics at the time of oocyte retrieval

There is a concern that the presence of an ovarian endometrioma at oocyte retrieval may increase the risk of pelvic infection and abscess formation. There are case reports and retrospective follow up studies of patients with ovarian endometrioma who have developed severe pelvic sepsis following transvaginal oocyte retrieval. There are no studies evaluating the use of antibiotics (type, dose, duration), different vaginal lavage protocols and intentional aspiration of endometriomas at the time of oocyte retrieval procedures.

Overall the risk of pelvic inflammatory disease after transvaginal oocyte retrieval seems to be low. In a retrospective study of 6 years and 5,958 transvaginal ultrasound-scan guided oocyte retrieval procedures the rate of PID was 0.12% with only one patient out

of ten having an ovarian endometrioma 3–4 cm in size (Moini et al., 2005).

There have been cases reported of endometrioma and oocyte retrieval-induced pelvic abscess, including those of late presentation (den Boon et al., 1999; Matsunaga et al., 2003; Moini et al., 2005; Sharpe et al., 2006; Yaron et al., 1994). A case report describes three patients with ovarian endometriomas who developed pelvic abscesses three weeks after transvaginal oocyte retrieval (Younis et al., 1997); in one case endometrioma was intentionally aspirated at oocyte retrieval, and pelvic abscess was managed conservatively with antibiotics. In the other two cases endometriomas were not punctured and surgical management was required to deal with complications of pelvic abscess formation (Younis et al., 1997). Another case was of a ruptured ovarian abscess needing surgical management two weeks after endometrioma aspiration during oocyte retrieval (Padilla, 1993).

Prophylactic antibiotics were administered in all case reports of pelvic infection in patients with endometrioma at the time of oocyte-retrieval. Broad spectrum antibiotics have been used as a single dose before transvaginal oocyte-retrieval in reports of late complications of pelvic abscess (Padilla, 1993; Younis et al., 1997). A retrospective follow up study of 214 IVF cycles in patients with persistent endometriomas (n = 119), administered a prolonged course of prophylactic ceftriaxone intramuscularly at 1 g for four days starting two hours before the oocyte retrieval procedure (Benaglia et al., 2008). There were no endometriomas intentionally aspirated, six (3%) were accidentally punctured and pelvic abscess was never reported as a complication, indicating that its risk is very low (0.0, CI 0.0–1.7%) (Benaglia et al., 2008). In the later study the vagina was disinfected with povidone-iodine and subsequently soaked with a sterile isotonic saline solution (Benaglia et al., 2008), whilst other case studies report performing vaginal lavage with no further specific details.

A retrospective cohort study reviewed acute infectious complications in patients with endometriosis over 4 years, regardless of whether ART was performed or not (Villette et al., 2016). Out of 10 patients with endometriosis admitted with acute infection, only 3 women had oocyte retrieval and associated endometrioma. The authors concluded that some putative complications of ART and endometrioma may actually not be linked to ART, but rather constitute sporadic occurrences in endometriosis (Villette et al., 2016).

Recommendations

- There is insufficient evidence to recommend the routine use of prophylactic antibiotics at the time of transvaginal oocyte retrieval in patients with endometriosis, but should be considered in patients with endometrioma. ***Good practice point.***
- There is no evidence to recommend any particular technique for vaginal lavage before performing transvaginal oocyte retrieval. ***Good practice point.***
- Elective aspiration of an ovarian endometrioma is not recommended at the time of transvaginal oocyte retrieval, unless necessary in order to access follicles. If puncture occurs, consider an extended course of antibiotics. ***Good practice point.***
- Women with endometriosis should be counselled regarding the need to report symptoms suggestive of infection following transvaginal oocyte retrieval. ***Good practice point.***

Method of fertilisation in couples with endometriosis and normal sperm parameters

The data regarding association between endometriosis and impaired fertilisation remain conflicting. Several studies reported reduced fertilisation rates amongst patients with endometriosis, those with moderate and severe endometriosis being more affected than those with minimal and mild stages (Pal et al., 1998). The possible mechanisms for reduced fertilisation may be related to compromised oocyte quality (Garrido et al., 2000) or altered peritoneal fluid in patients with endometriosis inhibiting the binding of spermatozoa to the zona-pellucida (Coddington et al., 1992; Faber et al., 2001).

Only one RCT has assessed fertilisation and embryonic development rates in couples with endometriosis and normozoospermic semen, where 786 sibling oocytes were randomly inseminated by a conventional IVF or ICSI (Komsky-Elbaz et al., 2013). Significantly higher fertilisation rate was found in the ICSI group (73.3 ± 23% vs 54.7 ± 31.9%), yielding a higher mean number of day 2 embryos (5.2 ± 3.4% vs 3.6 ± 2.9%) and cryopreserved embryos (3 ± 3.5% versus 1.5 ± 1.6%), but no difference was seen in the numbers of cryopreserved blastocysts. Triploid fertilisation rate was significantly higher in the IVF group compared to the ICSI group (3.9 ± 8.7% vs 0.9 ± 3.1%). There was no difference between conventional IVF and ICSI insemination in implantation rates, clinical pregnancy rates, ongoing pregnancy rates and miscarriage rates in both fresh and frozen cycles (Komsky-Elbaz et al., 2013). In a retrospective analysis of 368 couples with endometriosis and no male factor infertility, there was no difference in

clinical pregnancy rates and cumulative live birth rates from IVF and ICSI between women who had endometrioma in situ versus women who had undergone laparoscopic cystectomy (Scarafia et al., 2021).

There are no studies directly evaluating fertilisation and pregnancy outcomes between conventional IVF and ICSI in patients with endometriosis compared to other causes of infertility. Indirect evidence shows that fertilisation rates are no different between IVF and ICSI in those with tubal infertility (Bukulmez et al., 2000), but are higher with ICSI in patients with PCOS, potentially implying an oocyte factor in fertilisation capabilities like in endometriosis (Hwang et al., 2005). In a retrospective study of 503 IVF cycles, there was no difference in fertilisation rate between those with endometriosis and those with other causes of infertility (64.1%±25.5 vs 63.9%±24.8) (Metzemaekers et al., 2021).

Recommendations

- In patients with endometriosis and non-male factor infertility, there is insufficient evidence to recommend ICSI treatment over standard IVF. ***Good practice point.***

Frozen embryo transfer cycles

It is proposed that impaired endometrial receptivity is one of the processes contributing to infertility in patients with endometriosis. However, a retrospective cohort study of 459 euploid frozen embryo transfer (FET) cycles in 328 patients showed that there were no differences in clinical pregnancy, pregnancy loss, or live-birth rates in women with endometriosis compared to controls without endometriosis (Bishop et al., 2021), which would suggest that there is no endometrial effect.

Natural, modified and artificial frozen embryo transfers

There are no studies directly comparing natural or natural modified versus artificial cycle regimens in patients with endometriosis. Pregnancy outcomes, including rates of implantation, clinical pregnancy, live birth and miscarriage, were no different in natural cycle endometrial preparation for frozen-thawed embryo transfer cycles in patients with moderate and severe endometriosis (n = 233 cycles) compared to those with tubal factor infertility (n = 300 cycles) (Guo et al., 2016). A small retrospective study suggested improved clinical pregnancy rates in patients with endometriosis after an intrauterine injection of hCG a day before frozen embryo transfer in an artificial cycle (n = 46 vs n = 135 controls) (Xu et al., 2019). A subsequent larger cohort study showed a significant increase in clinical pregnancy rates (57.7% n = 355 vs 49% n = 296, p = 0.027) but not live birth rates (45.6% vs 38.5%) with hCG administration in artificial frozen embryo transfer in those with endometriosis-associated infertility (Du et al., 2020).

Downregulation protocols for frozen embryo transfers. A retrospective cohort study suggested higher live birth rates with GnRH agonist co-treatment than without GnRH agonist co-treatment for artificial frozen embryo transfer cycles for all types of infertility analysed (n = 1,003 cycles), including endometriosis (Xie et al., 2018). In another study, the hormone replacement and GnRH agonist protocol (n = 303 cycles) significantly increased the clinical pregnancy rates (55.6% vs 43.2%) and live birth rates (43.5% vs 33.5%) compared to the hormone replacement only group (n = 2,936 cycles) among patients with endometriosis (Qi et al., 2020). There are no studies comparing GnRH agonists versus GnRH antagonist protocol for artificial frozen embryo transfer in patients with endometriosis.

Letrozole

To our knowledge, only low quality evidence exists to suggest that letrozole, when used in a frozen embryo transfer cycle, can improve the clinical pregnancy rates in patients with endometriosis (n = 17) when compared to no endometriosis and no letrozole treatment group (n = 105) (Patel et al., 2011).

Atosiban

Atosiban, an oxytocin antagonist, was administered to patients 30 minutes before frozen embryo transfer, showing significantly higher clinical pregnancy rates (58.3% vs 38.3% n = 60 each arm) and implantation rates (41% vs 23.4%) versus controls. Outcome measures did not include live birth rates in this RCT (He et al., 2016).

Recommendations

- There is insufficient evidence to recommend either natural cycle or medicated cycle frozen-thawed embryo transfers in patients with endometriosis. ***Good practice point.***
- There is insufficient evidence to support the use of letrozole or atosiban in frozen embryo transfer cycles in endometriosis. ***Good practice point.***

Elective freeze all embryos

Given sex steroid dependence of endometriosis, hyperstimulation associated with IVF may exacerbate the condition and adversely affect endometrial receptivity thus leading to impaired implantation. Elective 'freeze all' deferred embryo transfer, or segmental IVF, has been therefore proposed as an approach to IVF in women with endometriosis.

Three retrospective studies were identified which explore the outcomes of elective freeze-all cycles in patients with endometriosis. A retrospective matched-cohort study, including 135 patients of endometriosis undergoing fresh and deferred embryo transfers, reported higher cumulative ongoing pregnancy rates (34.8% vs 17.8%, $p = 0.0005$) but no difference in live birth rates in the deferred embryo transfer compared to fresh embryo transfer group (Bourdon et al., 2018). The other study, involving those with mild endometriosis ($n = 521$ IVF/ICSI cycles), showed higher live birth rate (33.7% vs 28.4%) in the first frozen embryo transfer cycle after freeze-all cycle (Wang et al., 2018). In patients with advanced endometriosis (moderate and severe), freeze-all strategy ($n = 506$) was associated with significantly higher implantation (34.4% vs 25.5%, OR 1.6, 95% CI 1.26–2.02), clinical pregnancy (51.8% vs 38.8%, OR 1.69, 95% CI 1.25–2.3) and live birth rates (45.3% vs 31.8%, OR 1.74, 95% CI 1.27–2.39) compared to fresh transfer group ($n = 255$) (Wu et al., 2019). A subgroup analysis indicated that freeze-all cycles were more beneficial in terms of clinical pregnancy and live birth rates in patients with more than 15 oocytes recruited (Wu et al., 2019). There was no difference in neonatal outcomes, including gestation age and birth weight (Wu et al., 2019). A meta-analysis of six moderate methodologic quality studies in 3,010 patients with endometriosis showed higher frequency of live birth rates in the frozen embryo than the fresh embryo transfer group (OR 1.53, 95% CI 1.13–2.08, $p = 0.007$) (Chang et al., 2022).

To our knowledge there are no RCTs comparing elective 'freeze all' or segmented IVF cycles with conventional IVF cycles specifically for management of endometriosis in IVF.

Recommendations

- There is no evidence that Freeze all is better than fresh embryo transfer in patients with endometriosis. ***Good practice point***

Luteal phase support

A luteal phase defect in women with endometriosis has been demonstrated by endometrial biopsies and progesterone measurements. Various pathophysiological mechanisms have been described, including pituitary-ovarian dysfunction and reduced steroidogenesis, luteal cell dysfunction and hyperprolactinemia, contributing to corpus luteal incompetence (Cahill & Hull, 2000 Cunha-Filho et al., 2001; Cunha-Filho et al., 2003), although a causal mechanism remains unclear and is likely to be multifactorial.

A low quality study evaluated pregnancy outcomes in patients with endometriosis undergoing IVF cycles with luteal support using either vaginal progesterone inserts 100 mg twice or daily ($n = 94$) or thrice daily ($n = 75$), or 8% progesterone vaginal gel once daily ($n = 100$) (Zbella et al., 2013). There was no significant difference in either ongoing pregnancy rates or biochemical pregnancy rates across the treatment groups (Zbella et al., 2013).

Recommendations

- When considering luteal phase support, there should be no differentiation between patients with or without endometriosis who are undergoing IVF. ***Good practice point.***

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