NICE guidance

Laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 The evidence on laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain suggests that it is not efficacious and therefore should not be used.

2 The procedure

2.1 Indications

2.1.1 Chronic pelvic pain is commonly described as pain felt below the umbilicus which lasts for at least 6 months. Chronic pelvic pain includes dysmenorrhoea and dyspareunia. Secondary dysmenorrhoea describes period pain associated with a physical cause, whereas in primary dysmenorrhoea no underlying cause is identified.

2.1.2 One of the most common causes of chronic pelvic pain is endometriosis. In this condition, tissue that is normally found lining the inside of the uterus is also present outside the uterus, usually in the pelvic cavity. Definitive diagnosis is usually by laparoscopy or laparotomy. Other causes of chronic pelvic pain include pelvic inflammatory disease, pelvic congestion syndrome, nerve entrapment, neuropathic pain and postsurgical pain. In some patients a cause cannot be identified.

2.1.3 Treatment for chronic pelvic pain depends on the underlying cause. Treatment strategies for endometriosis depend on several factors including the patient's

age, symptoms, whether the patient wants to have children and whether there is associated subfertility. Hormonal treatments aim to stop ovulation, allowing the endometrial deposits to regress. Conservative surgery via laparoscopy or laparotomy aims to remove the endometrial deposits, usually by laser or electrocautery. Hysterectomy, with or without removal of the ovaries, may be considered for severe symptoms that do not respond to conservative treatment.

2.1.4 When the cause of chronic pelvic pain cannot be identified, conservative treatments include non-steroidal anti-inflammatory drugs or a trial of the oral contraceptive pill. Surgical treatment options which have been used if conservative measures are inadequate include vaginal uterosacral ligament resection, presacral neurectomy (PSN; involving total removal of the presacral nerves) and uterine nerve ablation (UNA; involving transection of the uterosacral ligaments at their insertion into the cervix by open surgical operation).

2.2 Outline of the procedure

2.2.1 Laparoscopic uterine nerve ablation (LUNA) is normally performed under general anaesthesia. The peritoneal cavity is insufflated with carbon dioxide gas and small incisions are made in the abdomen to provide access for the laparoscope and surgical instruments. The uterus is anteverted with a uterine manipulator and the uterosacral ligaments are identified and transected close to their attachment to the cervix. One or both of the ligaments may be transected. A small portion of ligament is sometimes resected and examined histologically to confirm the presence of nerve fibres. LUNA is often carried out during the course of other surgical treatment for endometriosis.

2.3 Efficacy

2.3.1 A systematic review of nine randomised controlled trials (RCTs) including 528 women treated with LUNA reported that there were no significant differences in pain relief between women treated with LUNA and women treated with diagnostic laparoscopy or conservative surgery alone at 6 months (odds ratio [OR] 1.15, 95% confidence interval [CI] 0.66 to 1.99), 12 months (OR 1.20, 95% CI

0.72 to 1.99) or 36 months (OR 0.84, 95% CI 0.39 to 1.80). In an RCT of 68 women with primary dysmenorrhoea, the OR for pain relief at 6 and 12 months was 1.43 (95% CI 0.56 to 3.69) and 6.12 (95% CI 1.78 to 21.03) respectively, in favour of LUNA. For women with secondary dysmenorrhoea, the OR for pain relief at 6 and 12 months was 1.03 (95% CI 0.52 to 2.02) and 0.77 (95% CI 0.43 to 1.39) respectively.

2.3.2 One RCT included in the systematic review compared laparoscopic PSN (LPSN) with LUNA. It reported that women treated with LPSN had significantly less pain at 12 months than women treated with LUNA (OR 0.10, 95% CI 0.03 to 0.32). A non-randomised comparative study reported that 91% (21 out of 23) of women treated with LPSN had relief of dysmenorrhoea at 6 months, compared with 76% (25 out of 33) of women treated with LUNA (p value not stated). One RCT comparing LUNA with vaginal uterosacral ligament resection reported similar proportions of women with no chronic pelvic pain, or pain not requiring treatment at 12 months (75% [27 out of 36] and 74% [28 out of 38] respectively, p=0.90).

2.3.3 In one case series of 85 women, 'excellent' or 'satisfactory' improvement (not otherwise defined) was reported by 76% (38 out of 50) of women with dysmenorrhoea and 80% (41 out of 51) of women with deep dyspareunia after a mean follow-up of 19 months.

2.3.4 One case series of 52 women reported an overall success rate (defined as a response of pain relief of 8 or higher on a scale of 0 to 10, no need for oral analgesics and the absence of pelvic pathology on pelvic examination) of 72% at 1 year, 58% at 2 years, 51% at 3 years and 40% at 4 years. For more details, see the overview.

2.3.5 The Specialist Advisers considered that, while the procedure could be considered established practice, there is uncertainty about its efficacy.

2.4 Safety

2.4.1 Few complications were reported. In one RCT and one non-randomised comparative study, more complications were reported for LPSN than for LUNA. Constipation was reported in 0% (0 out of 35) and 12% (4 out of 34) of women

treated with LUNA compared with 94% (31 out of 33) and 21% (5 out of 24) of women treated with LPSN (follow-up not reported). Urinary urgency and postoperative bleeding were also reported in the LPSN groups but not the LUNA groups.

2.4.2 Two case reports described a total of five women developing uterine prolapse after having LUNA; three women were young, nulliparous soldiers undergoing parachute training and the other two women had a history of vaginal childbirth. For more details, see the overview.

2.4.3 The Specialist Advisers stated that potential adverse events include vascular, bowel or ureter injury, bleeding, the need for conversion to open surgery, and prolapse.

3 Further information

3.1 NICE has issued interventional procedures guidance on laparoscopic helium plasma coagulation for the treatment of endometriosis.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.