

TITLE PAGE

**Surgeon-administered ilio-inguinal and pudendal nerve blocks for vulval
oncology surgery: An observational evaluation study with Visual Analogue
Pain Scoring**

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28 **Running Title/ Head:**

29 Ilioinguinal and pudendal block for vulval surgery

30 **ABSTRACT**

31 **Objective**

32 To assess pain scores and requirement for parenteral and oral analgesia in the
33 postoperative period following vulval surgery with blockade of the ilioinguinal nerve
34 (IIN) and pudendal nerve (PN).

35 **Design**

36 An observational study of consecutive patients undergoing major vulval and/or
37 related groin surgery. Sampling biopsies were excluded.

38 **Setting**

39 Women undergoing vulval surgery in a tertiary cancer centre.

40 **Population or Sample**

41 Eighteen women were included in the analysis. Median age 67 (range 34-81) years
42 and thirteen (72%) were >60 years.

43 **Methods**

44 Levobupivacaine 0.25% (2.5mg/ml) or 0.5% (5mg/ml) was administered at four sites
45 (2 sites abdominally for IIN block and 2 sites for PN block) with dosage calculated
46 based on the patient's weight. Patients were invited to record visual analogue pain
47 scores (VAS) days 1-5 postoperatively. Use of postoperative analgesia was
48 recorded.

49 **Main Outcome Measures**

50 VAS and use of postoperative analgesia.

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54 **Results**

55 VAS ranged from 0 to 3 for seventeen patients from day 0 to day 1 and fifteen
56 patients from day 2 to day 5. Two patients had pain scores >4 on one or more
57 postoperative days: one had chronic arthralgia and one had received a lower volume
58 of bupivacaine.

59 **Conclusions**

60 Ilio-inguinal and pudendal nerve block is a feasible and effective strategy for
61 postoperative pain management in women undergoing vulval surgery.

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64 article.

65 **Keywords**

66 Analgesia for vulval surgery, ilioinguinal and pudendal nerve block for vulval surgery

67

68 **Tweetable Abstract (100 characters)**

69 Ilioinguinal and pudendal nerve block for vulval surgery results in low visual
70 analogue pain score postoperatively

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80 **MAIN TEXT**

81 **INTRODUCTION**

82 Vulval cancer is rare, with an annual incidence of 3.9/100 000 in the United Kingdom
83 and 50—60 cases in Ireland annually, but remains the fourth most common
84 gynaecological cancer^{1,2}. Surgery tailored to the size and location of the primary
85 lesion is the mainstay of diagnosis, staging and treatment. Radical excision is
86 performed when the depth of invasion is more than 1mm below the basement
87 membrane, with radial margin of 1cm macroscopically normal skin and extending
88 deep as far as the muscles and periosteum.³ Excision of muscles of the bulb and
89 perineum may be required to achieve an adequate margin which can cause
90 significant physical, psychological, sexual, bladder and bowel dysfunction.⁴

91

92 Assessment of groin lymph nodes is an integral part of staging for primary lesions
93 with invasion greater than 1mm. Sentinel lymph node (SLN) sampling is performed
94 for lesions measuring less than 4cm that do not encroach on the midline.⁵ Full
95 lymphadenectomy may be recommended if the SLN contains metastases.⁵ SLN
96 excision is performed through an oblique incision measuring 2-3cm, while full
97 lymphadenectomy may be performed through an oblique transverse or vertical groin
98 to anterior thigh incision that extends to 8cm or more.

99

100 Other indications for vulval surgery include diagnostic biopsies and other benign
101 lesions including extensive condylomata.⁶

102 Surgical excision of the groin and vulva is a painful procedure usually performed
103 under general or spinal anaesthesia. Traditionally local anaesthetic was infiltrated

into and around the wound but the distribution varied and the somatic pain control was not reliable. The groin is innervated mainly by the ilioinguinal nerve (IIN), iliohypogastric nerve (IHN) and genitofemoral nerve (GFN). The innervation of the vulva is from IIN and GFN anteriorly, the pudendal nerve (PN) posteriorly and a small component of posterior cutaneous nerve of thigh laterally near the crural fold. Inspired by the success of the application of local anaesthetic (LA) peripheral nerve blocks for postoperative pain control with abdominal surgery, we introduced blockade of the IIN and PN into our practice to assess the impact on patients' postoperative analgesic requirement. There are, to our knowledge, no previous descriptions of the use of dual LA block of IIN-PN in vulval and groin surgery in oncology.

METHODS

This was an observational study of all patients undergoing major vulval and/or related groin surgery between September 2019 and June 2020 in our cancer centre. Sampling biopsies were excluded.

Technique of Local Anaesthesia

We consulted with the anaesthetist prior to the procedure regarding the dose of LA. We used levobupivacaine 0.25% (2.5mg/ml) or 0.5% (5mg/ml). Dosage was calculated based on the patient's weight with no more than 2mg/kg. For example, using 0.25% of levobupivacaine (2.5mg/ml) for a 70kg patient, 56ml is administered divided into 4, giving 14ml at each site.

IIN block based on anatomical landmarks

128 The technique of IIN block is as follows. With the anaesthetised patient in a supine
129 position and following topical application of chlorhexidine to skin, the anterior
130 superior iliac spine (ASIS) is palpated and a point is marked 2cm medially and 2cm
131 caudally (Figure 1). A 21-gauge needle is advanced perpendicular to the skin until a
132 “fascial click” is felt. Care is taken not to advance the needle too deeply. After
133 negative aspiration, half the LA is injected. The needle is then directed obliquely
134 towards the pubis and the remainder is injected.

135 **IIN block under ultrasound guidance**

136 We used a linear transducer with a sterile cover with the probe placed at the 2cm
137 medial to ASIS and manoeuvred to get good visualisation of the three layers of
138 abdominal wall muscles (external oblique [EO], internal oblique [IO] and transversus
139 abdominis [TA]). IIN and IHN appear as echogenic or white linear structures within
140 the fascial plane between the IO and TA muscles (Figure 2). The deep circumflex
141 iliac artery may appear close to the nerves and doppler can be used to confirm this.
142 We have found that the nerves were not always clearly visualised although the plane
143 between EO, IO and TA is very distinctive. LA is infiltrated under direct vision
144 between the IO and TA plane with a 21-gauge needle after negative aspiration.

145 **Pudendal nerve block**

146 With the patient in lithotomy position, and following betadine preparation of the
147 vaginal skin the ischial spine is palpated with the index or middle finger and the
148 pudendal needle with guard is introduced 1cm medial and posterior to ischial spine.
149 A pudendal needle with guard (Rocket®) is used to allow better control on the depth
150 of infiltration near the ischial spine. The guard limits the depth of needle

advancement to one centimetre. It is important to perform negative aspiration prior to injection of LA to ensure the needle has not entered the internal pudendal artery.

Postoperative care

Postoperative analgesia is prescribed on an as required basis and usually includes paracetamol and oxycodone. Prescription of non-steroidal analgesia is avoided in those over 60 years. Standard postoperative monitoring includes 4 to 6 hourly measurements of patients' vital signs with Early Warning Score monitoring, urine output and pain assessment. Visual Analogue Score (VAS) sheets were recorded at 6 hours and daily following surgery. VAS is a validated instrument used widely to promote more objective assessment of analgesic control, with scores ranging from 0 (no pain) to 10 (worst possible pain)⁸.

Patient data extracted from the electronic inpatient records included age, comorbidities, index diagnosis with cancer type and stage, surgical details and daily analgesic requirement for the first five postoperative days.

RESULTS

Nineteen sequential patients underwent major vulval and/or related groin surgery during the study period. One patient was excluded because her ischial spines could not be palpated through her short fibrosed vagina post radical hysterectomy and radiotherapy for prior cervical cancer. The median age of the remaining eighteen patients was 67 (range 34-81) years. Thirteen (72%) were over 60 years.

176 Comorbidities were none (1), obesity (1), hypertension (8), coronary artery disease
177 (1), atrial fibrillation (1), dyslipidaemia (7), type 2 diabetes (2), chronic arthralgia (2),
178 osteoporosis (2), lymphoedema (1), anxiety/depression (6), history of narcotic
179 dependence (1).

180

181 All patients had their surgery performed under general anaesthesia. Indications for
182 surgery were primary squamous cancer (10, 56%), recurrent squamous cancer (1,
183 6%), melanoma (1, 6 %), melanoma in situ (1, 6%), and high grade dysplasia (4,
184 22%). Types of surgery are shown in Table S1.

185

186 The LA agent was 35—60ml of 0.25% levobupivacaine for 17 patients and 28ml of
187 0.5% bupivacaine for one patient. LA was divided in equal portions for up to four
188 injection sites. Ultrasound guidance for IIN location was used in 4 cases.

189

190 VAS scores recorded at Day 0—5 are shown in Figure 3. Median VAS scores were
191 zero throughout in 13 patients. Two patients had pain scores >4 on one or more
192 postoperative day: one had chronic arthralgia and one had received a lower volume
193 of LA at higher concentration (0.5% bupivacaine, 28ml total, 7ml at each site).

194

195 Analgesic consumption postoperatively is shown in Figure 4. The five patients who
196 took opioid at any time postoperatively had chronic arthralgia (1), additional
197 abdominal surgery (1), received a lower volume of LA (1), and underwent surgery
198 outside of the cancer centre during the COVID-19 pandemic (2) (surgery was
199 undertaken by the same Gynaecological Oncology team but different postoperative
200 nursing care).

A single adverse outcome was a unilateral transient femoral nerve palsy in one patient. She had numbness over her anterior thigh associated with paraesthesia and quadriceps femoris weakness, all of which resolved overnight.

DISCUSSION

The IIN arises from the lumbar plexus (L1) and provides sensory innervation to the groin, upper anterior thigh and anterior vulva. Cutaneous branches travel through the transversus abdominis and internal oblique and course in the transversalis fascia. It lies close to the IHN in anterior abdominal wall and both nerves are likely to be blocked particularly when the local anaesthetic is injected without ultrasound guidance. Blockade of both nerves is widely used after inguinal hernia repair.⁹

The PN arises from ventral rami of spinal nerves S2, S3 and S4. PN passes between piriformis and ischiococcygeous muscles, runs posteriorly to the sacrospinous ligament towards its attachment at the ischial spine. PN then re-enters pelvis through the lesser sciatic foramen. The internal pudendal artery runs just lateral to the PN at the level of ischial spine before it enters the pudendal canal. Obstetricians are very familiar with the use of pudendal nerve blocks in the second stage of labour for assisted vaginal births. We are not familiar with any previous descriptions of the use of dual local anaesthetic block of IIN-PN in vulval and groin surgery in oncology.

Good quality and stepwise post-operative analgesia have a major role in enhancing recovery and positively affects the patient's perception of the surgical experience. According to Enhanced Recovery After Surgery protocols, early involvement and education are associated with improved surgical outcomes for patients.¹⁰ Counselling on anticipatory pain includes encouragement to request adequate analgesia. Poorly managed pain can have a negative impact on physical and psychological recovery with adverse consequences for patients and their carers.¹¹

Main Findings

We found that on Day 1 post operatively, pain was absent in almost three quarters of women and documented analgesic requirement was satisfactory with half requiring no postoperative analgesia on Day 1. On postoperative day 1, one third of women used paracetamol and just over one fifth used an opioid. This pattern was maintained throughout the inpatient stay.

The small number of patients receiving narcotic analgesia had one or more of the following features: additional abdominal surgical procedure, injection of a lower volume of LA owing to use of higher concentration bupivacaine, were on long term analgesics for chronic pain or had their surgery performed by the same Gynaecological Oncology surgical team but in an independent hospital with different postoperative nursing care during the COVID-19 pandemic. More than 70% of patients got through the first five days of recovery without narcotic analgesia. Usage

of paracetamol was low. Non-steroidal analgesics are rarely used in these patients as many are older or have comorbidities that prohibit their use. Avoidance of narcotics is desirable in this elderly group of patients with multiple comorbidities, provided it does not compromise comfort and mobilisation. Minimising analgesic needs is beneficial in all surgical patients and particularly in older patients with comorbidities. We strongly recommend this dual approach to sensory nerve block to enhance recovery after vulval surgery.

We prefer the higher volume of 0.25% levobupivacaine as it can be seen opening up the transversus abdominis plane very well and that gives better exposure of the nerve axons. We did not have access to ultrasound for direct visualisation in the majority of cases. Ultrasound has been shown to enhance the accuracy of injection.¹²

Femoral nerve palsy has been reported after IIN block. The transversus abdominis plane is in continuity laterally with the plane deep to the iliacus fascia through which the femoral nerve runs¹³, so the injectate can spill over into that space and cause a transient femoral neuropraxia.

Strength and Limitations

The consistent approach of the same surgical team minimised variation in approach to analgesia in our cohort. IIN and PN blockade are technically easy to perform by anatomical landmarks and in only one case was it not feasible to block the PN in a patient who had prior radical surgery and radiotherapy for cervical cancer.

275 We had limited access to ultrasound localisation which would delineate the tissue
276 planes and visualise the spread of the LA in the transversus abdominis plane. Our
277 failure to identify the Ilioinguinal and hypogastric nerves may have been due to
278 adipose tissue in the abdominal wall.

279

280 **Interpretations**

281 Our findings should be reproducible in other centres and we believe that
282 adoption of these techniques will improve recovery from and experience of vulval
283 and inguinal surgery.

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287 **Conclusion**

288 This observational study demonstrates that LA block is valuable in women
289 undergoing major surgical excision in the vulva and/or groin. Concentration of vulval
290 cancer care to a small group of tertiary gynaecological oncologists is key to delivery
291 of best surgical care for this rare cancer and provides a good milieu for making small
292 changes in aspects of care, such as analgesia, to significantly improve patients'
293 experience. Application to more patients and multiple centres would validate our
294 findings and we rely on international colleagues to support us in this endeavour.

295

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300 **Disclosure of interests**

301 The authors declare that they have no conflict of interests.

302 **Contribution to authorship**

303 NG presented the study model and the design of the study. YS, NG and PJM
304 contributed to data collection, interpretation and analysis. The manuscript was
305 written and the final edition was checked by all three prior to submission to BJOG.

306 **Ethics approval**

307 This study received full ethical approval from the St James's Hospital/Tallaght
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310

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323 [conditionsanddiseases/bulletins/cancerregistrationstatis](https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/cancerregistrationstatis) and National Cancer

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