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Comparison of continuous with single-injection regional analgesia on patient experience after ambulatory orthopaedic surgery: a randomised multicentre trial

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Abstract

Background: The optimal approach to improving patient experience and analgesia after ambulatory orthopaedic surgery remains unclear.

Methods: This multicentre, randomised clinical trial compared single-injection nerve block analgesia with home delivery of continuous nerve block analgesia by remote-controlled electronic pump. The primary outcome was patient-reported satisfaction (Evaluation du Vecu de l'Anesthesie Generale [EVAN-G]; 0–100) assessed on postoperative Day 2. Secondary outcomes focused on pain, opioid consumption, quality of rehabilitation, activity tracking using a wearable electronic device, and 90-day quality of life.

Results: We randomly assigned 294 patients to continuous pump delivery or single injection. For subjects with normal level of pain catastrophising (Pain Catastrophizing Scale <30; n=211), median global EVAN-G was higher with the electronic pump compared with the single injection (78 [69–86] vs 72 [63–84]; $P=0.03$), as were pain satisfaction scores ($P=0.01$). For the maximum pain levels, the numerical rating scale score was 2.0 (1.0–5.0) in the electronic-pump group vs 5.0 (3.0–7.0) in the single-injection group on the first 2 days after surgery ($P<0.0001$). Total opioid consumption in morphine equivalent was higher with single injection (mean [standard deviation]): 70.5 [73.8] vs 31.9 [54.2] mg; $P<0.01$). The groups did not differ in early rehabilitation on Day 1 or quality of life on Day 45. Electronic activity tracking indicated higher activity in the electronic-pump group ($P<0.01$).

Conclusions: Self-reported patient satisfaction at home was better with continuous nerve block analgesia via electronic pump vs single injection, without impairing early rehabilitation. Single-injection analgesia was associated with higher pain levels and opioid consumption and lower satisfaction. Patient catastrophising negatively affected the experience of pain.

Clinical trial registration: NCT 02720965.

Keywords: ambulatory surgery; analgesia; catastrophising; continuous nerve block; opioids; orthopaedic surgery; patient experience; rehabilitation

Editor's key points

- The optimal approach for postoperative analgesia after ambulatory orthopaedic surgery is unclear.
- In a randomised trial of 294 subjects undergoing various ambulatory orthopaedic procedures, continuous nerve block analgesia led to lower pain levels, lower opioid consumption, higher daily activities, and better global experience in non-catastrophising patients.
- Compared with single-injection analgesia, continuous nerve block infusion at home does not impair rehabilitation and is associated with better outcomes after ambulatory orthopaedic surgery.

Opioid-based analgesic protocols have contributed to a global opioid epidemic.^{1,2} Although relegating opioids to the status of rescue treatment appears to be necessary regarding public health,^{3,4} maintaining a high level of pain control and individual patient satisfaction without opioids can be challenging.⁵ Patient experience is an individual construct arising from the interaction of expectations and actual experiences.^{6–8} Shared decision-making about postoperative pain management should include the patient experience and satisfaction to define which strategy better addresses patient expectations^{9–11} instead of relying on expert assumptions that could be contradictory.¹² Pain catastrophising is a patient disposition to magnify the negative experience associated with pain stimuli, which can influence patient-reported outcomes and should be taken into account in the analysis of an analgesic strategy.¹³

Orthopaedic surgery is associated with high levels of postoperative pain,¹⁴ and the development of outpatient procedures has given rise to a debate about the best way to treat pain without hampering early rehabilitation.¹⁵ Continuous nerve blocks are linked to better analgesic efficacy,¹⁶ but some find them 'unrealistic' in daily practice,¹² while single-injection techniques are associated with greater freedom of movement and early rehabilitation.¹⁷

In this randomised clinical trial, we compared two bundles of care after ambulatory orthopaedic surgery: continuous nerve block at home by electronic pump delivery and single-injection nerve block. Both groups received the same multimodal oral analgesia protocol. We hypothesised that continuous nerve block analgesia would improve self-reported satisfaction after outpatient orthopaedic surgery without impairing early rehabilitation. Patients with a high level of pain catastrophising had their satisfaction analysed separately to reduce bias.

Methods

Study supervision

The study was a multicentre, randomised clinical trial. The protocol was approved by the ethics committee of Marseille University Hospital (Comité de Protection des Personnes Sud-Méditerrané, Marseille, France; no. 2016A00159-42) and prospectively registered at [ClinicalTrials.gov](https://www.clinicaltrials.gov) (NCT 02720965). The study was funded by the French National Hospital Program of Clinical Research (Programme Hospitalier de Recherche Clinique; grant 9677). The study report follows the Consolidated

Standards of Reporting Trials statement, and the trial was conducted in accordance with the original protocol.

Subjects

From June 2017 to October 2019, we screened for enrolment all patients age <80 yr with American Society of Anesthesiologists (ASA) physical status 1, 2, or 3 who were scheduled for outpatient, painful orthopaedic surgery according to the French recommendations for peripheral nerve block¹⁸ (Supplementary Table 1) at five hospitals in France (see list of investigators). Eligible surgeries were rotator cuff rupture, Bankart repair, Latarjet procedure, and remplissage procedure for shoulder surgery; ligamentoplasty and valgus osteotomy for knee surgery; ligamentoplasty and arthrodesis for foot and ankle surgery; and complex ligamentoplasty, rhizarthrosis, and bone grafting for hand and wrist surgery. Follow-up continued until January 2020. Exclusion criteria were contraindication to perineural catheter or single-injection nerve block, local anaesthetic allergy, spontaneous request by the patient for a specific analgesia protocol, documented chronic pain syndrome or preoperative use of strong opioids, cognitive impairment, pregnancy or breastfeeding, drug abuse, and use of neuroleptic medication or lithium. We anticipated a rate of 25% of subjects with a high level of catastrophising to be analysed separately.¹⁹

Study treatments

The electronic-pump group received an ultrasound-guided nerve block with the placement of a perineural curled-tip catheter (PAJUNK, SonoLong Curl Echo®, Geisingen, Germany) by a senior anaesthetist. A remote-controlled electronic pump allowing for distant monitoring of infusion parameters (Rhythmic™ Evolution; Micrel Medical Devices S.A., Athens, Greece) was started to deliver a basal flow rate of 5 ml h⁻¹ of ropivacaine 2 mg ml⁻¹, which was continued until the morning of the third postoperative day. Boluses consisted of 5 ml with a lockout period of 30 min and a dose limit of 40 ml in 4 h.²⁰ Patients feeling insufficient pain relief at 30 min after a bolus could take tramadol 100 mg p.o., with a maximum dose of 100 mg every 6 h. If pain persisted 30 min after taking tramadol, patients could take a tablet of oxycodone 10 mg every 6 h as rescue analgesia. The single-injection group received an ultrasound-guided nerve block injection of a single bolus of up to 20 ml of ropivacaine 5 mg ml⁻¹. Patients in this group could control their pain with tramadol on demand at a maximum dose of 100 mg every 6 h. If pain persisted for 30 min after taking tramadol, patients could take a tablet of oxycodone 10 mg every 6 h as rescue analgesia.

Treatment protocol and data collection

Patients were screened at the time of pre-anaesthetic consultation. All patients completed the Pain Catastrophising Scale²¹ (PCS) at the time of admission. Patients were randomly assigned (1:1 ratio) before entering the operating theatre by stratified randomisation by inclusion centres and type of surgery with minimisation process via a restricted web platform.

The anaesthetic protocol was strictly standardised for all randomised subjects. All subjects received multimodal analgesia at the time of surgical incision consisting of administration of paracetamol, nefopam, and ketoprofen, with

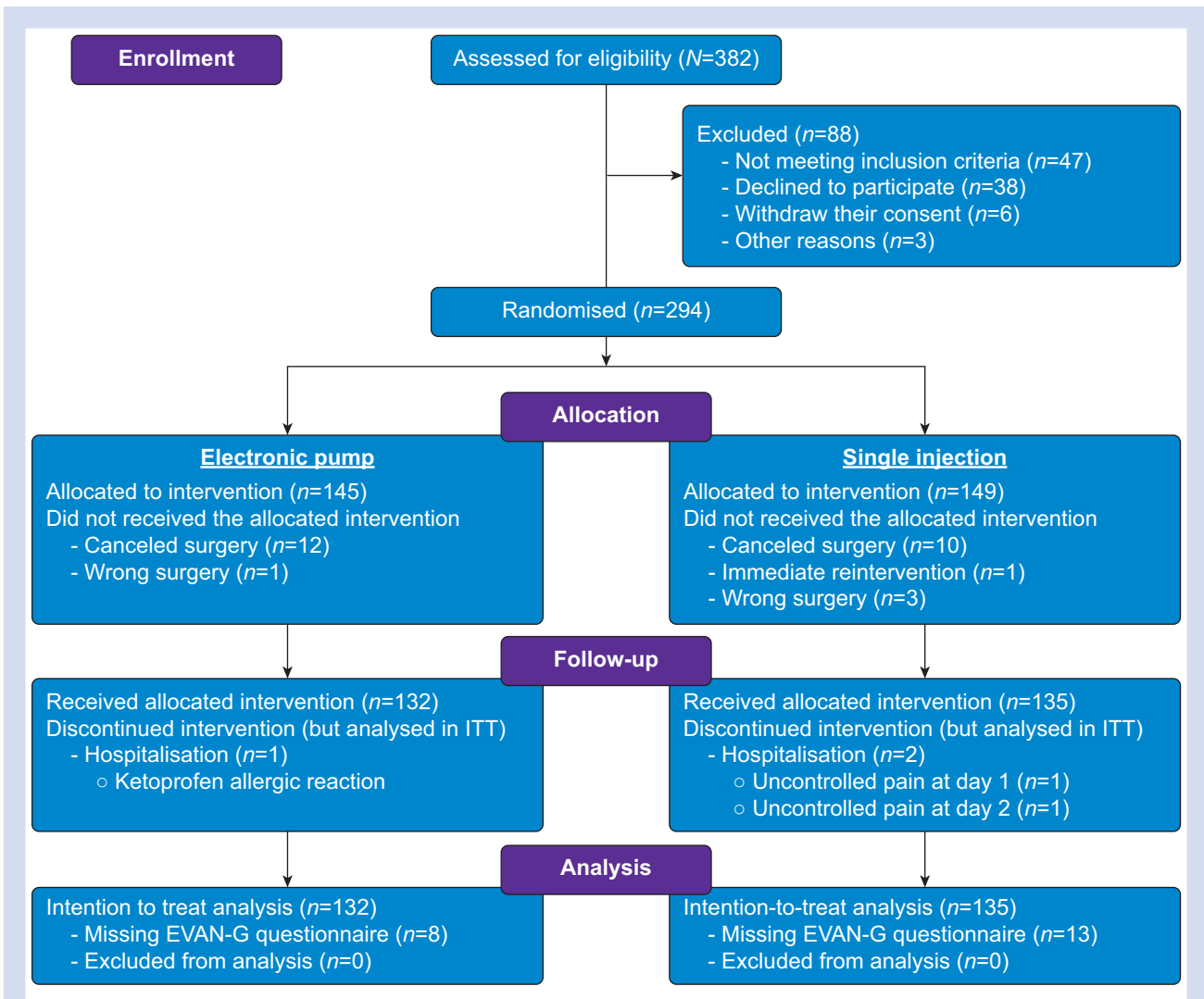


Fig 1. Flow chart. CONSORT, Consolidated Standards of Reporting Trials; EVAN-G, Evaluation du Vecu de l'Anesthesie Générale; ITT, intention to treat.

prophylaxis of postoperative nausea and vomiting by droperidol. Any deviation from this protocol was recorded and had to be justified (Supplementary Table 3). For all knee surgeries, the surgeon also performed infiltration of the popliteal fossa with 20 ml of ropivacaine 5 mg ml⁻¹.

After surgery, subjects were monitored in the PACU until they were rated as having a modified Aldrete scale score ≥ 9 . Discharge from ambulatory service to home was allowed after subjects reached a Chung scale score ≥ 9 .

At home, subjects from both groups received a multimodal analgesia protocol combining oral paracetamol and ketoprofen with prophylactic omeprazole, and they were instructed to follow the pain relief protocols for the respective study groups.

The day after surgery, subjects completed the Quality of Recovery-40 (QoR-40) scale.²² The second day after surgery, subjects were assessed by the Evaluation du Vecu de l'Anesthesie Generale (EVAN-G) satisfaction questionnaire. A wearable activity tracking electronic device recorded daily activity time and average sleep duration until Day 3. The perineural

catheter was removed on Day 3. On Day 45, answers to the Short Form-36 (SF-36) were collected in a telephone interview.²³ On Day 90, patients were screened in a final interview for persistent pain, and neuropathic pain characteristics were identified with the Douleur Neuropathique 4 (DN4) questionnaire.²⁴

Study outcomes

The primary outcome was the EVAN-G patient satisfaction global index evaluated on Day 2.²⁵ We considered a difference of 5 points to be the minimum clinically significant difference according to the EVAN-G validation study and published literature.^{25,26} EVAN-G is a validated self-reported questionnaire for general anaesthesia that assesses patient satisfaction during the perioperative period.²⁷ It consists of 26 patient-generated items structured in six dimensions and a global index. The robustness of EVAN-G has been highlighted by a

Table 1 Baseline characteristics of the included subjects. PCS, Pain Catastrophizing Scale; SD, standard deviation.

Characteristic	Electronic pump (n=132)	Single injection (n=135)
Age, yr, mean (SD)	45.3 (16.5)	44.4 (16.2)
Age group, n (%)		
≤65 yr	116 (88)	122 (91)
>65 yr	16 (12)	12 (9)
Weight (kg), mean (SD)	76.9 (16.6)	77.4 (16.4)
Height (cm), mean (SD)	171.3 (9.2)	171.8 (8.9)
Male sex, n (%)	84 (64)	92 (69)
BMI (m kg ⁻²), mean (SD)	26.1 (4.8)	26.2 (4.8)
Weight status, n (%)		
Underweight	0 (0)	2 (1)
Normal	67 (51)	55 (41)
Overweight	36 (28)	53 (39)
Obese	27 (21)	24 (18)
ASA physical status, n (%)		
1	88 (69)	94 (71)
2	34 (27)	37 (28)
3	6 (5)	2 (2)
Number of previous anaesthetics, mean (SD)	2.5 (2)	2.6 (1.8)
Current or prior use, n (%)		
Alcohol	3 (2)	2 (2)
Tobacco	35 (27)	36 (27)
Cannabis	6 (5)	5 (4)
Weak opioid	9 (7)	5 (4)
Antidepressant	4 (3)	4 (3)
Benzodiazepine	1 (1)	4 (3)
History, n (%)		
Depression	5 (9)	4 (8)
Anxiety	2 (4)	1 (2)
PCS, mean (SD)	17.1 (11)	16.9 (11.4)
PCS ≥30, n (%)	18 (14)	20 (15)
Preoperative pain (numerical rating scale), mean (SD)	2.6 (2.7)	2 (2.6)
Regional anaesthesia initial bolus (ml), mean (SD)	16.8 (4.2)	17.7 (3.5)
Associated neurostimulation, n (%)	9 (7)	16 (12)
Difficult intubation, n (%)	3 (2)	4 (3)
General anaesthesia protocol deviation, n (%)	5 (4)	10 (8)
Type of surgery, n (%)		
Shoulder	93 (70)	96 (71)
Interscalene catheter		Interscalene block
Knee	24 (18)	22 (16)
Femoral catheter		Femoral block
Ankle and foot	13 (10)	14 (10)
Sciatic catheter		Sciatic block
Wrist and hand	2 (2)	3 (2)
Infraclavicular catheter		Axillary block
Length of surgery (min), mean (SD)	50.3 (26.7)	53.2 (26.8)

qualitative systematic review of patient satisfaction measures.²⁸

We planned a primary analysis of pain catastrophising as assessed by the PCS, a validated instrument consisting of 13 questions with a cut-off of 30 for identifying a patient who tends to catastrophise.²¹

For secondary outcomes, pain maximum and mean levels were scored twice a day using a 0–10 numerical rating scale (NRS). Consumption of tramadol and oxycodone was converted to morphine equivalents as follows: opioid consumption in morphine equivalent (mg)=0.2 × tramadol (mg)+2 × oxycodone (mg).²⁹ The quality of rehabilitation was assessed by the QoR-40 scale.²² A wearable electronic activity tracker (Alta[®]; Fitbit, Inc., San Francisco, CA, USA) recorded the period of daily activity and average time of sleep. Quality of life was assessed by the SF-36 scale at 45 days.²³ At 90 days, subjects

were screened for persistent pain, neuropathic characteristics, and altered sensitivity, and they were asked about the completion of a rehabilitation programme and return to work. Adverse events were recorded.

Statistical analysis

Assumptions for the number of participants necessary were based on the global scores of the EVAN-G reported in previous studies.^{25,26} We considered a difference of 5 points to be the minimum clinically significant difference according to the EVAN-G validation study and published literature.^{25,26} With a standard deviation of 12, for an alpha risk of 5% and 80% power, the sample size was 100 in each group. The number of subjects to be included was increased to 300 to fit a proportion of 25% of patients with high level of catastrophising and to

Table 2 Comparisons of EVAN-G scores (medians and inter-quartile ranges) by Pain Catastrophizing Scale (PCS). *P-value for Mann–Whitney U-test and unpaired t-tests. EVAN-G, Evaluation du Vecu de l’Anesthesie Générale.

	Electronic pump	Single injection	P-value
PCS <30	n=108	n=103	
Attention	80 (60–100)	75 (50–95)	0.07
Information	75 (55–90)	65 (50–90)	0.17
Privacy	75 (50–91)	62 (50–87)	0.06
Pain	70 (55–80)	60 (50–75)	0.01*
Discomfort	90 (75–95)	85 (30–95)	0.27
Waiting	100 (75–100)	100 (75–100)	0.71
Index	78 (69–86)	72 (63–84)	0.03*
PCS ≥30	n=16	n=17	
Attention	97 (70–100)	100 (60–100)	0.5
Information	87 (50–95)	80 (50–100)	0.99
Privacy	75 (50–94)	75 (62–100)	0.37
Pain	67 (45–77)	75 (65–85)	0.04*
Discomfort	87 (75–95)	90 (80–100)	0.4
Waiting	81 (69–100)	87 (75–100)	0.79
Index	78 (69–89)	85 (67–92)	0.39
Whole population	n=124	n=120	
Index	78 (69–86)	74 (64–86)	0.13

anticipate missing questionnaires.¹⁹ For the primary outcome, the EVAN-G global index and dimension scores were analysed in the total population and by groups of pain catastrophising identified by the PCS with a cut-off of 30.²¹ In the univariate analysis, the comparisons between the electronic-pump and single-injection groups were performed using unpaired t-test or Mann–Whitney U-test, as appropriate. Multivariate linear regression was performed to assess the interaction between groups and subject catastrophising.

For secondary outcomes, continuous variables (pain evaluations in the hospital, consumption of opioids in morphine equivalents, quality of recovery, activity tracking, quality of life, and Day-90 follow-up) were compared with unpaired t-tests or Mann–Whitney U-test, depending on the distribution. The Shapiro–Wilk test was used to test the normality of continuous variables. Adverse events were compared with Fisher’s exact test.

For repeated pain evaluations, we ran linear regression models with mixed effects and with group, time assessment from postoperative Days 1–3, PCS, and surgery as fixed effects and subject as the random effect. The slope, group, and time–group interaction were tested. A model selection procedure (Bayesian information criterion minimisation) was used to determine the final model.

All randomised subjects were analysed by intention to treat. The significance level was set to 5% for all tests. The statistical analysis was carried out using SAS version 8.2 (SAS Institute, Cary, NC, USA).

Results

A total of 294 subjects were randomised into the trial, and 267 subjects were included in the intention-to-treat analysis (Fig 1). Their baseline characteristics are given in Table 1.

Primary outcome

For the whole population, the EVAN-G median global index, measuring overall patient experience and satisfaction, was 78

(median; inter-quartile range: 69–86) for the electronic-pump group and 74 (64–86; P=0.13) for the single-injection group.

In the group of subjects with PCS scores <30, the electronic-pump group had higher scores (78; 69–86) than the single-injection group (72; 63–84; P=0.03) on the EVAN-G median global index (Table 2). In contrast, for subjects with a PCS score ≥30, the satisfaction score for pain dimension was lower in the electronic-pump group (67.5; 45.0–77.5) compared with the single-injection group (75.0; 65.0–85.0; P=0.04), but we did not find a significant association between groups and the other domains of patient satisfaction assessed by the EVAN-G scale (Table 2).

Multiple linear regression, including group and catastrophising interaction, showed an increase in EVAN scores for the electronic-pump group with a normal level of pain catastrophising ($\beta=7.4$ [0.73; 14.1]; P=0.03).

Secondary outcomes

Pain

At home, the mean and maximum NRS pain levels were higher in the single-injection group compared with the electronic-pump group according to the mixed-model analysis (P<0.01; Fig 2). For maximum pain levels, NRS score was 2.0 (1.0–5.0) in the electronic-pump group vs 5.0 (3.0–7.0) in the single-injection group on Day 1 after surgery, 2.0 (1.0–5.0) vs 5.0 (3.0–7.0) on Day 2 after surgery, and 2.0 (0.0–10.0) vs 4.0 (0.0–10.0) on Day 3 after surgery (P<0.01; Fig 2).

Opioid consumption

Daily consumption of opioids was higher in the single-injection group vs the electronic-pump group (Fig 3). Total consumption of opioids in morphine equivalents was also higher in the single-injection group (mean [standard deviation] 70.5 [73.8] vs 31.9 [54.2] mg in the electronic-pump group; P<0.01). The opioid-sparing effect of the electronic pump was evaluated as 38.6 mg in morphine equivalents in the first 72 h after surgery.

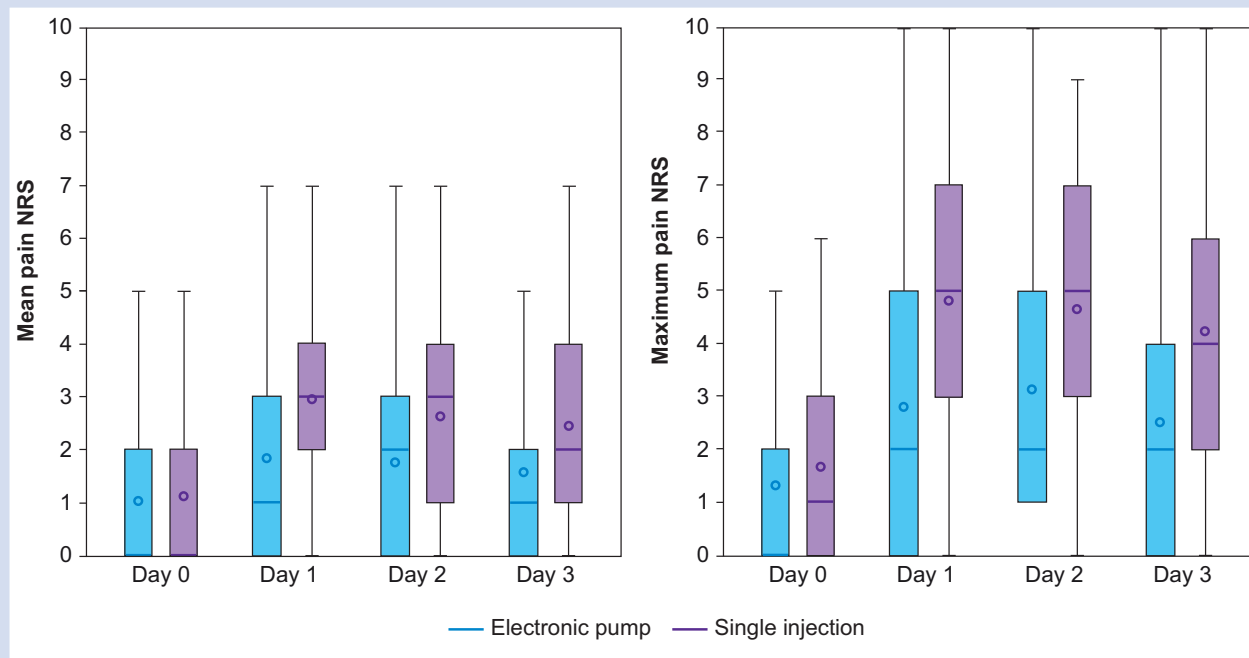


Fig 2. Mean (left) and maximum (right) pain, per the numerical rating scale (NRS) in the whole subject population. Postoperative (PO) mean pain levels as assessed by the NRS, with $P < 0.0001$ according to the mixed model. Boxes and bars: 25th–75th and 10th–90th centiles; bar inside the box (median value); circle inside the box (mean value).

Quality of rehabilitation

The groups did not differ in early recovery as assessed by the QoR-40 global index on Day 1 after surgery (Table 3). The daily activity tracking showed higher patient activity in the electronic-pump group, with 55 h of activity from Days 1–3 compared with 53 h in the single-injection group ($P < 0.01$).

Adverse events

Rates of nausea and shivering were higher with the single injection (17.3% and 7.9%, respectively; $P < 0.01$) than with the electronic pump (4.8% and 2.4%, respectively; $P = 0.05$) on the first day after surgery. Abnormal dressing outcomes at the regional anaesthesia puncture site (haematoma or local wound infection) were higher in the single-injection group (6.5%) compared with the electronic-pump group (1%) ($P = 0.03$; Supplementary Table 2). The groups did not differ in fall rates ($P = 0.45$; Supplementary Table 2). In the electronic-pump group, four (2.7%) subjects had spontaneous failure of the perineural catheter before the third postoperative day, all of whom were included in the intention-to-treat analysis. In the single-injection group, two subjects (1.3%) were readmitted to the hospital because of unbearable pain. No subject needed readmission in the electronic-pump group.

Quality of life at day 45 and long-term outcomes at day 90

The groups did not differ in SF-36 scores at Day 45 (Table 3) and in long-term outcomes (Supplementary Table 4).

Discussion

The results of this multicentre, randomised, open-label clinical trial show that continuous nerve block delivered at home with an electronic pump vs a single injection in the hospital is associated with better patient-reported satisfaction in patients who do not tend to catastrophise, along with offering better pain relief and reduced opioid use.

The increasing trend to day surgery has made postoperative management more challenging.³⁰ In this context, single injections of local anaesthetic, such as nerve block or wound infiltration, are easy to implement but deliver a short duration of postoperative pain relief,^{31,32} leading to potential pain rebound.^{33,34} Systematic use of opioids has thus become necessary to prolong postoperative analgesia until acute pain subsides.^{35,36} This suboptimal pain trajectory exposes the patient to a combination risk of a poor experience, opioid misuse, and persistent pain after surgery that could outweigh the benefits of enhanced recovery programmes.³⁷

Most reports describing a comparison of two analgesic regimens use only pain scores or opioid sparing as their primary outcome. When patient satisfaction is assessed, the usual method is an oversimplified dichotomised approach. The weak discriminatory capacity of this kind of evaluation is established²⁸ and can lead to a conclusion of non-inferiority for a treatment because of the high levels of satisfaction usually obtained.^{38,39} We chose EVAN-G, a synthetic patient satisfaction criterion, as our primary outcome. The analysis of catastrophising groups showed higher satisfaction for the pain dimension and global index for patients without catastrophising tendencies

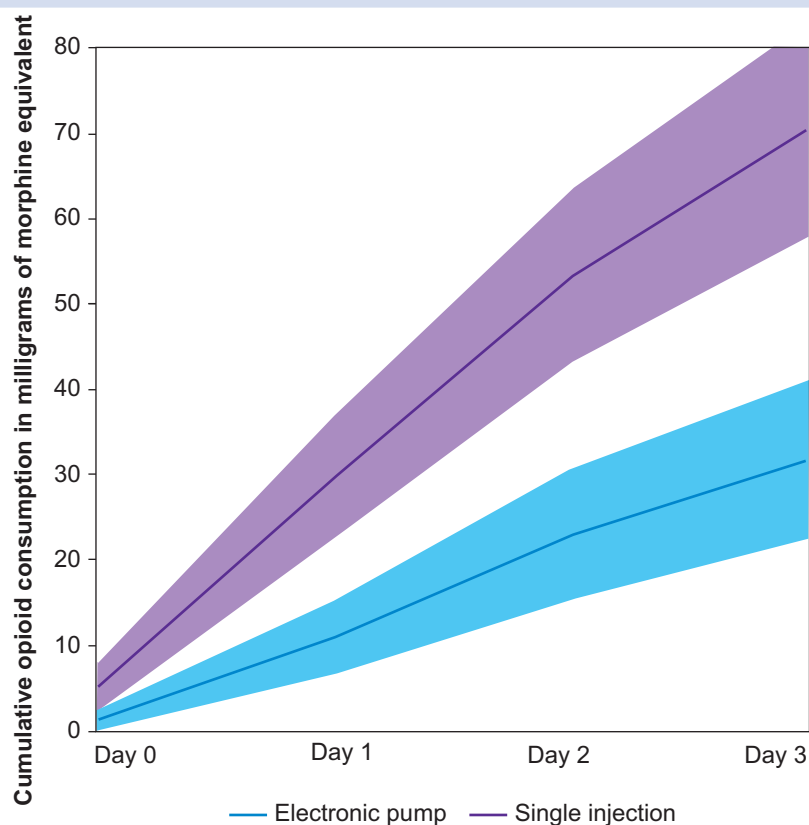


Fig 3. Cumulative opioid consumption in milligrams of morphine equivalent in the whole subject population. Milligrams of morphine equivalent: $0.2 \times \text{tramadol (mg)} + 2 \times \text{oxycodone (mg)}$. Bold lines represent the mean value. The shades encompassing the bold lines are 95% confidence intervals.

Table 3 Comparisons of QoR-40 scores on Day 1 and SF-36 scores on Day 45 in the whole subject population. *P-value for Mann–Whitney U-test and unpaired t-tests. QoR-40, Quality of Recovery-40; SF-36, Short Form-36.

	Electronic pump	Single injection	P-value
QoR-40 scores on Day 1 (medians and inter-quartile ranges)	n=127	n=124	
Emotional state	19 (17–22)	18 (16–20)	0.06
Physical comfort	25 (22–26)	25 (23–27)	0.09
Psychological support	30 (27–31)	31 (28–31)	0.12
Physical dependence	17 (13–20)	16 (13–21)	0.88
Pain	11 (9–13)	11 (9–14)	0.20
Index	100 (94–106)	100 (95–107)	0.24
SF-36 scores on Day 45 (mean and standard deviation)	n=111	n=120	
Physical functioning	65.4 (18.7)	67.2 (18.6)	0.35
Role (physical)	11.6 (23.5)	10.6 (20.9)	0.78
Bodily pain	47.38 (19.9)	49.27 (21.5)	0.31
General health	79.4 (14.4)	76 (18.3)	0.27
Vitality	66.6 (15.6)	66.7 (14.4)	0.96
Social functioning	65.5 (24.3)	70.7 (25.2)	0.09
Role (emotional)	49.1 (44.5)	51.1 (44.3)	0.82
Mental health	59.5 (12.6)	60.7 (13.5)	0.31
Health transition	46.6 (23.6)	48.5 (24.1)	0.52

who were allocated to the electronic-pump group. However, patients with a tendency to catastrophise pain, representing 15% of the whole population, reported lower pain dimension satisfaction in the electronic-pump group but with no differences in the global index of the EVAN-G. Pain is a cognitive and emotional construct that goes beyond nociception.⁴⁰ Catastrophising patients are more prone to magnify or exaggerate the threat associated with pain representation.¹³ Although catastrophising may not directly influence pain,⁴¹ it has been suggested to affect the experience of pain.⁴² The primary outcome of this study was the EVAN-G scale, an instrument that is used to assess patient satisfaction in the perioperative period. Patient satisfaction depends on the patient having an experience that matches expectations.⁶ Those who catastrophise are characterised by a tendency to magnify worry and expectations about pain.⁴³ One explanation of the lower satisfaction of these patients for the pain dimension of the EVAN-G scale could be related to their having had an actual experience that did not match their expectations.⁷ Having a perineural catheter connected to an electronic pump could have worsened the worry and expectations about pain for patients who catastrophise.

We found that continuous regional anaesthesia delivered with an electronic pump at home was associated with a 30 mg reduction in morphine equivalent consumption within the first 2 postoperative days. This reduction in morphine consumption was associated with fewer side-effects and could explain the higher rate of activity time in patients allocated to the electronic-pump group.⁴⁴

Moreover, subjects allocated to the electronic-pump group reported well-controlled pain during the first 3 postoperative days. A threshold of 4 out of 10 in pain NRS is usually used as an independent risk factor for developing persistent pain.^{45,46} In our study, 39% of subjects assigned to the single-injection group reported at least one postoperative day above this level, compared with 20% of subjects allocated to the electronic-pump group.

The large sample supports the robustness of continuous nerve block efficacy findings across various orthopaedic procedures. However, several criticisms of continuous nerve block analgesia have been made. First, perineural catheter placement is recognised as difficult in everyday practice. In our multicentre study involving five hospitals, the success rate for catheter placement was 98% (three failed catheter placements in 145 subjects allocated to the electronic-pump group; Fig 1). Some authors have criticised the reliability of continuous nerve block at home.¹² In our study, only four subjects had their catheter withdrawn before the scheduled time on Day 3, and none of them had to be readmitted. In accordance with our statistical plan, these subjects were included in the intention-to-treat analysis. However, two subjects in the single-injection group were readmitted because of unbearable pain. Continuous nerve blocks also have been criticised for causing motor blockade that could impair early rehabilitation.⁴⁷ However, we found no differences in quality of recovery as assessed by the QoR-40 or in subject fall rates. More specifically, the groups did not differ in the 'physical dependence' dimension of the QoR-40 score, suggesting that subjects were equally able to perform their activities of daily living at home without help. This result was emphasised by the greater daily activity in the electronic-pump group as recorded by the wearable activity trackers. One explanation for this greater activity level could be that subjects who are experiencing less pain could undergo their daily life activities more easily.⁴⁴ Another frequent criticism of home-based continuous pump

delivery is that a catheter left in place could increase the risk of infection. Our study was not designed to assess rates of catheter infection or haematoma, which are typically low, but the rate of haematoma or suspicious infection at the puncture site was significantly higher in the single-injection group. One explanation could be that placement of a perineural catheter is carried out in a sterile manner, whereas single injection requires only surface disinfection.

Our study has some limitations. The rate of patients with high level of catastrophising was lower than expected. This result could reflect a tendency of catastrophising patients to avoid participation in an experimental study about pain. Another explanation could be that patients scheduled for orthopaedic surgery differ from the chronic pain population in terms of catastrophising. However, to avoid bias in the analysis of the primary endpoint, the EVAN-G score was studied in the homogeneous sample of the non-catastrophist population, in accordance with recent literature on patient experience.⁴⁸

The intervention tested could not be blinded because we chose not to use a sham for ethical concerns. The purpose of the trial was not to test continuous administration of perineural ropivacaine but rather to compare two bundles of care. The catheter group used the electronic pump to provide analgesia with opioids on demand as a rescue. The single-injection group had only opioids on demand, which consisted of tramadol and oxycodone with the same modalities for both groups. Apart from this randomised intervention, both groups had the same non-opioid multimodal analgesia. The modalities for anaesthesia were also strictly protocolised with 95% without any deviations (Supplementary Table 3).

Conclusions

Self-reported patient satisfaction at home was better with continuous nerve block analgesia via electronic pump compared with single-injection nerve block, without impairing early rehabilitation. Single-injection nerve block analgesia was associated with higher pain levels and opioid consumption and lower satisfaction. Patient catastrophising negatively affected the experience of pain.

Authors' contributions

Study conception/design: AM-S

Data acquisition: AM-S, PG, PC, TG, LD

Data analysis: AM-S, PA, SB, XC

Data interpretation: AM-S, PG, PA, SB, XC

Drafting of article: AM-S, PA, SB, XC

Accountability for all aspects of the work: all authors

Declarations of interest

The authors confirm that there have been no involvement that might raise the question of bias in the work reported or in the conclusions, implications, or opinions stated.

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Appendix A. Supplementary data

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