Major lower limb amputation audit – introduction and implementation of a multimodal perioperative pain management guideline

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Abstract

Lower limb amputation is a frequent surgical intervention. It is well known to be associated with postoperative pain. Optimisation of perioperative pain has been shown to reduce the risk of chronic pain. There are no national guidelines for the perioperative pain management of lower limb amputations. Following a baseline audit, we devised a multimodal perioperative pain management guideline, which included the insertion of a local anaesthetic perineural catheter. All patients undergoing an elective or emergency above, through and below knee amputation were reviewed prior and following the implementation of this guideline. Patient postoperative pain scores and opiate usage were analysed. One hundred and twenty-four patients were reviewed (68 patients prior to the implementation of the guideline and 56 patients following the guideline introduction). Following the implementation of the guideline, a greater proportion of patient's pain scores were reported as 0 (i.e. no pain) compared to patients prior to its implementation (78% vs 61%). Pain scores were lower at all time intervals 6 days postoperatively following the guideline introduction. Statistically significant (Kendall's tau-b analysis) ($p < 0.05$) reduction in pain scores was found upon admission to the ward, 6, 12, 24 hours and 2 days postoperatively. Fewer patients required the use of opioid patient controlled of analgesia after the guideline was introduced (26% vs 4%). The implementation of a perioperative pain management guideline improved pain scores and reduced opioid consumption in patients undergoing lower limb amputations. We suggest a holistic and collaborative, multimodal pathway towards the perioperative pain management of lower limb amputations.

Keywords

Neuropathic pain, perioperative pain management

Introduction

Lower limb amputation occurs with a frequency of between 5.8 and 31 per 105 total population.¹ In particular, 50–85% of amputees go on to experience phantom limb pain (PLP) which is notoriously difficult to manage.² Postoperative pain can be severe, intractable and a major cause of morbidity with a profound impact on patients' functioning and well-being.³ Studies have shown that pre-surgical pain is an important predictive factor for chronic post-surgical pain but the evidence so far for pre-amputation pain influencing PLP is mixed.^{4,5}

In 2010, the Vascular Society of Great Britain and Ireland (VSGBI) released a quality improvement

framework for Major Amputation Surgery in which they recommended there should be a formal pain management protocol and access to an acute pain team. In

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2014, National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report 'Lower Limb Amputation: Working Together' stated postoperative pain control was only assessed as 'good' in 37.5% patients. NCEPOD suggested 'a review of all patients by a specialist pain team would improve patient experience and has the potential to improve early mobilisation and shorten length of stay'.⁶ The Royal College of Anaesthetists (RCoA) audit standard for postoperative care states that '<5% day patients should be associated with isolated occurrence(s) of moderate or severe pain in a 24 hour period'. There is growing evidence that a continuous peripheral nerve blockade via a perineural sciatic nerve catheter in patients undergoing major lower limb amputation improves analgesia and reduces opioid-related side effects.^{7,8}

Historically, our inpatient acute pain team reported poor postoperative pain scores. Here we present our perioperative pain management guideline for major lower limb amputation, which involved the use of a local anaesthetic (LA) perineural sciatic catheter. We describe a service evaluation audit comparing the quality of pain relief provided before and after implementation of the new guideline.

Methodology

Patients

All patients who underwent either elective or emergency above knee amputation (AKA), through knee amputation (TKA) or below knee amputation (BKA) during a 3-year period, were included in the audit. The hospital audit committee permitted the audit plan with no requirement for ethical approval.

Data collection

A standardised retrospective data collection proforma was produced. Patient notes were reviewed for age, gender, anaesthetic and analgesic techniques used, level of amputation, patient pain scores, opiate requirements during the perioperative period and concurrent anti-neuropathic agent use.

For patients in the post-guideline cohort, additional data were collected including evidence of preoperative assessment and analgesia optimisation by the acute pain team, commencement of gabapentinoids, use of a perineural sciatic catheter, requirement for breakthrough analgesia and any complications.

Pain scoring

Pain scores were based on a numerical rating scale (0–3) with a score of 0 = no pain, 1 = mild, 2 = moderate

and 3 = severe pain. Pain scores were recorded immediately in recovery (0 hours) and then upon admission to the postoperative ward. The highest pain score during the next 6, 12, 24 hours and then each day, for the subsequent 6 days was recorded.

Pre-guideline group. Historically, there was no protocol-based approach to perioperative amputation pain management. A retrospective audit identified 94 lower limb amputation surgeries between April 2010 and September 2012 prior to the implementation of the guideline. Twenty-six were excluded due to unavailability of notes or insufficient documentation of pain scores.

Post-guideline group. The guideline was produced in collaboration with the anaesthetic, pain and vascular surgery departments to generate a holistic, shared and multimodal approach to pain management for lower limb amputation surgeries (Figures 1 and 2).

The choice of anaesthetic technique was the decision of the consultant vascular anaesthetist. A mixture of regional and general anaesthesia (GA) could be considered, with or without additional peripheral nerve block.

At our Black Country Vascular Hub, perineural sciatic nerve catheters were placed surgically under direct vision alongside the exposed sciatic nerve by the surgeon intraoperatively. For BKA, the goal was to pass the catheter along the neural sheath high enough, to ensure it was proximal to the bifurcation into its peroneal and tibial components. The catheter was tunnelled externally and secured on the lateral proximal stump. Intraoperatively, a 10 mL bolus of 0.25% bupivacaine was injected into the catheter to confirm patency and establish block. Femoral nerve catheters or single-injection femoral nerve block were performed by the anaesthetist if deemed necessary.

In recovery, the catheter(s) was attached to a pre-programmed ambIT® patient-controlled analgesia (PCA) infusion pump (Summit Medical Products, Sandy, UT, USA) and 200 mL of pre-prepared 0.2% ropivacaine infusion was commenced. All patients who received preoperative regular opioid analgesia (n = 5), buprenorphine patches and morphine sulphate tablets were continued on these during the postoperative period.

Sixty-seven patients were identified between September 2015 and January 2016. Twelve patients were excluded due to unavailability of notes. One patient underwent staggered bilateral BKA during a single admission and each amputation was recorded separately.

Statistical analysis. Kendall's tau-b statistical analysis was performed on the pain scores before and after the implementation of the guideline.

PREOPERATIVE REGIME:

- Once decision for amputation, contact Acute Pain Team (Bleep 7851) during office hours to optimize preoperative analgesia
- Commence Gabapentinoids (after discussion with the surgeons and acute pain team) – Refer Box 1
 - Gabapentin (1st line)
 - Pregabalin (2nd line)
 - If previous treatment with gabapentin ineffective

INTRAOPERATIVE REGIME:

- Anaesthesia (GA/RA) – as per the anaesthetist choice
- Insertion of a perineural sciatic nerve catheter with an epidural catheter kit by surgeons +/- insertion of femoral nerve catheter with an epidural catheter kit or single injection femoral nerve block by the anaesthetist
- Initial intraoperative bolus of 10ml of 0.25% bupivacaine through both the catheters irrespective of mode of anaesthesia
- Continuous infusion – 0.2% Ropivacaine using an Ambit pump
 - Basal rate – 5-10ml/hr (10ml/hr if femoral + sciatic nerve catheters)
 - Bolus – 10ml of 0.2% Ropivacaine, 2 hour lockout
- PCA morphine if appropriate

POSTOPERATIVE REGIME:

- Gabapentinoids titrated to effect/side effects
- Postoperative day 4 – Trial cessation of sciatic nerve catheter infusion. If pain recurs, restart 0.2% Ropivacaine infusion after a bolus of 10ml of 0.2% Ropivacaine via the pump
- Postoperative day 6 – Repeat trial cessation
- Remove catheter at 7 days

Figure 1. Multimodal perioperative pain management guideline.

GABAPENTINOIDS

- Gabapentin
 - Initiate treatment preoperatively at 100mg TDS
 - To optimize dose, increase each dose by 100 mg every 2/3 days until 300mg TDS. If well tolerated to further increase by 100mg TDS every 2/3 days until desired dose reached
 - Aim for 600 mg TDS
- Pregabalin
 - Initiate treatment preoperatively at 75mg BD. If well tolerated to further increase to 150mg BD after 2-3 days
 - Aim for 150mg BD (300mg/day in divided doses)
- Faster titration of gabapentinoids if well tolerated

HIGH RISK PATIENTS

- Consider dose reduction – elderly, renal failure, multiple severe comorbidities

CESSATION OF TREATMENT

- Continue treatment for 2 weeks postoperatively once on established dose, unless intolerable side effects
- If no evidence of phantom limb pain or stump pain, gabapentinoids can be weaned off, with decreasing doses every 4-7 days

Figure 2. Gabapentinoid recommendations for the perioperative period.

Table 1. Comparison of pre-guideline and post-guideline patient cohorts.

	Pre-guideline	Post-guideline
Sample size	68	56
Mean age (range)	66 (20–91)	68 (29–94)
Male:female	45:23	42:14
AKA (%)	26 (38)	33 (59)
TKA (%)	4 (6)	8 (14)
BKA (%)	38 (56)	15 (27)

AKA: above knee amputation; TKA: through knee amputation;

BKA: below knee amputation.

No significant differences in mean age or sex distribution among the two groups were found ($p > 0.05$).

Table 2. Comparison of anaesthetic techniques before and after the implementation of the guideline.

	Pre-guideline	Post-guideline
General anaesthetic	43 (63%)	39 (70%)
+ Femoral single-injection block	14	15
+ Sciatic single-injection block	12	1
Spinal	25 (37%)	17 (30%)
Bupivacaine 0.5% only	10	0
Bupivacaine 0.5% and diamorphine	2	10
Bupivacaine 0.5% and fentanyl	11	2
+ Femoral single-injection block	0	3
+ Sciatic single-injection block	2	1
Epidural/CSE	4	0

CSE: Combined spinal epidural.

Results

A comparison of the two cohorts can be seen in Table 1.

Table 2 compares the anaesthetic preference and analgesic choices in the two cohorts.

Adherence to the guideline was examined. Preoperatively, 19 (35%) of patients were reviewed by the acute pain team after the guideline was implemented. Thirty-one patients (55%) were commenced on preoperative anti-neuropathics compared to 14 (21%) previously. All patients were seen by the acute pain team in the postoperative period following the implementation of the guideline compared to 37% before implementation.

A low pain score was equated to a median pain score of either zero or mild pain during the 7 days after surgery. Reviewing the patients prior to the guideline implementation, those that received neuraxial

Graph 1. Percentage of patients reporting each maximal pain score during the postoperative 6-day period, prior to the guideline (■) and following the implementation of the guideline (■).

anaesthesia had lower pain scores compared to GA alone (13% vs 19%). Spinal anaesthesia with LA (bupivacaine 0.5%) and opioids (diamorphine) provided the lowest pain scores over the following 7 days compared to plain spinal anaesthesia (10% vs 14%). PCA and rescue/breakthrough pain oral opiates provided very poor pain relief.

All patients had a perineural sciatic catheter sited intraoperatively. Forty-three (78%) patients received the 10mL bolus 0.25% bupivacaine in theatre. Eighteen patients (32%) received a single-injection femoral block in addition, performed by the anaesthetist. Of these, 11 (61%) were AKA.

Fifty-three percentage were commenced on a basal rate of 5mL/h of 0.2% ropivacaine via the ambIT pump. Two patients (4%) required an increase in the basal rate to 10mL/h. Forty-seven percentage were started on 10mL/h. There was no difference in pain scores between the two rates.

Only 19 patients (34%) required a breakthrough bolus of 10mL from the ambIT pump. The number of boluses given ranged from 2 to 16 mg per patient over the postoperative period. The majority of patients received either 1 ($n = 6$) or 2 ($n = 5$) boluses with two patients receiving more than seven boluses.

The median duration of perineural sciatic catheter was 4 days (range: 2–6 days). Catheter-related problems were seen in four patients; one patient's catheter was displaced and on two occasions, the patient inadvertently removed the catheter. Additionally, the infusion was stopped after 4 days in one patient due to the onset of oral metallic tasting symptoms possibly early LA toxicity. The symptoms immediately resolved and they had an uneventful postoperative follow-up.

Graph 1 describes the maximal pain scores reported by patients at any point during the postoperative 6-day period. The post-guideline group demonstrated a greater proportion of patients (34%) reporting no pain

(pain score=0) compared to the pre-guideline group (3%). After introduction of the guideline, 25 out of 56 (45%) reported a pain score of ≥ 2 in the postoperative period as compared to 73% in the pre-guideline group.

The total pain scores reported in the postoperative period are shown in Table 3. A greater proportion of patients reported pain-free episodes in the postoperative period (pain score=0) compared to pre-guideline.

Table 4 illustrates the statistical analysis comparing the highest pain scores at postoperative time intervals in both groups. Pain scores were lower at all time intervals in the postoperative period following the guideline introduction. Statistically significantly ($p < 0.05$) reduced pain scores were found upon admission to the ward, 6, 12, 24 hours and 2 days post surgery.

Fourteen out of 56 (25%) patients reported symptoms of PLP in the post-guideline implementation group. Thirty-one patients (55%) had been commenced on either gabapentin or pregabalin, an increase from 21% previously.

Graph 2 compares the percentage of patients with a pain score of ≥ 1 through the whole postoperative period. Prior to the guideline, a greater proportion of patients had moderate to severe pain at all time intervals.

The postoperative analgesia requirements in both groups are shown in Table 5.

Table 3. Global rate for each pain score and its respective proportion (%) prior and following introduction of the guideline.

	Pre-guideline (%)	Post-guideline (%)
Pain score 0	452 (61)	454 (78)
Pain score 1	128 (17)	60 (11)
Pain score 2	109 (15)	48 (8)
Pain score 3	54 (7)	17 (3)

Eighteen patients (26%) received a PCA prior to the guideline compared to two patients (4%) after the guideline introduction. All patients were prescribed regular paracetamol. With regard to opioids in recovery, 49 out of 56 (88%) patients required no rescue opiates in the guideline group. During the postoperative 6-day period, 12 patients (21%) required no breakthrough opioid analgesia compared to 6 patients (9%) prior to the guideline implementation.

Discussion

It is well established that poorly controlled preoperative pain can lead to severe postoperative pain and PLP.⁹ We successfully introduced a multimodal perioperative pain management guideline for major lower limb amputation. There was a significant reduction in pain scores postoperatively, with a smaller number of patients requiring breakthrough opioid analgesia.

Graph 2. Percentage of patients prior to the guideline (■) and following the implementation of the guideline (■) who had a pain score of ≥ 1 over during the postoperative period.

Table 4. Kendall's tau-b statistical analysis of pain scores at postoperative time intervals before and following introduction of the guideline.

	Pre-guideline pain scores (%)				Post-guideline pain scores (%)				Kendall's tau-b	p value
	0	1	2	3	0	1	2	3		
Recovery	54 (79)	4 (6)	6 (9)	4 (6)	45 (80)	6 (11)	1 (2)	4 (7)	-0.018	0.833
Ward	41 (60)	11 (16)	7 (10)	9 (6)	47 (84)	4 (7)	1 (2)	4 (7)	-0.241	0.005
6 hours	39 (57)	17 (25)	8 (12)	4 (6)	45 (80)	2 (4)	1 (2)	4 (7)	-0.198	0.02
12 hours	35 (51)	15 (22)	14 (21)	4 (6)	49 (88)	3 (5)	2 (4)	2 (4)	-0.351	0.001
24 hours	42 (62)	10 (15)	14 (21)	2 (3)	44 (79)	7 (13)	3 (5)	2 (4)	-0.181	0.035
Day 1	35 (51)	11 (16)	14 (21)	8 (12)	34 (61)	10 (18)	9 (16)	3 (5)	-0.11	0.197
Day 2	30 (44)	20 (29)	13 (19)	5 (7)	38 (68)	8 (14)	10 (18)	0 (0)	-0.212	0.012
Day 3	43 (63)	11 (16)	9 (13)	5 (7)	42 (75)	6 (11)	8 (14)	0 (0)	-0.128	0.141
Day 4	41 (60)	10 (15)	9 (13)	8 (12)	46 (82)	8 (14)	2 (4)	0 (0)	-0.259	0.003
Day 5	41 (60)	13 (19)	13 (19)	1 (1)	48 (86)	3 (5)	0 (0)	0 (0)	-0.263	0.003
Day 6	51 (75)	6 (9)	6 (9)	5 (7)	53 (95)	3 (5)	0 (0)	0 (0)	-0.269	0.001

Table 5. Postoperative opioid requirements in the pre-guideline and post-guideline groups.

	Pre-guideline (n=68)		Post-guideline (n=56)	
	Regular (%)	Break-through (%)	Regular (%)	Break-through (%)
PCA	18 [26]	–	2 [4]	–
Intravenous morphine	–	30 [44]	–	3 [5]
Oral morphine	9 [16]	43 [63]	4 [7]	27 [48]
Tramadol	14 [21]	4 [6]	2 [4]	3 [5]
Co-codamol (30/500)	23 [34]	5 [7]	7 [13]	1 [2]

PCA: patient-controlled analgesia.

Despite debate over the value of preoperative administration of anti-neuropathic medications to reduce the incidence of PLP, there is growing evidence that gabapentinoids are effective in reducing immediate postoperative pain and opioid consumption.¹⁰ A Cochrane review of 13 studies found that there was a trend towards benefit with the use of gabapentin in this group of patients.³ Higher dose regimens appear more effective than lower dose regimens. Adequate duration of treatment is unknown, but studies with the most compelling outcomes have prescribed gabapentinoids as an acute pain adjuvant for approximately 2 weeks postoperatively.¹¹ A significant number of our patients were already on anti-neuropathic agents for pre-existing pain and if required their doses were optimised. For those not on any gabapentinoids, gabapentin was commenced and then titrated perioperatively (see Figure 2). We started our patients on subtherapeutic doses and titrated up as tolerated to minimise the increased risk of drowsiness seen at therapeutic doses in gabapentinoid-naïve patients. In our study, gabapentin was discontinued on day 2 in one patient due to drowsiness. Pregabalin was not the first line gabapentinoid of choice due to financial implications and also was not part of the Trust formulary.

Neuraxial anaesthesia has been shown to provide better analgesia in the first postoperative week for patients undergoing major lower limb amputations.¹² This was in keeping with our audit and was highlighted in the pre-guideline cohort data. The use of intrathecal diamorphine was found to produce the lowest pain scores compared to plain (bupivacaine) or bupivacaine with fentanyl preparations. Basal infusions via perineural catheter improve baseline analgesia, decrease the incidence and severity of breakthrough pain, decrease the requirement for supplemental analgesia and reduce patient sleep disturbance.^{13,14}

Our perineural sciatic catheter infusion regime was not associated with any complications of increased stump swelling, wound breakdown or delayed healing. Where the higher initial basal rate of 10 mL/h was used, pain outcomes were similar.

We used the ambIT pump, a simple, hand-held, portable device which delivered a background infusion and

allowed the patients to self-administer bolus doses of 0.2% ropivacaine safely if breakthrough analgesia was required. This had the added benefit of decreasing overall nursing time.

Our surgical colleagues' feedback was that the perineural sciatic nerve catheters were technically straightforward to place and guide along the sciatic nerve. However, due to the blind placement technique, the operators were unable to confirm the location of the catheter tip. Usually, an attempt was made to advance the catheter in parallel to the sheath. Ensuring placement proximal to the bifurcation of the sciatic nerve could not be guaranteed in BKA patients. Ultrasound guided placement of the perineural sciatic catheter could have been performed in the upper/mid- thigh but was limited by operator expertise. However, it would allow consistent placement above the bifurcation. Thirty percentage of patients in the post-guideline group received a single-injection femoral block which is useful in AKA in particular.

Patients undergoing lower limb amputations are typically high-risk surgical candidates, presenting with a number of comorbidities. Opiate sparing interventions would appear to have numerous benefits in this group. Oral morphine administration for postoperative breakthrough pain was the main analgesic intervention in many patients. This may have been associated with greater familiarity with its use. Since the audit, we have increased the education and awareness of the use of LA boluses as first line for rescue analgesia.

All patients were reviewed postoperatively by the acute pain team and if needed, pain relief was optimised. The evidence of acute pain team input in reducing perioperative pain, improving morbidity and enhancing patient satisfaction is increasing.¹³ Anecdotal reports from the ward physiotherapists found increased engagement by the patients in the rehabilitation programmes, mainly due to reduced pain issues during the sessions.

Our sample size for both audits although small, was still greater than most of the studies in a recent systematic review and meta-analysis looking at the use of perineural catheters.¹⁴ In addition, we also analysed pain scores for more than 24 hours unlike other larger studies.¹⁵

However, achieving standardisation between the two audits was challenging and accurate recording of pain scores was dependent on the nursing staff. The time interval between administration of analgesia and obtaining pain scores would have likely affected the data.

Further work is needed to directly compare the use of current pain management techniques. Other interventions may also have a role.¹⁶ For example, salmon calcitonin (a peptide hormone with analgesic properties) administered subcutaneous for 5–7 days has been shown to demonstrate some limited benefit for PLP.¹⁷ Other suggested agents include *N*-methyl-D-aspartate (NMDA) receptors antagonists (e.g. ketamine and memantine).¹⁸ There is insufficient evidence that NMDA antagonists reduce the incidence of phantom or stump pain; however, studies report a decrease in severity of PLP which may lend itself as another adjuvant in the pathway.¹⁶ A systematic review has shown that ketamine infusions in low doses reduced postoperative opioid consumption by 40%.¹⁹

Since completion of the service improvement, we have devised and implemented a major lower limb amputation checklist (see Appendix 1). The aim of this was to ensure a holistic and robust practice in optimising a patient throughout the perioperative period. Pertinent to our work here, it includes a checklist prompting confirmation of acute pain service contact in the preoperative period.

Work is ongoing to identify an appropriate protocol for the perioperative pain management of lower limb amputations.²⁰ The results in our study are very promising and demonstrate potential towards a suitable pathway. A structured, guideline-based approach involving an acute pain team to provide a holistic service, would maximise the effectiveness of a pathway for these patients. In addition, a well-considered education and awareness system for the multidisciplinary team needs to be established in order to provide robust patient-centred care. It is hoped that this multimodal approach leads to better pain management, early rehabilitation and improved patient satisfaction and outcomes.

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Conflict of interest

The author(s) declare(s) that there is no conflict of interest.

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Appendix 1

Major lower limb amputation checklist. This includes confirmation of a pain team referral.

LLaMP Major Lower Limb Amputation Checklist																		
Vascular Consultant:																		
Base Hospital*																		
		Patient label																
Indication for surgery:		<table border="1"> <tr><td>Ischaemic rest pain</td><td></td></tr> <tr><td>Ischaemic rest pain with ulceration and/or gangrene</td><td></td></tr> <tr><td>Neuropathy</td><td></td></tr> <tr><td>Neuropathy with ulceration and/or gangrene</td><td></td></tr> <tr><td>Sepsis</td><td></td></tr> <tr><td>Severe deformity</td><td></td></tr> <tr><td>Other _____</td><td></td></tr> </table>			Ischaemic rest pain		Ischaemic rest pain with ulceration and/or gangrene		Neuropathy		Neuropathy with ulceration and/or gangrene		Sepsis		Severe deformity		Other _____	
Ischaemic rest pain																		
Ischaemic rest pain with ulceration and/or gangrene																		
Neuropathy																		
Neuropathy with ulceration and/or gangrene																		
Sepsis																		
Severe deformity																		
Other _____																		
Preoperative Checklist																		
Diabetes referral (if diabetic) via Intranet 'Think Glucose'																		
Pain referral (bleep weekdays)																		
Anaesthetic review* (via Th3 anaesthetist, Th4 anaesthetist or Ostarred anaesthetist)																		
Rehab Assessment																		
Revascularisation option explored and documented																		
Written information and counselling provided?																		
Formal patient and family discussion?																		
Assessment of Amputation Level		Above Knee	Through Knee	Below Knee														
Name/Stamp	Time of DTT	Date of DTT	Signature															
			Bleep:															
Notes <ul style="list-style-type: none"> • Post-FRCA Anaesthetist should be present • Consultant Surgeon should be present • Surgery performed within normal working hours • Urgent procedures should be performed within 48 hours of the decision to operate 																		

Lower Limb Amputation Checklist