

Original Article

The effect of continuous popliteal sciatic nerve block on unplanned postoperative visits and readmissions after foot surgery – a randomised, controlled study comparing day-care and inpatient management

A. Saporito,¹ E. Sturini,² A. Borgeat³ and J. Aguirre⁴

¹ Senior Consultant Anaesthetist, Anaesthesiology Service, Regional and Ambulatory Anesthesia Unit, Bellinzona Regional Hospital, Bellinzona, Switzerland

² Consultant Anaesthetist, Anaesthesiology Service, St. Chiara Clinic, Locarno, Switzerland

³ Head of Anaesthesia, ⁴ Consultant Anaesthesiologist, Division of Anaesthesiology, Balgrist University Hospital Zurich, Switzerland

Summary

Regional anaesthesia has been shown to have several advantages over general anaesthesia in reducing the need for, and hence cost of, unscheduled outpatient visits or readmission to hospital. However, the benefit has not been evaluated in a direct comparison between day-care patients and inpatients. We randomly allocated 120 patients undergoing unilateral foot surgery to either inpatient (two-day postoperative stay) or day-care management under continuous regional anaesthesia, and compared the impact on unscheduled postoperative outpatient visits, readmissions to hospital and the associated costs. The operations were performed under popliteal sciatic nerve block. A perineural catheter was inserted before surgery and removed from all patients on the third postoperative day. We found no significant difference in the incidence of outpatient visits (3.3% day-care vs 5.0% inpatient, $p = 0.640$), readmissions (6.7% day-care vs 3.3% inpatient, $p = 0.395$) or complications between the two groups. Costs were also significantly lower in the day-care group (net difference €8011 (£6684; \$10 986) per patient, $p < 0.001$). We conclude that continuous regional anaesthesia allows foot surgery to be performed as a day-care procedure more cheaply than inpatients, without an increase in clinical complications.

Correspondence to: J. Aguirre

Email: jose.aguirre@balgrist.ch

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Introduction

Cost constraints are encouraging the use of day-care surgery in Europe. In the USA, 70% of all elective surgery is ambulatory, with over 40% of all outpatient procedures involving orthopaedic surgery [1]. However, a major problem after orthopaedic surgery is severe and sustained postoperative pain [2, 3]; Fortier

et al. showed that pain was responsible for 12% of unplanned readmissions after ambulatory surgery, with 60% of these being after orthopaedic surgery [2]. Foot surgery is increasingly performed in a day-care setting, but moderate to severe postoperative pain challenges day-care management [4]. The use of continuous regional techniques for such patients is effective and

may reduce complications leading to readmission [3, 5]. Moreover, fast-track procedures in anaesthesia for day-care surgery have been introduced to decrease hospital costs [6]; bypassing the recovery room after regional anaesthesia saves time and money compared with general anaesthesia [7–9]. Pain at home and post-operative nausea or vomiting (PONV) remain the main two reasons for prolonged hospitalisation or readmission [10]. However, no previous study has compared day-care patients with inpatients and analysed the effect on unscheduled postoperative outpatient consultations, readmissions or costs of regional anaesthesia-associated complications [11, 12].

Our hypothesis was that a regional anaesthesia-based management technique for day-care patients after foot surgery would be equivalent to inpatient

management. The primary endpoint of the study was the incidence of unscheduled outpatient visits or readmissions. The secondary endpoints were the effects on costs, block quality, patient satisfaction and regional anaesthesia-associated complications.

Methods

After research ethics committee approval and informed consent, patients of both sexes, of ASA physical status 1–3 scheduled for elective, unilateral toe osteotomies or hallux valgus repair under tourniquet, were included in this prospective, randomised study. The study flowchart according to the CONSORT statement is shown in Fig. 1 [13]. Patients were randomly assigned according to a computerised list to either the day-care group or the inpatient group. The anaesthesiologist

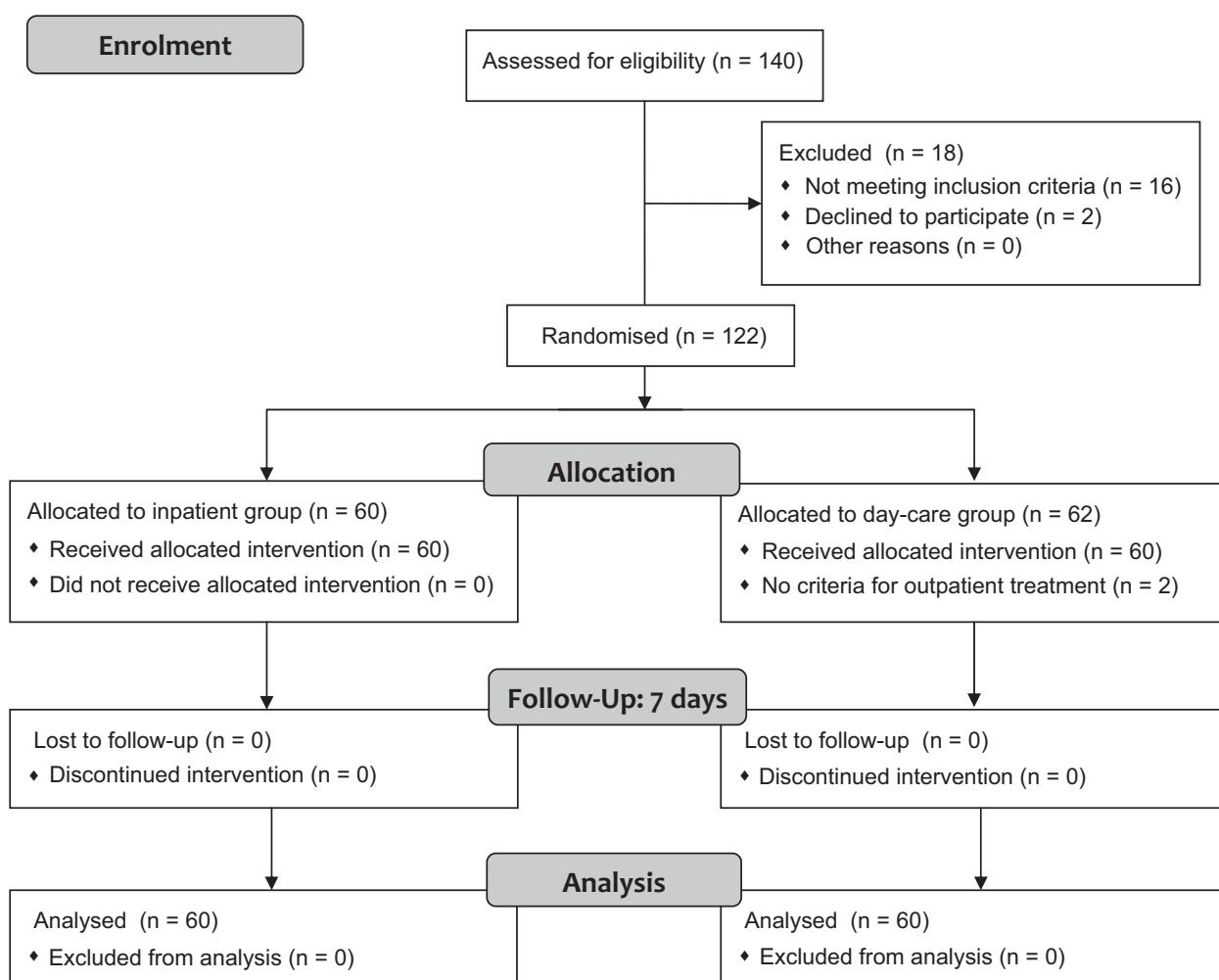


Figure 1 Enrolment flowchart according to the CONSORT statement.

performing all catheter placements (AS) and the study/pain nurses involved in the data collection and patient management were blinded to the final patient allocation; the nurses were only in contact with the patients by telephone. Doctors in the emergency department were also unaware of the group allocation. Therefore, in the case of unplanned visits, the management decisions were not influenced by the group allocation.

Our exclusion criteria were: known allergy to drugs used in the study; coagulopathies; known neuropathies; pregnancy; chronic pain, drug or alcohol abuse; psychiatric diseases or intellectual disability affecting compliance; and evidence of ongoing sepsis or local skin/subcutaneous infection in the popliteal fossa. We used the regional anaesthesia eligibility criteria of Illfeld et al. for treating day-care patients with regional anaesthesia [14]: accompanying person; easy accessibility to hospital (less than one hour's drive); and suitable layout of the patient's home with respect to stairs etc. All day-care patients were provided with additional information by a pain nurse not involved in the study, describing day-care treatment and management. The standard protocol for day-care patient education and follow up was similar to protocols reported in literature and was presented recently in a case report [15, 16].

After arrival in the pre-operative induction room, standard monitoring was applied and peripheral venous access was obtained. Sedation with $1 \mu\text{g}.\text{kg}^{-1}$ fentanyl and 1–2 mg midazolam intravenously was given. All patients underwent the same anaesthetic procedure including an ultrasound-guided sciatic nerve block at the level of the popliteal fossa using an in-plane approach with a 5-cm needle (Contiplex D; BBraun, Melsungen, Germany). Skin disinfection was performed with a two-layer application of an alcoholic povidone-iodine solution. Three minutes later, the area of the puncture point was surrounded with sterile drapes. Two fractioned boluses of mepivacaine 1.5% under sonographic control, aiming for a mean total volume of $20 \pm 5 \text{ ml}$. Thereafter, a perineural catheter (Contiplex set; BBraun) was placed under the nerve 4 cm beyond the tip of the needle, connected to a filter and tested for negative aspiration, flow obstructions and correct catheter tip position and local anaesthetic spread. Block success was evaluated using the presence

of pins-and-needles-type paraesthesiae at the tips of the first, third and fifth toes, and the degree of sensory block (cold test) over the distribution area of the tibial, deep and superficial peroneal nerves every 5 min for 20 min. Additionally, the degree of motor block over the distribution area of the corresponding nerves (no motor block, partial motor block, and complete motor block) was assessed every 5 min for 20 min. Block success was defined as (i) complete sensory block over all corresponding dermatomes and (ii) complete motor block of the corresponding nerves. In the case of an incomplete block 20 min after injection, a rescue block at the level of the ankle (superficial peroneal nerve block or tibial nerve block), with 10 ml mepivacaine 1.5%, was performed. Surgery was performed with no further sedation and 30 mg ketorolac was administered intravenously at the end of the procedure according to our standard clinical practice.

If patients met the criteria for bypassing the recovery room, they were directly discharged to our day-hospital clinic (day-care group) or to the orthopaedic ward (inpatient group) according to their group allocation. These criteria were: a modified Aldrete score ≥ 8 [17]; pain at rest scoring < 3 (0 = no pain; 10 = worst imaginable pain) and the absence of nausea and vomiting. Postoperative systemic analgesia consisted of oral diclofenac 50 mg twice a day and oral paracetamol 1 g every 6 h for the first three postoperative days. The quality of analgesia was assessed at rest and on movement (walking 10 m with half the patient's body weight on the operative side) hourly during the first 3 h by the nurses of the day clinic or the orthopaedic ward. Additional oral oxycodone 5–10 mg was administered if the pain score became 3 or above. Regional analgesia was provided using an elastomeric pump (Easypump; BBraun) with 400 ml ropivacaine 0.2% at 5 ml.h^{-1} with a possible 5-ml bolus every 60 min. The infusion was started 3 h after the initial injection. All patients were instructed to put only half of their body weight on the operative foot and to wear an orthopaedic shoe.

The treatment efficacy and complications, side-effects or incidental problems with perineural catheters were checked by telephone using a standardised questionnaire by the study/pain nurses at 3, 24, 48 and 72 h after surgery in both groups. It included: pain

score while walking; Bromage score for the motor block; PONV; a specific inquiry about stumbling/falling; signs of infection (high temperature, pain and/or redness around insertion point) and any other complication. An anonymous satisfaction questionnaire addressing the continuous regional analgesia protocol was handed out at hospital discharge to all patients, to be filled in and sent back one week after catheter removal.

Inpatients were managed according to our current clinical standard, with a two-night length of stay, whereas day-care patients were discharged home from the day-hospital clinic after an observation period of 3 h if the sensory and motor block of the toes and ankle had worn off. Patients were given a phone number manned 24 h a day by the study/pain nurses on duty, and managed with our standard questionnaire as mentioned above. The anaesthesiologist who inserted all catheters was available in case the patients or nurses had additional problems or questions.

A pain score of ≥ 3 was treated with a rescue bolus of 5 ml ropivacaine 0.2% and reassessed after 20 min. If pain was persistent, patients were readmitted to the day-hospital clinic to check catheter function. Persistent motor block of the ankle was treated with a temporary interruption of the infusion for 1 h by closing the clip on the infusion line. If this persisted after 20 min, they were checked in the emergency department by an anaesthetist not aware of group allocation. On the third postoperative day, patients in both groups were instructed over the phone to remove the perineural catheter themselves. Patients were managed as in Fig. 2.

The incidence of outpatient visits and readmissions was monitored for the first seven days after surgery. Readmission criteria were standardised and communicated to the emergency department to guarantee group-independent treatment to all patients: a pain score of ≥ 3 despite oral analgesics and functioning continuous perineural block; intractable PONV; clear signs of local infection (the appearance of pus at the catheter insertion site) or systemic infection (fever $>37.5^{\circ}\text{C}$ or the occurrence of rigors); and signs of systemic local anaesthetic toxicity. Indications for outpatient visits were standardised for inpatients and day-care patients as catheter-related complications

(local inflammation: redness, swelling or pain on pressure at the continuous perineural block insertion site; paresis despite stopped infusion), systemic complications such as PONV or technical problems that could not be solved over the telephone.

Costs for inpatients and day-care patients were calculated considering personnel costs (nursing, resident and consultant visits, nurses' time spent on the telephone and costs of phone calls, etc.), costs for the room and related services (food, cleaning, service, etc.) and material costs (drugs, pumps, etc.). All costs were calculated as mean costs per day for the orthopaedic ward multiplied by the days of stay. Costs for outpatient visits were calculated according to the actual Swiss Health System billing system, which charges every 30 min of consultation irrespective of the severity of the case. This direct and indirect cost calculation is in accordance with previous studies [18, 19]. Additional readmission costs were calculated according to the Swiss Health System billing system. An ambulatory rate was applied in the case of admission for less than 24 h. All costs were according to the data furnished by the hospital's finance department. Costs were expressed in different currencies (€, £, \$ with exchange rates at December 20th 2013) for better comparison with international literature.

Our previous pilot work suggested an incidence of outpatient visits due to complications for patients initially managed as inpatients was 8.5%, a rate reflected in published reports [3, 20–22]. We hypothesised that the incidence of outpatient visits in day-care patients after foot surgery treated with continuous perineural blocks would be similar to that in inpatients. The power calculation required a sample size of 30 patients per group to reject the null-hypothesis with an α risk of 0.05 and a power of 0.8. To increase the power of our results and to compensate for possible dropouts, we included 60 patients per group.

Differences in the level of analgesia and in the complication rate were taken into account for the economic assessment of the treatment in the two groups. This was performed through a cost-effectiveness analysis, expressed in terms of a ratio where the denominator is either 1 point on the numerical rating pain scale and/or a 1% reduction in complications, while the numerator is represented by the cost associated with the gain. Where

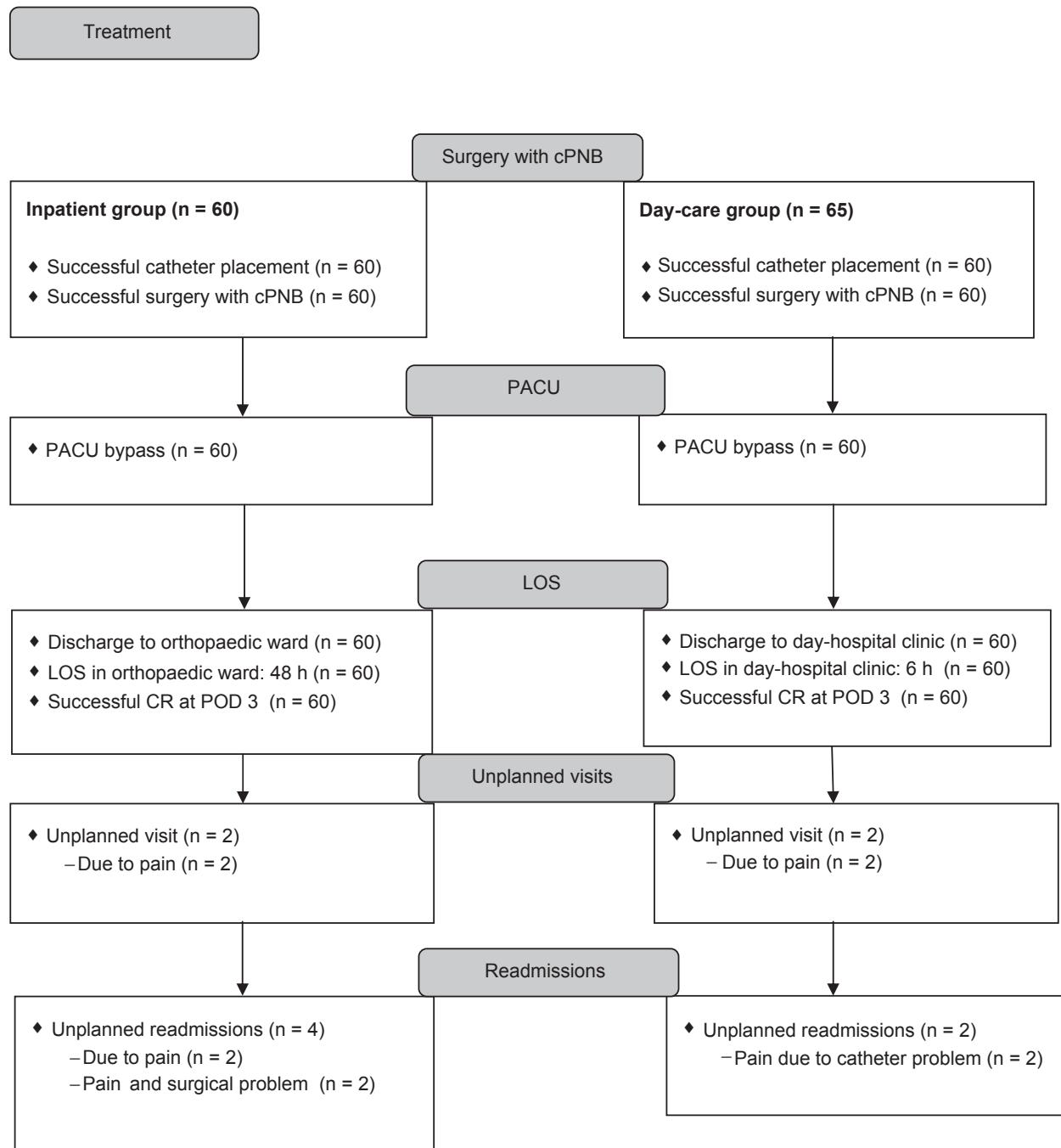


Figure 2 Treatment flowchart. cPNB, continuous popliteal nerve block; LOS, length of stay; PACU, postanaesthesia care unit; CR, catheter removal; POD, postoperative day.

the two treatments are equivalent, we applied a cost-minimisation evaluation instead [23, 24]. A 'top-down' technique was used to estimate the costs related to working time professionals spent in the processes, while micro-costing was adopted to address costs related to drugs and devices employed in the two groups. Fixed

costs (material and resources required for operation, anaesthesia and postoperative continuous regional analgesia), in-hospital management-related costs (orthopaedic ward vs day-hospital stay) and postoperative management-related costs (unexpected readmissions or outpatient visits, corrected for their respective

probabilities) were taken into account. Fixed costs were considered equivalent in the two groups, as operation and anaesthesia were standardised by protocol. We used the unpaired t-test for continuous data and the Mann–Whitney U-test for non-continuous data. A p value < 0.05 was considered statistically significant. Statistical analysis was performed using SPSS (IBM, New York, NY, USA) and Numbers '09 2.1 version (Apple Inc., Cupertino, CA, USA) software.

Results

We initially randomly allocated 122 patients for the study; two patients from the day-care group were not studied because they did not meet the criteria for day-care treatment (Fig. 1). Thus, data from 120 patients (60 patients per group) were available for analysis; no patient was lost to follow-up (Fig. 2). The two groups did not differ in terms of population and surgical characteristics (Table 1).

Both groups had a similar need for outpatient visits (3.3% day-care patients vs 5.0% inpatients, p = 0.640) and readmissions (6.7% day-care patients vs 3.3% inpatients, p = 0.395) (Fig. 2). Two patients in the day-care group were readmitted the day after discharge for catheter-related problems (obstruction and displacement). Four patients in the inpatient group were readmitted because of persistent pain despite oral medication at home.

Table 1 Characteristics, surgical details and post-anaesthesia care unit bypass (PACU) data of patients receiving continuous popliteal sciatic nerve blockade as day-care or inpatients. Values are mean (SD), number or number (proportion).

	Day-care patients (n = 60)	Inpatients (n = 60)
Age; years	59.4 (7.1)	60.1 (12.8)
Male/female	11/49	13/47
ASA status; 1/2	12/48	10/50
Type of surgery (osteotomies 2nd–5th toes/hallux valgus correction)	22/38	20/40
Incidence of incomplete block	5 (8.3%)	4 (6.7%)
Criteria fulfilled for PACU bypass	60 (100%)	60 (100%)
Follow-up successful	60 (100%)	60 (100%)

The cost-minimisation evaluation performed to compare in-hospital and out-of-hospital anaesthesia and analgesia-related costs during the first 72 h post-operatively is summarised in Table 2.

The net difference in costs in favour of day-care management was €8011 (£6684; \$10 986) per patient (p < 0.001). There was no difference in adverse events between the groups, as shown in Table 3. Inflammation at the catheter insertion point was reported in 4 (6.7%) patients in both groups; all occurred on the third postoperative day. Day-care patients were seen in the day-hospital clinic as outpatients by a consultant anaesthetist; in all these cases, catheters were removed. In four cases, systemic oral antibiotic therapy was prescribed with oral amoxicillin/clavulanic acid for signs of local infection. In all other cases, local disinfection therapy was performed. All patients in the day-care group were successfully discharged from the day-hospital clinic without need for rescue analgesia, while two inpatients required oxycodone during the first three postoperative hours.

There was no difference between the groups concerning pain during regional anaesthesia or after catheter removal (Table 3). No readmission was needed after catheter removal. Kinking of the catheter tip, probably due to insertion technique or to straining by surrounding tissue during leg flexion, was observed in 1.6% of day-care patients, while no case occurred in the inpatient group (p = 0.323). The complications are summarised in Table 3.

Table 2 Cost data of patients receiving continuous popliteal sciatic nerve blockade as day-care or inpatients. Values are mean (SD) in £ per patient.

	Day-care patients (n = 60)	Inpatients (n = 60)	p value
Material and personnel costs	2407 (84)	2407 (84)	1.000
Day-hospital/ward costs	1335 (209)	8216 (354)	< 0.001
Readmission related costs	438 (43)	249 (37)	< 0.001
Unexpected ambulatory visit costs	46 (10)	41 (9)	0.001
Total patient management costs	1785 (101)	8470 (271)	< 0.001

Table 3 Numerical rating pain scores (NRS), postoperative nausea and vomiting (PONV) and block follow-up data for patients receiving continuous popliteal sciatic nerve blockade as day-care or inpatients. Values are median [IQR] or number (proportion).

Characteristics	Day-care patients (n = 60)	Inpatients (n = 60)	p value
NRS on walking 3 h after surgery	2 (1-2.5 [0-4])	2 (1-3 [0-4])	0.550
NRS on walking 24 h after surgery	2 (1-2.5 [0-4])	2 (1-2 [0-3])	0.137
NRS on walking 48 h after surgery	2 (0-2 [0-4])	2 (1.5-3.5 [0-5])	0.563
NRS on walking 72 h after surgery	2 (1-3 [0-4])	2 (2-4 [1-5])	0.248
NRS > 3 for > 24 h after catheter removal	4 (6.7%)	4 (6.7%)	1.0
PONV 24 h after surgery	2 (3.3%)	3 (5.0%)	0.391
New motor block of the ankle after discharge	4 (6.7%)	5 (8.3%)	0.739
Catheter insertion point inflammation	4 (6.7%)	4 (6.7%)	1.0
Stumbling, without injury	1 (1.6%)	1 (1.6%)	1.0
Catheter failure	2 (3.3%)	2 (3.3%)	1.0
Malfunctioning of the elastomeric pump	0	0	1.0

The need for some kind of informal assistance at home during the first week of recovery in patients who did not require readmission or adjunctive ambulatory visits was reported in 15 (25.0%) and 20 (33.3%) patients in the day-care and inpatient groups, respectively ($p = 0.332$). Patients reported similar high levels of satisfaction regarding the different aspects of the treatment (effectiveness, appropriateness, safety, global management and assistance), in both groups.

Discussion

The results of this work supports our hypothesis that day-care management using continuous perineural block for foot surgery does not lead to higher rates of outpatient visits or readmission. Additionally, informal assistance at home during recovery was similar between the groups.

The use of ambulatory sciatic nerve block at home after foot surgery has been reported to be safe and well accepted by patients [3, 5, 25]. Ilfeld et al. showed that continuous perineural block for 3 days was superior to a single-shot popliteal sciatic nerve block in terms of pain, opioid use/related side-effects, sleep disturbance and overall satisfaction [3, 25]. However, 30% of patients required unscheduled phone calls after discharge, emphasising the role of a standard protocol for day-care education and follow-up to avoid complications or unscheduled outpatient visits [3, 15].

The only relevant cost-saving factor between the groups in our study was the reduced length of stay in the day-care group, as both groups had continuous regional anaesthesia [26, 27]. (In our study, both

groups had regional anaesthesia with comparable ready-for-surgery times and all patients bypassed the recovery room). However, complications are an important cost factor. Patients undergoing general anaesthesia show a high incidence of outpatient visits and readmission rates of between 7% and 27% [21, 25, 28]. After regional anaesthesia, outpatient visits and readmissions rates of 4–13% have been described [24]. Our results showed a similar need for outpatient visits and readmissions in both groups, suggesting that management was similar for these complications.

Macaire et al. showed in a prospective, descriptive study including 56 different continuous peripheral blocks (24 continuous peripheral nerve blocks) that this management at home was safe and effective, reducing surgery-dependent costs by 27–40% [29]. However, patients were only discharged on the first postoperative day, the anaesthesia regimen was not standardised and no focus was put on additional visits, readmissions or indirect costs. Moreover, their cost analysis was not described and the factors for cost reduction were not presented in detail. Current literature mainly analyses readmission costs without differentiating between outpatient visits and true hospital admissions, or without taking into account costs deriving from home assistance, additional family doctor visits, etc. [24, 30]. We did not find a difference between the groups either in the number of outpatient visits or in the number of readmissions. However, the costs for these events were higher in the outpatient group. This is related to the billing policy of our health system, in which outpatients visits are calculated in 30-min slots

irrespective of the complication. Apparently, day-care patients were treated for a longer time period, leading to an increase in costs. Additionally, readmissions are charged depending on the length of stay, irrespective of the reason for admission, and have different rates depending on status (day-care or inpatient). These two factors increased the costs of day-care patients even though there was no difference in the number of cases and complications leading to outpatient visits/readmissions, but represent the real costs charged to the (Swiss) health system. However, our results show that ambulatory continuous regional anaesthesia management is cost-effective, with a net saving of € 8011 (£6684/\$10 986) per patient for a similar quality of postoperative care. Moreover, the major money-saving effect of €8246 (£6881/\$11 307) per patient in our setting derived from direct and indirect hospitalisation costs.

The main limitation of this study was the impossibility of blinding patients to the group allocation. This could have led to some bias, such as the greater availability of drugs for pain and PONV for those remaining in hospital. However, all patients were well informed and had access to enough additional drugs; the effect of being aware of group allocation does not seem to have influenced the results. Additionally, the use of return visits to the hospital might be considered a rather crude and insensitive measure of block efficacy, as many patients may tolerate pain or motor block at home without feeling the need to return to hospital. However, the literature suggests that patients do in fact seek help for pain and/or catheter malfunction [14, 24, 25].

This study was not powered to analyse the rate of complications in regional anaesthesia and therefore we cannot draw a definitive conclusion as to whether the incidence of side-effects or complications is different in the inpatient or day-care setting. This question should be investigated on a larger number of patients. Moreover, the costs calculated in this study as a secondary endpoint should be assessed as a primary endpoint in further studies focusing on direct and indirect costs and comparing two regional anaesthesia-based management techniques.

In the light of our findings, we suggest that foot surgery should be performed under continuous

perineural block as a day-care procedure in selected patients.

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Competing interests

No external funding and no competing interests declared.

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