Follow-up of post-bunionectomy pain in two in- and outpatient cohorts: interest in patient analgesic education

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Dear Editor,

In day-case surgery, discharge on oral medication is at risk of inadequate analgesia and side effects in ambulatory patients [1-3]. To be efficient, analgesia has to provide long-lasting pain relief with minimal side effects including sedation, dizziness, nausea, or psychomotor impairment [4]. Bunionectomy is usually considered as painful surgery and continuous popliteal sciatic nerve block for postoperative pain control at home has been described [5]. However, such a sophisticated technique remains expensive, underused and moreover neurological complications have been described [6]. After agreement of appropriate boards and signed consent, this prospective, mono-centric, singleoperator study evaluated the analgesic efficacy of oral medication and preoperative advice to treat pain after discharge in two cohorts of in- and outpatients scheduled for bunionectomy from April 2015 to April 2016. Seventy-three patients were included and operated on under combined ultrasonic popliteal sciatic and saphenous blocks with 1.5% lidocaine at the dose of 4 mg kg⁻¹ and use of a tourniquet. Before surgery, each patient had a preoperative anesthetic consultation and received analgesic prescription and advice with a visual analogic scale (VAS) to take medicine at home and when using rescue doses. From discharge from the post-anesthesia care unit (PACU) on the first day, the analgesic oral protocol consisted of paracetamol $(4 \times 1 \text{ g})$ and ketoprofen $(2 \times 100 \text{ mg})$ for seven days. When VAS > 4, rescue was tramadol (50 mg

1 to 4 doses per day) in outpatient or immediate release morphine 10 mg – 1 to 3 doses in the group hospitalized on the first night. Figure 1 highlights the flow of patients throughout the study.

Mean daily pain as the main criterion was evaluated with the VAS at rest and walking, analgesic use and rescue treatment from day (D) 1 to day 7. Patient adherence to the protocol was assessed with a personal diary and phone interview. Fatigue at D2 and D7 was assessed using a Pichot scale from 0 to 32 with severe fatigue if > 22, measuring respectively depressive mood, fatigue and anxiety dimensions [7]. Quality of sleep and life was monitored through the EQ-5D questionnaire with eight items (pain, mobility, mood, self-care, activities, sleep, sex, and need for analgesic) [8]. Sixteen patients were excluded from the study.

Demographic data are summarized in Table 1.

VAS values (0-100 mm) from D1 to D7 in both groups are presented below with an average pain at rest < 30 mm of D3 and for walking on D4. Comparison of means for daily pain (VAS) in 73 individuals with reference to 30 mm was 19.67 ± 12.03 (95% CI: 16.86-22.47) at rest and 28.31 ± 14.85 (95% CI: 24.85-31.77) for walking, P < 0.0001 and P > 0.05 respectively (unilateral Student's *t*-test with $\alpha = 5\%$). In the postoperative period from D1 to D7, the average resting pain observed in the 73 patients was 19.67 \pm 12 mm (range 0 to 100 mm). The average pain in the ambulatory group was less intensive than in the hospitalization group (17.12 \pm 10.35 mm

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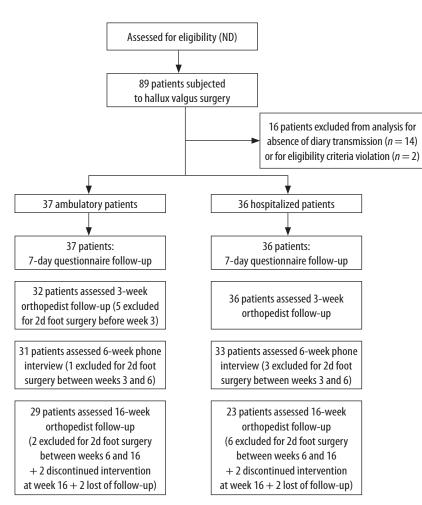


FIGURE 1. Consort diagram highlighting the flow of patients throughout the study

TABLE 1. Patients' characteristics

Demographic data, 89 patients	Outpatients , 44 patients (7 withdrawn)	Inpatients, 45 patients (9 withdrawn)	Sum, 89 patients (16 withdrawn)
Patient (n)	37	36	73
Working/no (%)	68/32	33/67	51/49
Age, years (M ± SD)	53.3 ± 12.4	58.9 ± 10.2	56.1 ± 11.4
Female/male (n)	33/4	35/1	68/5
BMI, kg m ⁻² (M \pm SD)	23.3 ± 3.5	25 ± 4.3	24.1 ± 3.9
Bunionectomy (n)	27	2	29
Bunionectomies plus other toes (n)	10	34	44
0/1/2 days (n)	37/0/0	0/9/27	37/09/27

vs. 22.28 ± 13.19 mm), but this difference is not significant at the 5% level. The objective of the study was to demonstrate that the analgesic protocol associating paracetamol, ketoprofen and tramadol was able to moderate rest pain lower than or equal to 3 on a numerical scale or 30 mm on a visual analog scale during the 7 postopera-

tive days. The observed mean of the primary endpoint was compared to the 30 mm baseline using one-tailed Student's test. The result gave a very significant value P < 0.0001.

All patients had P for at least 4 days, up to 80% from D5 to D7 and 75% of patients had K for 4 days and up to 50% on D7. Eighty percent of patients

had T on D1 but with less than 50% on D4 and 25% on D4. Adverse effects were reported in 80% of patients due to painkillers in 90% of the cases. 60% of patients took at least one rescue (T) between D1 and D7 (2.4 per patient), especially the first 24 hours (40%), then it decreased with a rebound from D5. Outside the call interview, no consultation relative to pain was registered for both groups. More than 80% of patients reported at least one nonserious adverse event (AE) during the 4 months of study. A total amount of 304 AEs were registered; 41 required corrective treatment (13.5% grade 2 AEs). There was no significant difference in the frequency of AEs between the 2 groups. The most common AEs were gastrointestinal disorders (253/304 or 83%) usually caused by analgesics (opioids, tramadol, ketoprofen) and 75% of patients were affected. Among these digestive AEs, nausea and constipation are the most common and represent one third of these disorders.

Sleep is essentially disturbed on the 1st night. Level of fatigue is low < 20 (Pichot scale). At D7, quality of life monitoring (EQ-5D) shows that 45% of patients complain of difficulties with autonomy, mobility, routine activities and anxiety. As more surgical procedures migrate to the outpatient setting, postoperative pain control at home will become increasingly more challenging to clinicians. Perineural techniques are good alternatives for painful orthopedic surgery but remain underused and clearly difficult to manage at home [9]. Guidelines for postoperative pain control recommend pain assessment using validated tools and VAS has to be used by a patient to manage his own treatment. Conversely our study supports the efficiency of only oral multimodal analgesia combined with patient education. Monitoring of the study may have facilitated patient adherence to the protocol, which is an efficacy factor. It also suggests the interest of immediate release morphine as rescue for only the first 24 hours. Complaints about autonomy, mobility, routine activities and anxiety recall the social

dimension of surgery and claims for specific help in isolated patients. Specific postoperative pain management protocols may reduce pain, improve patient satisfaction and reduce side effects.

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