



Original Article

Perioperative pain and post-operative nausea and vomiting (PONV) management after day-case surgery: The SFAR-OPERA national study



Frédéric Aubrun^{a,*}, Claude Ecoffey^b, Dan Benhamou^c, Laurent Jouffroy^d, Pierre Diemunsch^e, Kristina Skaare^f, Jean Luc Bosson^f, Pierre Albaladejo^{f,g}

^a Department of anaesthesiology and intensive care medicine, hospices Civils de Lyon, Lyon Croix Rousse university hospital, HESPER 7425 research team, Claude-Bernard Lyon 1 University, 69004 Lyon, France

^b Department of anaesthesia and intensive care, CHU de Rennes, Inserm UMR 991 and CIC 1414, Rennes 1 university, 35033 Rennes, France

^c Department of anaesthesiology and intensive care medicine, groupe hospitalier et faculté de médecine Paris Sud, AP-HP, hôpital Bicêtre, 94270 Le Kremlin-Bicêtre, France

^d Rhéna clinique de Strasbourg, Maison médicale des 2 Rives. 67000 Strasbourg, France

^e Department of anaesthesiology and intensive care medicine, university hospital of Haute-pierre, 67000 Strasbourg, France

^f Clinical investigation centre, Grenoble university hospital, ThEMAS, TIMC, UMR, CNRS 5525, university Grenoble-Alpes, 38700 Grenoble, France

^g Department of anaesthesia and intensive care medicine, Grenoble university hospital, 38700 Grenoble, France

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ABSTRACT

Objectives: Since pain and post-operative nausea and vomiting (PONV) are the main reasons for failed discharge after day-case surgery, assessing pain and PONV is important. The aim was to describe the perioperative pain and PONV management within selected day-case surgical procedures in France.

Methods: The OPERA trial was carried out on given days between December 2013 and December 2014. Each participating centre was required to fill out 3 separate questionnaires aiming at describing (1) protocols about pain and PONV, (2) patients' characteristics and procedures, (3) analgesic and PONV practice patterns for selected procedures.

Results: Over the two days of investigation in each of the 221 randomly selected healthcare institutions, 7382 patients were included, of whom 2144 patients above 12 years underwent one of 10 selected procedures. Among responding institutions, 40% [33;47] had a dedicated pain management written protocol. Combination of tramadol and paracetamol was the most commonly prescribed (78% [71;83] of centres). Oral morphine was prescribed in 59/199 (30% [23; 37]) centres, for home treatment in 25/59 (42% [30; 56]) centres. However, there was no standardised take-home analgesic and PONV strategies for selected surgical procedures at risk of moderate to severe pain. PONV management guidance after discharge was included in only 12 % of centres.

Conclusion: This survey demonstrates that practice patterns for pain treatment and PONV prophylaxis after ambulatory surgery vary among French centres and are not always in line with national guidelines. Strategies to improve practices and make them more homogeneous are necessary.

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1. Introduction

Ambulatory surgery is increasingly used in most western countries. In France, the goal is to reach a target close to 66% of patients treated in ambulatory conditions in the next years

* Corresponding author at: Department of anaesthesiology and intensive care medicine, hospices civils de Lyon, Lyon Croix Rousse university Hospital, 103, Grande rue de la Croix Rousse, 69004 Lyon, France.

E-mail address: frederic.aubrun@chu-lyon.fr (F. Aubrun).

[1]. Since pain and post-operative nausea and vomiting (PONV) are, by far, the main reasons for failed discharge after day-case surgery [1–6], having a focus of post-operative pain and PONV after day-case surgery is of major importance. Therefore, the French Society of Anaesthesia and Intensive Care Medicine (SFAR) designed an observational survey at a national level, the SFAR-OPERA study (“*Organisation PeriopERatoire de l’anesthésie en chirurgie Ambulatoire*”). The aim of this study was to describe the structure, organisation, patients' characteristics, and the perioperative and anaesthetic management for selected day-case

surgical procedures. Results from this study have been partially published previously [7] together with the methodology of the survey: description of facility organisation, patient characteristics, as well as anaesthetic and perioperative care details for a selection of programmed procedures.

No large-scale study has been published so far in France about pain management or nausea or vomiting prevention in outpatient surgery. The main objective of the study was to assess pain and PONV management after outpatient surgery using a prospective survey carried out on given days, in a large sample of French healthcare institutions and to compare results to guidelines previously published by the SFAR.

2. Methods

The methods of the OPERA study have been published elsewhere [7]. Briefly, OPERA is an observational, prospective survey carried out in randomly selected French healthcare institutions with an ambulatory facility, between December 2013 and December 2014. During two consecutive days which had been randomly distributed among the participating centres, each centre was required to fill out 3 separate questionnaires regarding [1] their structure and organisation (protocols and patient's information about pain), [2] the overall practice pattern by recording simplified patient characteristics and procedures, [3] a detailed description of perioperative pain and PONV management of patients undergoing one of 10 procedures [oral surgery (third molar removal), knee arthroscopy, surgery of the abdominal wall (including inguinal hernia), perianal surgery, varicose vein surgery, laparoscopic cholecystectomy, breast surgery (tumorectomy), uterine surgery, hallux valgus, hand surgery (excluding carpal tunnel)]. Questionnaires # 1 and # 3 were the only ones analysed in this study. The second questionnaire was focused of patients' characteristics and types of surgery and not on pain and PONV management.

Study coordination was carried out by the Clinical Investigation Centre at the Grenoble University Hospital. Approval by [1] the Clinical Investigation Centre Ethics Committee for the Rhône-Alpes Auvergne region, [2] the advisory Committee on Information Processing during Research in the field of Health (French National Committee) and [3] the national Commission on Computerised data and Liberties (France) were obtained on 25 February 2013, 18 April 2013, on 20 December 2013, respectively. The study was also declared on www.clinicaltrials.gov (NCT02380430). An information letter was provided to all included patients.

Statistical analyses were performed using STATA version 13 (StataCorp LP, 4905 Lakeway Drive, College Station, Texas 77845 USA). No replacement of missing data was performed. Some centres/patients omitted to complete all paragraphs of the questionnaires. In the case of binary yes/no questions, missing answers are treated as "no" for centres/patients who completed the paragraph and missing otherwise. For all other types of questions, percentages and medians are calculated on non-missing data. The number of answering centres and non-missing data is presented in the tables. Percentages are rounded to one decimal and presented with their 95% confidence interval. Quantitative variables are described by their median value and the 25th and 75th quantiles. No statistical tests are performed.

Statistical analyses were performed using STATA version 13 (StataCorp LP, 4905 Lakeway Drive, College Station, Texas 77845 USA).

Percentages are presented using the total number minus missing data for the denominator and the number of centres or patients with the studied characteristic for the numerator and are rounded to one decimal.

3. Results

3.1. Centre selection

A primary list of healthcare institutions with outpatient units was established by the SFAR ambulatory group based on data obtained via the *Agences Régionales de Santé* [Regional Health Agencies, France: www.ars-sante.fr]. Three hundred centres were randomly chosen from an updated version of the latter list (893 health institutions), with stratification according to type of healthcare institution [general hospital, university teaching hospital, private institution, non-profit private institution (of public interest)] and region. A complementary list of 71 additional centres was also selected to make up for potential participation refusal or lack of response. After this first recruitment campaign, a second list of 114 centres accompanied by a supplementary list of 18 centres was randomly selected from the residual list. Spontaneous applications were accepted (15 centres) and 43 university hospitals were directly contacted. A total of 561 centres were contacted, 262 health institutions agreed to participate and 221 actually completed the survey. The practice survey was thus carried out between December 2013 and December 2014.

A total of 206 health institutions participated to the structure survey. Over the two days of investigation, 7382 patients were included in the patients' survey in 210 centres. Among these 7382 patients, 2174 patients underwent one of 10 selected procedures [7] (Fig. 1), and 2144 were above 12 years.

4. Structure survey: facility's structure and organization

4.0.1. Protocols and patient's information about pain

Among responding institutions, 40% [33; 47] (81/201) had a dedicated written protocol for post-operative pain management after day-case surgery. Protocols were mainly written by anaesthetists [60% [49; 71] (49/81)] and by CLUD (Local Pain Committee) (25% [16; 36]) or by joint work between surgeons and anaesthesiologists (14% [7; 23]). Post discharge pain management guidance was included in 65% [54; 76] (53/81) of the protocols. Specific protocols for pain management in children were implemented in 42% [35; 49] (85/201) of the centres (51% [40; 61] in private hospitals). Specific protocols for pain management in elderly patients were implemented in 18% [13; 24] (37/201) of responding centres (8% [2; 22] in university hospitals). Pre-operative information on post-operative pain was given to patients in 87% [81; 91] (174/201) of cases; either orally [48% [40; 55] (83/174)], by leaflets (5% [2; 10] (9/174)), or both [47% [40; 55] (82/174)]. Patients were asked to sign the information document in 23% [17; 29] (46/201) of the centres. Analgesic prescriptions were standardised and pre-printed in 41% [34; 48] (82/199) of centres. They were mostly signed by surgeons [57% [50; 64] (114/199)] and given to patients at the time of discharge [92% [87; 95] (183/199)]. In 59% [52; 66] (117/199) of centres, analgesic pills were given to the patient before discharge.

4.0.2. Pain assessment

Among tools that were used, VAS (visual analogue scale) and NRS (numerical rating scale) were the most frequently used evaluation tools in 72% [65; 78] (144/201) and 51% [44; 58] (102/201), respectively (Fig. 2A). Pre-operative information on how the tool had to be used was provided in 44% [37; 51] (88/201) of centres. Pain was assessed in the PACU in 97% [93; 99] (194/201), before discharge in 91% [86; 94] (182/201), at home in 40% [33; 47] (80/201) and by phone in 39% [32; 46] (78/201) (Fig. 2B) and

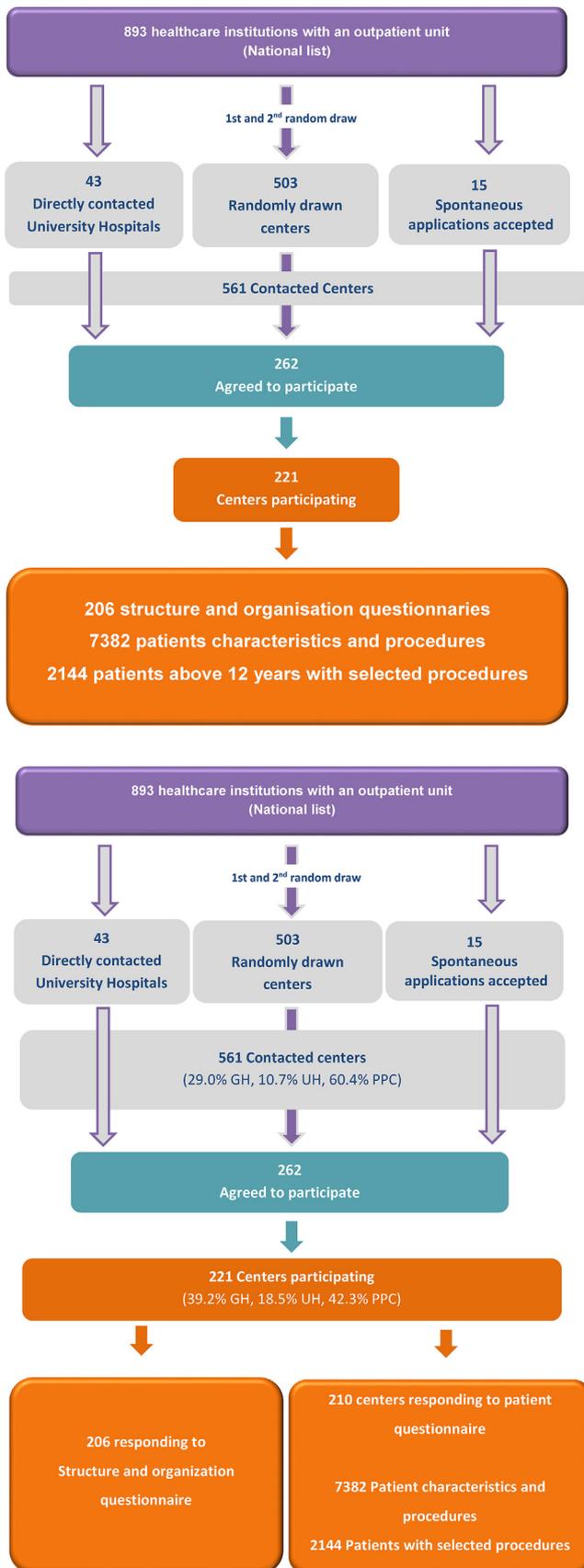


Fig. 1. Flow chart.

recorded in nursing records in 99% [96; 100] (198/201) of centres. The Aldrete score was frequently used before discharge from PACU [82% [76; 87] (165/201)] but the pain evaluation item of this score was assessed only in 53% [45; 61] (87/165) of centres. The post-anaesthesia discharge scoring system (PADSS) was also frequently used [77% [70; 82] (154/201)], including the pain evaluation item [86% [80; 91] (133/154)]. Anxiety was evaluated in 58% [51; 65] (117/201) of the centres, mostly preoperatively [97% [91; 99] (113/117)] and less frequently postoperatively [50% [40; 59] (58/117)].

4.0.3. Analgesics

Only 34% [27; 41] (67/199) of centres declared prescribing analgesics as premedication, mostly paracetamol (acetaminophen) and NSAIDs (79% [67; 88] (53/67) and 43% [31; 56] (29/67) respectively). The use of morphine and WHO level 2 analgesics are described Table 1. Morphine was mostly given for surgical procedures classified as severely painful [55% [48; 62] (110/199) of centres]. Oral morphine was prescribed in 59/199 (30% [23; 37]) centres. It was prescribed for use within the centre in 49/59 (83% [71; 92]) centres and for home treatment in 25/59 (42% [30; 56]) centres.

Combination of tramadol and paracetamol was the most often prescribed WHO level 2 drug (78% [71; 83] (155/199) of centres). Before withdrawal of dextropropoxyphene, this WHO level 2 analgesic was prescribed in 56% [49; 63] (112/199) of centres, mainly private hospitals [67% [56; 77] (59/88)] (Table 1).

4.0.4. Regional anaesthesia

Plexus or nerve blocks were widely used for anaesthesia and pain management (i.e. in 90 [85; 94%] (179/199) of responding institutions). Patients were discharged before the full recovery of the block in 69% [61; 75] (123/179) of centres. When perineural catheters were used for local anaesthetic continuous infusion [20% [14; 26] (39/199)], a private nurse was in charge at home in 69% [52; 83] (27/39) of the centres. Spinal anaesthesia with opioids was used in 38% [31; 45] (75/199) of centres.

4.0.5. Alternative analgesic techniques

Alternative and complementary techniques were used in 62% [25; 38] (124/199) of centres and included hypnosis, acupuncture, cold pressure, analgesic posture, and others (such as music) (Table 2).

4.0.6. Nausea and vomiting management

A written protocol for PONV management was available in 75% [69; 81] (149/198) of centres and was dedicated to day-case surgery in 10% [6; 16] (15/149). These protocols were mainly written by anaesthetists (85% [78; 90] (126/149)). PONV management guidance after discharge (at home) was included in 12% [7; 18] (18/149) of the centres. The Apfel Score was used by 83% [77; 88] (164/198) of centres. Systematic PONV prevention was used in 88% [82; 92] (144/164) of the centres. The three main prophylactic antiemetic drugs administered in the operating room were dexamethasone (90% [84; 95], 130/144), droperidol (85% [79; 91], 123/144) and ondansetron (59% [51; 67], 85/144). Opioids and nitrous oxide were avoided in 24% [18; 32] (35/144) and 47% [39; 56] (68/144) of the centres respectively.

5. Analysis of pain and PONV management in the ten selected surgeries (third questionnaire)

Among the 7382 patients included, 2144 were scheduled for one of the 10 selected surgeries and older than 12 years. Patient, surgery and anaesthetic characteristics are presented in Table 3.

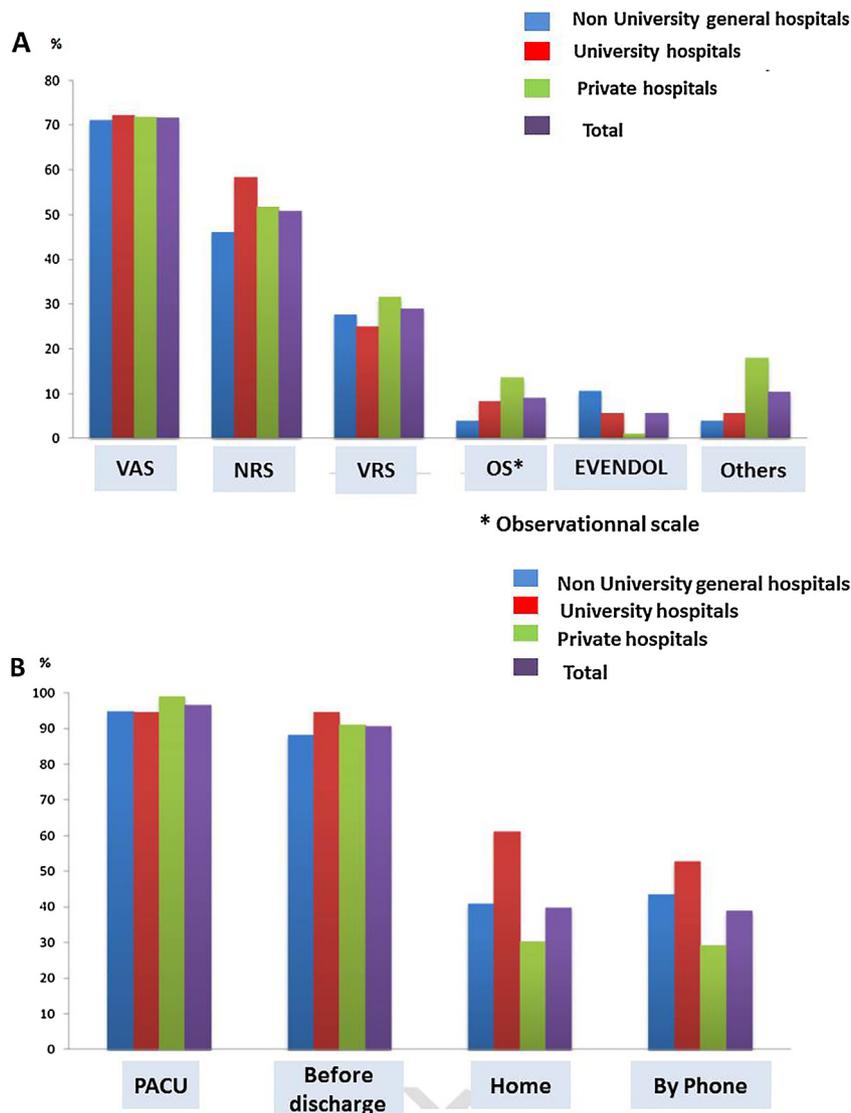


Fig. 2. A. Pain assessment tools used (percentages) in general hospitals, university hospitals, private hospitals. VAS: visual analogue scale; NRS: numerical rating scale; VRS: verbal rating scale; OS: observational scale; others: other scales. B. Pain assessment (percentages of patients assessed) during hospital stay, in the post anaesthesia care unit (PACU), before discharge (in the outpatient surgical unit) and at home (questionnaire and/or by phone), in general hospitals, university hospitals, private hospitals.

VAS and NRS were the most frequently used pain scales, 35 [33; 37] (756/2144) and 35% [33; 37] (753/2144), respectively. Evaluation was performed on arrival in 25% [23; 27] (543/2144), in the PACU for 78% [76; 79] (1663/2144), before discharge in 72% [70; 74] (1539/2144), at home in 25% [23; 27] (537/2144) of responding centres. Pain assessment was not obtained in 12/2144 patients (0.6% [0.03; 0.1]). A post-anaesthesia discharge scoring system was used in 68% [66; 70] (1457/2144) of the patients. It was the score developed by Chung et al in 80% [78; 82] (1164 / 1457).

Analgesics prescribed before, during and after the procedure are presented in Fig. 3. Nearly half of the patients did not receive any analgesic before the surgery. Multimodal analgesia was the rule but paracetamol was the most frequently prescribed drug during the hospital stay, at home and as rescue analgesics.

General anaesthesia was performed in most of patients except for those who undergone a hallux valgus or a hand surgery (table 4). Infiltration and plexus blocks were used in 22% [20; 23] (463/2144) and 15% [13; 16] (316/2144) of patients, respectively. Plexus block with catheter were prescribed only after knee arthroscopy (33.3%), hallux valgus (18.8%) and hand surgery

Table 1

Prescription of opioids (WHO level 2 and level 3 analgesics) in the post-operative period. Data are presented as n (% of centres).

All centres	n = 199
Centres using morphine for post-operative pain	125 (63%)
IV morphine titration in PACU	118 (59%)
Subcutaneous morphine	23 (12%)
Oral morphine	59 (30%)
In hospital	49 (25%)
At home	25 (13%)
Centres using WHO level 2 analgesics	
Tramadol	108 (54%)
Tramadol + paracetamol	155 (78%)
Codeine + paracetamol	96 (48%)
Opium containing drugs	41 (21%)
Dextropropoxyphene (before its withdrawal)	112 (56%)

(3.1%) (Table 4). Rescue analgesics at home were prescribed in 41% [39; 43] (877/2144) of patients.

The traditional Apfel scoring system to assess PONV risk was used in 23% [20; 28] (104/443) (hand surgery) to 47% [32; 64] (19/

Table 2

Rate of use and types (%) of alternative analgesic techniques in ambulatory facilities in France (Several alternative techniques may be used in a single center leading to the total that may exceed 100%).

n = 199	
Alternative analgesic techniques	62%
Hypnosis	38%
Acupuncture	4%
Cold pressure	86%
Antalgic posture	65%
Others (music, relaxation...)	7.3%

Table 3

Practice survey: detailed description of perioperative management of patients undergoing one of the 10 selected procedures.

Patients' characteristics and types of surgical procedures	n = 2144
Age [year; median (25th–75th)]	42 (26–58)
Male (%) (n = 2031)	919/2117 (43%)
ASA (I/II/III/IV) (%)	60%/32%/8%/0%
Type of surgery: (n, %)	
Stomatology surgery: third molar removal	467 (21.7%)
Knee arthroscopy	215 (10%)
Abdominal wall surgery	150 (7%)
Perineal and anal surgery	172 (8%)
Stripping for varicosities	148 (6.9%)
Laparoscopic cholecystectomy	130 (6%)
Breast tumorectomy	37 (1.7%)
Uterine surgery	342 (15.9%)
Hallux valgus	40 (1.8%)
Hand surgery	443 (21%)

40) (hallux valgus) of cases. During the pre-anaesthesia visit, between 33/172 (19%) [14;26] (perineal and anal surgery) and 57/148 39% [31 ;47] (stripping for varicosities) of patients were fully assessed for PONV risk. Prophylactic antiemetic drugs were administered during the surgical procedure in 5% [3; 7] (20/443) of cases (hand surgery) to 63% [54; 71] (82/130) of cases (laparoscopic cholecystectomy). Antiemetic drugs (mostly ondansetron) were administered in PACU in 0.5% of patients undergoing

hand surgery and 8% of patients undergoing knee arthroscopy. PONV assessment was performed before discharge 66% [64 ;68] (1416/2144) of patients but antiemetic drugs were prescribed for at home use in less than 2% of cases (except for breast tumorectomy: 8% [2; 22] (3/37).

6. Discussion

This study is the first large-scale survey describing perioperative practice patterns for ambulatory patients in France and also the first focusing on pain and PONV assessment and management in outpatient surgery in adults. The goal was neither to measure the number of patients treated in ambulatory conditions in France (as this is provided by the French Ministry of Health) nor to examine post-operative pain levels and inadequately controlled pain in patients undergoing day surgery but to make a focus on perioperative strategies used in ambulatory surgery. The purpose was also to compare our results with current guidelines for management of post-operative pain published by the French Health Agency [8] and the French Scientific bodies [5]. In this survey, we decided to analyse in a single study PONV and pain since it has recently been shown that these two symptoms are significantly related in ambulatory surgery patients and that patients with high pain report a significantly greater degree of nausea in the ambulatory unit as well as during the first days after discharge [9].

Post-operative pain is a major factor associated with an increased risk of time spent before discharge [10–13], an increased admission or readmission rate, sleeping problems and dissatisfaction [10]. More specifically, pain at home is the most commonly observed complication after day surgery in adults [14,15].

6.1. Comparison to recommendations

There are discrepancies between recommendations of French National Authority for Health (HAS) [8] or recommendations of experts about pain management in outpatient surgery of the French Society of Anaesthesia and Intensive Care Medicine (SFAR) [5] on one hand and the results of the survey on the other hand. For

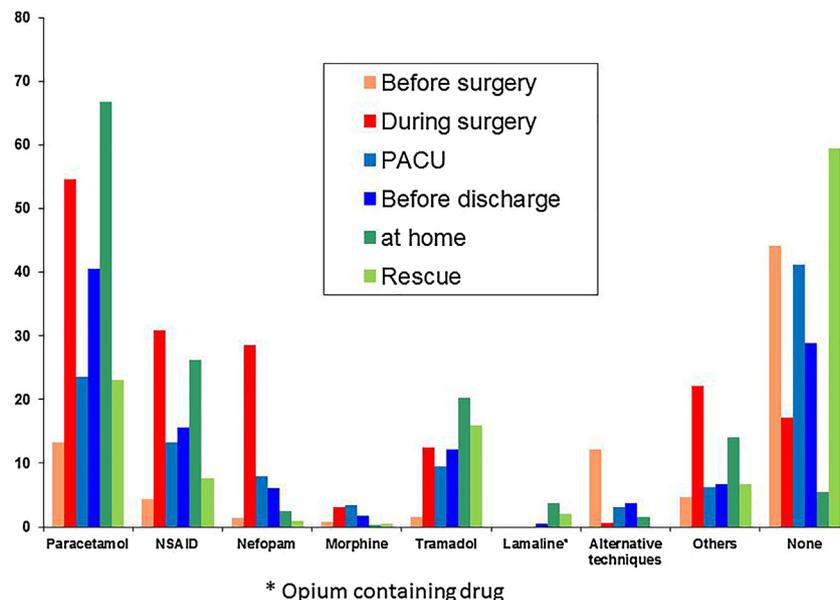


Fig. 3. Analgesic drug prescription in patients (percentage of prescriptions) undergoing ambulatory surgery. Prescription before surgery (premedication), during surgery (operating room), post anaesthesia care unit (PACU), before discharge (outpatient surgical unit); at home and as rescue analgesia. Drugs are: paracetamol (acetaminophen), non-steroidal anti-inflammatory drugs (NSAIDs), Nefopam, morphine, tramadol, opium containing drug, alternative techniques (hypnosis, acupuncture, cold pressure, antalgic posture, music, relaxation), others (corticosteroids, gabapentinoids).

Table 4
Practice survey: anaesthetic and analgesics techniques in patients undergoing the 10 selected procedures.

Type of surgery	General anaesthesia only (%)	Spinal/epidural analgesia (%)	Plexus or nerve blocks (%)/with catheter (%)	Wound infiltration (%)
Third molar removal	87.6	-	-	41.2 ^b
Knee arthroscopy	79.3	18.9	1.4/33.3	30.9 ^a
Abdominal wall surgery	64.1	13.8	3.3/0	47.4 ^a
Perineal and anal surgery	65.5	7.5	-	10.3 ^a
Stripping for varicosities	75.7	15.9	1.3/0	11.5 ^b
Laparoscopic cholecystectomy	89.3	.8	1.5/0	24.2 ^a
Breast tumorectomy	89.5	-	2.7/0	16.2 ^a
Uterine surgery	87.5	2	-	5.2 ^b
Hallux valgus	23.1	2.5	40/18.8	40 ^a
Hand surgery	11.7	-	63.9/3.1	5.3 ^b

Wound infiltration: main Local Anaesthetics agent used.

^a ropivacaine.

^b lidocaine.

example, these recommendations state that analgesic prescriptions should be standardized. In the same way, treatment of PONV after discharge should be based on prescription of antiemetic drugs according to the risk assessment. Centres performing day surgery should develop a specific strategy for assessing and treating post-operative pain at home. It is also recommended that protocols for post-operative pain management (POPM) should be regularly assessed by a multidisciplinary team [5]. In the survey, POPM were implemented in only 41% of centres and mainly written by anaesthetists and were not the result of a multidisciplinary teamwork. There were no specific protocols for the paediatric and geriatric populations and 35% of centres had not implemented any protocol for POPM at home.

Careful management of post-operative pain at home has already been addressed in guidelines formulated by national scientific bodies. It is recommended that assessment of factors that can predict post-operative pain and tolerance to prescribed analgesics at home, be done during the pre-operative consultation [5]. The type of oral analgesia should be explained during the preoperative visit with the surgeon and/or the anaesthetist. An analgesic prescription should be given to the patient by the surgeon or the anaesthetist during the preoperative consultation. It should specify the times at which the analgesics should be regularly taken and the conditions of use of any rescue analgesic [5]. In the survey, preoperative information was properly delivered but analgesic prescriptions were not delivered to patients during the preoperative consultation but later when the patient was leaving the hospital.

6.2. Analgesics used during surgery, in the day surgery unit and at home

Opioids: intravenous morphine titration was prescribed in only 4% [3;4] (75/2144) of the patients in the PACU. The reason is probably four-fold: fear of morphine-related adverse events in outpatients, controversy about the role of morphine as a factor delaying discharge after ambulatory surgery [16,17], underestimation of pain severity in the immediate post-operative period or low level of immediate post-operative pain despite some major surgical procedures. Morphine was rarely used at home (8/2144). Among WHO step-2 analgesics, tramadol was the most frequently administered during the surgical procedure [13% [11; 14] (269/2144)] and prescribed after surgery and at home (Fig. 2).

Non-opioid drugs: paracetamol was the most frequently prescribed analgesic during surgery, in PACU, and after surgery especially at home, even after surgery associated with significant inflammation (Fig. 2). NSAIDs were rarely prescribed even after inflammatory procedures (13% [10;17] (62/467) after stomatology surgery, 17% [12;23] (37/215) after knee arthroplasty, 18% [7;33]

(7/40) after hallux valgus surgery, 9% [5;15](16/172) after perineal and anal surgery).

One of the most important results was the lack of rescue analgesic prescription after discharge. In this survey, there was no standardised take-home analgesic strategy for surgical procedures at risk of moderate to severe pain. This is an important result since it has recently been shown that inadequate post-operative pain at home is a significant cause of delayed hospital visit or readmission [18]. Harmonisation of practice could be implemented by using for example pre-printed analgesic prescriptions focused on painful (inflammatory) surgical procedures.

6.3. Local anaesthetics

Pavlin et al. demonstrated that wound infiltration with a local anaesthetic is associated with a decrease of one point (on a 10 point Scale) in pain score in ambulatory surgery [10]. In this study, 40% of patients having breast surgery received local anaesthesia with sedation [10]. In the survey, infiltration was used in 16% [6;32](6/37) of cases after breast tumorectomy. Infiltration was mainly performed in oral surgery, knee arthroplasty, hallux valgus and abdominal wall surgery.

6.4. Non-pharmacological strategies

In the survey, a majority of centres used complementary techniques for analgesia, such as hypnosis, cold pressure and analgesic positioning (Table 2). The morphine sparing effect of these alternative techniques is not demonstrated in day-case surgery and very few studies about these analgesic strategies have been published. Non-pharmacological strategies were rarely used in the study published by Watt-Watson et al. at any of the time periods after surgery for any patient (cholecystectomy, shoulder and hand surgery) (1–6%) [19]. Cold was used in 4% of shoulder and 3% of hand surgical procedures [20]. In a study on the role for hypnosis in cataract surgery (slightly painful surgery), patients in the hypnosis group reported a mean comfort rating of 8.4/10, and 100% were satisfied with this hypnosis experience [21].

7. PONV

As post-operative pain and emetic complications may be related in ambulatory patients, looking at both problems together is logical [9]. There were discrepancies between the results of the first part of the study (facility's structure and organisation) and the practice survey of the ten selected surgeries. In the first part, the survey was declarative and suggested a widely stated standardisation of PONV management: a majority of centres had a dedicated

written protocol of PONV after day-case surgery. In the analysis of the selected surgeries however, prophylactic treatment of nausea and vomiting was not standardised and prescriptions given to the patient during the surgical procedure insufficient. Very few patients received prescription of antiemetic drugs after discharge.

7.1. Limitations

Several limitations should be emphasised, the first one relates to the answer by only 211 facilities over 893 healthcare institutions with an outpatient unit (National list). The overall participation rate was 78.6% among centres, which had agreed to participate, representing 23.1% of all health facilities listed by the Regional Health Agencies (ARS) (and 36.7% among the centres which had been contacted). The large absolute number of facilities (and patients) assessed however brings some strength to our study. The second limitation relates to the design of the survey (the first questionnaire of the survey was a declarative study). Nevertheless, because a large number of patients undergoing one of the ten selected surgical procedures were precisely assessed, real practices could be determined with a reasonable degree of certainty. The third limitation is the lack of information regarding pain management and satisfaction of patients at home.

7.2. Conclusion

This survey demonstrates that practice for pain treatment and PONV prophylaxis after ambulatory surgery is very heterogeneous among French centres. Characteristics, severity and duration of pain after day-surgery should not be overlooked. Persistent post-operative pain after day-case surgery is found to be a factor of increasing time spent in the PACU and in the ambulatory unit, increasing admission or readmission rates, increasing rate of consultation outside hospitals, dissatisfaction, limitation of physical activity and sleeping problems. Multimodal analgesic and PONV prophylactic treatments should be provided according to the recommendations of the Healthcare Agencies and national scientific bodies.

Ethical statement

Data analysis without ethical problem

Funding

Support was funded by an unrestricted grant from SANOFI Company to the French Society of Anaesthesia and critical care. This prospective study was performed following approval by an Ethical Committee (Comité de Protection des Personnes, CPP Auvergne Rhone Alpes region, France). The study was conducted according to Good Clinical Practice standards and the Helsinki Declaration. The study has been registered (NCT02380430), www.clinicaltrials.gov.

Authors contribution

FA: study design, data collection, and writing up of the first and final draft of the paper, co-author and senior author. CE: study design, co-author. DB: study design, co-author. LJ: study design, co-author. PD: study design, co-author. KS: statistical analysis, co-author. JPB: study design and statistical analysis, co-author. PA: study design, data collection, and writing up of the final draft of the paper, co-author and senior author.

Disclosure of interest

All authors have declared that they have no conflict of interest

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