Reports of Investigation

Treatment efficacy is not an index of pain intensity

Chantal Mamie MD,*
 Alfredo Morabia PhD,†
 Martine Bernstein MD,†
 C.E. Klopfenstein MD,*
 Alain Forster MD*

Purpose: To determine if the efficacy of pain treatment assessed by the patient is a valid indicator to evaluate pain management.

Methods: Three hundred and ninety one adult patients were investigated on the day of surgery and on the two following days after intraperitoneal or orthopedic surgery. Pain scores and efficacy of pain treatment were evaluated using ungraduated visual analog scales (VAS). According to the evolution of pain between two consecutive days, patients were classified as having "worse pain", "same pain" or "lower pain".

Results: During the first time interval, pain treatment was considered effective by 42% of patients with worse pain, compared with 55% with less pain (OR = 1.9, 95%CI = 1.1- 3.7) and to 58% of patients with the same pain (OR = 2.0, 95%CI = 1.2-3.0). During the second time interval, these proportions were: 46% (worse pain), 63% (lower pain vs worse: OR = 1.8, 95%CI = 1.0-3.2) and 66% (same pain vs worse: OR = 2.1, 95%CI = 1.1- 4.1). Using pain evolution as a "gold standard", patient assessment of pain treatment efficacy had sensitivity of 0.55 and specificity 0.5 during the first time interval, and of 0.63 and 0.43 during the second time interval.

Conclusion: Patient evaluation of the efficacy of pain treatment can mislead the clinician about the severity of pain. Patients tend to be satisfied with pain treatment, even when pain is not relieved. The relation of intensity of pain to patient perception of treatment efficacy is weak.

Objectif : Déterminer si l'évaluation de l'efficacité du traitement analgésique par une échelle visuelle analogique (EVA) est une mesure valide du soulagement de la douleur.

Méthode : Trois cent quatre-vingt-onze patients adultes ayant subi une intervention orthopédique ou intrapéritonéale ont été étudiés le jour de l'intervention et les 2 jours suivants. L'intensité de la douleur et l'efficacité du traitement analgésique ont été évaluées au moyen de deux EVA non graduées. Ces patients ont été répartis en 3 groupes selon l'évolution de la douleur sur 2 jours consécutifs : groupes de «douleur accrue», «douleur identique» et «douleur moindre».

Résultats : Pendant la première période, la proportion de patients considérant le traitement efficace est de 42 % dans le groupe «douleur accrue», 55 % dans le groupe «douleur moindre» (OR = 1,7; IC 95 % = 1,1- 3,7) et 58 % dans le groupe «douleur identique» (OR = 2,0; CI 95 % = 1,2- 3,0). Pendant la deuxième période, le traitement analgésique est considéré efficace par 46 % des patients de «douleur accrue» comparé à 63% des patients de «douleur moindre» (OR = 1,8; IC 95 % = 1,0-3,2) et à 66 % des patients de «douleur identique» (OR = 2,1; IC 95 % = 1,1- 4,1). L'évolution de la douleur étant considérée comme un point de référence, l'évaluation de l'efficacité du traitement analgésique faite par le patient présentait une sensibilité de 0,55 et de 0,63 et une spécificité de 0,5 et 0,43 respectivement pendant la première et la seconde période.

Conclusion : L'évaluation de l'efficacité du traitement analgésique par le patient peut conduire à sous-estimer la douleur, les patients ayant tendance à se satisfaire du traitement même quand la douleur n'est pas soulagée. La relation entre l'intensité de la douleur et la perception par le patient de l'efficacité du traitement analgésique est faible.

From the Divisions of Anesthesiology* and Clinical Epidemiology,† University Hospital, rue Micheli-du-Crest, 1211 Geneva 4, Switzerland.

Address correspondence to: Dr. Chantal Mamie, Division of Anesthesiology, University Hospital, rue Micheli -du-Crest, 1211 Geneva 4, Switzerland. Phone: 41-022-372-33-11; Fax: 41-022-382-75-11; E-mail: Chantal.Mamie@hcug.ch

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MANY audits have reported that pain management remains unsatisfactory, since between 60 to 70% of patients experience moderate to severe postoperative pain.^{1,2} The difficulty of evaluating pain and the quality of its management is one of the main reasons to explain this unsatisfactory situation. Although the pain score rated by the patient on a visual analog scale (VAS) appears to be the best recognized method of measurement,³ it is a point estimate that does not reflect fluctuation of pain over time or in different situations (e.g., movement, treatment, nursing care).

In order to improve the quality of pain management, guidelines have been developed, for example by the American Pain Society, which recommended evaluating patient satisfaction.⁴⁻⁶ However, several studies^{4,5,7} demonstrated that satisfaction was not related to pain scores: patients were generally satisfied even when their pain was maximal. Thus, evaluating only patient satisfaction can lead to the erroneous conclusion that the problem of postoperative pain has been solved. Patient satisfaction is a multidimensional variable which depends not only on the intensity of pain, but on others factors such as the age of the patient, cultural background, expectations (influenced by previous pain experience) and the psychosocial aspect of care. The quality of communication with health care providers can lead to satisfaction, if clinicians say they want to provide pain management, regardless of its efficacy.⁸

The hypothesis underlying the present study was that a more valid assessment of pain treatment efficacy would be obtained if patients were asked to evaluate the efficacy of pain treatment rather than their satisfaction. The goal of the study was to establish if the efficacy of pain treatment rated by the patients is in accordance with pain scores and can be a relevant indicator, which could be used in clinical practice.

Methods

After approval of the Ethics Committee of our institution and oral consent from the participants, the study was conducted over 12 mo on consecutive patients between 18 and 74-years old, scheduled for elective orthopedic or intraperitoneal procedures in the University Hospitals of Geneva. Exclusion criteria were: admission to the Intensive Care Unit before or after surgery, communication problems, polytrauma, laparoscopic procedures and removal of osteosynthesis material. The choice of the anesthetic and analgesic techniques was decided by the anesthesiologist in charge of the patient.

Patients were instructed, on the evening before surgery, how to use the visual analog scales (VAS).

The interviewer was a psychologist not involved in the medical care. Pain intensity and the efficacy of treatment were evaluated using two ungraduated 10 cm visual analog scales, scored with *no pain* or *excellent treatment* on the left side of the scale and *unbearable pain* or *ineffective treatment* on the right side.

The VAS of pain intensity at rest and after coughing after abdominal surgery and at mobilization after orthopedic surgery were evaluated once on the day of surgery after the end of the procedure (Day 0), once during the first postoperative day (Day 1) and once during the second postoperative day (Day 2). The VAS scores of the efficacy of treatment were evaluated once on Day 1 and once on Day 2.

Statistical analysis

Variable definitions: Data are expressed in absolute numbers and in percentage. The VAS scores were measured in centimeters. The VAS of the efficacy of treatment rated by the patient was the dependent variable of interest. It was divided in three groups according to its distribution in order to obtain groups of same size: VAS < 2 was defined as an effective treatment, VAS 2-4 as a fair treatment and > 4 as an ineffective treatment.

Pain evolution was assessed by the difference in pain score rated by VAS between Day 0 and on Day 1 (Day 0 minus Day 1 = first interval), as well between Day 1 and Day 2 (Day 1 minus Day 2 = second interval). Patients were then categorized as having "*worse pain*" if pain scores increased between two consecutive days of at least one unit; "*same pain*": if there was no difference; or "*lower pain*": if pain scores decreased between two consecutive days.

Demographic data included age (< 40, 40-60, > 60), education (less or more than 12 yr of schooling) and geographic origin (Swiss, Southern Europe and others). There is a large immigration from South Europe in Geneva.

Orthopedic surgery included shoulder surgery, foot surgery, internal fixation of limb, total hip replacement, second total hip replacement, bilateral hip replacement, total or partial knee replacement, vertebral osteosynthesis, arthrodesis. Abdominal surgery included open cholecystectomy, Hartmann procedure, bowel surgery (colo-rectal), stomach, oesophagus, liver and pancreatic surgery.

The anesthetic technique was classified as general anesthesia, regional techniques (spinal or epidural) and combined techniques "(general anesthesia associated with epidural analgesia or regional blocks (inter-scalenic, femoral, sciatic, axillary)).

Analysis: The relation between pain groups and efficacy of pain treatment was first explored by uni-

variate analysis (chi-square). A P value < 0.05 was considered as significant. Odds ratios adjusted for sex, age, anesthetic technique, intervention and chronic preoperative analgesic intake were obtained by logistic regression. The 95% confidence interval of an odds ratio is statistically significant when the interval does not include unity (since one is identical to the reference). Sensitivity, specificity and predictive values of efficacy of treatment were calculated, using pain evolution as "gold standard".

Results

Among the 449 eligible patients, 26 refused to participate and 24 became ineligible because of unplanned admission to intensive care unit or because of cancellation of surgery and eight patients were excluded for other reasons: incomplete answers, or personal decision to stop the study. On the second postoperative day 15 patients (essentially hallux valgus surgery) left the hospital before our evaluation and three decided to stop the study.

Demographic data of the 391 patients are summarized on Table I. There were 184 men, mean and 207 women. Most (71%) underwent orthopedic surgery. The anesthetic techniques were mainly general anesthesia (47%) or combined techniques (34%).

Mean VAS $\pm$ SD at rest were in the same range: 3.5 ± 2.7 on Day 0, and 3.3 ± 2.5 on Day 1 and Day 2. Median VAS was 3 on each of the three days.

Mean VAS $\pm$ SD at cough/mobilization were: 5.0 ± 3.0 on Day 0, 4.9 ± 2.8 on Day 1 and 2.2 ± 2.0 on Day 2. Median VAS at cough/mobilization were 5 for Day 0 and Day 1 and 4 for Day 2.

The mean $\pm$ SD and median of the efficacy of pain treatment were respectively 2.3 ± 2.3 and 2 on the first postoperative day and 1.8 ± 2.1 and 1 on the second postoperative day.

During the first time interval, 51% of patients considered the treatment effective for pain at rest, 31% fair and 18% ineffective (Table II), while 47% of patients had lower pain, 18% same pain and 35% worse pain. During the second time interval, 61% of patients considered the treatment effective, 26% fair and 13% ineffective, while 59% of patients indicated less pain, 22% the same pain and 19% worse pain.

Table II relates pain treatment evaluation to pain evolution. During the first interval, 55% of patients presenting with less pain evaluated the treatment as effective, 33% considered the treatment fair and 12% ineffective ($P < 0.05$ for ineffective *vs* effective and fair). Among the patients with the same level of pain, 58% rated the treatment effective, 27% fair and 15% ineffective ($P < 0.05$ for ineffective *vs* effective and

TABLE I Demographic, surgical and anesthetic characteristics of 391 patients

Variables	Categories	n	%
Sex	Male	184	47.1
	Female	207	52.9
Age (yr)	≤ 40	99	25.3
	41-60	150	38.4
	>60	142	36.3
Origin	Swiss	241	61.6
	Southern Europeans	120	30.7
	Others	30	7.7
Education (yr)	≤ 12	238	60.9
	>12	148	37.9
Surgical procedure	Orthopedic	277	70.8
	Intraperitoneal	113	28.9
Anesthetic technique	General	182	46.5
	Regional	77	19.7
	Combined	131	33.5
Chronic analgesic intake	Yes	121	69.1
	No	270	30.9

TABLE II Treatment evaluation according to pain evolution during Day 0 to Day 1 and Day 1 to Day 2.

Time interval	Pain evolution	n	Treatment evaluation		
			effective %	Fair %	ineffective %
Day 0 to Day 1	Lower	182	55	33	12*
	Same	72	58	27	15*
	Worse	137	42	31	27
	All	391	51	31	18
Day 1 to Day 2	Lower	219	63	24	13
	Same	84	66	22	12
	Worse	70	46	36	18
	All	373	61	26	13

* Significant difference *vs* effective or fair

fair). In patients presenting with worse pain 42% considered the treatment effective, 31% fair and 27% ineffective. During the second interval, 63% of patients with less pain considered the treatment effective, 24% rated it fair, and 13% ineffective. In patients with the same level of pain 66% considered the treatment effective, 22% fair and 12% ineffective. In patients with worse pain, 46% considered the treatment effective, 36% rated it fair and 18% ineffective (P : ns).

The evolution of the percentage of patients considering the pain treatment effective for the three groups of pain is showed on the Figure. The percentage of patients considering the pain treatment effective increased without statistical significant difference between the first and the second time intervals. However, there was a statistically significant difference

TABLE III Multivariate analysis of treatment evaluation according to pain evolution between day 0 and day 1 or day 1 and day 2

Time interval	Pain evolution	Treatment evaluation		crude Odds Ratio		adjusted Odds Ratio*	95% CI
		Effective	Fair or ineffective				
Day 0 to Day 1	Lower	n 99	% 55	n 83	% 45	1.7	1.1 - 3.7
	Same	42	58	30	42	2.0	1.2 - 3.0
	Worse	57	42	80	58	1.0	reference
Day 1 to Day 2	Lower	139	63	80	37	2.0	1.04 - 3.2
	Same	56	66	28	34	2.5	1.1 - 4.1
	Worse	32	46	38	54	1.0	reference

95%CI: 95% confidence interval

* Simultaneously adjusted for gender, age, surgical procedure, anesthetic technique and chronic preoperative analgesic intake.

TABLE IV Sensitivity, specificity and predictive values of the efficacy of treatment compared to pain evolution, considered as “gold standard”.

Time interval	Pain evolution	Effective treatment	Fair/ineffective treatment	Sensitivity	Specificity	Positive PV*	Negative PV†
Day 0 to Day 1	Lower pain	99	82	0.55	0.53	0.50	0.57
	Same/worse pain	99	110				
Day 1 to Day 2	Lower pain	139	80	0.63	0.43	0.62	0.45
	Same/worse pain	88	66				

* Positive PV: Positive predictive value = proportion of patients considered the treatment effective and were in the group “lower pain”.

† Negative PV: Negative predictive value = proportion of patients considered the treatment ineffective or fair and were in the group “worse and same pain”

FIGURE Evolution of the percentage of patients considering the pain treatment effective (VAS<2) for the three groups of pain.

($P < 0.05$) between the 3% of patients considering the treatment as effective.

For each day the odds ratios and 95% confidence intervals of good efficacy vs fair or ineffective treatment for the three possible evolutions of pain were calculated, with adjustment for the following potential confounding

variables: gender, age, chronic preoperative analgesic intake, surgical procedure and anesthetic technique (Table III). The group with worse pain was the reference. During the first time interval, subjects who rated the treatment as effective were more likely to present with the same (OR: 2.0, 95%CI= 1.2-3.0) or lower pain score (OR: 1.9, 95%CI=1.1-3.7). During the second time interval, the odds of considering the treatment as effective was 2.1 higher for patients presenting with the same pain (95%CI= 1.1- 4.1) and 1.8 for patients with less pain (95%CI= 1.04-3.2).

No statistically significant differences were found when the same analysis was applied to the VAS at cough/mobilization.

Sensitivity and specificity of efficacy of treatment relative to pain evolution were low: respectively 0.55 and 0.53 for the first interval and 0.63 and 0.43 for the second interval. The positive predictive value (to detect the patients with lower pain) was 0.5 and 0.62 for each interval and the negative predictive value (to detect the patients with worse pain) 0.57 and 0.45.

Discussion

Although there is a tendency for patients whose pain evolves favourably (less or same pain at rest) to consider more frequently pain treatment as effective than for

patients who have worse pain, the difference is of borderline statistical significance. Moreover, it is not found at cough/mobilization. Sensitivity and specificity are mediocre (about 50%). Thus, the association between pain evolution and treatment efficacy assessed by patients is too weak to suggest that the latter can be used as a substitute for classical VAS pain scores in the clinical setting. The main reasons for that is the very high prevalence of ineffective treatment: during the first interval, more than 80% of the patients who evaluated a deterioration in pain score (group worse) scored pain treatment as effective or fair.

Previous studies have compared satisfaction, and not efficacy of pain treatment, with pain scores. In a survey investigating 72 patients, Miakowski observed that 70% of the patients were satisfied with pain management, even though those with moderate to severe pain reported long delays before obtaining pain medications.⁴ Assessment of pain management in a quality insurance program failed to find a correlation between pain scores and satisfaction with analgesia.⁵

One striking result of our study is that 42% of patients in the "worse pain" group rated their treatment efficacious. This could be because patients with major surgery, who found the treatment effective, expected postoperative pain. The result may have been quite different if the study had been performed in an obstetric setting, since most parturients are aware that pain-free delivery is possible and since effective analgesia is expected when arriving in the delivery room. It took more than 20 yr for obstetricians and anesthesiologists to obtain such good results in a homogenous population with a same source of pain. In postoperative pain, the wide variability of patients and of nociceptive stimuli is a greater challenge and may require much more efforts, time and resources.

Patients can be reluctant to state to the medical staff that the treatment was ineffective and overestimated pain treatment efficacy. To prevent this potential bias, the patients were explicitly informed that a psychologist who was independent of the medical team interviewed them.

The pain VAS was first developed for assessing chronic pain, which allowed evaluation of its reliability by test-retest, interrater and internal test. Their use for acute pain is more problematic since, during postoperative period, residual anesthesia, blurred vision or nausea, acute treatment by opioids could affect the VAS report reproducibility. It has been reported that a VAS pain score in the immediate postoperative period should be considered to have an imprecision of $\pm 20\%$.⁹

In conclusion, The VAS pain score remains the best, even though imperfect indicator of pain management. More research is warranted to identify accurate measures of postoperative pain measurement.

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