Clinical validation of a new “call-out algorithm” for postoperative pain management: a two-center prospective randomized trial

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Abstract

Introduction
The goal of modern postoperative pain management is to relieve pain while keeping side effects to a minimum. Still, in recent investigations, between 20% and 40% of all postoperative patients report high levels of pain after surgery, while 20-30% experience adverse effects of opioid analgetics [1,2]. In a study, in which the hospitals had introduced pain management guided by the patients' own numerical scale scores, the investigators unexpectedly found that the side effects of drugs had more than doubled [3]. The authors suggested that more than just a one-dimensional numerical assessment of pain should be undertaken, for the postoperative treatment to be safe and effective [3]. Recently, Efficacy Safety Score (ESS), a new "call-out algorithm" for monitoring of efficacy and safety of postoperative pain management and its side effects, was developed and implemented in clinical practice at Kongsberg hospital in Norway [4]. ESS was established after obtaining consensus between 10 international experts in a DELPHI process on which parameters that should be included in the score [4]. ESS consists of the sum of two subjective scores (Verbal Numeric Rate Scale of pain (VNRS) at rest and during mobilization) and four vital scores (consciousness level, postoperative nausea and vomiting, circulation and respiration status) [4]. In the present trial, we aimed to validate the influence of ESS registration and the application of a "call-out algorithm" on hospital length of stay (LOS) in two university hospitals of Kazakhstan and Russian Federation in which a policy of routine registration of pain as "the fifth vital sign" had not been adopted yet. Thus, the primary endpoint for the study was to assess LOS in groups of patients with different types of clinical data registration, while secondary endpoints were to compare the degree of mobilization, number of postoperative nonsurgical complications, and 28 days survival between the groups.
Methods
The study was approved by the Ethical Committees of both university hospitals. During one year a total of 1152 surgical patients were randomized into three groups: 1) an ESS group (n=409), detailed information about ESS is available on http://esscore.org and http://essdb.no 2) a VNRS group (n=417) with registration of pain with Verbal Numeric Rate Scale: 0-10, where 0 is no pain and 10 is "worst imaginable pain" and 3) an ordinary registration of clinical variables (Control) group (n=326). Medical staff not involved in the trial registered all clinical variables of the patients in an program for mini iPad (Figure 1) hourly during the first 8 hours after surgery. A score of ESS > 10 or VNRS > 4 at rest or ordinary evaluation by nurses served as a "call-out alarm" for a telephone consultation or visit by the anesthesiologist on duty.
Results
No differences in age, BMI, gender, mobility degree, ASA classification, type of anesthesia, number of postoperative non-surgical complication and 28 days survival were found between the groups. We found a difference between the groups in type of surgery (P=0.0001). LOS differed between 12.7±6.3 days in the ESS group and 14.2±6.2 days in the Control group (P=0.006) and between 7.8±2.7 days in the ESS group and 10±3.8 days in the Control groups (P=0.005) in a subgroup of 114 patients who underwent laparoscopic cholecystectomy.
Conclusion
Registration of ESS during the first 8 hours after surgery and extra attention of anesthesiologists on duty might have contributed positively to the reduction of LOS.

Introduction

Efficacy Safety Score (ESS), a new “call-out algorithm” for monitoring of efficacy and safety of postoperative pain management was developed at Kongsberg hospital in Norway [4]. The score was subsequently validated in a small prospective, clinical observational study [4]. However, there was a bias towards female elderly mainly ASA I-II patients who got almost only total intravenous anesthesia and the patients went through only orthopedic, gynecological and ENT surgery in this study [4].

Aims

To validated the influence of ESS registered hourly during the first 8 hours after surgery on mobility degree, number of postoperative non-surgical complications and length of hospital stay (LOS).

Methods and Materials

Ethics: Ethical approval of this clinical trial was provided by the Ethical Committee of Scientific Research Institute of Traumatology and Orthopedics, Astana, Kazakhstan and the Ethical Committee of Kuban State Medical University, Krasnodar, Russian Federation. In both countries, the study was evaluated as a quality assessment of efficacy and safety of pain treatment without any intervention apart from enforced surveillance. Thus, the project was approved with no need for informed consent of the patients.
Hospital setting: Abdominal Surgery, Orthopaedic, Gynaecology, Urology, Vascular Surgery, and high dependency units (HDU) at Astana University Hospital, Astana, Kazakhstan and Krasnodar University Hospital, Krasnodar, Russian Federation.
Inclusion criteria: all surgical patients whom were expected to need observation in hospital for more than 8 hours postoperatively, and were able to communicate adequately with the nursing staff immediately after surgery.
Exclusion criteria: Patients < 18 years of age, poor communication capabilities due to psychiatric diseases, dotage, language problems, or that the patient refused to communicate. After inclusion, we randomized patients by means of sealed envelopes into one of three groups: A) registration with ESS (ESS group), Table 1), B) registration of pain with Verbal Numeric Rate Scale (VNRS group) 0-10, where 0 is no pain and 10 is “worst imaginable pain” and C) ordinary clinical documentation (Control group) during the first 8 hours after surgery. In all groups, we registered the degree of mobility from 0 to 3, where 0 is lack of mobility, 1 is mobilization in bed, 2 is mobilization to a chair (bedside) and 3 is mobilization to standing. All subjective and objective clinical data were registered in an especially created program for mini iPad (Figure 1) and subsequently transferred to the Structured Query Language (SQL) database using Clouds technology. All data were tested for normal distribution by Kolmogorov-Smirnov test. Statistical data analyses was performed with cluster analyses of intra-cluster correlation coefficient, one-way ANOVA, Bonferroni post-hoc test and Chi square analyses using IBM® SPSS® Statistics 21.0. The data are presented as means ± standard deviations (SD) for age, Body Mass Index (BMI) and hospital length of stay in days, and as numbers and percentages for the ESS values, gender, ASA classification, and type of surgery and anesthesia.

Results

A total of 1152 patients were included in the study during the period from 03 March 2014 to 26 May 2015, 679 patients from Astana and 473 patients from Krasnodar. We computed intra-cluster correlation coefficient, which demonstrated a similarity of clustered data. Therefore, the results from both hospitals were pooled for further analyses. Table 2 displays basic characteristics and clinical data of the three groups of patients. As depicted in Table 2, there were no statistically significant differences between the groups as demographic variables, such as age, BMI, gender, ASA classification and type of anesthesia are concerned. We found intergroup differences in type of surgery (P=0.0001), but no differences in degree of mobilization, number of postoperative non-surgical complications or mortality during the 28 days of observation time (data not presented). As shown in Table 2, LOS differed significantly between the ESS group (12.7±6.3 days), the VNRS group (13.5±6.2 days) and the control group (14.2±6.2 days) (P=0.008). Applying Bonferroni post hoc testing, we found a significant difference in LOS between the ESS group and the Control group (P=0.006), but no significant differences in LOS between ESS and VNRS groups. In order to exclude the influence of different types of surgery on LOS, we carried out an analysis of a subgroup of 114 patients, who underwent laparoscopic cholecystectomy. Table 3 displays the demographic and clinical characteristics of the patients. We did not find any significant differences between the three groups in such demographic or clinical characteristics as age (P=0.15) gender (P=0,61) or ASA classification (P=0,39). There were no differences between the groups in degree of mobility, and number of postoperative non-surgical complications (data not shown). However, as LOS is concerned, ANOVA demonstrated significant differences (P=0.006) between ESS (7.8±2.7 days), VNRS (9.0±1.8 days) and control groups (10.0±3.8 days). In turn, Bonferroni Post Hoc Test revealed significant differences in LOS only between the ESS and the Control groups (P=0.005).

Discussion

On the average, pooled data showed that LOS was between 12 and 14 days in both hospitals. This is in consistence with previously published health data in Organisation for Economic Co-operation and Development (OECD) [5] demonstrating that the average LOS in Russian Federation is approximately 13,6 days. However, according to European statistics published on the Internet [6], the average length of a hospital stay for in-patients ranged from 5.5 days in Bulgaria to 9.6 days in Croatia, with Finland peaking the list with an average LOS of 10.6 days. Today, LOS is often used as an indicator of hospital efficiency [6]. However, too short average of LOS might cause negative effects on health outcomes [7]. A retrospective study of three hospitals in Japan and two in the USA demonstrated that median LOS in elderly hip fracture patients was 34 days in Japan and 5 days in the USA [7]. Survival rate in the study was 89.5% in Japan and 77.2% in the USA among patients who could be followed-up six months after surgery. The Cox regression demonstrated that every 10 day increase in the LOS after surgery was associated with a 26% reduction in the risk of mortality (Hazard ratio = 0.744, p = 0.014) after adjusting for LOS before surgery, patients' basic characteristics and number of complications. Based on these findings, the authors concluded that shorter LOS after surgery did not predict better survival rate [7]. Further studies are needed to determine optimal LOS in hospital with minimal risk of mortality and morbidity after surgery.

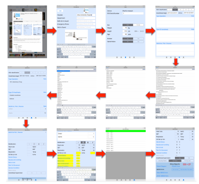
Tables and Figure

Table 1. Description of Efficacy Safety Score (ESS)

Mental status	Score
Awake and alert patient	0
Awake patient, but influenced by drugs. Difficulties in communication.	5
Acutely confused, upset/uneasy, hallucinated or euphoric patient	10
Unresponsive patient	15*
Postoperative nausea and vomiting (PONV) status	
No postoperative nausea or vomiting	0
Postoperative nausea only	5
Postoperative nausea and vomiting/retching	10
Pain status at rest	
No postoperative pain	0
Low intensity postoperative pain (VNRS 1–3)	1–3
Moderate intensity postoperative pain (VNRS 4–6)	4–6
Severe intensity postoperative pain (VNRS 7–10)	7–10
Pain status during movement	
No postoperative pain	0
Low intensity postoperative pain (VNRS 1–3)	1–3
Moderate intensity postoperative pain (VNRS 4–6)	4–6
Severe intensity postoperative pain (VNRS 7–10)	7–10
General condition status	
No remarks	0
Minor discomfort (e.g. light-headedness, minor itching, blurred vision, decreased urination etc.)	5
Excessive discomfort (e.g. severe dizziness, itching, restlessness, urine retention, sensation of cold/warmth, cold sweating)	10
Acute circulatory abnormalities (blood pressure ≤80 or ≥200 mmHg, heart rate ≤40 or > 110)	15*
Acute respiratory abnormalities (dyspnoea, respiration rate < 9 or >20/min, long pauses in breathing, shallow breathing)	15*

*Any single score of 15 (on either consciousness, circulation or respiration) should call for IMMEDIATE activation of acute assistance with the patient

Figure 1. Registration of ESS in iPad program



https://itunes.apple.com/us/app/ess-efficacy-safety-score-postoperativ-monit-syst/id1097020217?mt=8

Table 2. Patient Demographics, Anthropometrics, and Clinical Characteristics (n=1152)

Variable	ESS Group (n=409)	VNRS Group (n=417)	Control Group (n=326)	P value
Age: mean±SD	48,7±16,7	48,2±17,2	48,4±16,4	P=0.92*
BMI: mean±SD	26,5±5,4	26,8±5,6	26,1±5,1	P=0.24*
Gender				P=0.24**
Male: n (%)	185 (45,2%)	201 (48,2%)	169 (51,8%)	
Female: n (n)	224 (54,8%)	216 (51,8%)	157 (48,2%)	
ASA classification: n (%)				P<0.66**
ASA I	13 (3,2%)	16 (3,8%)	14 (4,3%)	
ASA II	244 (59,6%)	231 (55,3%)	1 96 (60,1%)	
ASA III	148 (36,1%)	167 (40%)	115 (35,2%)	
ASA IV	4 (0,9%)	3 (0,7%)	1 (0,3%)	
Type of Surgery: n (%)				P=0.0001**
Abdominal	125 (30,5%)	139 (33,3%)	70 (21,5%)	
Endocrine	29 (7%)	18 (4,3%)	5 (1,5%)	
Gynaecology	19 (4,6%)	9 (2,1%)	12 (3,7%)	
Orthopaedic	202 (49,4%)	199 (47,7%)	207 (63,5%)	
Urology	13 (3,1%)	18 (4,3%)	16 (4,9%)	
Vascular	21 (5,1%)	34 (8,1%)	16 (4,9%)	
Type of Anaesthesia: n (%)				P=0.19**
Sevo+Fentanyl	174 (42,5%)	184 (44,1%)	117 (35,8%)	
Sevo+Fentanyl +EDA	77(18,8%)	68 (16,3%)	45 (13,8%)	
SA or/+EDA	109(26,6%)/10(2,4%)	108(25,9%)/11(2,6%)	103 (31,6%)/10(3%)	
TIVA	17 (4,1%)	11 (2,6%)	13 (3,9%)	
Regional	38 (9,3%)	46 (11%)	45 (13,8%)	
LOS (days): mean±SD	12.7±6.3	13.5±6.2	14.2±6.2	P=0.008*

*ANOVA; ** Chi square analysis

Table 3. Demographics, Anthropometrics, and Clinical Characteristics of patients after laparoscopic cholecystectomy (n=114)

	ESS Group (n= 36)	VNRS Group (n= 54)	Control Group (n= 24)	P value
Age: mean±SD	51,8±214,9	49,7±13,4	56±12,5	P=0.15*
BMI: mean±SD	26,8±4,2	29,2±5,8	27,1±4,5	P=0,06*
Gender				P=0.61 **
Male: n (%)	10 (27,7%)	11 (20,4%)	5 (20,8%)	
Female: n (n)	26 (72,3%)	43 (79,6%)	19 (79,2%)	
ASA classification: n (%)				P=0.39**
ASA I	1 (2,7%)	4 (7,4%)	3 (12,5%)	
ASA II	23 (63,8%)	34 (62,9%)	11 (45,8%)	
ASA III	12 (33,3%)	16 (29,6%)	10 (41,6%)	
Type of Anaesthesia: n (%)				
Sevo+Fentanyl	36 (100%)	47 (100%)	15 (100%)	
LOS (days): mean±SD	7.8±2.7	9.0±1.8	10.0±3.8	P=0.006*

*ANOVA; ** Chi square analysis

Conclusions

In summary, hourly registration of Efficacy Safety Score during the first 8 hours after surgery, and the extra attention of the anesthesiologist on duty might have contributed to the significant reduction of LOS in both the hospitals. Assessing the impact of ESS application on length of hospital stay after different types of surgery warrants further randomized clinical studies.

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