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Brief Pain Inventory (BPI) Health Survey After Midline Laparotomy With the Rectus Sheath Block (RSB) Analgesia: A Randomised Trial of Patients With Cancer and Benign Disease

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Abstract. *Background/Aim: Our original hypothesis was that the rectus sheath block (RSB) analgesia could enhance patient satisfaction and decrease pain following midline laparotomy. Patients and Methods: Initially, 56 patients were randomized into four groups; control group (n=12), single-dose (n=16), repeated-dose (n=12) and continuous infusion (n=16) RSB analgesia groups. The BPI (Brief Pain Inventory) survey was conducted preoperatively and at one and four weeks and 12 months postoperatively. The patients pain 24 h postoperatively and satisfaction 48 h postoperatively was filled on an 11-point numeric rating scale (NRS). Results: The repeated-dose group had lower BPI severity score (p=0.045) and BPI interference score (p=0.043) mean values postoperatively compared to the three other groups separately. Also, the time effect on the linear mixed model in BPI interference score mean values was statistically significant (p=0.008), which means that in the repeated dose group preoperative BPI severity score [2.7 (3.9)] and interference score [4.3 (4.2)] mean (SD) values were significantly higher than the BPI severity score [1.3 (0.8)] and interference score [1.5 (1.8)] mean (SD) values following surgery. Conclusion: The higher elevation in BPI severity score and decrease in interference score values in the repeated dose group and also the time effect in a linear mixed model in BPI interference score were statistically significant.*

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The possible contribution of different analgesia procedures in the medical treatment has aroused substantial interest. The final goals of analgesia treatment procedures are to relieve pain and improve quality of life (1-9). The analgesia and pain relief issue is complex, but in general the three most commonly used rating scales of pain are the numerical rating scale (NRS), the visual analogue scale (VAS), and the verbal rating scale (VRS). The NRS and the VAS have high sensitivity in estimating patient's experience of pain changes (9, 10) and both rating scales seem to provide almost equal values of the patient following surgery (11). The Brief Pain Inventory Scale (BPI) is a self-administered questionnaire developed to assess the impact and severity of pain in daily life (12). The BPI interference score contains a total of eleven domains (general activity, mood, walking, standing, sitting, clothing, lifting, work, relations, sleep, enjoy) and an assessment of total BPI interference score is a mean of these eleven domains (1, 12). The BPI severity score is formed by adding the four domains (most pain in last 24 h, least pain in last 24 h, average pain in last 24 h, current pain) and calculating the mean score (1, 12). It has been translated and validated into multiple languages, but no previously published reports have examined the BPI scale in the context of midline laparotomy with Rectus Sheath Block (RSB) analgesia in patients with benign disease and cancer. Therefore, the present study was focused on the health status as measured by the BPI questionnaire and, the study hypothesis was that the health status measured with BPI in patients with benign disease *versus* cancer is similar.

Patients and Methods

The study was approved by the Ethics Committee of Northern Savo Hospital District, Kuopio, Finland (DNRO 120/2011, November 11, 2011), and was registered in the EudraCT database (EudraCT number 2011-005136-25, Consort diagram, Figure 1) and in the ClinicalTrials.gov database (ClinicalTrials.gov Identifier: NCT02869841). It was conducted in accordance with the Declaration of Helsinki. Participants gave written consent after receiving verbal and written information.

Operations were carried out in Kuopio University Hospital, Kuopio between 2012 and 2015. The CONSORT flowchart of the study is presented in Figure 1. The study design was a prospective, randomised, clinical trial with four parallel groups. The patients with midline laparotomy were randomized into the control group or into one of the three active groups; single-dose, repeated-dose or continuous infusion RSB analgesia groups. The study patients had intravenous oxycodone pumps as the patient-controlled analgesia (PCA). The randomisation list was generated by a computer (13), a sealed enveloped method was used for blinding and randomisation was done preoperatively. The patients in the control group had no RSB catheters inserted. However, the patients in the control group were blinded, using the similar wound dressing as the patients in the active groups. The design of this study, the exclusion and inclusion criteria and the RSB analgesia procedure are described in our earlier reports (14-16).

The patients pain 24 h postoperatively was assessed using an 11-point numeric rating scale (NRS_{24}, 0=no pain and 10=most pain) and is shown in Figure 2. An opinion on the success of the analgesia procedure and the overall satisfaction of the analgesia were surveyed and filed on a 11-point numeric rating scale (NRS_{48}, 0=fully unsatisfied; 10=fully satisfied) (Figure 3). The BPI interference score consists of seven questions related to the episodes of pain and the interference on function and four questions related to the severity of pain. Each BPI item yields a score of zero and ten and the test with the eleven variables ranges from zero to 110. The BPI interference score contains a total of eleven domains (general activity, mood, walking, standing, sitting, clothing, lifting, work, relations, sleep, enjoy) and the assessment of the total BPI interference score is a mean of these eleven domains (1). The primary outcome measures were the eleven BPI interference score domains measured at four time points; before operation (PRE, n=56), at discharge (POP1, n=41), 4 weeks postoperatively (POP2, n=42) and 12 months after operation (n=39, POP3) in the placebo *versus* the three active groups. The BPI Severity Score is formed by adding the four domains (most pain in the last 24 h, least pain in the last 24 h, average pain in the last 24 h, current pain) and calculating the mean score (1).

The data were entered and analyzed with a statistical software program (IBM SPSS Statistics 24.0, IBM, Armonk, NY, USA). Data are shown as means and standard deviations or frequencies and percentages, as appropriate. Differences in baseline characteristics between groups were tested by Fisher's exact test and in the case of continuous data, the analysis was performed by the Kruskall-Wallis *t*-test. Group differences in four time points were tested by the Linear mixed effect model. *p*-Values under 0.05 were considered statistically significant.

Results

The control group and three active groups were similar in terms of the perioperative data; age, gender, height, weight, body mass index, time in the operative room, operative time, perioperative bleed, American Society of Anesthesiologists physical status classification, length of the skin incision, type of disease and patients without pain (Table I). The study group consisted of 15 patients with benign disease, nine patients with gastrointestinal cancer, 17 patients with gynaecological cancer and three patients with other malignancies (Table I).

Table II shows patient satisfaction four weeks following surgery, patient's pain assessed using an 11-point NRS rating scale following surgery, BPI severity score and interference score between study groups measured at four time points: before (PRE), after discharge (POP1), 4 weeks (POP2) and 12 months (POP3) postoperatively. No statistically significant differences were detected in the NRS, BPI severity score and BPI interference score mean (SD) values between the control group and the three active groups preoperatively and after operation (Table II). Table II shows that patient satisfaction at 4 weeks following surgery was significantly higher in the repeated dose and in the continuous-infusion groups (p=0.043). Although linear mixed model *p*-values shown in Table II between the control group and study groups are not statistically significant, a time effect in the linear mixed model in BPI interference score was statistically significant (p=0.008). This means that in the repeated dose group, preoperative BPI severity score [2.7 (3.9)] and interference score [4.3 (4.2)] mean (SD) values were significantly higher than the BPI severity score [1.3 (0.8)] and interference score [1.5 (1.8)] mean (SD) values following surgery (Table II).

Table III shows the BPI severity score and BPI interference score mean (SD) values between benign (n=15) and cancer patients (n=29) measured at four time points: before (PRE), at discharge (POP1), 4 weeks (POP2) and 12 months (POP3) postoperatively. There were no statistically significant differences between benign group patients and cancer patients in BPI severity score and BPI interference score mean (SD) values (Table III). Table III also shows the statistically non-significant linear mixed model *p*-values.

Figure 2 shows that the jitterplot of patients BPI interference score mean values preoperatively *versus* patients mean NRS pain score 24 h postoperatively (NRS_{24}) are highly significantly correlated (r=0.80, p<0.001). Figure 3 shows that the jitterplot of patients BPI interference score mean values 4 weeks following surgery *versus* the mean value of opinion on the success of the analgesia procedure and the overall satisfaction 48 h postoperatively (NRS_{48}) are inversely correlated (r=–0.40, p<0.016).

Discussion

Pain is associated with many problems such as anxiety, depression and other mood disorders, sleep disturbance, chronic fatigue, inability to participate in social and physical activities and decreased immune function. The

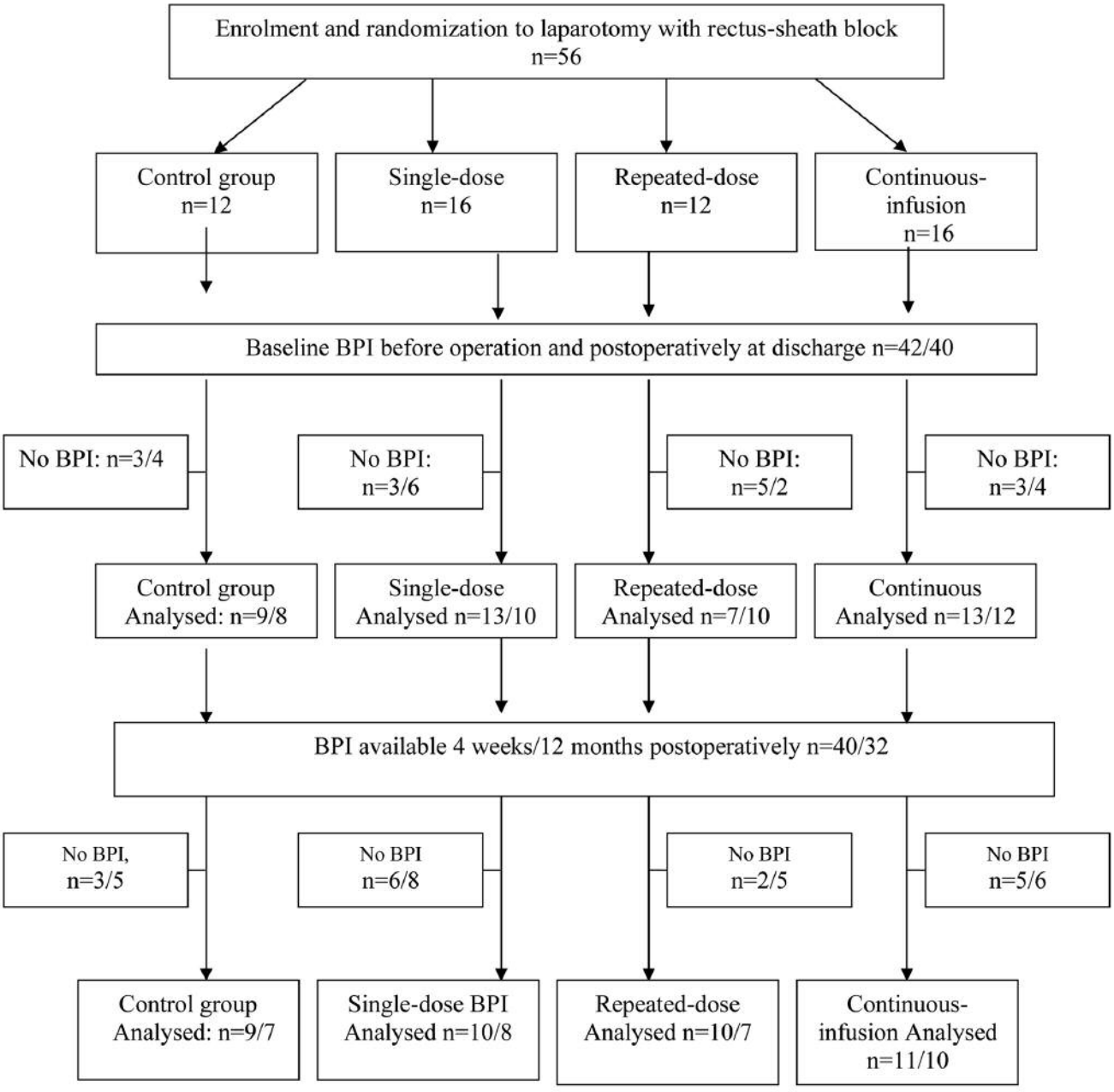

Figure 1. *Design of the study as flowchart.*

IASP (International Association for the Study of Pain) has recommended the following definition for pain (17); an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. It is known that pain could be difficult to describe and patients often complain that they could not find the right words to do so. However, the reports of pain intensity and description of a pain condition will provide valuable information for the diagnosis and physical therapy in order to improve the patient's condition. Therefore, assessment and control of pain are some of the most important goals of surgical patients' therapy. Recent data indicate that the severity of acute postoperative pain during the first hours after surgery is highly predictive of chronic postsurgical pain (18). Thus, surgical patients should have repeated pain assessment and should be provided effective pain management in the early phase of recovery.

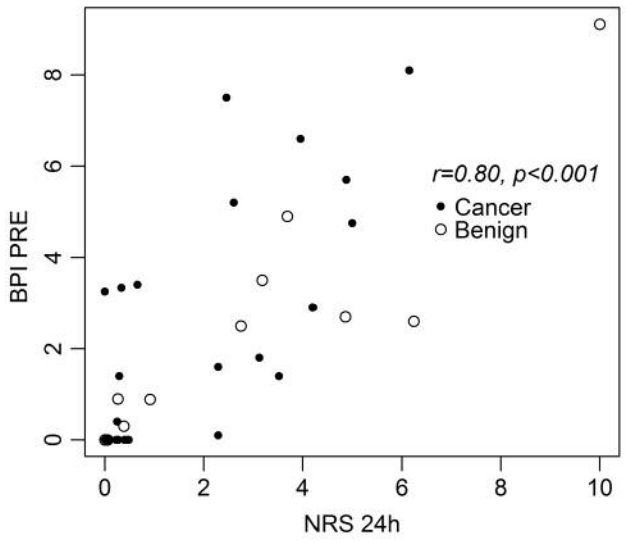

Figure 2. *The jitterplot of patient's pain assessed using a 11-point rating scale (NRS_{24}; 0=no pain; 10=worst pain ever) at 24 h following surgery versus Brief Pain Interference Score using a 11-point rating scale preoperatively (BPI_{PRE}; 0=no pain; 10=worst pain ever) in benign and cancer patients (r=0.80, p<0.001).*

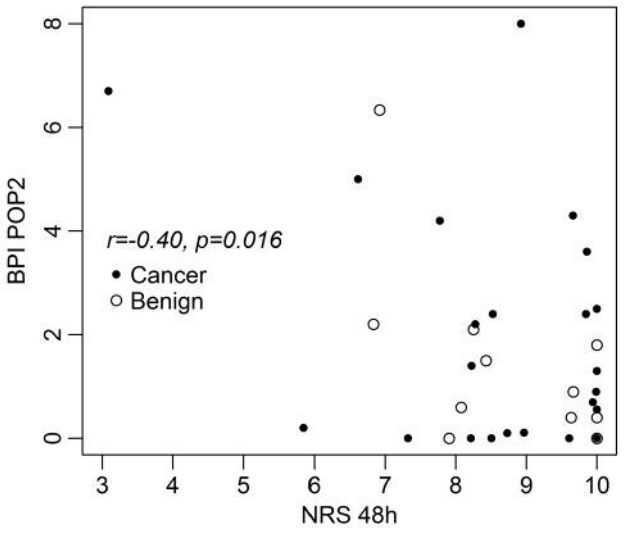

Figure 3. *The jitterplot of patient satisfaction assessed using a 11-point rating scale (NRS_{48}; 0=fully unsatisfied; 10=fully satisfied) at 48 h following surgery versus Brief Pain Interference Score using a 11-point rating scale (BPI_{POP2}; 0=no pain; 10=worst pain ever) 4 weeks postoperatively in benign and cancer patients (r=–0.40, p=0.016).*

Table I. *The midline laparotomy patients' clinical data in the four study groups. Data are mean (standard deviation) or number of cases.*

Variable	Control n=8	Single n=11	Repeated n=11	Continuous n=14	*p*-Value
Age, years	62.6 (14.3)	60.8 (12.6)	63.3 (10.8)	58.0 (10.1)	0.74
Gender, male/female	4/4	4/7	2/9	2/12	0.22
Height, cm	166.6 (8.6)	168.4 (7.9)	165.7 (7.2)	164.3 (6.6)	0.62
Weight, kg	78.6 (11.8)	83.7 (12.8)	67.8 (13.7)	68.8 (10.6)	0.007
BMI, kg/m^2	28.3 (3.8)	29.6 (4.4)	24.6 (4.3)	25.7 (4.9)	0.03
Time in the operative room, min	229.4 (113.4)	274.9 (148.4)	235.7 (112.0)	279.7 (178.5)	0.85
Operative time, min	209.6 (141.2)	221.8 (156.4)	154.4 (95.0)	253.3 (168.9)	0.55
Perioperative-bleed, ml	696 (741)	822(906)	697 (967)	1340(928)	0.31
ASA 1/2/3/4	0/6/2/0	0/7/3/1	0/5/6/0	2/7/5/0	0.43
Length of the skin incision(s), mm	27.2 (6.6)	24.4 (7.8)	24.2 (7.9)	29.7 (7.3)	0.31
Type of disease					0.32
Benign (n=15)	1	3	5	6	
GI cancer (n=9)	3	2	2	2	
Gyn cancer (n=17)	3	4	4	6	
Other cancer (n=3)	1	2	0	0	
Patients without pain	5/8	4/12	2/11	3/14	0.494

GI: Gastrointestinal tract; Gyn: gynecological; BMI: body mass index; ASA: American Society Anesthesiologists physical status score.

Several studies have evaluated BPI in benign disease and in cancer patients (1, 5, 6, 19, 20). Among the variety of methods assessing pain, BPI has been proven to be a sensitive instrument in evaluating the quality and interface of pain in patients with cancer and other surgical diseases (1, 5, 6, 19, 20). To our knowledge, BPI is far rarely evaluated in patients with midline laparotomy and has not been addressed earlier in midline laparotomy patients with RSB analgesia. Therefore, our study aimed to investigate BPI domains preoperatively and repeatedly following

Table II. *Patient satisfaction at 48 h following surgery (NRS_{48}; 0=fully unsatisfied; 10=fully satisfied), patient's pain assessed using a 11-point rating scale (NRS_{24}; 0=no pain; 10=worst pain ever) 24 h following surgery, BPI Severity Score and BPI Interference Score in four study groups measured at four time points: before (PRE), at discharge (POP1), 4 weeks (POP2) and 12 months (POP3) postoperatively. Values are mean (standard deviation).*

Variable	Control n=8	Single n=11	Repeated n=11	Continuous n=14	*p*-Value
Satisfaction NRS_{48}	7.5 (1.8)	8.4 (1.9)	9.3 (0.9)	8.9 (1.7)	0.043
Pain NRS_{24}					**0.532**
PRE	0.9 (1.4)	1.3 (2.0)	2.8 (3.9)	2.3 (2.3)	0.523
POP1	2.4 (1.3)	1.9 (1.1)	1.6 (1.0)	2.2 (1.3)	0.612
POP2	1.8 (1.9)	2.4 (3.0)	0.8 (0.9)	1.8 (1.1)	0.509
POP3	2.0 (3.5)	1.7 (2.2)	1.0 (1.8)	2.3 (2.1)	0.478
BPI Severity Score					**0.246**
PRE	1.2 (1.4)	1.1 (1.6)	2.7 (3.9)	2.3 (1.9)	0.301
POP1	2.3 (1.3)	1.5 (0.7)	1.3 (0.8)	2.4 (1.6)	0.255
POP2	1.7 (1.8)	2.2 (3.0)	0.8 (0.8)	1.8 (1.8)	0.588
POP3	1.3 (1.9)	1.9(2.4)	0.7 (1.0)	2.6 (2.2)	0.295
BPI Interference Score					**0.127**
PRE	1.3 (1.9)	2.1 (2.7)	4.3 (4.2)	1.7 (1.6)	0.180
POP1	3.6 (2.8)	2.3 (1.9)	1.5 (1.8)	3.1 (2.7)	0.274
POP2	2.1 (2.5)	1.6 (2.6)	0.8 (0.7)	2.3 (1.9)	0.409
POP3	1.8 (1.9)	1.8 (2.4)	0.4 (0.6)	2.5 (2.3)	0.248

Linear mixed model *p*-values for interaction time group are in bold. Time effect in linear mixed model in BPI Interference Score was statistically significant (p=0.008).

surgery. In addition, the follow-up interview was conducted asking the patients if they had any symptoms or pain following surgery and the pain intensity and satisfaction of treatment and surgery were reported on an 11-point NRS. The original study hypothesis was that RSB analgesia could decrease postoperative pain and enhance patient satisfaction in benign and cancer patients. On the contrary to our study hypothesis, no statistically significant differences were detected in the NRS pain scores and BPI severity score and BPI interference score between the control group and the three RSB study groups, showing that our original hypothesis was not fully realized. However, statistically significant differences were detected in patients' satisfaction 48 h following surgery (NRS_{48}) between the control group and the repeated dose and the continuous infusion groups, supporting our main hypothesis. The second end-point of our study was to determine differences in BPI pain scores *versus* NRS pain and NRS satisfaction scores in benign disease and cancer patient groups. The surprise of the present study was that the midline laparotomy patients who had repeated doses of RSB analgesia had higher BPI pain scores preoperatively than other patient groups. All study groups benefited from the RSB analgesia and after discharge, 4 weeks and 12 months following surgery the BPI pain scores had improved in all groups (linear mixed model *p*-value=0.008 for time effect). The repeated dose group patients were more satisfied 48 h following surgery than other patient groups. A novel finding was also that the relatively high correlation between preoperative BPI interference score and the patients NRS pain score 24 h following surgery. The inverse correlation between the BPI interference score following surgery and the patients satisfaction 48 h following surgery is in line with the finding that RSB patients, who had RSB repeated doses of analgesia were preoperatively more painful, but following

Table III. *The BPI Severity Score and Interference Score of benign and cancer patients measured at four time points: before (PRE), at discharge (POP1), 4 weeks (POP2) and 12 months (POP3) postoperatively. Values are mean (standard deviation).*

BPI	Benign	Cancer	*p*-Value
BPI Severity Score			**0.783**
PRE	2.1 (2.9)	1.5 (1.7)	0.490
POP1	1.8 (1.1)	1.8 (1.3)	0.895
POP2	1.4 (1.6)	1.7 (2.1)	0.608
POP3	1.9 (2.0)	1.5 (2.1)	0.693
BPI Interference Score			**0.586**
PRE	2.0 (2.6)	2.2 (2.6)	0.831
POP1	2.8 (2.5)	2.3 (2.3)	0.577
POP2	1.5 (1.8)	1.7 (2.2)	0.718
POP3	2.1 (1.9)	1.4 (2.1)	0.453

Linear mixed model *p*-values for interaction time group are in bold.

surgery they were satisfied by the success of the RSP analgesia procedure compared to other patient groups.

We have previously studied the RAND-36-Item Health Survey as a measure of quality of life following surgery (21). The BPI is a 11-item questionnaire used to measure the severity of pain (4 questions) and includes 7 questions related to episodes of pain and interference on function. The BPI was developed more than 25 years ago by Charles S. Cleeland especially as an adjunct to the Visual Analog Scale for pain (VAS) (12). Higher BPI score indicates more severe pain, and each BPI item yields a score of zero to ten and the test with eleven variables ranges between zero and 110. Our data also indicate that BPI is a feasible tool to evaluate quality of life following surgery.

Sufficient postoperative analgesia yields better functional ability and better patient satisfaction. In midline laparotomy, these are possible to achieve with repeated dose rectus sheath block.

Conflicts of Interest

The Authors report no conflicts of interest or financial ties. The Authors alone are responsible for the content and writing of this article.

Authors' Contributions

All Authors have met all of the following four criteria: 1. Substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work, 2. Drafting the work or revising it critically for important intellectual content, 3. Final approval of the version to be published, 4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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