

Pain Management Following Anorectal Surgery Using Patient-Controlled Analgesia vs. Pudendal Nerve Block: A Clinical Trial

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Abstract

Background: The use of patient-controlled analgesia (PCA) has increased in recent years. Data regarding PCA's usefulness following anorectal surgery are equivocal, and it still needs to be further studied and discussed. Therefore, the current study was conducted to compare PCA with pudendal nerve block (PNB) for pain management in patients undergoing anorectal surgery.

Methods: Patients candidate for elective anorectal surgery under general anaesthesia were considered eligible. Prior to the surgery, the patients were divided into PCA and PNB groups. PNB was performed at the end of the surgery just before extubation. PCA was initiated in the recovery room. The patients' pain scores were recorded based on an 11-point numerical rating scale (NRS) at 2, 6, 12, and 24 hours into the post-operative period. The total dose of morphine sulfate consumed, the overall satisfaction, and any side effects were recorded.

Results: 100 patients with a mean age of 44.55 ± 11.45 years were enrolled (71% male). Both methods resulted in effective pain control. The difference in the consumed doses of morphine was not statistically significant ($P = 0.2$). The PNB group patients were more satisfied than those in the PCA group (8.6 ± 1.9 vs. 7.3 ± 2.2 ; $P = 0.037$). The recorded side effects were significantly higher in the PCA group ($P < 0.001$).

Conclusions: Although both morphine-contained PCA and PNB with Marcaine resulted in effective pain control following anorectal surgery, it is likely that local anaesthesia with Marcaine is accompanied by fewer side effects and more satisfaction.

Keywords: Pain management, General surgery, Clinical Trial, Fissure, Haemorrhoid

1. Background

Anorectal symptoms and complaints are common that may be caused by a wide spectrum of conditions such as haemorrhoid, fissure, abscess, and fistula. Although most of the patients can be successfully treated as an outpatient, it is important to perform surgery in some circumstances (1-4). Post-operative pain (POP) is one of the most annoying and disturbing aspects of such a surgery. Some approaches have been introduced for POP management in these cases. Patient-controlled analgesia (PCA) is an approach that has been increasingly used in recent years (5, 6). It is claimed that PCA is not only effective in pain management, but also in reduction of opioid consumption and occurrence of related side effects (7). Data regarding PCA's usefulness following anorectal surgery are equivocal, and it still needs to be further studied and discussed (8-11). Comparing the efficacy and side effects of nerve block with those of systemic medication was the main goal of the current study. While some believe that local anaesthesia should be the method of choice, others believe in systemic medication. Therefore, the current study was undertaken to compare PCA with pudendal nerve block (PNB) of Marcaine for pain

management in patients undergoing anorectal surgery.

3. Methods

This randomized clinical trial was conducted from March 2012 to February 2013 at Imam Hossein Hospital, Tehran, Iran.

3.1. Study Population

Patients with American society of Anaesthesiologists (ASA) Class I or II, who were candidates for elective anorectal surgery under general anaesthesia, were considered eligible. Pregnancy, opium addiction, documented cardiovascular or pulmonary disease, and allergy to the drugs used in the clinical trial were the exclusion criteria of the current study.

3.2. Sampling and Randomization

Sampling was performed with the census method in a simple, non-blind manner. In the next step, the enrolled patients were randomly recruited to two intervention groups by using random numbers table. Figure 1 il-

illustrates the CONSORT diagram of patients' flows in this study.

3.3. Data Collection

To assess the inclusion and exclusion criteria, all the patients were interviewed by the researchers in the operating room. For those who were eligible, a prepared checklist was used to record data on demographic and baseline characteristics.

3.4. Intervention

All the patients had undergone surgery under general anaesthesia. Prior to the surgery, the patients were divided into PCA and PNB groups. PNB was performed at the end of the surgery just before extubation. PCA was initiated in the recovery room. The PCA group patients were connected to a pump containing 20 mg of morphine sulfate diluted in 100 cc normal saline adjusted infusion rate at 4cc/hour and 1cc for bolus every 15 minutes if required by the patient. In the PNB group, for conducting bilateral pudendal nerve block, 5 mL Marcaine 0.5% diluted with normal saline to reach the volume of 8 cc was administered at 3 and 9 o'clock of perianal area. We did not use nerve stimulator, and PNB was performed by an expert anaesthesiologist using only anatomical markers. The patients' pain scores were checked based on an 11-point numerical rating scale (NRS) every 30 minutes until 2 hours and every 1 hour until 24 hours. If patients had NRS > 3, they received 3 mg of morphine sulfate as extra slow intravenous bolus dose. These patients were excluded from the final analysis (Figure 1).

3.5. Outcome Measurement

Although the patients' pain scores were checked every 30 minutes until 2 hours and every 1 hour until 24 hours, for statistical analysis only the scores based on NRS at 2, 6, 12, and 24 hours into the post-operative period were recorded in the related checklist. The total dose of morphine sulfate consumed was also registered. All the patients were asked to rate their overall satisfaction using NRS. Any reported side-effects including nausea, vomiting, vertigo, itching, and hemodynamic change were also recorded.

3.6. Statistical Analysis

SPSS-16 software was used for statistical analysis in this study. To describe the quantitative data, mean \pm standard deviation (SD) was used, while frequency and percentage were used for qualitative data. Comparison of the quantitative data was performed with t-test and Wilcoxon signed-rank test. Qualitative data analysis was performed using Fisher's exact test and chi-square test. P values less than 0.05 were considered statistically significant.

3.7. Ethical Issues

The protocol of the study was approved by the ethics committee of Shahid Beheshti University of Medical Sciences, Iran, under the number IR.SBMU.MSP.REC.1390.123. The patients were informed about the study details and they signed a written consent form. All the authors declare conformity to the Helsinki ethical principles for medical research involving human subjects throughout the study. We followed the CONSORT statement guidelines during the preparation and reporting of this randomized controlled trial. The trial's methodology was registered on www.IRCT.ir under the registration number IRCT2016100515640N4.

4. Results

A total of 100 patients with a mean age of 44.55 ± 11.45 years were enrolled (comprising 71% males). As per Table 1, the demographic and baseline characteristics of the study patients showed no significant difference between the two groups.

Table 1. Demographic and Baseline Characteristics of Study Patients

Variable	Group		P Value
	PCA	PNB	
Age (year)	45.4 \pm 10.5	43.7 \pm 12.4	0.638
Sex			0.509
Male	34 (68%)	37 (74%)	
Female	16 (32%)	13 (26%)	
Anorectal pathology			0.809
Hemorrhoid	24 (48%)	19 (38%)	
Fistula	11 (22%)	14 (28%)	
Abscess	9 (18%)	8 (16%)	
Polyp	4 (8%)	6 (12%)	
Fissure	2 (4%)	3 (6%)	

Abbreviations: PCA, patient controlled analgesia; PNB, pudendal nerve block.

3 patients in the PCA group and 8 patients in the PNB group requested a one-time extra bolus dose of morphine. Although the difference was clinically apparent, it was not statistically significant ($P = 0.2$). These patients were excluded from the final analysis.

Table 2 and Figure 2 illustrate the comparative pain intensity between the two groups. There was no significant difference in any of the occasions when the patients were asked about their pain scores.

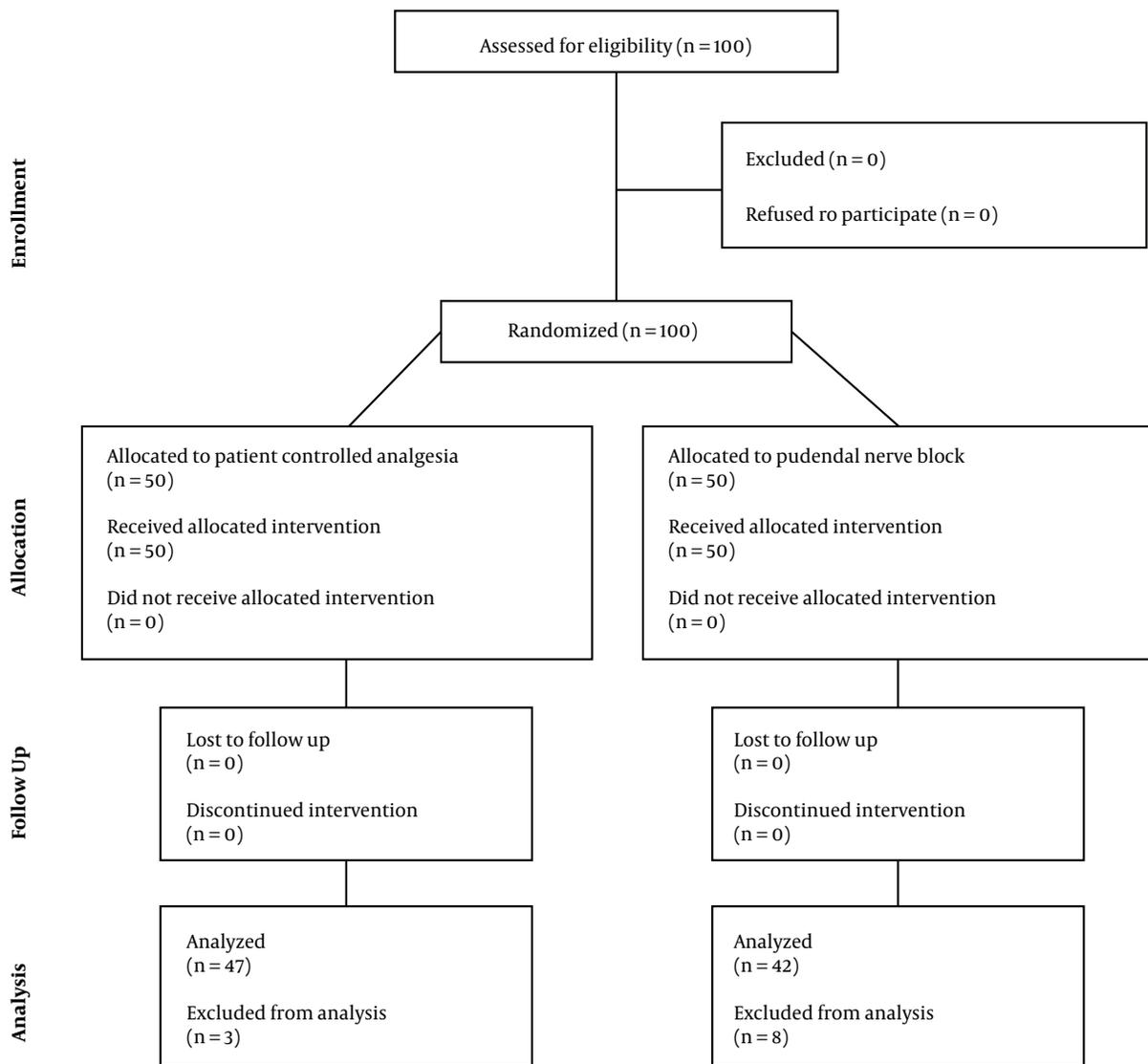


Figure 1. The CONSORT Diagram of Patients' Flows

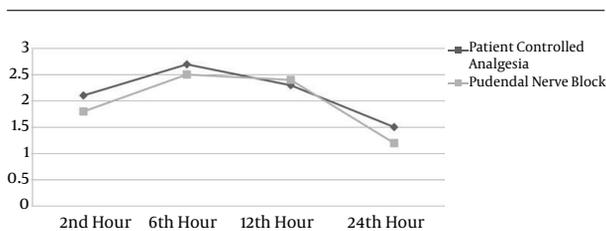


Figure 2. Comparison of Pain Intensity Based on Numerical Rating Scale Between the Two Groups

The mean satisfaction scores in the PCA group and the PNB group were 7.3 ± 2.2 and 8.6 ± 1.9 , respectively. This difference was statistically significant ($P = 0.037$).

11 patients in the PNB group and 42 patients in the PCA group experienced post-operative nausea and vomiting. 2 male patients in the PNB group suffered from transient penile anaesthesia. 23 patients in the PCA group reported itching. The difference between the recorded side-effects in the two groups was statistically significant ($P < 0.001$).

Table 2. Comparison of Pain Intensity Based on Numerical Rating Scale Between the Two Groups

Time	Group		P Value
	PCA	PNB	
2nd hour	2.1 ± 0.9	1.8 ± 0.8	0.242
6th hour	2.7 ± 1.0	2.5 ± 0.3	0.086
12th hour	2.3 ± 0.7	2.4 ± 0.5	0.291
24th hour	1.5 ± 0.9	1.2 ± 0.2	0.139

Abbreviations: PCA, patient controlled analgesia; PNB, pudendal nerve block.

5. Discussion

Based on the findings of the current study, both morphine-contained PCA and PNB with Marcaine resulted in effective pain control following anorectal surgery. However, it is evident that local anaesthesia with Marcaine was accompanied by fewer side-effects and more satisfaction.

In the current study, high satisfaction rate was seen in both groups that is to say that the patients approved the methods' usefulness for pain control after anorectal surgery. This finding is in line with the results of similar studies that compared PCA with regional nerve block (12). However, in comparison with conventional opioid treatment, PCA is more preferable (5, 13). Despite lots of advantages, the ambiguity around pain medication delivery and the failed attempts during the lockout period may contribute to the patients' perception that PCA is an unreliable modality for pain treatment (14).

Post-operative nausea and vomiting were more frequent in the PCA group. PCA was compared with regional block in some other studies, and it was almost always accompanied with such side-effects, which were not reported in case of regional nerve block (12). However, some other researchers have reported less post-operative nausea and vomiting using PCA when it was combined by other drugs such as hydromorphone (5).

Transient penile anaesthesia, which was recorded only in the local anaesthetic group in the current study, has also been reported in other studies that assessed pudendal nerve block efficacy and has almost always resolved spontaneously (15, 16). Despite penile anaesthesia following PNB, urinary retention and other annoying post-operative voiding complications are not common (17).

Despite high satisfaction rate, there were some patients in both groups who needed extra bolus dose of morphine. Although the number of these patients was not statistically significant, it is an important negative point that should be considered as a topic for further research.

Although using the PCA method for post-operative

pain management has become popular, research on its indications is still ongoing. It seems that traditional methods are as effective as the newer ones, and more aspects like cost, side-effects, and patient preference should be kept in mind when choosing the proper pain treatment modality.

5.1. Limitation

Different anal pathologies need different methods of anorectal surgery. The effect of the specific procedures that were used during surgery was not taken into account during the current analysis. The surgeon's expertise and less tissue damage during surgery may also affect the outcome, but were not included in this study. The majority of previous studies evaluated the efficacy of pain treatment modality for longer durations than the current study.

5.2. Conclusion

Although both morphine-contained PCA and PNB with Marcaine resulted in effective pain control following anorectal surgery, it is evident that local anaesthesia with Marcaine was accompanied by fewer side-effects and more satisfaction.

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Footnotes

Authors' Contribution: All the authors meet the requirements of authorship based on the standards recommended by the international committee of Medical Journal Editors.

Conflict of Interest: The authors declare that there is no conflict of interest regarding the present study.

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