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A prospective randomized trial comparing the efficacy of temperature-responsive gel with local anesthetics *versus* local anesthetic infusion pump device for postoperative pain control after bariatric surgery

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Purpose: Bariatric surgery is the gold standard for the treatment of morbid obesity, but postoperative pain impedes recovery. Currently available pain-recovery treatments have patient safety concerns. This led to a noninferiority study of Welpass (Genewel Co., Ltd.) *vs.* On-Q PainBuster (B. Braun), each used alongside a traditional method of continuous local anesthetic administration, in patients undergoing bariatric surgery.
Methods: In this single-center prospective randomized clinical trial, patients were assigned in a 1:1 ratio to the treatment group (Welpass) and the control group (On-Q PainBuster), with ketorolac administered as needed after surgery according to the protocol. To assess efficacy, the total amount of ketorolac used up to 72 hours postoperatively was measured. Additionally, ketorolac usage and numerical rating scales (NRS) were recorded at 6, 24, 48, and 72 hours after operation.
Results: The total amounts of ketorolac used in the 72 hours postoperatively were 188.0 ± 84.6 mg in the treatment group and 198.7 ± 50.0 mg in the control group. The efficacy of the treatment group was noninferior to that of the control group, since the lower limit (–29.9 mg) of the confidence interval for the difference with the control group was greater than the prespecified noninferiority margin (–35.0 mg). Furthermore, when the NRS was evaluated after bariatric surgery, there was no significant difference in scores between the 2 groups at each time point ($P > 0.05$).
Conclusion: We found no difference in effect on pain between the 2 groups, supporting the use of Welpass in clinical practice for pain management in patients undergoing bariatric surgery.
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Key Words: Bariatric surgery, Postoperative pain, Local anesthetics, Temperature-responsive gel, Drug delivery systems

INTRODUCTION

Bariatric surgery is one of the most effective treatments for morbid obesity, with demonstrated medical benefits in Korea since 2019. This advancement has enabled the active treatment of patients with morbid obesity who have not responded to nonsurgical interventions and lifestyle modifications [1,2]. A domestic report found that the number of bariatric surgeries has quadrupled since 2010 due to increased medical benefits and a low postoperative complication rate [3]. Additionally,

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bariatric surgery significantly improves the remission of obesity-related comorbidities, survival rates, and quality of life, and provides social benefits [3].

On the other hand, postoperative pain following bariatric surgery is believed to delay patient recovery by inhibiting both physical and psychological activities [4]. Effective management of postoperative pain is essential, as bariatric surgery is associated with significant complications, including pain, diminished respiratory and physical function, and prolonged hospitalization, all of which can elevate healthcare costs [5,6].

Various strategies, including nerve blocks with local anesthetics, have been explored to alleviate postoperative pain in patients who underwent bariatric surgery, in addition to the use of intravenous (IV) or oral anesthetics. Prior studies have shown that using a combination of narcotic analgesics with either continuous local anesthetic delivery at the surgical site post-laparotomy (On-Q PainBuster, B Braun) or a topical form (Welpass, Genewel Co., Ltd.) applied through a temperature-responsive gel containing a blend of local anesthetics for slow absorption, can effectively reduce pain with noninferior outcomes [7,8]. Nevertheless, combining topical anesthetics with narcotic analgesics following bariatric surgery requires caution due to potential pharmacokinetic alterations after surgery, adverse effects associated with topical anesthetics, and an increased risk of peripheral catheter infections, particularly in obese patients [9-11].

Therefore, it is necessary to minimize the dosage of topical anesthetics and explore their integration with conventional pain management approaches for improved pain control [12]. This study aims to assess the analgesic effectiveness of Welpass *vs.* On-Q PainBuster alongside traditional pain management techniques among patients undergoing bariatric surgery through a comparative analysis of pain relief outcomes.

METHODS

Ethics statement

This study was a single-center, prospective, randomized clinical trial. The study protocol was designed following the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) of 2013 [13] and was approved by the Institutional Review Board of Seoul National University Bundang Hospital (No. B-2305-829-002). We conducted the study in accordance with the Declaration of Helsinki and ensured that all participants were fully informed and gave their written consent before joining. The protocol of the study was registered with the Clinical Research Information Service of the Korea Centers for Disease Control and Prevention (No. KCT0009540).

Patient selection

The study enrolled participants who satisfied the National Health Insurance criteria for bariatric surgery, which necessitates a body mass index (BMI) of ≥35 kg/m^2 or a BMI of ≥30 kg/m^2 with associated obesity-related complications such as hypertension, hyperlipidemia, diabetes mellitus, fatty liver, and polycystic ovary syndrome.

The exclusion criteria were as follows: (1) current or prior participation in another investigational study, or the presence of any medical condition that could impact the assessment of the medical device's safety or effectiveness; (2) known contraindications to the use of ketorolac; (3) known hypersensitivity to ropivacaine or any other amide-type local anesthetics; (4) presence of massive bleeding or shock; (5) inflammation at or near the proposed site of injection; (6) current diagnosis of sepsis; (7) receipt of IV regional anesthesia; and (8) any condition considered by the investigator to be unsuitable for study participation, such as lack of cooperation.

Intervention

Participants eligible for inclusion, who were scheduled for bariatric surgery beginning on July 10, 2023, were randomized in a 1:1 ratio to either the treatment group or the control group prior to surgery. This randomization was conducted according to a pre-generated schedule based on a random number table.

In the treatment group, a temperature-responsive gel containing local anesthetics (Welpass) was applied to the surgical wounds immediately before the end of the operation (Fig. 1A). For the Welpass group, wounds were managed with an application of 6 mL of poloxamer 407 (Kolliphor P407,

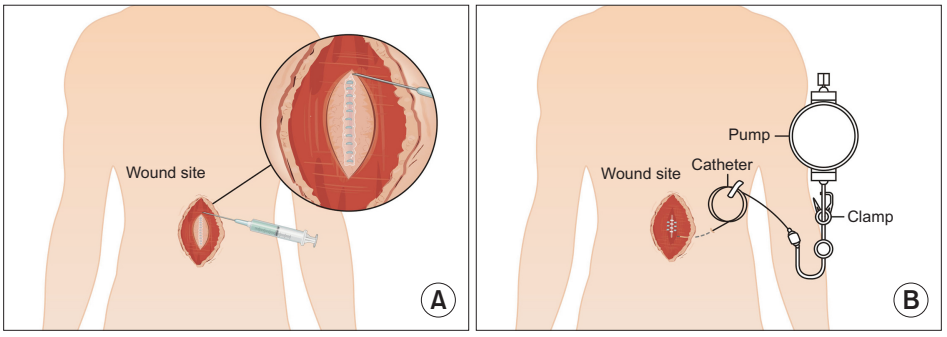

Fig. 1. Local anesthetic applications at the surgical wound site. (A) Welpass (Genewel Co., Ltd.) is applied directly inside the surgical wound before the site is completely closed. (B) On-Q PainBuster (B. Braun) is inserted with a catheter near the incision site and is connected to a pump for continuous drug delivery.

BASF) and alginate combined with 3 mL of 0.75% ropivacaine injection, resulting in a total dose of 22.5 mg ropivacaine. Meanwhile, the control group was administered a continuous local anesthetic delivery system (On-Q PainBuster) at the surgical wound before closing it (Fig. 1B). The On-Q PainBuster group received a continuous infusion of 0.2% ropivacaine at a rate of 2 mL/hr through a 6.5-cm catheter over 48 hours, totaling 192 mg ropivacaine.

Additionally, IV patient-controlled analgesia (PCA) was administered to all patients in both groups immediately after surgery. The PCA solution contained 180 mg of ketorolac in 50 mL of normal saline, delivered continuously at a rate of 1 mL per hour. When the patient pressed the button on the PCA, an additional 1 mL was administered, followed by a locking period of 15 minutes. This protocol resulted in a continuous administration of at least 24 mL per day, equivalent to 86.4 mg of ketorolac. Each button press delivered an additional 1 mL, equivalent to 3.6 mg of ketorolac. Based on these calculations, we monitored the daily dosage of ketorolac used in the PCA for each patient.

If additional analgesia was required during or after the PCA application, IV ketorolac was prescribed as the first drug on an as-needed basis to manage postoperative pain during a 72-hour period.

Following our hospital's clinical pathway for bariatric surgery, patients are generally discharged on postoperative day (POD) 3. Ambulation is initiated 6 hours after transfer from the recovery room to the ward. During their hospital stay, patients begin sipping water on POD 1, transition to a semifluid diet on POD 2 and are discharged on POD 3 when they tolerate both diet and pain. Pain monitoring using the numeric rating scale (NRS) and pain management are maintained until discharge (Fig. 2).

Outcomes

The primary endpoint was defined as the cumulative dosage of ketorolac administered during the first 72 hours after surgery, specifically excluding any other narcotic or nonnarcotic analgesics not part of the study interventions for postoperative pain management. Secondary endpoints included the amount of ketorolac administered immediately after surgery, as well as at 24, 48, and 72 hours postoperatively. Pain intensity was also assessed using the NRS at 6, 24, 48, and 72 hours following the surgery.

Statistical analyses

The sample size for this study was derived based on the primary endpoint, which was the total ketorolac consumption over 72 hours after bariatric surgery in the groups treated with On-Q PainBuster and Welpass. Using a 1-tailed noninferiority test, the study calculated a 97.5% confidence interval for the mean difference in total ketorolac usage at 72 hours, with the noninferiority margin set at –35.0 mg and an assumed standard deviation (SD) of 40.0 mg [14]. To achieve a power of 80% at 1-tailed significance level of 0.025, the required sample size was determined to be 21 participants per group. Factoring in a projected dropout rate of 10%, the final sample size was adjusted to 24 participants per arm, totaling 48 participants for the study.

Continuous variables were presented as means ± SDs, and categorical variables were expressed as counts and percentages. Differences in continuous variables between groups were assessed using the Student t-tests, while the chi-square tests (or Fisher exact test) were employed to compare categorical variables. All statistical analyses were conducted using R software (ver. 4.2.1, R Foundation for Statistical Computing). A P-value of less than 0.05 was deemed to indicate statistical

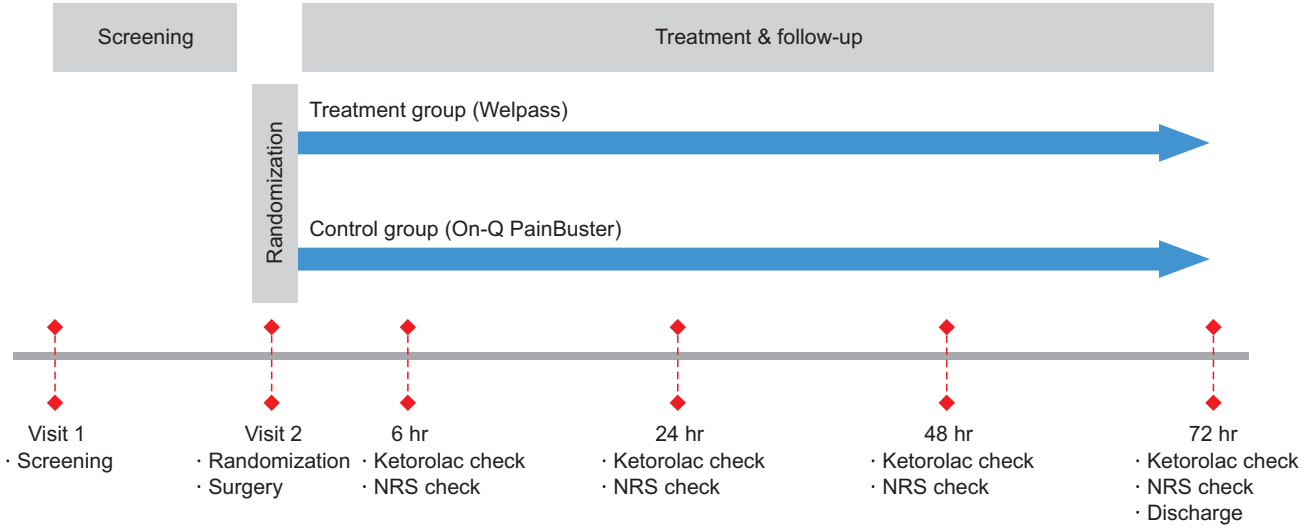

Fig. 2. Flow chart of the clinical trial. NRS, numeric rating scale. Welpass, Genewel Co., Ltd.; On-Q PainBuster, B. Braun.

significance.

RESULTS

Demographic information

The study successfully enrolled and retained 48 patients from July 2023 to December 2023. Demographic and baseline characteristics of the participants are systematically outlined in Table 1. Participants were evenly distributed into 2 groups, with 24 in the Welpass group and 24 in the On-Q PainBuster group. The statistical evaluation showed no significant differences between the 2 groups concerning age, sex, height, weight, BMI, existing medical conditions, smoking habits, or initial laboratory findings.

Postoperative information

Table 2 provides a comparative summary of surgical details and postoperative outcomes for the patients in the study. The types of operations performed were sleeve gastrectomy (83.3% in the Welpass group *vs.* 91.7% in the On-Q PainBuster group), gastric bypass (4.2% in both groups), and duodenal switch (12.5% in the Welpass group *vs.* 4.2% in the On-Q PainBuster), which were not significantly different between the 2 groups (P = 0.578).

Surgical approaches varied with 20.8% of the Welpass group and 37.5% of the On-Q PainBuster group undergoing procedures using reduced ports, whereas 79.2% of Welpass and 62.5% of On-Q PainBuster underwent multiport surgeries (P = 0.341). The operation time was 120.4 ± 29.5 minutes for the Welpass group and 107.1 ± 30.2 minutes for the On-Q PainBuster group (P = 0.119). The average postoperative hospital stay was longer in the Welpass group at 3.4 ± 1.0 days compared to 3.0 ± 0.7 days in the On-Q PainBuster group although the difference was not statistically significant (P = 0.065).

Laboratory tests performed on POD 2 showed no significant difference between the groups, with blood urea nitrogen levels at 10.2 ± 4.9 mg/dL for Welpass and 10.0 ± 2.8 mg/dL for On-Q PainBuster (P = 0.830), and creatinine levels at 0.7 ± 0.2 mg/dL and 0.6 ± 0.1 mg/dL, respectively (P = 0.375).

Postoperative complications were minimal and comparable between the groups. Major early complications and minor early complications each occurred in 1 patient (4.2%) in the Welpass group, with no occurrences in the On-Q PainBuster group (P = 0.990). Other specific complications, such as anastomosis leakage, bleeding, bowel perforation, small bowel obstruction, incisional hernia, respiratory failure, sleeve stenosis, anastomosis stricture, acute renal failure, dehydration, urinary tract infection, readmission, and death, had no reported cases in either group.

Notably, nausea and vomiting were the most common complications, with 41.7% of the Welpass group and 33.3% of the On-Q PainBuster group experiencing these issues (P =

Table 1. Demographics of study participants

Characteristic	Treatment group	Control group	P-value
No. of patients	24	24	
Age (yr)	36.5 ± 9.9	35.5 ± 9.9	0.738
Sex			0.341
Female	15 (62.5)	19 (79.2)	
Male	9 (37.5)	5 (20.8)	
Height (cm)	168.0 ± 8.4	165.5 ± 8.3	0.294
Weight (kg)	117.7 ± 18.7	110.2 ± 28.4	0.058
BMI (kg/m^2)	41.6 ± 4.9	39.9 ± 7.8	0.372
Underlying disease			
Hypertension	20 (83.3)	15 (62.5)	0.194
Dyslipidemia	14 (58.3)	9 (37.5)	0.248
Diabetes mellitus	10 (41.7)	5 (20.8)	0.213
NAFLD	15 (62.5)	10 (41.7)	0.248
Psychosis	3 (12.5)	8 (33.3)	0.170
Smoking (%)			0.931
Current smoker	4 (16.7)	5 (20.8)	
Nonsmoker	16 (66.7)	15 (62.5)	
Ex-smoker	4 (16.7)	4 (16.7)	
Preoperative laboratory test results			
BUN (mg/dL)	12.3 ± 5.2	11.8 ± 2.9	0.662
Creatinine (mg/dL)	0.8 ± 0.2	0.7 ± 0.2	0.464

Values are presented as number only, mean ± standard deviation, or number (%).
BMI, body mass index; NAFLD, nonalcoholic fatty liver disease; BUN, blood urea nitrogen.

Table 2. Patients' surgical information

Variable	Treatment group (n = 24)	Control group (n = 24)	P-value
Operation type			0.578
Sleeve gastrectomy	20 (83.3)	22 (91.7)	
Gastric bypass	1 (4.2)	1 (4.2)	
Duodenal switch	3 (12.5)	1 (4.2)	
Approach method			0.341
Reduced ports	5 (20.8)	9 (37.5)	
Multiports	19 (79.2)	15 (62.5)	
Operation time (min)	120.4 ± 29.5	107.1 ± 30.2	0.119
Postoperative hospital stay (day)	3.4 ± 1.0	3.0 ± 0.7	0.065
Laboratory test results at postoperative day 2			
Blood urea nitrogen (mg/dL)	10.2 ± 4.9	10.0 ± 2.8	0.830
Creatinine (mg/dL)	0.7 ± 0.2	0.6 ± 0.1	0.375
Postoperative complication			
Major early complications	1 (4.2)	0 (0)	0.990
Minor early complications	1 (4.2)	0 (0)	0.990
Anastomosis leakage	0 (0)	0 (0)	0.990
Bleeding	1 (4.2)	0 (0)	0.990
Bowel perforation	0 (0)	0 (0)	0.990
Small bowel obstruction	0 (0)	0 (0)	0.990
Incisional hernia	0 (0)	0 (0)	0.990
Respiratory failure	0 (0)	0 (0)	0.990
Nausea/vomiting	10 (41.7)	8 (33.3)	0.551
Sleeve stenosis	0 (0)	0 (0)	0.990
Surgical site infection	1 (4.2)	0 (0)	0.990
Venous thromboembolism	0 (0)	0 (0)	0.990
Anastomosis stricture	0 (0)	0 (0)	0.990
Acute renal failure	0 (0)	0 (0)	0.990
Dehydration	0 (0)	0 (0)	0.990
Urinary tract infection	0 (0)	0 (0)	0.990
Readmission	0 (0)	0 (0)	0.990
Death	0 (0)	0 (0)	0.990

Values are presented as number (%) or mean ± standard deviation.

0.551). Surgical site infections occurred in 1 patient (4.2%) in the Welpass group and were absent in the On-Q PainBuster group (P = 0.990). The patient in the Welpass group who experienced a surgical site infection was treated successfully with bedside dressing, which was graded as Clavien-Dindo grade I.

Ketorolac usage

Table 3 and Fig. 3 present the ketorolac doses administered after bariatric surgery for patients in both the Welpass and On-Q PainBuster groups. On the day of surgery, the average ketorolac dose was 97.2 ± 33.0 mg for the Welpass group and 99.5 ± 26.1 mg for the On-Q PainBuster group, with no significant difference between the groups (P = 0.795). At 24 hours after surgery (POD 1), the doses were 79.5 ± 48.0 mg for Welpass and 96.7 ± 29.7 mg for On-Q PainBuster, also showing no significant difference (P = 0.143). At 48 hours after surgery (POD 2), the Welpass group received an average dose of 7.5 ± 18.2 mg compared to 2.5 ± 8.5 mg in the On-Q PainBuster group, though this difference was not statistically significant (P = 0.232). By 72 hours after surgery (POD 3), the Welpass group had an average dose of 3.8 ± 13.5 mg, while no ketorolac was administered in the On-Q PainBuster group; this difference also did not reach statistical significance (P = 0.185).

The total ketorolac administered over the 72 hours after surgery averaged 188.0 ± 84.6 mg for the Welpass group and 198.7 ± 50.0 mg for the On-Q PainBuster group, without a statistically significant difference (P = 0.597). A 1-tailed 97.5% confidence interval of the mean difference in the total amount of ketorolac used showed a lower bound of –29.9 mg, exceeding the noninferiority margin set at –35.0 mg, indicating that the difference in total ketorolac usage over 72 hours between the 2 groups was not statistically significant.

During the postoperative phase, a pattern emerged showing increased ketorolac consumption in the Welpass group at both 48 and 72 hours following surgery, though these variations were not statistically significant. Additionally, both groups

Table 3. Doses of ketorolac administered on the day of bariatric surgery and postoperatively

Postoperative time (hr)	Ketorolac dose (mg)		P-value
	Treatment group (n = 24)	Control group (n = 24)	
The day of surgery	97.2 ± 33.0	99.5 ± 26.1	0.795
24	79.5 ± 48.0	96.7 ± 29.7	0.143
48	7.5 ± 18.2	2.5 ± 8.5	0.232
72	3.8 ± 13.5	0.0 ± 0.0	0.185
Total	188.0 ± 84.6	198.7 ± 50.0	0.597

Values are presented as mean ± standard deviation.

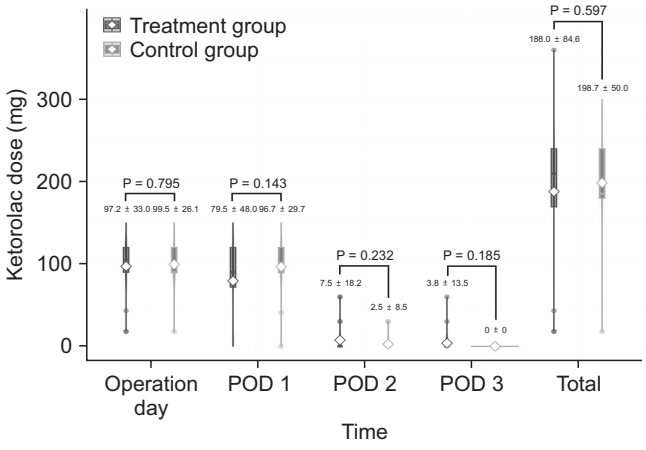

Fig. 3. Ketorolac usage at postoperative time points. POD, postoperative day.

exhibited a decrease in ketorolac use at 72 hours relative to the immediate postsurgical period.

Postoperative pain assessment using numerical rating scales

NRS scores were assessed at 6, 24, 48 and 72 hours after operation to evaluate pain levels following bariatric surgery in the 2 groups (Table 4, Fig. 4). The Welpass group scored 3.4 ± 0.9 *vs.* 3.1 ± 0.4 in the On-Q PainBuster group at 6 hours (P = 0.102), 3.3 ± 0.8 *vs.* 3.0 ± 0.7 at 24 hours (P = 0.171), 2.9 ± 0.7 *vs.* 2.8 ± 0.7 at 48 hours (P = 0.512), and 2.8 ± 0.5 *vs.* 2.6 ± 1.0 at 72 hours (P = 0.482).

The analysis showed no significant differences in pain scores between the groups at any of the postoperative intervals. While pain scores were consistently slightly higher in the Welpass group compared to the On-Q PainBuster group, these differences were not statistically significant. Additionally, a trend was observed in both groups showing a reduction in pain scores from the initial assessment at 6 hours to 72 hours postoperatively, suggesting effective management of

Table 4. Numerical rating scale (NRS) on the day of bariatric surgery and postoperatively

Postoperative time (hr)	NRS		P-value
	Treatment group (n = 24)	Control group (n = 24)	
6	3.4 ± 0.9	3.1 ± 0.4	0.102
24	3.3 ± 0.8	3.0 ± 0.7	0.171
48	2.9 ± 0.7	2.8 ± 0.7	0.512
72	2.8 ± 0.5	2.6 ± 1.0	0.482

Values are presented as mean ± standard deviation.

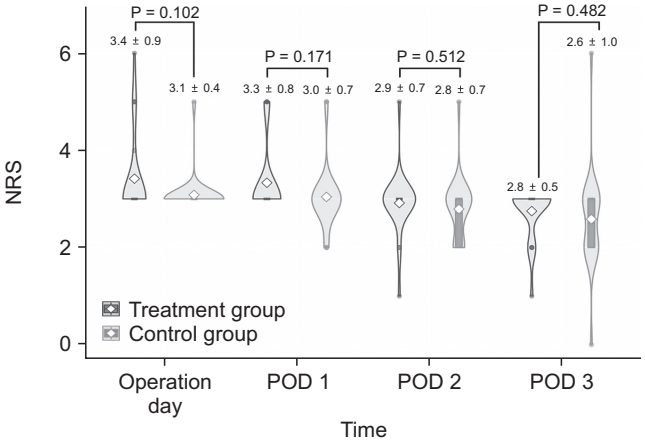

Fig. 4. Results of postoperative numerical rating scale (NRS) assessment. POD, postoperative day.

postoperative pain across both treatment modalities.

DISCUSSION

This study assessed the noninferiority of Welpass, a sustained-release drug delivery system, in comparison with conventional continuous regional anesthesia using the On-Q PainBuster, alongside standard ketorolac treatment for postoperative pain management following bariatric surgery. The findings revealed no significant differences between the 2 methods in terms of ketorolac usage and NRS pain scores. Unlike the On-Q PainBuster, which requires catheterization and subsequent removal, Welpass simplifies the process by eliminating these procedures, potentially enhancing patient comfort during postsurgical recovery.

Welpass is a sustained-release drug delivery surgical kit that utilizes poloxamer 407, an amphiphilic agent, to release drugs over time. Poloxamer 407 is a nonionic amphiphilic polymer widely used in pharmaceuticals, medical devices, cosmetics, and other fields due to its self-assembly properties and versatile applications [15]. Poloxamer 407 exhibits excellent biocompatibility and temperature-dependent reversible

properties, transitioning from liquid to gel. This allows it to be mixed with various drugs or active ingredients, making it valuable in drug delivery systems [16,17].

This polymer transitions from liquid to gel at body temperatures, enabling it to construct a uniform matrix that gradually releases ropivacaine at the surgical site for up to 72 hours. Such features not only improve the ease of application by allowing a single administration without the need for post-application management, as required with the On-Q PainBuster but also ensure sustained pain control.

The comparative analysis of postoperative conditions, including ketorolac consumption and NRS pain evaluations, further supports the efficacy of Welpass as a viable alternative for pain management in bariatric surgery. Notably, Welpass employs a significantly lower dose of ropivacaine (22.5 mg) compared to the conventional method using the On-Q PainBuster, which administers a total of 192 mg of ropivacaine. This reduction in ropivacaine dosage potentially decreases the risk of systemic side effects.

Despite these promising results, the study faced limitations, including the non-blinded design, which might have introduced bias. Although randomization was employed to reduce this effect, the influence on outcomes cannot be entirely ruled out. Additionally, the study's duration was confined to 72 hours after surgery, which restricts the assessment of long-term pain management efficacy. Future research should extend beyond this timeframe to explore the long-term benefits of Welpass in surgical pain management.

In conclusion, this study confirms that Welpass provides effective postoperative pain management in bariatric surgery with a simpler application and lower dose of ropivacaine, making it a safer and more convenient alternative to the On-Q PainBuster.

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Conflict of Interest

Young Suk Park, serving as the associate editor of *Annals of Surgical Treatment and Research*, did not participate in the review process of this article. No other potential conflicts of interest pertinent to this article were reported.

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