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Prospective Comparative Analysis of the Incidence of Vasovagal Reaction and the Effect of Rectal Submucosal Lidocaine Injection in Stapled Hemorrhoidopexy: A Randomized Controlled Trial

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Purpose: This study was performed to evaluate the incidence of vasovagal reactions (VVRs) and the efficacy of lidocaine injection for prevention.

Methods: One hundred seventeen patients diagnosed with hemorrhoids and scheduled to undergo a stapled hemorrhoidopexy (SH) were randomly divided according to submucosal injection to the rectum: lidocaine group (n = 53, lidocaine injected just before full closure of the stapler) and control group (n = 58). Outcomes included baseline patient characteristics (American Society of Anesthesiologists physical status classification, body mass index, diabetes mellitus, hypertension, and previous VVR history), vital signs during the operation, incidence of VVRs (hypotension, bradycardia, dizziness, diaphoresis, and nausea/vomiting), and postoperative complications (pain, bleeding, and urinary retention).

Results: Baseline characteristics were similar between groups. The number of patients with lower abdominal pain after firing the stapler and incidence of dizziness were lower for the lidocaine group than for the control group (9.4% vs. 25.9%, P = 0.017; 0% vs. 8.6%, P = 0.035, respectively). However, there were no significant between-group differences in incidence of nausea and diaphoresis (0% vs. 3.4%, P = 0.172) and syncope (1.9% vs. 3.4%, P = 0.612). Fewer patients in the lidocaine group complained of postoperative pain (41.5% vs. 58.6%, P = 0.072), and these patients used analgesics less frequently than those in the control group (28.3% vs. 36.2%, P = 0.374).

Conclusion: Patients who received a submucosal lidocaine injection prior to SH experienced less lower abdominal pain and dizziness compared with those who received standard treatment. A larger, more detailed prospective study is needed for further analysis.

Keywords: *Vasovagal syncope; Stapled hemorrhoidopexy; Local anesthetics; Randomized controlled trial*

INTRODUCTION

Stapled hemorrhoidopexy (SH) was introduced by Longo in 1998 as a minimally invasive new technique for treating hemorrhoidal disease [1]. Instead of submucosal excision of the prolapsed hemorrhoidal pedicles, a stapling device is used to reposition the prolapsed hemorrhoids, which involves simultaneous circumferential excision and anastomosis [2, 3]. Compared with conventional hemorrhoidectomy, this approach is advantageous because of less postoperative pain, shorter hospital stay, and shorter duration of convalescence; these improvements in patient outcomes have resulted in widespread use of SH by coloproctologists [4-6]. Although the procedure is generally well-tolerated, some patients experience pain, and there is risk of a vasovagal reaction (VVR).

VVR is also referred to as neurocardiogenic or neuromediated syndrome because the usual cause stems from the nerves of the

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heart, are relatively frequent during medical interventions, and pose a challenge to physicians, with an annual incidence of 1.3 to 2.7 events per 1,000 individuals [7]. The incidence of VVRs in interventional cardiology procedures is between 3.4% and 13.9% [8], and in colonoscopy, this rate varies between 0.2% and 0.5% with a mortality rate of 0.03% to 0.05% [9]. VVR occurred in 16% of patients with conventional hemorrhoidectomy, one of the most common procedures performed by coloproctologists, and 0.6% in rubber band ligation [10, 11]. The presence of pain, tissue injury, and strong emotional reactions may contribute to development of VVR [12, 13]. In patients with a mild pathology, the symptoms are limited to presyncope or aura (dizziness, mental confusion, weakness, and diaphoresis) without loss of consciousness. Most patients do not experience transient loss of consciousness [14, 15]. Though it is frequently benign, a malignant form of this disorder with episodes of prolonged cardioinhibition has been reported; these can often be caused by surgery. These episodes can culminate in asystole and, if not interrupted, may simulate a sudden cardiac deathlike episode [16, 17].

It has been suggested that use of local anesthesia may reduce pain or prevent VVR. Several reports have been published on the effect of local anesthetic injection on the rectal mucosa during open hemorrhoidectomy and rubber band ligation [10, 11]. However, no published clinical studies have discussed the incidence or prevention of VVR during SH. To address this, we conducted a prospective randomized controlled trial (RCT) aimed to analyze the incidence of VVR and the effect of rectal submucosal lidocaine injection in SH.

METHODS

The trial was approved by the Institutional Review Board of Seoul Song Do Hospital (No. 2018-005), and all patients provided written informed consent to participate in the study. Between May and October 2018, the study enrolled 117 patients diagnosed with hemorrhoids and scheduled to undergo SH. Patients with a history of inflammatory bowel disease (e.g., Crohn disease or ulcerative colitis), tuberculosis, or coexisting anorectal diseases such as anal fistula and anal fissure and those who requested a sedative agent during the procedure were also excluded. Six patients were excluded as they declined to participate in the study (Fig. 1).

Patients were randomly assigned by a computer-generated list to either the lidocaine group, which received a local anesthetic injection during the procedure, or the control group with no injection. Allocations were sealed in opaque, numbered envelopes. All patients received spinal anesthesia administered by a single anesthesiologist (0.5% heavy bupivacaine 0.05 mg/cm injected by a 25 gage spinal needle on the L2–3 interspace). The procedures were performed by 2 colorectal surgeons using 2 stapler devices, PPH 33 (DAVID, Ningbo, China) and TST33-S180 (Touchstone, Suzhou, China). At completion of purse-string suture and before firing of the device, the patients in the lidocaine group received 5% lidocaine in the rectal submucosal area to be stapled (Fig. 2).

During circular SH, 1 mL of lidocaine was injected around the anus at each of the 12, 3, 6, and 9 o'clock positions. During partial SH, 1 mL of lidocaine was injected onto each of the 3 rectal mucosae protruding through the circular anal dilator window. At each step of the procedure (before the operation, after the closure by the stapler, after firing, and after completion of the procedure), vital signs (systolic pressure, diastolic pressure, and pulse rate) were measured and recorded by the circulating nurse. During the procedure, the surgeons and anesthesiologist monitored the patients for complications such as lower abdominal pain, dizziness, nausea, diaphoresis, and syncope.

After the surgery, patients were transferred to the general ward, and pain was recorded at 1 hour, 6 hours, and 24 hours postoperatively using a visual analogue scale (VAS; 1 to 10). Patients were reviewed for complications including bleeding and urinary retention. Patients with pain and those with a VAS score greater than 4 were given injections of 10 to 30 mg of ketorolac.

Statistical analysis was completed using IBM SPSS Statistics ver. 23.0 (IBM Corp., Armonk, NY, USA). Categorical data were ana-

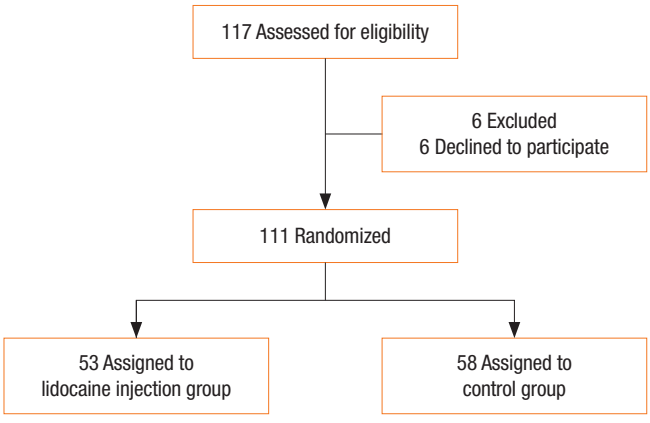

Fig. 1. Flow diagram showing the study design.

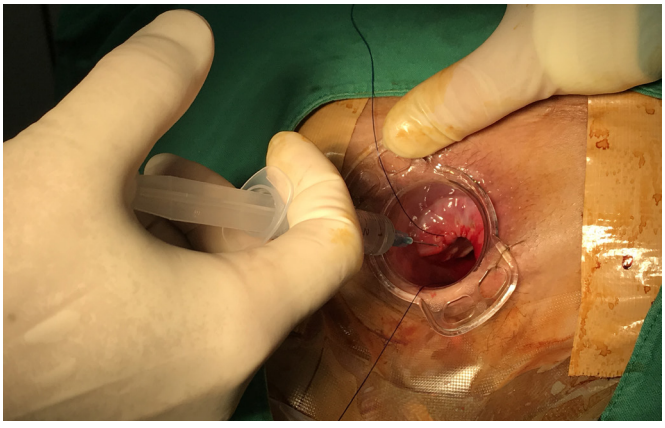

Fig. 2. Submucosal lidocaine injection.

lyzed using the chi-square test, and continuous data were analyzed using Student t-test. Data were expressed as mean ± standard deviation or number (percentage). $P < 0.05$ was considered statistically significant.

RESULTS

There were no significant between-group differences in baseline characteristics (Table 1). Comparison of the monitored vital signs (systolic pressure, diastolic pressure, and pulse rate) revealed no significant difference between the 2 groups (Table 2). The rate of intraoperative complications, such as lower abdominal pain (9.4% [5 of 53] vs. 25.9% [15 of 58], P = 0.017) and dizziness (0% [0 of 53] vs. 8.6% [5 of 58%], P = 0.035) was significantly lower in the lidocaine group than in the control group (Table 3). Additional

Table 1. Baseline characteristics of the patients

Characteristic	Lidocaine group (n = 53)	Control group (n = 58)	P-value
Age (yr)	50.8 ± 20.1	50.2 ± 19.5	0.639
Sex			
Male	37 (69.8)	44 (75.9)	0.374
Female	16 (30.2)	14 (24.1)	0.508
Body mass index (kg/m^2)	23.7 ± 4.2	24.7 ± 3.8	0.412
ASA PS classification			0.385
I	30 (56.6)	34 (58.6)	
II	22 (41.5)	21 (36.2)	
III	1 (1.9)	3 (5.2)	
Alcohol (g/day)	6.0 ± 11.9	4.5 ± 10.9	0.516
Smoking (pack-yr)	1.1 ± 6.0	2.0 ± 5.9	0.206
Preexisting disease			
Hypertension	17 (32.1)	14 (24.1)	0.352
Diabetes	4 (7.5)	5 (8.6)	0.836
BPH	5 (9.4)	4 (6.9)	0.625
Hyperlipidemia	6 (11.3)	11 (19.0)	0.264
Cardiovascular (angina, stroke, MI)	1 (1.9)	4 (6.9)	0.204
Syncope	1 (1.9)	0	0.293
Hemorrhoid grade			0.099
II	1 (1.9)	7 (12.1)	
III	35 (66.0)	37 (63.8)	
IV	17 (32.1)	14 (24.1)	
Preoperative manometry (maximal, mmHg)			
Resting	74.7 ± 18.4	75.0 ± 19.8	0.983
Voluntary contraction	227.6 ± 49.3	230.0 ± 27.5	0.749
Squeezing	152.2 ± 50.1	153.8 ± 29.3	0.841

Values are presented as mean ± standard deviation or number (%).
ASA, American Society of Anesthesiologists; PS, physical status; BPH, benign prostate hypertrophy; MI, myocardial infarction.

Table 2. Patient vital signs during procedures

Variable	Lidocaine group (n = 53)	Control group (n = 58)	P-value
Baseline			
SP (mmHg)	127.93 ± 15.80	129.94 ± 14.14	0.375
DP (mmHg)	76.03 ± 12.85	78.89 ± 12.32	0.751
PR (beats/min)	75.58 ± 12.37	78.08 ± 11.68	0.638
Closure			
SP (mmHg)	128.00 ± 13.45	127.23 ± 12.81	0.596
DP (mmHg)	84.88 ± 11.22	81.96 ± 11.14	0.841
PR (beats/min)	75.45 ± 13.42	76.39 ± 12.23	0.566
Firing			
SP (mmHg)	130.14 ± 14.79	128.34 ± 16.06	0.458
DP (mmHg)	82.07 ± 10.95	80.96 ± 9.83	0.433
PR (beats/min)	75.22 ± 12.77	76.66 ± 11.71	0.530
Postoperative			
SP (mmHg)	128.81 ± 14.20	127.40 ± 13.70	0.673
DP (mmHg)	79.72 ± 11.26	79.51 ± 10.18	0.739
PR (beats/min)	77.00 ± 11.04	76.72 ± 11.53	0.523

Values are presented as mean ± standard deviation.
SP, systolic pressure; DP, diastolic pressure; PR, pulse rate.

Table 3. Complications and pain scores in the 2 groups

Variable	Lidocaine group (n = 53)	Control group (n = 58)	P-value
Intraoperative			
Lower abdominal pain	5 (9.4)	15 (25.9)	0.017
Dizziness	0 (0)	5 (8.6)	0.035
Nausea	0 (0)	2 (3.4)	0.172
Diaphoresis	0 (0)	2 (3.4)	0.172
Syncope	1 (1.9)	2 (3.4)	0.612
Postoperative			
Operation site pain	22 (41.5)	34 (58.6)	0.072
Urinary retention	3 (5.7)	6 (10.3)	0.366
Bleeding	1 (1.9)	2 (3.4)	0.612
Postoperative VAS			
1 hr	0.40 ± 0.66	0.53 ± 0.77	0.220
6 hr	3.00 ± 1.68	3.31 ± 1.83	0.237
24 hr	2.29 ± 0.97	2.14 ± 1.17	0.448
Analgesia use	15 (28.3)	21 (36.2)	0.374

Values are presented as number (%) or mean ± standard deviation.
VAS, visual analogue scale.

nonsignificant differences in rates of intraoperative and postoperative complications were smaller in the lidocaine group. Postoperative VAS scores were nonsignificantly different between the 2 groups.

DISCUSSION

VVRs during surgery are relatively frequent, cause discomfort to patients, and can pose a clinical challenge for physicians. Several methods have been proposed to solve this problem, most of which depend on the experience of physicians. There is little-to-no published research or data available regarding VVR in SH. This RCT evaluated the incidence of VVR during SH for the first time and analyzed the effect of rectal submucosal lidocaine injection on this incidence rate.

In general, VVR has 3 subsequent symptomatologic phases. The first phase is presyncope, or aura, with premonitory symptoms (dizziness, mental confusion, weakness, sweating). Second is loss of consciousness, with possible convulsions caused by anoxia (oxygen deprivation), which is generally referred to as syncope. Third, the postsyncopal period is usually characterized by recovery of consciousness and orientation [18].

Stimulation of afferent vagal nerves can occur from either the heart or from other anatomical structures, including the great vessels (carotid bulb), eyes (oculocardiac reflex), and viscera such as gastrointestinal tract and urinary bladder [19]. Pain due to mesenteric stretching and colonic distension can trigger increases in vagal tone [20]. In an RCT, Kim et al. [10] reported that submucosal lidocaine injection significantly reduced VVRs such as nausea, vomiting, sweating, and dizziness following lower abdominal pain at open hemorrhoidectomy. In another randomized trial, Kwok et al. [11] concluded that injection of submucosal bupivacaine reduced pain during and after rubber band ligation hemorrhoidectomy.

Therefore, we hypothesized that pain is likely to occur during the surgery, especially when the stapler is closed fully; pain during stapler firing may trigger VVR. This study found that, while the incidence of syncope was not significantly different between the 2 groups, the incidence of dizziness corresponding to presyncope was significantly different, and this corresponded with a significant between-group difference in pain.

There were some limitations to this study, including the small sample size and the difficultly in accurately determining whether pain reduction during surgery was due to the anesthetic effect of lidocaine or bulging of the rectal mucosa. Further study is needed to determine the effects of injecting a substance other than lidocaine. Reclassifying the 2 groups according to presence of pain can provide a more accurate understanding of the cause and prevention of pain and in identifying the most common and important cause of VVR. The randomization protocol did not consider the type of SH (circular or partial) or the grade of hemorrhoids. Given that partial SH preserves more normal mucosa than circular SH and that higher grade of hemorrhoid was associated with larger amount of tissue resection during SH, future studies on the amount of rectal mucosa should consider specific operation type and hemorrhoid grade.

To the best of our knowledge, this study is the first to prospectively analyze the incidence of VVR during SH. Our results show that injecting lidocaine into the rectal submucosa may have positive effects on prevention of VVRs.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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