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Comparing the effect of intramural injection of vasopressin and oxytocin for hemorrhage reduction in laparoscopic myomectomy: A randomized double-masked study

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Abstract

Background: Uterine leiomyoma is the most prevalent benign gynecologic tumor. This study compared the effectiveness and safety of vasopressin versus oxytocin intramyometrial injections in reducing blood loss during laparoscopic myomectomy.

Methods: In this randomized double-masked study, forty-six women were randomly assigned to receive either a sub-capsular intramyometrial injection of 10 IU oxytocin, diluted in 20 ml saline solution or a sub-capsular intramyometrial injection of 20 IU vasopressin at the time of uterine incision.

Results: The primary outcome measure was intraoperative bleeding, which was considerably lower in the group receiving vasopressin (97.73 82.53 vs 187.83 129.33, *P* value=0.008). No significant difference between the two groups was observed regarding hemoglobin reduction from baseline levels or the need for transfusion. During the operation, patients receiving vasopressin injections experienced a lower pulse rate than those receiving oxytocin injections (74.95 bpm vs 81.67 bpm, *P* value=0.02).

Conclusion: Vasopressin appears to be an effective option for bleeding reduction during laparoscopic myomectomy procedures; however, because of its cardiac effects, close uterine and cardiac monitoring and careful collaboration between the anaesthesiologist and the gynecologist are required. We can reserve oxytocin injections for cases where vasopressin is contraindicated due to cardiopulmonary problems.

Keywords: leiomyoma, Vasopressin, Oxytocin, Hemoglobin, Bleeding, Laparoscopic myomectomy

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Introduction

Uterine leiomyoma, also known as fibroid or myoma, is the most prevalent tumor in women. The prevalence of uterine fibroids varies, with estimates ranging from 5% to 21% (1). However, the prevalence of uterine fibroids rises to 40% by the age of 35, to almost 70% by age 50 in Caucasian women, and to over 80% in Black women by the age of 50 (2). Myomas constitute a significant reason for premenopausal hysterectomies in the United States, accounting for 200,000 hysterectomies per year (3). Surgery is required when a myoma is symptomatic, unresponsive to treatment, or interferes with reproduction (4). Myomectomy is a procedure used to remove readily apparent myomas while reconstructing the uterus. Due to the rich vascular supply of the uterus, myomectomies can cause considerable intra-operative blood loss. Maintaining hemostasis during this surgery is crucial to the procedure's success and the following recovery (5). Numerous studies have been carried out to find various treatments to lessen blood loss during abdominal myomectomy.

Vasopressin is a uterotonic hormone that induces uterine contractions in non-pregnant women. The posterior pituitary gland releases this substance, which controls plasma volume, blood pressure, and osmolality. Dillon first mentioned using vasopressin for abdominal myomectomy in 1962 (6). Vasopressin promotes vasoconstriction by acting on the vasopressin receptor (V1), and it also activates myometrial receptors (V1a), which cause uterine

contractions (7). These receptors are available in both pregnant and non-pregnant women's myometrium. During myomectomy, intramyometrial vasopressin injection can significantly lessen blood loss and postoperative decline in hemoglobin levels (8). Additionally, it alleviates the danger of thromboembolic events and unintended, irreversible ischemia damage to the uterus brought on by mechanical procedures (9). However, vasopressin, as a potent systemic vasoconstrictor, has also been linked to bradycardia and cardiac arrest in doses of more than 5 units and when it is accidentally injected into a blood vessel (10).

The hypothalamus produces oxytocin, a nonapeptide with many physiological functions. It is frequently used to induce labor, produce contractions, and lessen postpartum bleeding and plays a significant role in childbirth and breastfeeding (11). The binding of oxytocin to its receptors induces contractions, which can lower bleeding. According to a study by Sendemir et al (12). oxytocin receptors are infrequent in a healthy myometrium but more prevalent in fibroid tissue. Because of these variations in oxytocin receptors, this hormone has a suitable therapeutic impact in regulating myoma hemorrhage.

Consequently, oxytocin infusion during myomectomy reduces intraoperative hemorrhage and the need for subsequent blood transfusions. Oxytocin analogs have recently been used in gynecological procedures such as myomectomy to lessen bleeding during surgery (10, 13-15). A recently published systematic review and meta-analysis of randomized placebo-controlled trials showed that administering oxytocin and carbetocin reduced intraoperative bleeding in patients undergoing abdominal myomectomy (16). However, its effect on lowering blood loss is controversial (17). This study aimed to compare the effectiveness and safety of vasopressin versus oxytocin intramyometrial injections in reducing blood loss in abdominal and laparoscopic myomectomy.

Methods

In this randomized double-blinded study, women aged 20–45 years scheduled for laparoscopic myomectomy due to symptomatic myoma requiring surgery were recruited from a single center (Rasoul Akram Hospital, Tehran, Iran) from 2021 to 2022. The patients, the circulating nurses in the operating theatre, and the nurses in the gynecologic ward who measured the patient's bleeding were masked to the treatment modality. The exclusion criteria included pregnancy, breastfeeding, history of allergy to oxytocin or vasopressin, hypertension, and contraindications to laparoscopic surgery.

Participants were randomly assigned to receive either oxytocin or vasopressin during myomectomy. Randomization was performed using computer-generated random numbers, and allocation concealment was ensured using sealed envelopes. Two surgeons performed laparoscopic-assisted myomectomy (LAM); first, the umbilical 10 mm port was placed via direct entry, then the suprapubic port and two 5 mm lateral ports were placed. The gas pressure during the operation was 12 mm Hg. Patients in the oxytocin group received a sub-capsular intramyometrial injection of 10 IU of oxytocin diluted in 20 mL of normal saline. The participants received up to three injections of diluted oxytocin. The participants in the vasopressin group received a sub-capsular intramyometrial injection of 20 IU vasopressin diluted in 50 mL of normal saline at the time of uterine incision.

Then, the leiomyoma was removed intact by increasing the suprapubic incision and using the Alexis retractor without using an electric morcellator in the abdominal cavity. Uterine defects were repaired in layers using the standard abdominal myomectomy closing method. The primary outcome measure was intraoperative blood loss, estimated by measuring the volume in the suction at the end of the surgery, the need for blood transfusion, 12-hour postoperative hemoglobin levels, and the reduction in hemoglobin from baseline levels. Secondary outcome measures included preoperative, intraoperative, and 12-hour postoperative systolic and diastolic pressure, pulse, and temperature. The sample size of 20 participants per group was sufficient to detect a clinically significant difference in intraoperative blood loss with a power of 80% and alpha error rate of 0.05.

The continuous variables were compared between the two groups using a student *t*-test, and categorical variables were compared using a chi-square test. Moreover, the continuous variables in each group, before and after the intervention, were compared using paired *t*-tests. The Kolmogorov-Smirnov test was used to check the variables' normality assumption. Data analysis was done using Stata version 16 software, and the considered level of statistical significance was less than 0.05.

The ethics committee approved the study, and all participants provided written informed consent before enrollment. The study was registered with a clinical trial registry (IRCT20150817023666N15) and conducted following the principles of the Declaration of Helsinki.

Results

The patients' selection process is shown in Figure 1. According to Table 1, age, marital status, gravidity, live births, abortions, infertility, use of iron supplements, use of hormone therapy, anemia, and myoma signs and symptoms were not significantly different between the two groups.

Due to severe anemia, six patients receiving vasopressin and two patients receiving oxytocin needed blood transfusions prior to myomectomy. The uterus size, diameter, and location of the largest myomas are summarized in Table 2.

Compared to the group receiving oxytocin, individuals receiving vasopressin experienced considerably less blood

loss (97.73 ± 82.53 vs 187.83 ± 129.33, *P* value = 0.008) (Table 3). The value of preoperative hemoglobin was not significantly different between groups. The vasopressin group experienced a slightly smaller decrease (0.71 ± 1.25 g/dL) in hemoglobin levels after surgery compared to the oxytocin group (0.94 1.21 g/dL), but the difference was not statistically significant (*P* value > 0.05). No patient in either of the groups required blood transfusions following the procedure. As seen in Table 4 and Figure 2, patients receiving vasopressin experienced a lower pulse rate

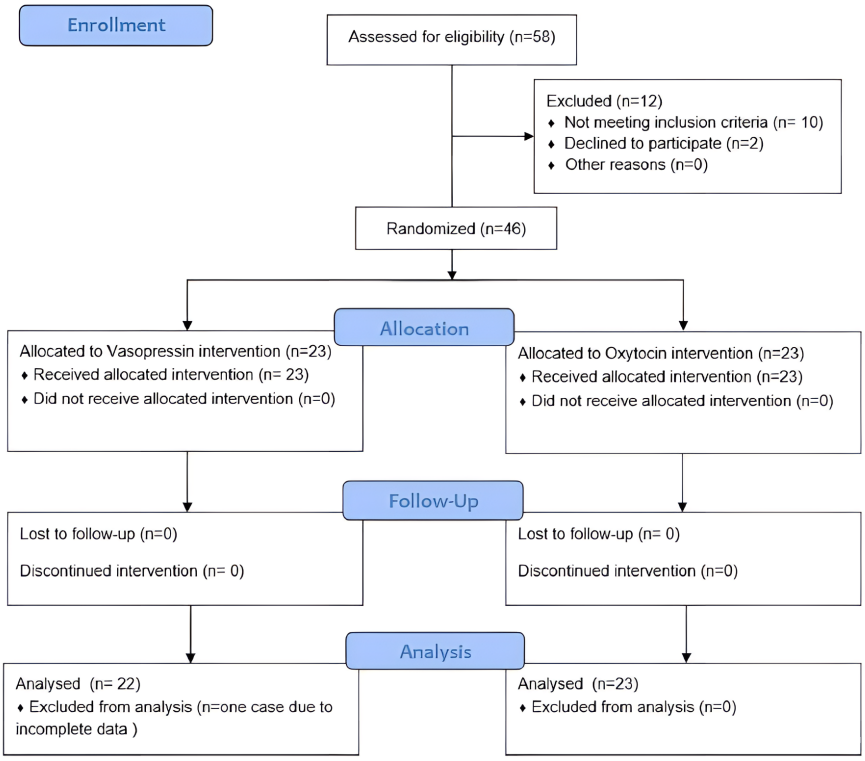

Figure 1. CONSORT flow diagram for patient selection, follow-up, and analysis

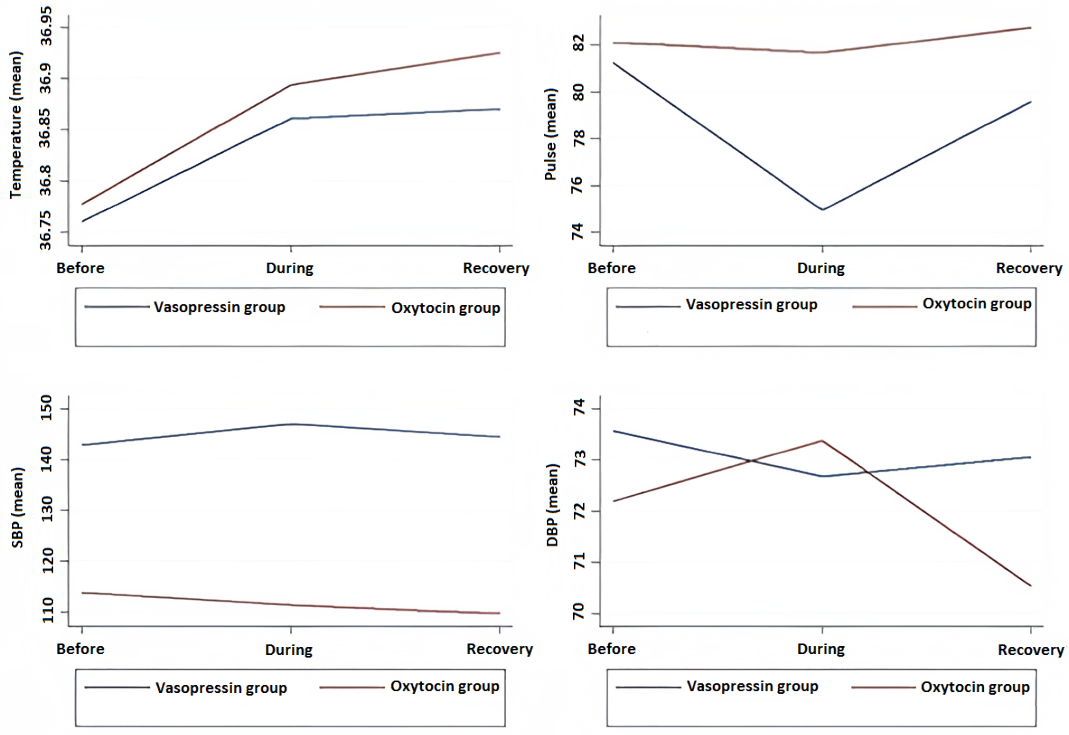

Figure 2. Comparison of temperature, SBP, DBP, and pulse between the study groups before the intervention, during the intervention, and in rec

Table 1. Baseline characteristics

Variable			Vasopressin group ($n=22$)	Oxytocin group ($n=23$)	*P* value
Age (year)			37.18±3.43	36.22±6.28	0.53
Marital status		Single	15 (68.18)	18 (28.26)	0.45
		Married	7 (31.82)	5 (21.74)	
Gravidity		0	11 (50)	13 (56.52)	0.73
		1	5 (22.73)	6 (26.09)	
		2 and more	6 (27.27)	4 (17.39)	
Live birth		0	11 (50)	14 (60.87)	0.76
		1	6 (27.27)	5 (21.74)	
		2 and more	5 (22.73)	4 (17.39)	
Abortion		No	21 (95.45)	21 (91.30)	1
		Yes	1 (4.55)	2 (8.70)	
Infertility		No	17 (77.27)	18 (78.26)	0.52
	Yes	Primary	2 (9.09)	3 (13.04)	
		Secondary	3 (13.64)	1 (4.35)	
		Male cause	0	1 (4.35)	
History of using iron supplements		Yes	15 (68.18)	11 (47.83)	0.17
		No	7 (31.82)	12 (52.17)	
History of hormone therapy		Yes	5 (22.73)	1 (4.35)	0.1
		No	17 (77.27)	22 (95.65)	
Anemia		Yes	14 (63.64)	11 (47.83)	0.29
		No	8 (36.36)	12 (52.17)	
Blood transfusion before surgery		Yes	6 (27.27)	2 (8.70)	0.13
		No	16 (72.73)	21 (91.30)	
Signs and symptoms		AUB	15 (68.18)	17 (73.91)	0.67
		Abdominal enlargement	11 (50.00)	16 (69.57)	0.18
		Feeling pressure	10 (45.45)	14 (60.87)	0.3
		Flatulence	11 (50.00)	19 (82.61)	0.02
		Abdominal pain	11 (50.00)	13 (56.52)	0.66
		Frequent urination	14 (63.64)	8 (34.78)	0.053
		Urinary retention	1 (4.55)	1 (4.35)	1
		Dysphagia	0	1 (4.35)	1
		Constipation	9 (40.91)	7 (30.43)	0.46
		Straining	2 (9.09)	2 (8.70)	1

Table 2. Diameter and location of the largest myoma and uterus size

Parameter	Unit	Group 1 (mean ± SD)	Group 2 (mean ± SD)	*P* value
Diameter of the largest Myoma	length (mm)	75.41±24.29	76.87±26.97	0.94
	width (mm)	59.82±20.66	57.39±25.47	
Uterus size	length (mm)	103.91±21.09	103.65±24.55	0.90
	width (mm)	71.32±21.17	71.13±25.44	
Location of the largest myoma	IM	12 (54.5)	13 (56.5)	0.37
	IM-SM	3 (13.6)	3 (13.0)	
	SS	7 (31.8)	7 (30.4)	

IM: Intramural myoma
IM-SM: intramural to submucosa myoma
SS: subserosal myoma

Table 3. Comparison of the outcome measures

Variable		Vasopressin group ($n=22$)	Oxytocin group ($n=23$)	*P* value
Blood loss (mL)		97.73 ± 82.53	187.83 ± 129.33	0.008
Pre-operation hemoglobin (g/dL)		10.4 ± 1.82	11.6 ± 1.63	0.02
Post-operation hemoglobin (g/dL)		10.03 ± 1.22	10.84 ± 1.27	0.04
Hemoglobin reduction from base value (g/dL)		0.071 ± 1.25	0.94 ± 1.21	0.54
Blood transfusion after surgery	Yes	0	0	1
	No	22 (100)	23 (100)	

Table 4. Comparison of temperature, SBP, DBP, and pulse rate

Variable		Before intervention	During intervention	In recovery
Temperature (C)	Vasopressin group	36.76 ± 0.22	36.86 ± 0.16	36.87 ± 0.14
	Oxytocin group	36.78 ± 0.21	36.89 ± 0.1	36.93 ± 0.1
P value		0.81	0.48	0.22
Systolic blood pressure (mmHg)	Vasopressin group	142.86 ± 13.71	147.09 ± 134.5	144.5 ± 15.94
	Oxytocin group	113.81 ± 11.17	111.43 ± 14.76	109.74 ± 9.50
P value		0.72	0.23	0.27
Diastolic blood pressure (mmHg)	Vasopressin group	73.57 ± 6.92	72.67 ± 9.31	73.05 ± 8.72
	Oxytocin group	72.19 ± 7.77	73.38 ± 10.08	70.53 ± 9.70
P value		0.55	0.81	0.4
Pulse (bpm)	Vasopressin group	81.24 ± 9.39	74.95 ± 11.01	79.6 ± 7.27
	Oxytocin group	82.09 ± 5.85	81.67 ± 6.48	82.74 ± 9.27
P value		0.72	0.02	0.25

during the operation than patients receiving oxytocin (74.95 ± 11.01 vs 81.67 ± 6.48, *P* value = 0.02).

Systolic blood pressure in the vasopressin group was generally higher than in the oxytocin group (147.09 ± 134.5 mmHg), but the difference was not statistically significant (*P* value = 0.23) (Table 4). However, diastolic blood pressure (72.67 ± 9.31 vs 73.38 ± 10.08, *P* value = 0.81) was similar between the two groups. Systolic, diastolic, and body temperatures between the two groups were not significantly different before, during, and 12 hours after the surgery (*P* value > 0.05) (Table 4). There were no notable side effects for any group.

Discussion

This randomized controlled study aimed to assess the efficacy and safety of vasopressin administration versus oxytocin administration. In previous studies, both vasopressin and oxytocin have been compared to placebo (8, 10, 17-22). However, to the best of the authors' knowledge, this is the first study to assess the efficacy of vasopressin compared to oxytocin in reducing hemorrhage during myomectomy.

Reducing blood loss during myomectomy is critical since blood loss can result in life-threatening complications, including the need for blood transfusions and emergency hysterectomy. Several strategies to reduce blood loss during surgery have been investigated. In a study to examine the role of intramyometrial vasopressin injection in reducing blood loss during laparoscopic myomectomy, Elgendy et al. concluded that vasopressin may effectively minimize blood loss and the need for blood transfusions as well as less reduction in hemoglobin and hematocrit (10). In their study, the vasopressin group's average hemoglobin drop was 80 mg/dL, slightly higher than our findings (71 mg/dL). Additionally, according to their results, the average amount of bleeding reported in the vasopressin group was 115.53 ml, which was higher than the 97.73 ml we observed in our study. The differences between the two studies are due to our concern about bleeding control during surgery in both groups. Therefore, we did not need more blood transfusions in this group than in the control group. Soliman et al. reached the same conclusion about vasopressin in terms of lowering blood loss and the requirement for transfusions. Still, they also proposed that vasopressin injection is associated with cardiovascular problems (22). Similar to our results, they observed elevated blood pressure in the vasopressin group accompanied by bradycardia and atrial extrasystole (22). A vasopressin-induced rise in blood pressure causes a vagal-mediated decrease in heart rate. Hobo et al. reported a case of vasopressin-induced bradycardia during a myomectomy in which the patient received 11 units (0.2 U/mL) of intramyometrial vasopressin injection (23). According to Hobo et al., the pulse rate dropped from 58 to 35 beats per minute, and cardiac arrest occurred shortly after. The dosage of vasopressin should be between 0.05 and 0.3 U/

mL, and the total delivered dose should thus be as low as feasible (23). Despite the rarity of such occurrences, local intramyometrial infiltration of low-dose vasopressin may result in fatal cardiac consequences. They advised that close observation is necessary for uterine hemostasis. To recognize and manage this uncommon complication, which the local infiltration of vasopressin can occasionally cause, a careful collaboration between the anesthesiologist and the gynecologist is necessary (23).

Vasoconstriction is the primary mechanism by which vasopressin lowers blood loss. Meanwhile, oxytocin promotes contractions in the myometrium via the oxytocin receptor (OXTR), causing blood vessels to collapse and reducing blood flow. Furthermore, fibroids have more oxytocin receptors than the normal myometrium (24). As the blood flow in the healthy myometrium did not change during oxytocin infusion, it seems likely that the effect is related to the fibroid itself or the supplying circulation (25). Oxytocin receptors are also found in human uterine myometrial microvessels and endothelial cells from big vessels (26). In addition to regulating myometrial contraction, oxytocin can also control the vasomotor tone of the myometrial vasculature (20).

Aslan Çetin et al. observed that using oxytocin infusions (10 IU in 500 mL) during abdominal myomectomies reduces both intraoperative blood loss and the need for blood transfusions (21). They reported higher values than we observed, with an average intraoperative blood loss of 489.20 mL and a hemoglobin decrease of 1.49 g/dL. Aslan Çetin et al. claimed that blood loss during myomectomy was closely proportional to fibroid features such as the excised quantity and weight of fibroids (21). In another trial, Agostini et al. found that oxytocin administration during myomectomy did not diminish preoperative blood loss (17). This observation could be related to the fact that Agostini et al. administered oxytocin during the uterine incision, while Aslan Çetin et al. administered oxytocin after general anesthesia went into effect prior to surgery (21). In terms of safety, we agree with Wang et al. that adverse reactions may also occur after systemic administration of oxytocin (such as hypotension, arrhythmias, or hyponatremia). However, the margin of safety is still greater than that of vasopressin (20).

Conclusion

The present study's findings show that sub-capsular intramyometrial vasopressin injections can significantly minimize bleeding and cause a smaller hemoglobin drop following surgery than oxytocin injections. However, the difference in hemoglobin drops between the two groups was not statistically significant. Because of the smaller drop in hemoglobin levels, vasopressin appears to be a favorable treatment modality in myomectomy procedures; however, because of the cardiac complications of using vasopressin, the anesthesiologist should be informed and provide consent prior to its administration. However, we can reserve oxytocin injections for cases where vasopressin is contraindicated due to cardiopulmonary problems.

The study's limitations include its small sample size and the absence of follow-ups once the patients were discharged, which could limit the understanding of the long-term effects. We did not weigh the total excised fibroid mass, which could cause bias if it differed across groups.

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Competing Interests

The authors declare that they do not have any conflict of interest.

Ethical Approval

This study has been approved by the Research Ethics Committee of Iran University of Medical Sciences (IR.IUMS.REC.1401.273).

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