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A Comparative study of the Effect of Intramyometrial Carbetocin Injection and Rectal Misoprostol on Blood Loss during Myomectomy Operations

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Abstract: Background: The aim of the work is to compare between the safety and clinical efficacy of intramyometrial Carbetocin injection and rectal Misoprostol on blood loss and operative time in abdominal myomectomy operation. **Methods:** This study is a randomized comparative study, which was done at Obstetrics and Gynecology Department of Tanta University Hospital in the period from October 2017 to February 2019 Randomization and allocation were done by using a randomized numbers table designed by computer random allocation software. Patients were given a random number from 1 to 60 and were allocated into one of two groups (I or II) with the ratio 1:1 between the two groups. Sixty female patients with uterine fibroids fulfilling the inclusion criteria were subjected to do abdominal myomectomy were divided randomly into 2 equal groups (each group 30 patients). **Group (I):** 30 participant female patient (Carbetocin group). **Group (II):** 30 participant female patient (Misoprostol group). **Results:** This study was done at Obstetrics and Gynecology Department of Tanta University Hospital**:** 60 patients who are sonographically diagnosed with single intramural fibroids, 4cm or more in diameter, who had hospitalized undergoing myomectomy operation were included according to inclusion and exclusion criteria. **Conclusions:** The current study showed that the use of intramyometrial Carbetocin injection during abdominal myomectomy operation is more effective in decreasing the blood loss and operative time than, the use of rectal Misoprostol.

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Keywords: Myomectomy, Carbetocininjection, Rectal Misoprostol.

1. Introduction

Fibroids are firm benign tumors that are made of smooth muscle cells and fibrous connective tissue. Benign uterine leiomyomas (fibroids) are the most common pelvic tumor in women, affecting 20-40% of all women, over the age of 35 and 50% of African-American women. Less commonly, women with a uterine mass presumed to be a leiomyoma are found to have a uterine sarcoma or a leiomyoma variant.[1, 2].

Most of uterine myomas are asymptomatic and require no treatment, but some women with fibroids have significant problems that interfere with some aspects of their lives and need therapy. Abnormal uterine bleeding is the most common symptom, in the form of heavy or prolonged menses, pelvic pressure and pain as dysmenorrhea, dyspareunia, and the most complex symptom that it may lead to infertility[3].

The current treatments for uterine fibroids are many, medical as progesterone's and progesterone antagonist's, surgical, and recent myoma therapies as uterine artery embolization (UAE), but surgical resection is still the main treatment, including hysterectomy and myomectomy. With hysterectomy, uterine fibroids can be completely cured, but it cannot keep women's reproductive functions. Despite the rate of relapse, myomectomy is still the most popular surgical treatment for fibroids in women [4,5].

As hemorrhage is the main complication so, reduction of intra-operative bleeding has become a major concern. This can be achieved by the use of mechanical or pharmacologic methods, which can be done preoperative and intra-operative. Mechanical methods include the use of tourniquets and clamps that occlude the uterine blood supply to reduce blood loss during myomectomy. Pharmacologic methods include local Oxytocin injection, vasoconstrictors like Vasopressin[6].

Carbetocin is an Oxytocin derivative exerting its effect via the same molecular mechanisms as Oxytocin. It was first described in 1987 and is a long-acting synthetic analogue of Oxytocin, with agonist action. The clinical and pharmacological properties of Carbetocin are similar to those of naturally occurring Oxytocin. Carbetocin functions as an agonist at peripheral Oxytocin receptors, particularly

in the myometrium, resulting in rhythmic contractions of the uterus, increased frequency of existing contractions and increased uterine tone.[7]

Misoprostol, a synthetic analogue of natural prostaglandin El (PGE1), was approved by the US Food and Drug Administration (FDA), almost 30 years ago, initially for the treatment of gastric ulcers due to its inhibiting effect on the secretions of stomach. Also Misoprostol is used widely for cervical ripening, labour induction, postpartum hemorrhage and second trimester termination. It increases myometrial contractions and decrease hemorrhage. This property of Misoprostol can facilitate every surgical operation on myometrium, limiting blood losses to a minimum. [8]

2. Methods

This study is a randomized comparative study, which was done at Obstetrics and Gynecology Department of Tanta University Hospital in the period from October 2017 to February 2019.

Patients:

- Number: 60 patients**.**

- Eligibility:

A- Inclusion criteria

The study included patients who were clinically and sonographically diagnosed with single intramural fibroids, 4cm or more in diameter, and had symptoms like heavy menstrual flow, irregular vaginal bleeding and infertility.

B- Exclusion criteria:

- Previous uterine surgery (scar) including previous cesarean section.
- Multiple fibroids.
- Hypersensitivity to Oxytocin or Carbetocin.
- Anticoagulants treatment.
- Pre-existing chronic diseases e.g.
- Pre-existing hypertension.
- Asthmatic patient.
- Cardiac patient.
- Renal disease.
- Liver disease.
- Vascular disease.
- Endocrine disease.

- Randomization and allocation:

Randomization and allocation were done by using a randomized numbers table designed by computer random allocation software.

Patients were given a random number from 1 to 60 and were allocated into one of two groups (I or II) with the ratio 1:1 between the two groups.

Sixty female patients with uterine fibroids fulfilling the inclusion criteria were subjected to do abdominal myomectomy were divided randomly into 2 equal groups (each group 30 patients).

- **Group (I):** 30 participant female patient (Carbetocin group).
- **Group (II):** 30 participant female patient (Misoprostol group).

Methods (Intervention):

I- Pre-operative assessments:

- Careful history taking regarding age, parity, gravidity, abortion, menstrual history, obstetric history and history regarding previous cesarean section.
- General and vitals examination: temperature, blood pressure and body mass index.
- Abdominal examination, abdominal and ultra-sonography for confirmation of diagnosis and determine myoma size and side.
- Complete blood count to determine hemoglobin and hematocrite.
- All included patients were informed about the aim of the study and any complications.
- Written consent from all included patients.
- In the group (II), Misoprostol administered rectally two tablets 400mcg (cytotec 200mcg Pfizer Pharmaceutical, New York City, United States) one hour before abdominal myomectomy operation.

II- Anesthesia:

The anesthesia in all operations is general anasethia with Atracurium Besylate, Fentanyl and propofol **(**Diprivan).

III- Procedure:

- All myomas were removed by the same procedure, using a Pfannenstiel skin incision.
- Anterior abdominal wall incision in layers superficial fascia (fatty and membranous), deep fascia, anterior rectus sheath, rectus abdominis muscle, transversalis fascia, extraperitoneal connective tissue, and peritoneum, with catherization hemostasis.
- Delivery and palpate the uterus Then uterus to locate the leiomyomas.
- For group (I) Carbetocin group: intramural; preparation of 100µg Carbetocin (Paba L; Ferring Pharmaceuticals, Copenhagen, Denmark) diluted within 10 cm saline (0.9%) in sterile syringe, this step done by scrub nurse while preparing for operative instruments and placed on the surgical instrument table, when exploration of the uterus and the myoma required to be removed is done, the scrub nurse handles the syringe to the operating doctor who then inject the substance into the multiple sites intramyometrial in circumferential manner 1-2 cm away from the margins of the myoma in the planned uterine incision site just before uterine incision for myoma extraction.
- Care was taken to avoid intravascular injection; the surgeon would withdraw the plunger of

the syringe to check for blood. The anesthesiologist was always notified before the injection.

- Careful planning and placement of midline uterine incision then Removal of myomas by extending down**.**
- The uterine incision through the myometrium and entire fibroid pseudo capsule. The least vascular plane can be reached by extending this incision just deep to the capsule after the myoma is initially visualized.
- The uterine incision through the myometrium and entire fibroid pseudo capsule. The least vascular plane can be reached by extending this incision just deep to the capsule after the myoma is initially visualized.
- The myoma will then clearly be visible and may bulge slightly. Then surgeons put traction on the myometrial edges with Allis clamps to expose the myoma. The myomas are then unchelated by grasping them with a single tooth tenaculum or towel clamp. The plane between the myometrium and myoma is typically dissected bluntly using a sponge or the back end of an empty knife handle.
- The uterine defects are closed with sutures in layers. If the myometrial defect is deep (>2 cm), two layers may be needed to approximate the tissue and achieve hemostasis. In our study, we used a size 0 polyglactin 910 (Vicryl™) suture for the myometrium.
- The serosa is closed with a running suture; we used size 2-0 polydioxanone (PDS™).

III- Post operative care:

- Complete blood count was done 24 hours after the operation to detect amount of decline in hemoglobin and hematocrit.
- Post-operative hospital stays and postoperative complications need for blood transfusion, need for ICU admission is collected for both groups.

Potential risks

- No potential risks are considered by using Oral Dudrogesterone or vaginal Progesterone.
- Side effects of both drugs include: hypotension, headache and drowziness.
- Any unexpected risks appeared during the course of the research will be cleared to participants and the ethical committee on time.

Ethical committee

- The study was started after medical ethical committee approval.
- Written consent from all included patients.
- All included patient knows about the aim of present study, risk factors, possible complications and risk of failure.

Provision of privacy

There are adequate provisions to maintain privacy of participants and confidentiality of the data, the patient name was replaced by serial number and her address kept confidential. There is no conflict of interest. Authors don't receive any fund from any institute. Authors didn't give any compensation to the participant. Authors didn't represent any risk to the environment. Authors took verbal and written consent from the participants. The work is stopped if the patient refuses to continue. No differentiation between patients according to religion and race.

3. Results

This study was carried on (60) patients who are sonographically diagnosed with single intramural fibroids, 4cm or more in diameter, who had hospitalized undergoing myomectomy operation were included according to inclusion and exclusion criteria.

These cases were divided randomly into 2 equal groups (each group 30 patients).

- **Group (I):** 30 participant female patients (Carbetocin group).
- **Group (II):** 30 participant female patients (Misoprostol group).

From table shows that the mean age of cases in group (I) was 35.67 ± 3.85years years and in group (II) was 37.07 ± 4.16 years. There was no significant difference in age between the two groups (p=0.182).

The Body Mass Index (BMI) was (25.20 ± 1.86 in group I, 25.42 ± 1.57 in group II). There was no significant difference in BMI between the two groups (p=0.623).

Regarding the gravidity and the parity of studied cases in both groups. There was no significant difference in the parity between the two groups (p=0.573).

There was no significant difference in temperature after operation between the two groups (p=0.663).

This table shows the abortion number of studied cases in both groups. There was no significant difference in the abortion number between the two groups (p=0.615).

The mean myoma size in group I was 5.65± 1.00 cm and in group II was 5.99 ± 0.96 cm. There was no significant difference in age between the two groups (p=0.185).

From table 2 The blood loss was more in Misoprostol (group II) than the Carbetocin (group I) with a significant difference between the two groups, it was in group I 542.00 ± 49.72ml and in group II was 574.00 ± 63.87ml.

From table 3 Preoperatively there was no significant difference in Hb between the two groups as the Hb was (11.05 ± 0.70g/dl in group I, 10.82 ±

0.72g/dl in group II), but postoperatively there was a significant difference between both groups as it was lower in Misoprostol group since it was (9.99 ± 1.15g/dl in group I, 9.02 ± 1.10g/dl in group II).

From table 4 The hematocrit value before operation (34.15 ± 1.84 in group I, 33.83 ± 1.05 in group II). There was no significant difference in hematocrit value between the two groups (p=0.413). And after operation was (30.99 ± 1.22 in group I, 30.14 ± 0.94 in group II). There was a significant difference in hematocrit value between the two groups (p=0.002).

From table 5 The operative time was (91.67 ± 9.65 in group I, 94.67 ± 11.99 in group II). There was no significant difference in operative time between the two groups (p=0.290).

From table 6 The hospital stay was (3.53 ± 0.43 in group I, 3.62 ± 0.36 in group II). There was no significant difference in hospital stay between the two groups (p=0.424).

From table 7 The temperature after operation was (37.26 ± 0.22 in group I, 37.29 ± 0.22 in group II). There was no significant difference in temperature after operation between the two groups (p=0.557).

From table 8 The blood transfusion of studied cases in both groups. There was no significant difference in the blood transfusion between the two groups (p=0.197).

Table (1): Demographic data of the studied cases.

		Group I Carbetocin group (n=30)			Group II Misoprostol group (n=30)			Test	p. value
Age (years)	**Range**	29	–	41	30	–	45	T: 1.829	0.182
	Mean ± SD	35.67	±	3.85	37.07	±	4.16		
BMI (kg/m^2)	**Range**	23	–	30	23	–	30	T: 0.244	0.623
	Mean ± SD	25.20	±	1.86	25.42	±	1.57		
Gravidity	**0 (%)**	12 (40%)			12 (40%)			X^2: 2.401	0.663
	1 (%)	8 (26.7%)			8 (26.7%)				
	2 (%)	4 (13.3%)			6 (20%)				
	3 (%)	4 (13.3%)			4 (13.3%)				
	4 (%)	2 (6.7%)			0 (0%)				
Parity	**0 (%)**	20 (66.7%)			22 (73.3%)			X^2: 0.317	0.573
	1 (%)	10 (33.3%)			8 (26.7%)				
Abortion	**0 (%)**	16 (53.3%)			14 (46.7%)			X^2: 1.801	0.615
	1 (%)	6 (20%)			10 (33.3%)				
	2 (%)	4 (13.3%)			4 (13.3%)				
	3 (%)	4 (13.3%)			2 (6.7%)				
Myoma size (cm)	**Range**	4	–	7	4	–	7	1.799	0.185
	Mean ± SD	5.65	±	1.00	5.99	±	0.96		

Table (2): The mean of blood loss in ml in the studied groups.

		Group I Carbetocin group (n=30)			Group II Misoprostol group (n=30)			t. test	p. value
Blood loss (ml)	**Range**	450	–	650	500	–	700	4.689	0.034*
	Mean ± SD	542.00	±	49.72	574.00	±	63.87		

Table (3): The preoperative and postoperative hemoglobin (Hb) (g/dl) in both groups.

Hemoglobin (g/dl)		Group I Carbetocin group (n=30)			Group II Misoprostol group (n=30)			t. test	p. value
Before	**Range**	10	–	12.5	10	–	12.4	1.608	0.210
	Mean ± SD	11.05	±	0.70	10.82	±	0.72		
After	**Range**	7.2	–	11.8	7	–	11	11.045	0.002*
	Mean ± SD	9.99	±	1.15	9.02	±	1.10		

Table (4): The preoperative and postoperative hematocrit value in both groups.

Hematocrit value %		Group I Carbetocin group (n=30)			Group II Misoprostol group (n=30)			t. test	p. value
Before	**Range**	32	–	39.8	32.3	–	35.3	0.681	0.413
	Mean ± SD	34.15	±	1.84	33.83	±	1.05		
After	**Range**	29	–	33.6	29	–	32.3	11.045	0.002*
	Mean ± SD	30.99	±	1.22	30.14	±	0.94		

Table (5): The mean of operative time in both groups.

		Group I Carbetocin group (n=30)			Group II Misoprostol group (n=30)			t. test	p. value
Operative time (min.)	Range	40	–	60	42	–	60	0.678	0.414
	Mean ± SD	50.10	±	5.31	49.03	±	4.70		

Table (6): The mean of hospital stays in both groups.

		Group I Carbetocin group (n=30)			Group II Misoprostol group (n=30)			t. test	p. value
Hospital stay (day)	Range	1	–	2	1	–	2	0.587	0.447
	Mean ± SD	1.47	±	0.51	1.57	±	0.50		

Table (7): The mean of temperature after the operations.

		Group I Carbetocin group (n=30)			Group II Misoprostol group (n=30)			t. test	p. value
Temp. post (□)	Range	37	–	37.7	37	–	37.6	0.349	0.557
	Mean ± SD	37.26	±	0.22	37.29	±	0.22		

Table (8): Description of blood transfusion of studied cases in both groups.

Blood transfusion			Group I Carbetocin group (n=30)	Group II Misoprostol group (n=30)	Total
Yes		N	4	8	12
		%	13.3%	26.7%	20.0%
No		N	26	22	48
		%	86.7%	73.3%	80.0%
Total		N	30	30	60
		%	100.0%	100.0%	100.0%
Chi-square	X^2		1.667		
	P-value		0.197		

4. Discussion

The current study aimed to compare between the safety and clinical efficacy of intramyometrial Carbetocin injection and rectal Misoprostol on blood loss and operative time in abdominal myomectomy operation. This study is a randomized comparative study that was conducted in Obstetrics and Gynecology Department of Tanta University Hospital at the period from October 2017 to the end of February 2019.

The study involved 60 women undergoing myomectomy for symptomatic uterine myoma divided randomly into two groups. Group (I) (Carbetocin group) which includes 30 patients who received intramural; injection of a preparation of 100 µg Carbetocin (Paba L; Ferring Pharmaceuticals, Copenhagen, Denmark) diluted within 10 cm saline (0.9%) in sterile syringe, 1-2 cm away from the margins of the myoma, group (II) (Misoprostol group) which includes 30 patients who received rectally two tablets 400mcg (cytotec 200 mcg Pfizer) one hour before abdominal myomectomy operation.

As regard preoperative data of the patients, comparison between two groups was done including, preoperative haemoglobin, and hematocrit values and no statistically significance difference was found which also coincides with the results of study reported by **(Celik and Spamaz)** [9].

In this study it was found that the average blood loss in the Carbetocin group was 542.00±49.72 ml and it was 574.00±63.87 ml in the Misoprostol group which agrees with **Schuring et al** [10] which stated that the average volume of blood loss for abdominal myomectomy varies across studies from approximately 200 to 800 ml.

The current study showed that the use of intramyometrial Carbetocin injection during abdominal myomectomy operation is effective in decreasing the blood loss and operative time than Misoprostol. And this agree with another study reported by **Fang** [11] In his study a total of 54 patients under myomectomy were divided into 2 groups. The patients in test group were injected 100 µg Carbetocin, and in control group were injected 20 U oxytocin in the uterus after the myomectomy. The contraction of uterine, the volume of bleeding and the differences in adv56erse drug reactions were observed. Uterine contracted stronger in test group than in control group and the test group had less volume of bleeding than that in control group. Carbetocin may promote uterine contraction and reduce bleeding during the myomectomy.

This also agreed with another randomized controlled study that was done by **Gad Allah et al** [12] at, Kasr Alainy Hospital, Cairo University, in his study women allocated for myomectomy were divided into two groups of 20 patients each. In the control group, hemostasis was performed with the uterine artery tourniquet technique. Meanwhile, in

the study group, hemostasis was performed through an intramyometrial injection of Carbetocin.

In the current study; the injection of intramyometrial Carbetocin was associated with less blood loss during myomectomy. Moreover, it may lower the need for blood transfusion. Patients in whom Carbetocin was used showed lower drop in their hemoglobin and hematocrit levels when measured 48 h postoperatively, as shown in table (3, 4).

Another study supports our results was done by **Shen et al** [(13)] In this studyfifty-eight patients underwent laparoscopic myomectomy with Carbetocin (n = 30) or Oxytocin (n = 28) during operation were analyzed. The blood loss, reduction of haemoglobin, and the operation time were compared. All operations were performed successfully with no operation-related complications occurred in these cases. The mean blood loss in operation of the Carbetocin group were significantly less than that of the Oxytocin group (111± 35) mL vs. (160±49) mL, the mean reduce of haemoglobin of the Carbetocin group were also less than that of the Oxytocin group, and there was no significant difference in operation time between the two groups (123±33) min vs. (128±30) min.

Another study supports our result reported by **Zhang and Chen** [(14)] retrospective analysis of the clinical data of 80 patients with myoma of uterus, all patients were injected Carbetocin, 43 patients applied laparoscopic treatment, as the laparoscopic group, 37 cases do the traditional open surgery, as the open group. Intraoperative bleeding and postoperative bleeding situation were compared between the two groups. the difference was statistical significance. Carbetocin reduce laparoscopic myomectomy bleeding amount more than in open myomectomy applications, hemostatic effect better, significantly reduce the incidence of postoperative bleeding.

Another study supports our results reported by **Sallam and Shady** [(15)] was done in Aswan University, Egypt, in a randomized double-blind placebo-controlled trial, 86 women undergoing abdominal myomectomy for symptomatic uterine leiomyomas were randomly assigned to receive a single dose of pre-operative IV 100 µgCarbetocin (n = 43) or placebo (n = 43) just before the operation. The primary outcome was intra-operative blood loss. The Intra-operative blood loss was significantly lower in those women randomized to receive IV Carbetocin versus the placebo group (714.19±186.27 ml versus 1033.49±140.9 ml), The incidence of blood transfusion was increased in placebo group (69.8%) compared with (18.6%) in Carbetocin group. Also, there was a significant reduction in operative time in Carbetocin group (66.35±10.18) min compared with placebo group (95.95±9.16) min.

Another study supports our results by **Yang et al** [(16)] The objective of this study was to evaluate the clinical effect and safety of Carbetocin administered to prevent bleeding in laparoscopic myomectomy. A retrospective analysis of April, 2006 to April, 2011 laparoscopic myomectomy hand clinical data of 70 patients was carried out. The 70 patients were divided into treatment group and control group; the treatment group was given preoperative Carbetocin, while the control group was given preoperative Oxytocin, which was administered in the same way as in the treatment group. Blood loss, operative time, postoperative hemoglobin (Hb) values, decrease exhaust time, and postoperative hospital stay were observed. All the patients were operated on successfully with no conversion to open surgery; 100% success rate was recorded in the treatment group as blood loss and operative time, Hb value, and hospital stay were lower in that group than in the control group, showing a significant difference.

On contrary; results of **Abdel - Hafeez et al** [(17)] disagreed with ours. A randomized double - blind placebo - controlled trial, 50 women undergoing abdominal myomectomy for symptomatic uterine leiomyomas were randomly assigned to receive a single dose of pre - operative of rectal 400 µg Misoprostol (n = 25) or placebo (n = 25) 1 h before the operation. The primary outcome was that Intra - operative blood loss was significantly lower in those women randomized to receive rectal Misoprostol versus the placebo group (574 ± 194.8 mL vs 874 ± 171.5 mL). Additionally, the drop in postoperative haemoglobin was significantly less in the Misoprostol group (1.7 ± 0.4 g/dL) compared with the placebo group (2.1 ± 0.5 g/dL).

Another study which also disagree with ours by **Kalogiannidis et al** [(18)] that was a randomized clinical trial to estimate if the preoperative use of Misoprostol may reduce intraoperative blood loss of patients treated by minimally invasive surgery (MIS), such as laparoscopic (LM) or laparoscopically assisted myomectomy (LAM). Sixty-seven menstruating patients with three or less myomas of a maximum diameter of 90 mm, scheduled for MIS, were randomly allocated to receive a preoperative single dose of intravaginal Misoprostol or placebo. Sixty-four patients remained in the final analysis: 30 in the Misoprostol (I) and 34 in the placebo group (II). Estimated blood loss (EBL), decline of postoperative hemoglobin (Hb) and side-effects of administered agent were the outcomes of main interest. The EBL was significantly higher in the placebo versus Misoprostol group (217±74ml vs 126±41ml). Similarly, the decline of postoperative

Hb was significantly higher in group II (1.6±0.43) compared to group I (1±0.33). The operative time was comparable in both groups.

Another disagree study by **Celik and Sapmaz** [9] Conducted a placebo-controlled randomized prospective study. Twenty-five women with symptomatic uterine leiomyomas. Among patients undergoing abdominal myomectomies, an hour before the operation women in the study group (n = 13) were given a single dose of vaginal Misoprostol (400 μg); those in the control group (n = 12) were given placebo. Intraoperative blood loss, duration of operation, duration of postoperative hospitalization and the need for blood transfusion were compared between the control and study groups. Blood loss, operation time, and need for postoperative blood transfusion were significantly reduced in the group given vaginal Misoprostol. No difference was observed among patients in terms of the time of hospitalization.

Conclusion:

The current study showed that the use of intramyometrial Carbetocin injection during abdominal myomectomy operation is more effective in decreasing the blood loss and operative time than, the use of rectal Misoprostol.

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