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Original Article

A Comparative Study to Assess Blood Loss during Abdominal Myomectomy by Tourniquet Application versus Intramyometrial Vasopressin Injection

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Abstract

Objective: The objective of this study was to determine the efficacy of applying uterine artery tourniquet and intramyometrial vasopressin injection to reduce intraoperative blood loss during abdominal myomectomy.

Methods: A comparative interventional study comparing parameters in the two groups of patients containing 24 each where one received tourniquet application and other received intramyometrial vasopressin.

Results: Pre-operative hemoglobin (Hb) was comparable in both mean 10.5 ± 0.50 g/dl in tourniquet group and 10.5 ± 0.47 g/dl in vasopressin group. Pre-operative hematocrit (Hct) was also comparable in both mean 31.8 ± 1.44% in tourniquet group and 31.7 ± 1.51% in vasopressin group. Mean operative time was 49.0 ± 10.33 min in tourniquet group and 48.8 ± 9.62 min in vasopressin group which was statistically indifferent. Amount of mean blood loss in the tourniquet group was 467.9 ± 74.50 cc and 356.45 ± 58.35 cc in vasopressin group which is significantly higher in former. Post-operative day 3 Hb was lower in tourniquet group 8.94 ± 0.52 g/dl than 9.45 ± 0.52 g/dl in vasopressin group. Reduction in Hb postoperatively was more in tourniquet group 1.43 ± 0.45 g/dl than vasopressin group 0.92 ± 0.20 g/dl. Reduction in Hct postoperatively was more (4.82 ± 1.4%) in tourniquet group than in vasopressin group (2.74 ± 0.62%). Blood transfusion was required 5 (20.83%) cases in tourniquet group, but only in 2 (8.33%) cases of vasopressin group though it was statistically indifferent between both groups.

Conclusion: Application of tourniquet had more mean operative time, intraoperative blood loss, and requirement of blood transfusion. There is more reduction in Hb and Hct postoperatively in tourniquet application.

Key words: Hemoglobin, Hematocrit, Myoma, Myomectomy, Uterine artery, Vasopressin

INTRODUCTION

Uterine myoma (fibroid, leiomyoma, and leiomyofibroma) is the most common benign pelvic tumor in females originating from the myometrium of uterus occurring during the middle and late reproductive age group having an incidence of 40% by age 35 Caucasian women.[1] They are composed of large amounts of the extracellular matrix - mainly collagen type 1 and type 2 fibers.[2] Although precise causes are unknown, the hormonal and growth factors are considered responsible for myoma.[3]

Size and location are the main factors that determine symptoms and problems.[4] Different locations are intramural, subserosal, and submucosal myoma. Removal is necessary in large myoma causing pain, abnormal uterine bleeding, pressure symptoms, infertility, or significant cavity distortion. Removal of submucous myoma improves fertility to near-baseline rates.[5]

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Despite many options, myomectomy is important for women desiring to preserve uterus for reproduction or menstruation. Myomectomy has different routes depending on location, number of lesions, the experience, and preference of the surgeon.

Uterine myomas have more arterioles and venules causing significant blood loss.[6] The average blood loss during myomectomy is 200–800 ml.[7,8] Myoma distorts normal vascular architecture.[9,10]

Traditional abdominal incision during myomectomy may transect these vessels causing profuse hemorrhage. Other options are laparoscopy or by robotic surgery, but robotic surgery is not superior to laparoscopy.[11] A submucous myoma <5 cm may be removed by hysteroscopy.[12] Open approach is often preferred for large myomas. Despite different methods, recurrence of new myomas occurs in 42–55% of cases.[13] Furthermore, these methods do not prevent the rupture of uterus in later pregnancy.[14]

Each myoma is surrounded by a dense vascular layer separated from the myometrium by a narrow avascular cleft.[15] Bleeding can be prevented if dissection is done through the avascular cleft or decreased with mechanical or pharmacological methods. Intramyometrial vasopressin injected into the planned uterine incision site for each myoma reduces blood loss. Vasopressin acts by constricting the smooth muscles in the capillaries, small arterioles, and venules. It also causes retention of water in the body.[16,17]

Another method to reduce blood loss is to apply a uterine artery tourniquet. Using uterine artery tourniquet compared without tourniquet resulted in a significant decrease in blood loss in the tourniquet group.[18] Previous randomized trials showed that blood loss during myomectomy was reduced significantly with intramyometrial vasopressin use than with placebo (299 ml less)[19] and also less than or comparable to using uterine artery tourniquet.[20,21] Till date, there are few studies comparing the effect of intramyometrial vasopressin injection versus tourniquet application to reduce intraoperative blood loss. There are also very few clear inferences regarding which one is better method to reduce blood loss. Therefore, this study aims to compare the effectiveness of intramyometrial vasopressin injection versus using uterine artery tourniquet in reducing blood loss during myomectomy.

METHODS

Study Area

This study was conducted at the Department of Obstetrics and Gynaecology, South Eastern Railway Hospital, Garden Reach, Kolkata.

Study Period

The study duration was from December 15, 2013, to December 14, 2014.

Study Population

Women of reproductive age group are attending at the outpatient department (OPD) of gynecology and admitted for myomectomy.

Study Design

A comparative interventional study in which comparison of parameters was made in the two groups of patients.

Sample Design

Patients were allocated randomly in two groups "A" and "B" groups - "A" group receiving conventional tourniquet application and "B" group receiving intramyometrial vasopressin injection.

Sample Size

This is a comparative interventional study comparing parameters in a total of 48 subjects made in the two groups of 24 each. Subjects were randomly chosen from women of reproductive age group attending at gynecology OPD and were admitted for myomectomy between December 15, 2013, and December 14, 2014.

Inclusion Criteria

The following criteria were included in the study:

- Women of reproductive age group having symptomatic myoma, not responding to medical therapy.
- Women of reproductive age group having asymptomatic myoma, sonologically diagnosed, with desire for fertility.
- The size of uterus is 10–16 weeks.
- The total number of myoma not more than three (sonologically diagnosed)

Exclusion Criteria

The following criteria were excluded from the study:

- Women of above and below reproductive age group (15–45 years).
- Women not desiring to preserve their uterus.
- Women having myoma >16 weeks size.
- Women having more than three (sonologically diagnosed).
- Women having severe anemia or hemodynamic instability.
- Women unfit for anesthesia.
- History of a bleeding disorder, heart disease, renal disease, etc.
- Women on concurrent anticoagulant therapy.
- Pre-operative hemoglobin (Hb) level of <9.0 g/dl.
- Women having other concomitant conditions such as pregnancy or any malignancy or endometriosis having impact on blood loss.

- The intraoperative time for removal of myoma >2 h.
- History of previous myomectomy.

Study Variables

- Pre-operative Hb and hematocrit (Hct)
- Immediate and 3rd post-operative Hb and Hct
- Duration of surgery
- Blood loss during surgery
- Requirement of blood transfusion

Study Tools

- Clinical history and detailed examination - Uterine size and shape (multiple or single myoma).
- USG of pelvic organs: Pre-operative sonographic evaluation size, number, location, and volume of myomas.
- Pre-operative investigations: Pre-operative Hb and Hct values.
- Intraoperative uterine size by direct examination

Estimation of Blood Loss in Both Groups

1. Weighing of all dry mops before operation and all blood-soaked mops after operation
2. Collecting blood from the suction machine collection bottle (at the starting, the bottle was empty every time)
    - Total blood loss during operation = X + Y ml
    - (Weight of blood-soaked mops – weight of dry mops) = X gm ≈ X ml
    - 1 g blood ≈ 1 ml of blood
    - Blood collected from suction bottle = Y ml
3. Intra- and post-operative blood transfusion
4. Reduction of Hb and Hct (measured immediate post-operative day and day 3 uniformly) from pre-operative values
5. Blood transfusion requirement in post-operative period
6. Operative time

Study Technique

- Approval from the Ethical Committee, Central Hospital, S.E. Railway, Garden Reach, was obtained.
- After admission for myomectomy, written informed consent of the patient was taken after proper counseling for either of the procedures.
- Patients are allocated randomly in two groups, i.e.,
- Group A (Tourniquet group): 24 women randomized for myomectomy with tourniquet application.
- Group B (Vasopressin group): 24 women randomized for myomectomy after vasopressin administration.
- Detail clinical examination and pre-operative investigations were done - Hb, Hct, abdominal ultrasonography, etc.
- Operative methods:
- The skin incision was Pfannenstiel incision. The uterus was exteriorized, bowels packed away with two large dry mops.
- 20 units of vasopressin, diluted in 100 ml of normal saline, were injected intramyometrial and surrounding myoma before giving incision over myoma; but the volume of vasopressin injected varied depending on the number of myomas to be removed.
- In the other group, tourniquet was applied to occlude the uterine vessels:
    - Palpate the broad ligament just above the level of internal OS to identify a space that is free of vessels and the ureter, lateral to uterine artery.
    - Make 1 cm incision in this clear space bilaterally.
    - Pass the tourniquet (A latex-free tourniquet in a latex allergic patient) through the incisions with the ends protruding anteriorly.
    - Pull the tourniquet tight and secure by securing the ends with a clamp. Tightness was assured by blanching of uterus after tourniquet application. Take care to avoid enlarging the broad ligament incisions and damaging the surrounding structures.
    - Simultaneously atraumatic clamps or tourniquets were applied over infundibulopelvic ligaments bilaterally to reduce blood flow from ovarian vessels, especially in fundal fibroids. Every 15–20 min clamps or tourniquets were released to maintain blood flow to ovaries. Care was taken for not to damage tubes, ureters, ovaries, and vessels.

- Intraoperative blood loss estimation by:
    - Weighing of all dry mops before operation and all blood-soaked mops after operation.
    - Collection of blood from the suction machine collection bottle (at the starting of the operation, the bottle was empty every time).

- Intraoperative blood transfusion.
    - Reduction of Hb and Hct (measured immediate post-operative day and day 3 uniformly) from pre-operative values.
    - Blood transfusion requirement in post-operative period.
    - Operative time and complications are noted.

Pre-operative, intraoperative, and post-operative data were collected in prescribed pro forma. Data were collected during a span of 1 year and were charted in Excel worksheet; then, the data were analyzed using Epi Info™ 3.5.3 to detect effectiveness of both methods in reducing blood loss.

Statistical Analysis

Statistical analysis was performed with the help of Epi Info™ 3.5.3., a trademark of the Centers for Disease

Control and Prevention. Using this software, basic cross-tabulation, inferences, and associations were performed.

Descriptive statistical analysis was performed to calculate means with corresponding standard deviations (SD). Test was used to test the association of different study variables with the study groups. Z-test (standard normal deviate) was used to test the significant difference between two proportions. *t*-test was used to compare the means. Odds ratio (OR) with 95% confidence interval had been calculated to find the risk factors. Multivariate logistic regression was used to estimate the OR after adjusting the confounding factors. $P \leq 0.05$ was considered statistically significant.

RESULTS

Mean Hb and Hct (Hct) Level in Pre-operative, Immediate, and 3rd Post-operative Period [Table 1]

Chi-square test showed no significant association between the groups in terms of pre-operative Hb (= 0.62; $P = 0.73$) and Hct (= 0.43; $P = 0.80$). However, Chi-square and *t*-test showed significant association between Hb level in two groups in both immediate (= 8.58; $P = 0.013$) and 3rd post-operative period (−11.37; $P = 0.003$). Similarly, significant association between Hct levels in two groups in both immediate (= 20.97; $P = 0.00001$) and 3rd post-operative period (= 19.76; $P = 0.0001$). *t*-test showed that Group B had significantly higher mean Hb and Hct level in both immediate and 3rd post-operative day.

Mean Fall of Hb in Immediate and 3rd Post-operative day [Figure 1]

t-test showed that mean fall of Hb both in immediate ($t_{46} = 4.63$; $P < 0.00001$) and 3rd post-operative period ($t_{46} = 3.17$; $P < 0.0001$) in two groups was significantly higher for Group A.

Mean Fall of Hct in Immediate and 3rd Post-operative Day [Figure 2]

t-test showed that the mean fall of Hct both in immediate ($t_{46} = 6.07$; $P < 0.00001$) and 3rd post-operative day ($t_{46} = 4.82$; $P < 0.0001$) in two groups was significantly higher for Group A.

Intraoperative Blood Loss [Table 2]

Chi-square test showed that there was a significant association between loss of blood during surgery between groups ($P = 0.0002$).

t-test showed that mean amount of blood loss during surgery in Group-A was significantly higher than that of Group-B ($t_{46} = 5.26$; $P < 0.0001$).

Duration of Surgery (Table 3)

Chi-square test showed that there was no significant association between duration of surgery and groups ($P > 0.05$). The mean duration of surgery (mean ± SD) of the patients of Group-A was 49.00 ± 10.33 min with range 30.0–65.0 min and the median was 49.0 min. The mean duration of surgery (mean ± SD) of the patients of Group-B was 48.79 ± 9.62 min with range 30.0–65.0 min and the median was 46.5 min.

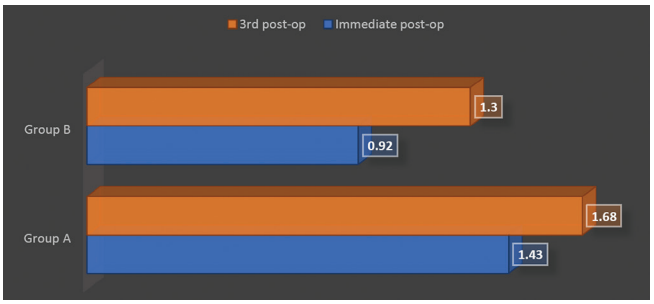

Figure 1: bar diagram showing the mean fall of Hb (in gm%) in immediate and 3rd post-operative day after intervention in each

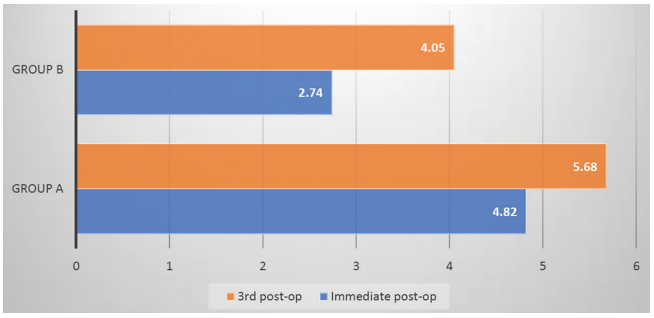

Figure 2: Bar diagram showing the mean fall of Hct (in %) in immediate and 3rd post-op period after intervention in each group

Table 1: Mean Hb and Hct level in pre-operative, immediate, and 3rd post-operative day

Period	Parameter*	Group A (Mean±SD)	Group B (Mean±SD)
Pre-operative	Hb	10.54±0.5	10.45±0.46
	Hct	31.80±1.44	31.69±1.51
Immediate post-operative	Hb	9.11±0.51	9.52±0.48
	Hct	26.97±1.51	28.95±1.57
At 3rd post-operative	Hb	8.94±0.52	9.45±0.52
	Hct	26.45±1.55	28.74±1.69

*Hb levels are expressed in "gm%" and Hct levels are expressed in "%." Hb: Hemoglobin, Hct: Hematocrit, SD: Standard deviation

Table 2: Distribution of patients according to their loss of blood during surgery

Blood loss (in ml)	Group A (n=24)	Group B (n=24)	Total
300–400 ml	7	21	28
401–500 ml	8	2	10
501–600 ml	9	1	10
Total	24	24	48
Mean±SD	467.91±74.49	356.45±58.35	

P=0.0002, S - Significant. SD: Standard deviation

Table 3: Distribution of patients according to their duration of surgery

Duration of surgery (in min)	Group A (n=24)	Group B (n=24)	Total
30–45	11	12	23
46–60	12	11	23
>60	1	1	2
Total	24	24	48
Mean±SD	49.00±10.33	48.79±9.62	

P=0.95, NS - Not significant. SD: Standard deviation

Table 4: Distribution of patients according to the requirement of blood transfusion

Requirement of blood transfusion	Group A (n=24)	Group B (n=24)	Total
Yes	5	2	7
No	19	22	41
Total	24	24	48

t-test showed that there was no significant difference between the mean duration of surgery of the two groups ($t_{46} = 0.06$; $P > 0.05$).

Requirement of Blood transfusion (Table 4)

Test of proportion showed that proportion of patients with requirement of post-operative blood transfusion was significantly higher in Group-A than that of Group-B ($Z = 2.51$; $P < 0.05$).

DISCUSSION

The total number of patients was 48. 24 of them were recruited in each group (tourniquet group or Group A and vasopressin group or Group B). No one was lost from the study.

In literatures, various methods are described to reduce blood loss during myomectomy,[18-21] but studies comparing intramyometrial vasopressin versus tourniquet application were minimum.[21]

Pre-operative Hb values were comparable in both groups, i.e., mean 10.5 ± 0.50 g/dl in tourniquet group (Group A) and 10.5 ± 0.47 g/dl in vasopressin group (Group B) ($P = 0.515$) [Table 1]. Pre-operative Hct values were also comparable in both groups, i.e., mean 31.8 ± 1.44% in tourniquet group (Group A) and 31.7 ± 1.51% in vasopressin group (Group B) ($P = 0.808$) [Table 1]. These are important parameters required for the calculation of the reduction of Hb and Hct postoperatively. Taylor *et al.* included all patients having pre-operative Hb ≥10.5 g/dl.[22]

Immediate mean post-operative Hb was lower in tourniquet group (Group A) 9.11 ± 0.51 g/dl than 9.52 ± 0.48 g/dl in vasopressin group (Group B) ($P = 0.00001$) [Table 1]. There was a significant mean reduction in Hb in post-operative period in both groups ($P \leq 0.00001$), but it was more in tourniquet group (Group A) (1.43 ± 0.45 g/dl) in comparison to vasopressin group (Group B) (0.92 ± 0.20 g/dl) [Figure 1].

Immediate post-operative Hct was lower in tourniquet group (Group A) 26.45 ± 1.55% (R: 24.5–31%) in comparison to 28.95 ± 1.57% (R: 25.5–32%) in vasopressin group (Group B) ($P \leq 0.0001$) [Table 1]. Mean reduction in Hct value in post-operative period was 4.82 ± 1.4% in tourniquet group (Group A) versus 2.74 ± 0.62% in vasopressin group (Group B) ($P \leq 0.0001$), and it was more in tourniquet group [Figure 2].

Post-operative day 3 Hb was lower in tourniquet group (Group A) 8.94 ± 0.52 g/dl (R: 8.1–10.4 g/dl) than g/dl (R: 8.4–10.6 g/dl) in vasopressin group (Group B) (*P* 001) [Table 1]. There was significant mean reduction in Hb in post-operative period in both groups ($P \leq 0.00001$), but it was more in tourniquet group (Group A) (1.68 ± 0.16 g/dl) in comparison to vasopressin group (Group B) (1.3 l) [Figure 1].

Post-operative day 3 Hct was lower in tourniquet group (Group A) 26.45 ± 1.55% (R: 24.5–31%) in comparison to 28.74 ± 1.69% (R: 25.5–32%) in vasopressin group (Group B) ($P \leq 0.0001$) [Table 1]. Mean reduction in Hct value in post-operative period was 5.68 ± 0.45% in tourniquet group (Group A) versus 4.05 ± 0.07% in vasopressin group (Group B) ($P \leq 0.0001$), and it was more in tourniquet group [Figure 2]. Frederick *et al.* showed in his study 1.7 g/dl fall in Hb and 5 % fall in Hct at post-operative period with the use of vasopressin.[23] Recently, in a study done in Japan, in 26 patients who underwent myomectomy, the intraoperative blood loss was reduced by the vasopressin administration, and their treatment results were compared with seven patients who underwent only myomectomy. The vasopressin was administered by the intramyometrial injection. There was no difference in the operation time between both groups, but intraoperative blood loss was lower in vasopressin group.[24]

An average intraoperative blood loss of 540 ml was reported in a review of abdominal myomectomy for

uterine size exceeding 14 weeks despite the use of different non-mechanical techniques to reduce blood loss during surgery.[25] In our study, the amount of mean blood loss in the tourniquet group (Group A) was 467.9 ± 74.50 cc versus 356.45 ± 58.35 cc in vasopressin group (Group B) which is significantly higher in the tourniquet group ($P \leq 0.001$) [Table 2], and it was almost nearly comparable with the review report of Royal Australian and New Zealand College of Obstetricians and Gynaecologists where also showed the superiority of intramyometrial vasopressin administration.[26]

The mean operative time was 49.0 ± 10.33 min (R: 30–60 min) in tourniquet group (Group A) and 48.8 ± 9.62 min (R: 30–65 min) in vasopressin group (Group B) which was statistically indifferent ($P = 0.943$) [Table 3].

Blood transfusion was also required more, i.e., 5 (20.83%) cases in tourniquet group (Group A) and only in 2 (8.33%) cases of vasopressin group (Group B) though it was statistically indifferent between both groups ($P = 0.416$) [Table 4]. However, despite the use of one or more of these techniques to reduce blood loss during abdominal myomectomy up to one-third of the United Kingdom gynecologists use blood transfusion,[22] but it was comparatively less in our study.

Histological examination of the resected tissue showed leiomyoma tissue in all patients and confirmed the diagnosis as myoma uteri.

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