

Impact of Adding B-Lynch Transverse Compression Suture to Internal Iliac Artery Ligation in the Conservative Management of Morbid Adherent Placenta Previa: A Randomized Controlled Trial

Nahla W. Shady¹, Hany F. Sallam¹, Salah Maklad²

¹Department of Obstetrics and Gynecology, Faculty of Medicine, Aswan University, Aswan, Egypt, ²Department of Radiology, Faculty of Medicine, Aswan University, Aswan, Egypt

ABSTRACT

Objective: The current study aims to investigate the effect of B-Lynch transverse compression suture on measured blood loss during and after a cesarean section in patient undergone internal iliac artery ligation (IIAL) due to morbid adherent placenta previa (MAPP). **Materials and Methods:** A single center open-labeled randomized clinical trial was carried out in a tertiary university hospital between June 2015 and June 2018; 142 women were undergoing cesarean delivery for MAPP, were randomly allocated to managed conservatively either with IIAL (71 patients in Group I) or IIAL plus B-lynch transverse compression suture (71 patients in Group II) to control intraoperative blood loss and postpartum hemorrhage. In the case of conservative treatment protocol failure, cesarean hysterectomy was performed. **Results:** There was a great reduction in intraoperative blood loss in Group II (921.83 ± 237.69) compared with Group I (1397.04 ± 305.53) ($P = 0.0001$). Furthermore, there was a great reduction in post-operative bleeding either vaginal bleeding or blood in intra-abdominal drain in Group II than Group I ($P = 0.0001$ and 0.0001); hence, the total estimated blood loss in Group II (1162.11 ± 295.46) showed highly reduction compared with Group I (1726.06 ± 368.94) ($P = 0.0001$). **Conclusion:** Adding B-lynch transverse compression suture to IIAL in the management of MAPP is a novel combination approach to preserve the uterus as possible and change in the concept of placenta accrete management always mandates hysterectomy.

Key words: B-lynch transverse compression suture, internal iliac artery ligation, morbid adherent placenta previa, postpartum hemorrhage

INTRODUCTION

Morbidly adherent placenta previa (MAPP) represents one of the most night mare's conditions in modern obstetrics, with high rates of hysterectomy, hemorrhage, and intensive care unit admission.^[1]

The term MAPP implies abnormal implantation of the placenta into the uterine wall. This term has been used to describe placenta accreta, increta, and percreta. Placenta accreta is strictly defined as direct attachment of the placental trophoblast to the uterine

myometrium, with no normal intervening decidua basalis layer. Cases with a partial or complete invasion of trophoblast through the uterine wall are called increta and percreta, respectively, though all three categories are collectively identified as accreta in the epidemiologic literature.^[2]

MAPP appears to be on the rise paralleling the rise in cesarean section (CS) rate as a major risk factor.^[3]

MAPP is one of the most common reasons for cesarean hysterectomy^[4] which associated with high rates of severe

Address for correspondence:

Hany F. Sallam, Department of Obstetrics and Gynecology, Faculty of Medicine, Aswan University, Aswan, Egypt.
Email: hany.farouk@aswu.edu.eg

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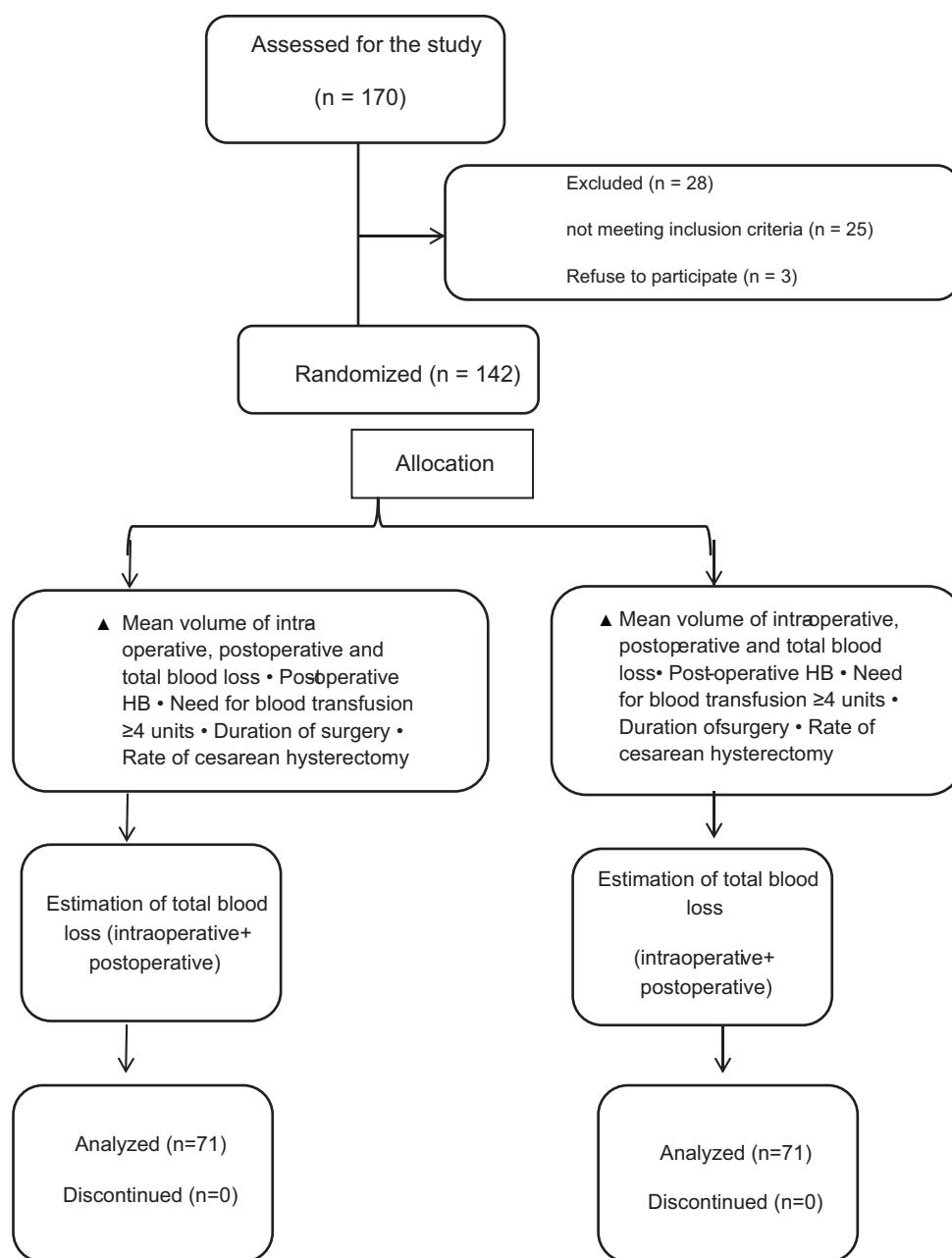


Figure 1: Flowchart of the study

maternal morbidity (40–50%),^[4] with reported mortality rates up to 7%. And, might not be considered first-line treatment for women who have a strong desire for future fertility.^[5]

The main types of conservative management which have been described: One-step conservative surgery,^[6] expectant management or leaving the placenta *in situ*,^[7] extirpative treatment,^[8] and the triple-P procedure.^[9]

Internal iliac artery ligation (IIAL) is one of the effective techniques used to control postpartum hemorrhage (PPH). The aim is to decrease the blood supply to the uterus and to prevent or help to arrest PPH.^[10] Moreover, still plays a role in

the management of PPH before proceeding to hysterectomy when other conservative methods fail, however, preventive devascularization achieved by IIAL used to treat PPH may be less effective in cases of MAPP.^[11]

The transverse B-lynch suture was reported for management of placenta previa.^[12]

Till now, there are debates about the optimal conservative management protocols of MAPP, although primary goals in MAPP are to prevent intraoperative and post-operative hemorrhage, the ideal treatment of MAPP should restore the uterine anatomy and ensure a new pregnancy with minimal

risk of complications. The ideal treatment of MAPP still elusive and debatable. With the rising incidence of abnormal placentation, it is important to define management strategies with a focus on reducing maternal morbidity and mortality mainly decrease PPH.^[13]

Hence, the aims of our study to assess the effect of the additive role of B-lynch transverse compression suture on measured blood loss during and after a caesarian section in patient undergone hypogastric artery ligation due to MAPP.

MATERIALS AND METHODS

The study was conducted in accordance with the Declaration of Helsinki and was approved by the local departmental Ethics Committee. Informed written consent was obtained from all patients before their enrollment in this study.

Assuming a type-1 error of 0.05 and a power of 90%, a sample size of 71 women per group was calculated to detect: a 564-ml difference in total blood loss (1726.06 ± 368.94) in the control arm versus (1162.11 ± 295.46) in intervention arm. After almost 3 years, and has recruited 142 women to the trial, an interim analysis was undertaken, and a decision made to cease enrollment, having considered the feasibility of continuing recruitment to reach an adequate sample size.

A single center open-labeled randomized clinical trial was carried out in a tertiary care hospital between June 2015 and June 2018 [Figure 1]. Study inclusion criteria were women undergoing elective cesarean delivery for MAPP. Diagnosis of MAPP based on ultrasound in which one or more of ultrasonographic features was present [Figure 2]: (1) Loss of the retroplacental clear space, (2) thinning of the myometrium overlying the placenta, (3) multiple irregular placental lacunae with a “moth-eaten” or “Swiss cheese” appearance of placenta, and (4) turbulent blood flow through the lacunae on Doppler velocimetry.^[2]

This ultrasonographic feature confirmed at CS by placental adherence requiring digital separation [Figure 3]. Exclusion criteria were: (1) Patients with the cardiac, hepatic, renal or thromboembolic disease, (2) patients with placenta percreta (ultrasound features showed invasion of the placenta into the bladder or increased vascularity of the uterine serosa-bladder interface), and (3) patient show to have placenta previa without signs of invasion (placenta previa without accreta).

Eligible participants

There were 170 patients who were asked to participate, 28 patients were excluded, 25 patients not meeting inclusion criteria, and 3 patients refused to participate. Therefore, the remaining 142 patients were included in the study. All participants underwent the detailed history, general

examination, abdominal examination, and both abdominal and vaginal ultrasound examinations. The participants who fulfilled the eligibility criteria were explained about the study with the beneficial and possible adverse effects of the conservative management using hypogastric artery ligation plus B-lynch transverse compression suture. Informed consent was obtained from them, after that participant was randomized to two groups: Group I (71 patients received 20 IU oxytocin [syntocinon. Novartis company] IV infusion plus bilateral IIAL after fetus delivery) and Group II (71 patients received 20 IU oxytocin [syntocinon. Novartis company] IV infusion plus bilateral IIAL after fetus delivery plus B-lynch transverse compression suture after placental delivery).

Randomization

Patients were randomized to two groups, each compromised 71 patients according to a two-blocked randomization list which was coded (a or b) at 1:1 ratio. The two parallel groups were prepared using a computer-generated randomization system. The allocated groups will be concealed in serially numbered sealed opaque envelopes that will only be opened after recruitment. The trial was open label.

Intervention

Eligible participants were allocated to one of two groups after induction of general anesthesia and before the operation and before skin incision. In all eligible participants, CS was performed under general anesthesia by the same operative and anesthesia team. The abdomen was exposed through Pfannenstiel incision, after skin incision, the subcutaneous fat and abdominal fascia were opened crosswise, and the rectus muscle was opened on the midline, the parietal peritoneum was opened longitudinally, the visceral peritoneum was opened transversely and dissected downward with the bladder and kept against symphysis pubis by a Doyen retractor, followed by transverse incision of the uterus at the upper border of the placenta to avoid transplacental incision which provokes severe bleeding. The fetus was delivered. Bilateral IIAL was done before placental delivery by transabdominal/transperitoneal approach [Figures 4 and 5].

20 IU oxytocin was given IV infusion after IIAL to prevent premature separation of placenta which provoked severe bleeding then placenta delivery was done.

In the B-lynch transverse compression suture group (26) after acceptable control of bleeding from the placental bed, uses the suture material 1 VICRYL with a 70 mm ½ circle needle mounted on a 90 cm VICRYL suture [Figure 6].

It is essential that the ureters are identified by palpation or visual observation after the bladder is displaced inferiorly and held by traction. Any observed bleeding should be dealt

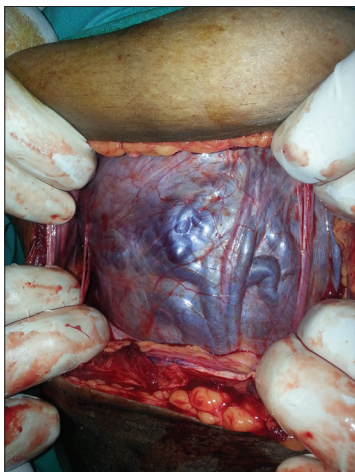


Figure 3: Morbid adherent placenta previa

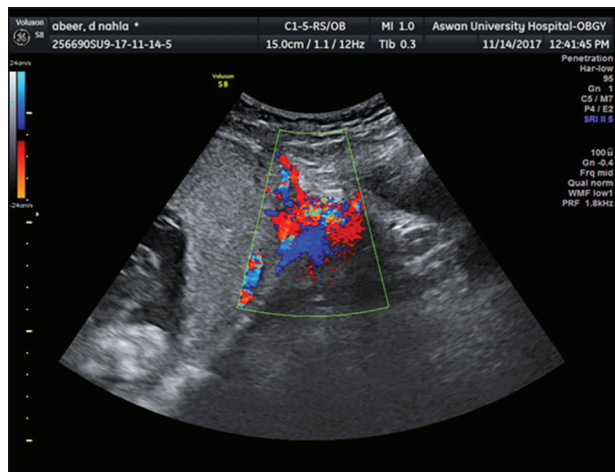


Figure 2: Placenta accreta suspected by Doppler US

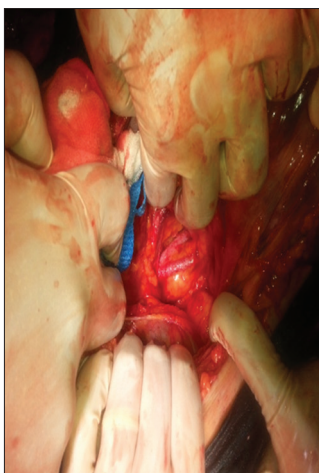


Figure 4: Demonstration of IIA

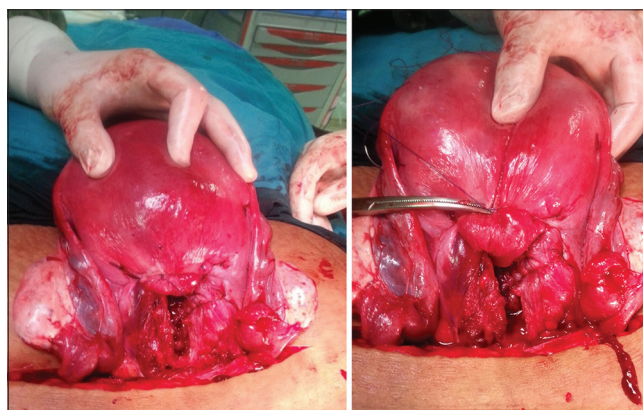


Figure 6: B-lynch transverse compression suture

bleeding has ceased by swabbing the vagina again.

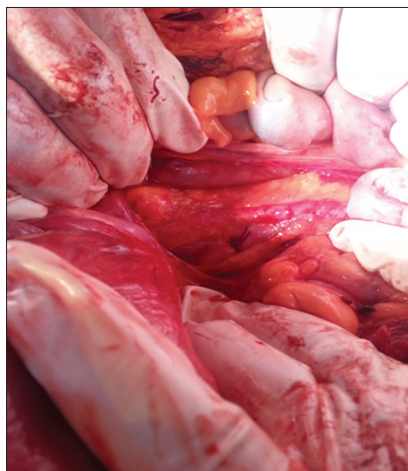


Figure 5: IIA after ligation

with in the usual way. At the end of the suture application and before tying the knots, the lower segment is compressed again transversely while the suture is held taut to ensure that

A wide pore drain was then inserted into the Douglas pouch, and the abdominal wall was repaired. In the case of conservative treatment protocol failure, cesarean hysterectomy was performed.

Blood loss estimation

Intraoperative blood loss was measured by adding the volume of the contents of the suction bottle after removal of liquor and contaminated blood and the difference in weight (in grams) between the dry and the soaked operation sheets and towels (1 g = 1 ml). Post-operative blood loss was measured by adding the volume of the contents of the pelvic drain which measured every 12 h and on removing the drain and the difference in weight (in grams) between the dry and the soaked vaginal pads after 6 h post-operative (1 g = 1 ml). After that, the total blood loss was calculated by the addition of intraoperative and post-operative blood loss.

In the case of conservative treatment protocol failure, cesarean hysterectomy was performed.

Study outcome

The primary outcome was the estimation of intraoperative, post-operative, total blood loss (ml), and the incidence of cesarean hysterectomy.

The secondary outcome measures included pulse rate, blood pressure, and temperature which recorded continuously intraoperative, then every 30 min after operation; therefore, the mean was calculated. Furthermore, measures included the need for blood transfusion ≥ 4 units, operative time, the period for hospitalization bladder injury and 24 h post-operative hemoglobin concentration. After collecting all the data, the data were tabulated and analyzed.

Statistically analysis

Data were entered and statistically analyzed using the Statistical Package for the Social Sciences (SPSS) version 16. Qualitative data were described as numbers and percentages. Chi-square test was used for comparison between groups. Quantitative data were described as means (SD) after testing for normality by Kolmogorov–Smirnov test. Independent sample *t*-test was used for comparison between groups. Odds ratios and their 95% confidence interval were calculated. “ $P \leq 0.05$ ” was considered to be statistically significant.

RESULTS

Our study started with 170 patient who was asked to participate, 28 patients were excluded, 25 patients not meeting inclusion criteria, and 3 patients refuse to participate. Therefore, the remaining 142 patients were randomized to two groups each group comprised 71 patients: Group I (71 patients received 20 IU oxytocin IV plus bilateral IIAL after fetus delivery) and Group II (71 patients received 20 IU oxytocin IV and bilateral IIAL after fetus delivery plus B-lynch transverse compression suture after placental delivery).

There was no significant difference between the two groups with respect to their age, weight, height, parity, gestational age, pre-operative pulse, systolic blood pressure (SBP), diastolic blood pressure (DBP), temperature, initial hemoglobin, and number of previous CS [Table 1].

There was a great reduction in intraoperative blood loss in Group II (921.83 ± 237.69) compared with Group I (1397.04 ± 305.53) ($P = 0.0001$). Furthermore, there was a great reduction in post-operative bleeding either vaginal bleeding or blood in intra-abdominal drain in Group II than Group I ($P = 0.0001$ and 0.0001); hence, the total estimated blood loss in Group II (1162.11 ± 295.46) showed highly reduction compared with Group I (1726.06 ± 368.94) ($P = 0.0001$).

The incidence of cesarean hysterectomy was decreased in Group II (7%) than Group I (16.9%); however, this reduction showed no significant difference ($P = 0.07$) [Table 2].

The number of patients needs blood transfusion ≥ 4 bags was significant increase in Group I; (41 patients [57.7%]) versus 12 patients in Group II (16.9%) ($P = 0.0001$). Furthermore, the number of patients need admission to ICU was significant increase in Group I (23 patients [32.4%]) versus 5 patients in Group II (7%) ($P = 0.0001$). The mean post-operative hemoglobin in Group I was (9.19 ± 0.55) and in Group II was (9.57 ± 0.59) with statistically significant difference ($P = 0.0001$).

There was a significant increase in post-operative hospital stay in Group I (5.0 ± 1.54) compared with Group II (3.96 ± 0.96) ($P = 0.0001$). There was a significant increase in post-operative pulse in Group I (92.21 ± 10.34) compared with Group II (85.82 ± 6.14) ($P = 0.0001$). Furthermore, there was a significant decrease in both post-operative SBP (112.21 ± 7.57) and DBP (73.87 ± 5.43) in Group I

Table 1: Pre-operative characteristics of pregnant women in the study groups

Parameters	Group I (n=71)	Group II (n=71)	Significance
Age (year)	30.7±2.79	31.27±3.01	0.393
Weight (kg)	77.97±5.33	77.21±5.01	0.501
Parity	3.04±0.96	2.99±0.99	0.489
Hight	3.04±3.96	162.63±3.95	0.103
Pulse	80.63±4.98	79.62±4.96	0.456
Temperature	36.999±0.14	36.96±0.13	0.344
SBP	119.99±2.53	119.77±2.58	0.636
DBP	78.85±3.2	78.03±3.1	0.685
Initial hemoglobin (%)	9.91±0.67	9.98±0.64	0.836
Gestational age (weeks)	36.58±0.6	36.54±0.63	0.928
Previous cesarean section (CS)	2.99±0.84	2.96±0.92	0.656

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, CS: Cesarean section. #Variables are presented as mean and standard deviation, Statistical significance if p value ≤ 0.05

Table 2: Primary outcome in the study groups

Variables	Group I (n=71)	Group II (n=71)	Significance
Blood loss			
Intraoperative	1397.04±305.53	921.83±237.69	0.0001*
Postoperative vaginal bleeding	210 (60–280)	140 (80–250)	0.0001*
Blood in drains	110 (60–280)	80 (50–300)	0.0001*
Total blood loss <1000	1726.06±368.94 6 (8.5)	1162.11±295.46 21 (29.6)	0.0001*
1000–1500	11 (15.5)	41 (57.7)	
1500–2000	31 (43.7)	4 (5.6)	0.0001*
>2000	23 (32.4)	5 (7.0)	
No of cesarean hysterectomy (%)	12 (16.9)	5 (7.0)	0.07

*Statistical significant difference, #variables are presented as mean and standard deviation, median (minimum-maximum) and number (percentage).

Table 3: Secondary outcome in the study groups

Variables	Group I (n=71)	Group II (n=71)	Significance
Pulse	92.21±10.34	85.82±6.14	0.0001*
Temperature	36.5±0.16	36.94±0.14	0.908
SBP	112.21±7.57	118.51±2.46	0.0001*
DBP	73.87±5.43	77.04±3.44	0.0001*
Post op hemoglobin (%)	9.19±0.55	9.57±0.59	0.0001*
NO of ICU admission	23 (32.4)	5 (7.0)	0.0001*
Bladder injury	7 (9.9)	5 (7.0)	0.774
Need Blood transfusion >4 unit	41 (57.7)	12 (16.9)	0.0001*
Nausea	6 (8.5)	8 (11.3)	0.816
Vomiting	2 (2.8)	3 (4.2)	0.875
Diarrhea	1 (1.4)	2 (2.8)	0.286
Operative times	12.19	9.37	0.662
Hospital stays	1.54	0.96	0.0001*

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, *statistical significant difference, #variables are presented either mean and standard deviation and number (percentage)

compared with SBP (118.51 ± 2.46) and DBP (77.04 ± 3.44) in Group II ($P = 0.0001$ and 0.0001).

There was no significant difference between both groups with respect to post-operative temperature, incidence of urinary bladder injury, and operation time ($P = 0.908$, 0.774 , and 0.062 , respectively) [Table 3].

DISCUSSION

In the current study, prophylactic use of IIAL plus B-lynch transverse compression suture is effectively reduce intraoperative, post-operative blood loss; blood transfusion needs more than 4 IU as well as lower the incidence of PPH due to MAPP as compared with IIAL alone. Also, cesarean hysterectomy associated with a decrease in cesarean hysterectomy for post-partum hemorrhage. In the best of

our knowledge, our study is the first to evaluate the novel combination of B-lynch transverse compression suture during CS for MAPP adjunctive to IIAL for the aim of prevention of intraoperative and postpartum hemorrhage with aiming for conservative management.

Preventive devascularization can be achieved by techniques used to treat PPH (bilateral ligation of internal iliac artery, embolization, bilateral uterine artery ligation, and stepwise uterine devascularization), although these uterine-sparing procedures may be less effective in cases of MAPP.^[14,15]

Conservative management for MAPP has become an alternative valid option to planned cesarean-hysterectomy in well-selected cases, with appropriate counseling, and close surveillance. The internal iliac arteries and their branches have been targeted with the assumption that intravascular

occlusion results in a decrease in pulse pressure distal to the occlusion and potentially results in a decrease in the risks of massive hemorrhage and blood transfusion.^[10]

Rauf *et al.* investigated maternal outcomes of conservative management of postpartum hemorrhage due to MAPP using IIAL and endo-uterine hemostatic suture to lower uterine segment. Patients who were managed conservatively with hypogastric artery ligation and endo-uterine hemostatic suture to control postpartum hemorrhage secondary to MAPP, suffer from lower hysterectomy rate compared with the other conservative methods reported in the literature.^[13]

In our department, the procedure of IIAL is promptly considered in the management of severe PPH. Finally, IIAL is performed much more frequently and physicians are more familiar with the procedure. This technique continues to be a surgical option in severe PPH when medical treatment has failed to control hemorrhage with the desire to preserve fertility. Moreover, IIA ligation may play a role in the arrest of persistent bleeding following hysterectomy.

The success rate of IIA ligation for PPH has been reported as 42–75% in previous works.^[17] Yildirim *et al.*^[18] also stated it as high as 90% in their study. In our study, the success rate of IIA ligation for PPH is in concordance with other studies, and this may be due to early resort to IIA ligation for patients with MAPP. In our study IIAL refrain hysterectomy in 84% of the patient, with adding B-lynch transverse compression suture in combination with IIAL refrain hysterectomy in 93% of the patients, and this agreed with the literature.^[19-21]

Angstmann *et al.* demonstrated it is possible that prophylactic devascularization carried out in the absence of bleeding could reduce the risk of secondary hemorrhage in the setting of conservative treatment in stable women with MAPP.^[24]

Palacios-Jaraquemada *et al.* described outcomes of one-step conservative surgery on 68 women presenting with the placental invasion of adjacent organs (invasion of the posterior upper bladder section [$n = 46$; Group I] and the posterior lower vesical section [$n = 22$; Group II]). The main steps of this uterine-sparing technique achieved through a median or Pfannenstiel incision are vascular disconnection of newly formed vessels and the separation of invaded uterine from invaded vesical tissues, performance of an upper-segmental hysterotomy, resection of all invaded tissue and the entire placenta in one piece, use of surgical procedures for hemostasis, myometrial reconstruction in two planes, and bladder repair if necessary. Uterine preservation was achieved in 95.7% (44/46) and 27.3% (6/22) of cases, respectively.^[16]

In our study, we did not encounter any serious intraoperative complications such as injury to the internal iliac vein or ureter

during ligation of internal iliac artery, inadvertent ligation of the external iliac artery. Similarly, no such complications were noted in various other studies.^[22,23]

Modified B-Lynch suture was successfully reported for management of MAPP with IIAL.^[25]

Our study had some strength; first, it was a randomized clinical trial providing the first evidence that B-lynch transverse compression suture is a simple procedure for reduced intraoperative blood loss and need for blood transfusion during CS due to MAPP in adjunctive with IIAL.

Second, the homogeneity of the selected cases (only patients with MAPP with the exclusion of PP without morbid adhesion and percreta) could be considered another merit. The main limitation of our study was probably related to the lack of blinding of the surgeons by the participants' group. Additionally, being a single-center study with a relatively small sample size of the included women may limit the generalizability of the results. Further trials should be done to confirm our results. Finally, the study was not powered enough to assess the secondary outcomes as the occurrence of adverse events or the need for cesarean hysterectomy.

Future studies designed prospectively with a large sample size need to be performed to further clarify the place of IIAL alone or in combination with B-lynch transverse compression suture in the management of placenta accrete.

CONCLUSION

Adjunctive B-lynch transverse compression suture adding to IIAL in the conservative management of MAPP is a novel approach may be, safe, economical, and highly efficient to preserve the uterus as possible and change in the concept of placenta accreta management always mandates hysterectomy.

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