ORIGINAL ARTICLE

# Prophylactic hypogastric arterial ligation before cesarean hysterectomy for controlling complications in pregnant women with placenta adherent abnormality: A randomized controlled clinical trial

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**Background:** Placenta adherent abnormality (PAA) is abnormal attachment of the placenta to the myometrium. This abnormal placenta binding has severe clinical consequences for the mother and the fetus. We investigated the outcomes of hypogastric arterial ligation (HAL) before hysterectomy compared to hysterectomy alone in pregnant women with PAA. **Materials and Methods:** In this randomized controlled clinical trial, 70 patients were randomly allocated to HAL along with hysterectomy and hysterectomy alone groups (35 in each Group). The total amount of intraoperative blood loss, the need for intraoperative blood products transfusion, frequency of deep vein thrombosis, duration of surgery, duration of hospitalization, and visceral trauma were compared between 2 Groups. **Results:** Finally, 64 patients completed the study protocol with mean age of 33.84 ± 4.25 years. The study groups were comparable in terms of basic baseline demographic and clinical characteristics. Visceral trauma was less frequently occurred in HAL group compared to hysterectomy alone (0% vs. 15.6%; $P = 0.02$). Intraoperative blood loss (1525 ± 536.41 cc vs. 2075 ± 889.36 cc; $P = 0.001$) and were significantly lower in HAL group compared to hysterectomy alone. Duration of operation (179.06 ± 36.28 vs. 197.66 ± 39.47; $P = 0.05$) and hospitalization (4.97 ± 2.20 vs. 6.10 ± 2.39; $P = 0.03$) also were significantly lower in HAL group. **Conclusion:** Our findings suggest that prophylactic HAL has a protective effect on the reduction of blood loss and less visceral trauma in pregnant women with PAA.

**Key words:** Deep vein thrombosis, hemorrhage, hypogastric, hysterectomy, placenta accrete

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## INTRODUCTION

Placenta adherent abnormality (PAA), as the most problematic issue in obstetric surgery, has substantially over the past 30 years, with one estimate increasing from 4 to 14.4/10,000 deliveries.[1,2] PAA is divided into accreta, increta, and percreta based on invasion of the placental to the myometrium and visceral organs such as the bladder and intestine.[3,4]

An attempt to separate it following delivery of the fetus may cause severe bleeding (as the most common complication), deep vein thrombosis (DVT), multiple organ dysfunction, and failure such as acute respiratory

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distress syndrome, renal failure, and even maternal death.[1,5-7]

The recommended approach to abnormally invasive placenta (AIP) is total hysterectomy following delivery of the fetus.[8] Blood loss during hysterectomy might be severe during operation especially in placenta percreta cases.[9] Thought, the literature has been described that nonsurgical measures such as administration of tranexamic acid and the use of cell-saver equipment during surgery[10-13] and also surgical measures such as hypogastric (internal iliac) artery ligation (HAL), intraoperative balloon occlusion of the aorta, common iliac, internal iliac, and uterine arteries[14-16] are both effective to reduce blood loss and facilitate surgery. However, there is no clear consensus on effective measures that should be used at the time of cesarean hysterectomy (CH) to prevent massive blood loss and reduce the principal uterine vascularity during surgery.[14,17]

To date, the most of studies attempt to control postpartum hemorrhage (PPH)[18-20] or these therapeutic modality have been limited to case reports and case–control comparisons.[14,21,22] Furthermore, it has been shown that balloon occlusion of the internal iliac artery (IIA) by interventional radiology was found to be ineffective for reducing blood loss and decreasing blood transfusion rates.[15,22-26] Papillon-Smith *et al*. study recently revealed that the prophylactic placement of HAL during CH for PAA disorders had advantage such as lower complication rate, shorter total procedure time, and less blood loss compared to those Undergoing endovascular balloons.[17]

It looks like the most efficient procedures in reducing blood flow are the methods performing during operation, not postoperation. Hence, we design this randomized clinical trial study, as the first study in Iran and scare studies over the world to investigate the prophylactic effect of HAL method compared to hysterectomy alone on the blood loss, transfusion rates, and other complications of CH in pregnant women with confirmed diagnosis of PAA.

## MATERIALS AND METHODS

This single blind parallel-randomized controlled clinical trial study was conducted in the Gynecology Department of Alzahra Hospital, Isfahan, Iran, during October 2018 to September 2019. This study was approved by the Ethics Committee of Isfahan University of Medical (Code: IR.MUI.MED.REC.1397.156). Furthermore, the protocol of the study was registered to the Iranian Registry of Clinical Trials (IRCT; Code: IRCT20190123042467N1). All participants and their families were fully informed about how the study was conducted, the possible benefits, and its side effects then provided written and informed consent. The inclusion criteria were pregnant women with the placental adherent abnormality diagnosed by two experienced specialists using color Doppler ultrasonography or the pregnant women who were candidate for hysterectomy during cesarean section according to the physician's discretion with gestational age ≥24 weeks.

The exclusion criteria were HAL after hysterectomy to control bleeding, discontinue the intervention due to possible injuries to the participants, and women with a false-positive diagnosis of PAA by color Doppler ultrasound.

Sample size was determined in the current study to be 33, considering type one error rate ($\alpha = 0.05$), statistical power 80% ($1-\beta = 0.80$) for detecting standardized effect size 0.7 for blood loss during operation as study main outcome. We recruited 35 patients in each group and allocation was done using simple randomization by generated random numbers by SPSS software. Allocation concealment was done by a nurse who was not a research team member using encrypted envelopes (A and B). Due to the nature of the intervention, it was not possible to blind the researcher, but the patient and the person who performed the statistical analyzes were blind to assigned groups.

### Interventions and study outcomes evaluation

Women underwent HAL and then CH as intervention group, while control group underwent CH alone. Participants in both groups underwent general anesthesia with the same operating room conditions. In study (HAL) group, before hysterectomy, a right-angle clamp was placed under the IIA's anterior division after the posterior branches had branched from the main trunk (3.5 cm after the origin of IIA). To prevent damage to the external iliac vein, located in the lower lateral part of the IIA, the right-angle clamp was moved inward from under the IIA. In contrast, the endpoint of the clamp was held upward. After getting on the other side beneath the hypogastric artery, the suture material was grasped and pulled backward in the same direction. The ureter, external iliac artery, and other important anatomic landmarks are re-checked, and finally, the suture is tied carefully. An experienced gynecologist performed all HAL procedures. A vascular surgeon was on standby during the surgery for safety. All participants were given postoperative low molecular weight heparin (enoxaparin, 40–60 mg) daily during 10 days and the DVT pump was used in the recovery room, whenever the patient was not weight-bearing until discharge from hospital, to avoid thromboembolism. The amount of intraoperative blood loss, as a primary outcome, was calculated from the volume of blood in the suction canisters and the weighed laps (obtained from the pre and postoperative difference in weight of

the towels and drapes placed beneath the patients).[27,28] As the secondary outcomes, the need for intraoperative blood products transfusion, frequency of DVT, duration of surgery, duration of hospitalization (days), and visceral trauma were assessed. Duplex ultrasonography was used to investigate the existence of DVT in case of clinical suspicion. The number of blood products transfusion and the extent of visceral trauma were measured by direct counting. A timer recorded the duration of surgery and the duration of hospitalization was obtained by reading participants' medical records. The history of previous deliveries and gynecological procedures was gathered from medical documents of subjects. Full investigations in the form of complete blood picture investigated individualized.

### Statistical analysis

Statistical analysis was done by SPSS software for Windows version 25 (SPSS Inc., Chicago, IL). Numerical data were reported as mean ± standard deviation and categorical data as frequency and percentage. The normality of data was assessed by Kolmogorov–Smirnov test. Nonnormally positive skewed data were subjected to logarithmic transformation for normalizing data. Continuous and categorical baseline variables were compared between two groups using independent samples *t*-test or Mann–Whitney *U*-test and Chi-squared, respectively. Furthermore, the continuous and categorical study outcomes were compared by using independent sample *t*-test and Chi-squared (or Fisher exact *t*-test when appropriate). For evaluating the interaction between intervention and type of PAA, we use two-way multivariate analysis of variance (two-way MANOVA).

## RESULTS

Of 70 participants who initially entered in this study, 6 persons excluded (declined to participate), and finally 64 women were included in the analysis [Figure 1]. The characteristics of these women were described in Table 1.

The mean age of participants was 33.84 ± 4.25 years (range 24–44 years). All diagnoses were made in the second and third trimesters, at a mean gestational age of 24.5 ± 1.7 weeks (range 18–36 weeks). The mean gestational age at CH was 33.2 ± 0.9 weeks. Mean overall gravida was 3.42 ± 1.47. Mean duration of operation was 188.36 ± 38.76 min. The initial hemoglobin level was 11.48 ± 2.63.

Among the 64 patients, the most frequent indication for PAA was found to be placenta percreta, accreta, and increta, respectively. There were no significant differences between 2 groups in terms of maternal age, gestational age, gravidity and parity, caesarean section and curettage history and PAA [Table 1].

The mean values of blood loss during operation ($P = 0.01$), duration of operation ($P = 0.05$), time of hospitalization ($P = 0.03$) were significantly lower in women who underwent the prophylactic HAL technique during CH compared with women who underwent hysterectomy. The number of intraoperative transfused packed red blood cells although was not statistically different between 2 groups ($P = 0.11$); it was clinically lower in prophylactic HAL group than control group. There was no visceral trauma during operation in study HAL group compared to control group (0 vs. 15.6%) ($P = 0.02$); there were bladder (3

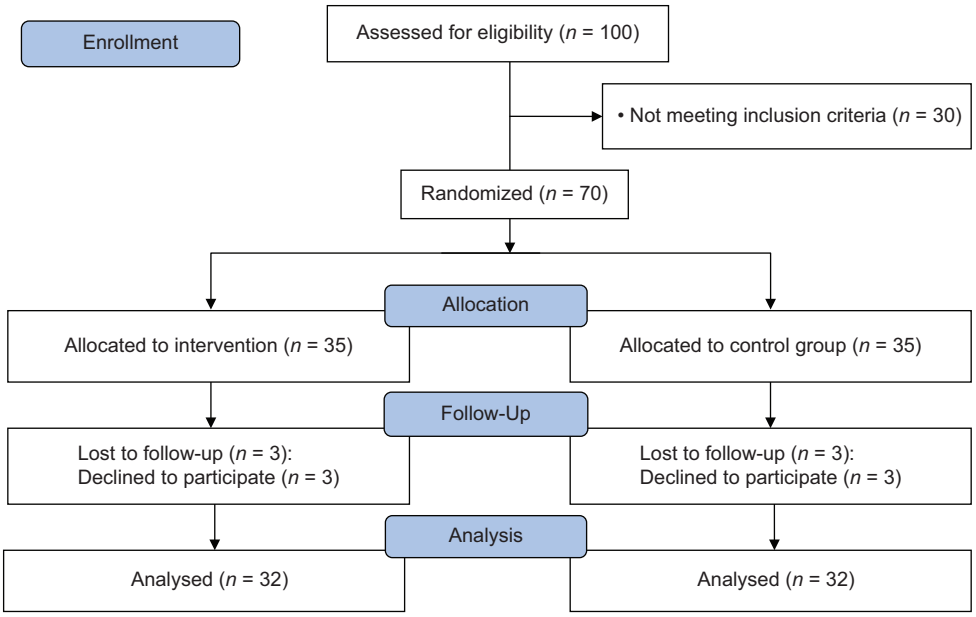


**Figure 1:** Consort flow diagram of the patients' recruitment into the study

**Table 1: Maternal demographic and basic clinical characteristics of study participants in two study groups (*n*=32/each group)**

| Variables | Study group (CH + HAL) | Control group (CH) | *P* |
|---|---|---|---|
| Age (year)* | 34.28±4.93 | 33.4±3.46 | 0.42 |
| Gravidity* | 3.25±1.81 | 3.59±1.04 | 0.36 |
| Number of previous cesarean sections (%) | | | |
| 1 CS history** | 14 (43.8) | 11 (34.3) | 0.443 |
| ≥2 CS history** | 18 (56.2) | 21 (65.7) | 0.442 |
| Curettage history** | 4 (12.5) | 6 (18) | 0.495 |
| Preoperative Hb (g/dL)* | 11.87±0.81 | 11.50±1.22 | 0.311 |
| Postoperative Hb (g/dL)* | 10.44±0.99 | 10.18±1.07 | 0.492 |
| Abnormal placental adherent in sonography** (%) | | | |
| Accreta | 12 (37.5) | 13 (40.6) | 0.09 |
| Increta | 1 (3.1) | 6 (18.8) | |
| Percreta | 19 (59.4) | 13 (40.6) | |

*Data are presented as mean±SD, analyzed by independent samples *t*-test or Mann-Whitney U-test; **Data are presented as *n* (%), analyzed by Chi-squared test. CS=Cesarean sections; CH=Cesarean hysterectomy, HAL=Hypogastric artery ligation; Hb=Hemoglobin; SD=Standard deviation

**Table 2: Comparison of study outcomes between two study groups (*n*=32/each)**

| | Study group (CH + HAL) | Control group (CH) | *P** |
|---|---|---|---|
| Intraoperative complications | | | |
| Visceral trauma, *n* (%) | 0 | 5 (15.6) | 0.02 |
| Intraoperative blood loss (cc) | 1525±536.41 | 2075±889.36 | 0.01 |
| PRBC (unit) | 4.74±2.72 | 6.94±5.51 | 0.10 |
| Postoperative complication | | | |
| Duration of operation (min) | 179.06±36.28 | 197.66±39.47 | 0.05 |
| Duration of hospitalization (day) | 4.97±2.20 | 6.10±2.39 | 0.03 |
| DVT, *n* (%) | 0 | 0 | - |

*Independent samples *t*-test for numerical and Chi-squared or Fisher's exact test for categorical variables. CH=Cesarean hysterectomy; HAL=Hypogastric artery ligation; PRBC=Packed red blood cells; DVT=Deep vein thrombosis

persons) and intestine (2 persons) injuries in control group [Table 2].

We used MANOVA for comparing the mean values of study outcomes in cross categories of interventions and type of PAA (interaction between intervention and PAA). We did not find significant interaction for each study outcome, indicating that the intervention effects did not depend on type of PAA [Table 3].

## DISCUSSION

According to the best of our knowledge, this is the second randomized trial evaluating the efficacy of bilateral HAL, as an intervention to decrease the blood loss during CH for PAA. We found that bilateral HAL on the amount of blood loss during CH for PAA is beneficial. As, the gynecologist of our study described that, the bilateral HAL intervention decreased perceived difficulty and improved vision due to less bloody and decreased problematic of surgical procedure compared to control group that associated with significantly lower visceral trauma in women undergoing HAL ($P = 0.02$) and shorter operative duration time (179.06 ± 36.28 vs. 197.66 ± 39.47), however, is not statistically significant ($P = 0.05$).

In agreement with our finding, previous studies retrospectively[17,21,29] or prospectively[30] reviewed the medical records of all patients diagnosed with PAA; the estimated blood loss was significantly decreased in the study group compared with the control group. Whereas, in some studies,[31-33] the mean blood loss with or without IIA ligation (IIAL) was not significantly different. Kuhn *et al.*'s study[33] showed that IIAL was not effective in reducing bleeding in cases diagnosed with placenta percreta, which may partially due to the method of study that blood loss was estimated and not quantified, as well as small sample size of the study. Another reason that other studies[31,32] have been raised that is in some cases massive blood flow was observed from external iliac artery to anastomosis lines, and even anastomoses with inferior epigastric and inferior mesenteric arteries contributed blood buildup of uterus again through uterine artery, which would explain the failure of IIAL in controlling the bleeding in AIP.

In line with previous study[34] which indicated more surgical trauma followed by abdominal hysterectomy operation, our finding declares that the visceral trauma in women undergoing HAL is significantly lower than the control group. This may be due to less bloody leading to the better sight of anatomical location of viscera and deep

**Table 3: The comparison of mean values of complications in cross categories of interventions and type of placenta adherent abnormality**

| Complications | Groups | PAA | Mean±SD | *P*# | | |
|---|---|---|---|---|---|---|
| | | | | Intervention | PAA | PAA* intervention |
| Duration of surgery (min) | Study group (CH + HAL) | Accreta (*n*=12) | 175.91±22.674 | <0.001 | 0.14 | 0.42 |
| | | Increta (*n*=1) | 120.00±00 | | | |
| | | Percreta (*n*=19) | 182.50±42.642 | | | |
| | Control group (CH) | Accreta | 194.23±28.929 | | | |
| | | Increta | 185.00±52.440 | | | |
| | | Percreta | 206.92±43.086 | | | |
| Intraoperative blood loss (cc) | Study group (CH + HAL) | Accreta | 1545.45±498.726 | 0.024 | 0.60 | 0.57 |
| | | Increta | 2000.00±00 | | | |
| | | Percreta | 1488.89±577.916 | | | |
| | Control group (CH) | Accreta | 2346.15±1015.394 | | | |
| | | Increta | 1666.67±560.952 | | | |
| | | Percreta | 1992.31±843.071 | | | |
| Intraoperative blood products transfusion (unit) | Study group (CH + HAL) | Accreta | 5.18±3.601 | 0.28 | 0.79 | 0.63 |
| | | Increta | 5.00±00 | | | |
| | | Percreta | 4.56±2.255 | | | |
| | Control group (CH) | Accreta | 7.15±6.842 | | | |
| | | Increta | 4.17±3.061 | | | |
| | | Percreta | 8.00±4.761 | | | |
| Duration of hospitalization (day) | Study group (CH + HAL) | Accreta | 5.62±2.873 | 0.54 | 0.42 | 0.603 |
| | | Increta | 4.33±1.751 | | | |
| | | Percreta | 4.62±1.502 | | | |
| | Control group (CH) | Accreta | 6.09±1.514 | | | |
| | | Increta | 4.00±00 | | | |
| | | Percreta | 6.17±2.813 | | | |

#Two-way-MANOVA was used for evaluating of interaction between intervention and type of PAA. CH=Cesarean hysterectomy; PAA=Placenta adherent abnormality; HAL=Hypogastric artery ligation; MANOVA=Multivariate analysis of variance; SD=Standard deviation

vascular structures in study group that makes it easier to do CH and leads to less tissue and visceral trauma. However, it should be noted that the risks are related to experience and technique, with principal concerns being injury to the nearby external iliac vein or inadvertent ligation of the posterior division.

As, the superiority of undergoing prophylactic HAL previously have been demonstrated compared to preoperative placement of balloon-occlusive devices during CH for PAA.[17] Furthermore, the Chitragari *et al*. meta-analysis study reported that HAL is safer than hypogastric arterial embolization and coverage for ischemic complications.[35] On the other hand, the alternative method of decreasing arterial pelvic perfusion is vessel ligation, that is recognized as an integral component in the surgical management of major obstetrical hemorrhage.[36] This technique also has the advantage of being inexpensive, available in low-resource settings, and can be performed in under 10 min by an experience surgeon.[17]

Altogether, it seems that HAL is an effective prophylactic method in decreasing hemorrhage during a hysterectomy in women with PAA and other emergency conditions like postpartum hemorrhage.[37]

The strength of the study lies in being the first randomized control trial in Iran, to compare between the ligation and nonligation of IIA in cases of PAA undergoing CH. While, the most of previous studies were retrospective or prospective (based on medical document) which their nature may have introduced information bias.

Furthermore, we obtained a large sample size of women with various PAA (accreta, increta, and percreta) in this study, whereas most studies investigated just one spectrum the of PAA.

Another strength of our study is that all patients undergoing CH by an expert gynecologist with the definite experience, talent, and speed at the same hospital. This will minimize interoperator skill variability between groups to avoid performance bias that provides a more valid assessment of the procedure being evaluated.

## CONCLUSION

According to the findings of this study, it could be concluded that HAL is a safe and effective prophylactic technique that should be considered as a therapeutic option for controlling blood loss during hysterectomy performed

for pregnant women with PAA. More studies with larger populations are required to confirm our data.


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### Conflicts of interest

There are no conflicts of interest.


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