Prognostic value of the proper timing of bladder dissection in surgical management of placenta accreta spectrum. A randomized controlled trial

Fatma El-Desouky MBBC *, Ahmed El-Zayadi MD**, Ahmed Ragab MD**, Mahmoud Thabet MD **
* Resident of Obstetrics and Gynecology Samanode General Hospital, Egypt
**Obstetrics and Gynecology Department, Faculty of Medicine, Mansoura University, Mansoura, Egypt

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Running title: timing of bladder dissection in PAS

Abstract

Background and aim: the management of PAS during CD is already a challenge owing to the presence of maternal comorbidities and suspected mortality. This study aimed to determine proper timing of bladder dissection during CD thus improving the outcome via decreasing blood loss and urinary tract injuries.

Methods: a randomized controlled trial included 100 patients planned for elective CD at Mansoura University Hospitals, Egypt from July 2020 to July 2021. They were assigned into two equal groups. Group 1, bladder was dissected earlier before uterine incision meanwhile in group 2, bladder was dissected late after uterine incision and fetal extraction. Outcome measures were intra and postoperative blood loss, pre and postoperative hemoglobin levels, associated urinary tract injuries and emergent hysterectomy.

Results: baseline patients' characteristics did not show any statistically significant change in both groups [p>0.05]. The mean estimated blood loss during and after cesarean delivery was significantly lower in group 2 compared to group 1 (2654.12 ± 1412.48 ml vs. 3356.2 ± 1906.63, p=0.039). Similarly, the need for additional packed RBCs and plasma were significantly higher in group 1 than group 2 (p values are 0.001 and 0.046 respectively). Also, there was more urinary bladder injuries and emergent hysterectomy in group 1 compared to group 2 (10 vs 4 cases, p =0.04 and 12 vs 5 cases, p =0.02 respectively). Therefore, the mean operative time (±SD) is longer in group 1 (p = 0.02). On the other hand, there were irrelevant differences regarding the need for platelet or Voluven transfusion, postoperative Hb level, maternal or neonatal ICU admission, PPH, fever or hospital stay time (p values >0.05).

Conclusion: surgical management of PAS by CD proved

Corresponding author:
Fatma El-Desouky
Resident of obstetrics and gynecology in Samanode General Hospital, Gharbia, Egypt
Address. Samanode, Gharbia, Egypt.
Mobile. 00201274661637
Email. Fatmafatma1991@yahoo.com

that bladder dissection after delivery of the baby is much better in terms of decreasing blood loss, urinary tract injuries and emergent hysterectomy than if done earlier.

Keywords: Placenta accreta, bladder dissection time.

Synopsis: the proper time of bladder dissection during CD in patients with PAS was confirmed to be after uterine incision and fetal extraction as this proved less intra and postoperative complications.

Introduction

Placenta previa is broadly defined as a placenta inserted totally or partially into the lower uterine segment. In these situations, there are various degrees of placental tissue invasion ranging from just attachment to the decidua up to deep invasion involving the surrounding structures including the cervix, the bladder, or even the bowel [1]. This group of placental abnormalities, with varying degrees of invasion, has been recently redefined into the placenta accreta spectrum (PAS). When the invasion is limited to the deep endometrium it would be named "adherent placenta accreta", while the myometrial invasion is categorized as "placenta increta", and invasion of the full thickness of the myometrium up to the uterine serosa or adjacent organs is called "placenta percreta" [2-4]. Surely; there is a rapid increase in the incidence of PAS over the past few decades from approximately 1/2500 to 1/500 [5]. This increase was attributed mainly to an increase in cesarean delivery (CD) rates; however, other causes may be implicated as interruption with the lining of the uterus namely manual placental delivery, uterine curettage, hysteroscopic endometrial resection, or even previous minor hysteroscopic surgery [6]. Unexpectedly, there were some reported cases with no previous history of uterine surgery as those proved with some cases of submucous myoma, uterine adenomyosis, and bicornuate uterus [6]. Ultrasonographic evaluation is recommended as the first-line modality for diagnosing PAS with some suggestive features such as loss of the normal retroplacental clear zone, reduced retroplacental myometrial thickness, presence of intra-placental lacunar spaces, a decrease of the uterine-bladder interface, and connecting or anastomosing vessels between the placenta and urinary bladder [7]. Indeed, PAS is responsible for one of the main causes of obstetric hemorrhages with subsequent significantly increased maternal morbidity and or mortality [8]. More than half of the direct maternal deaths are attributed now to PAS and its dilemma of management as there is increased liability for urinary tract injuries and rarely bowel injuries. This is estimated to be 4% in developed and up to 14% in developing countries [8].

This study was held to evaluate the role of proper timing of bladder dissection during the management of morbidly adherent placenta in CD or cesarean hysterectomy thus modifying the operative techniques aiming to reduce the likelihood hemorrhage and urinary tract injuries.

Materials and Methods

This prospective interventional randomized controlled trial was conducted at the department of obstetrics and gynecology, Mansoura University Hospitals, Mansoura, Egypt from July 2020 through July 2021. The local research ethical committee at Mansoura faculty of medicine (institutional research board "IRB") approved the study with IRB number [20.9.2151]. Therefore, the study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Patients allocated for the study verbally consented and then each participant gave written consent before being included in the trial. The study involved 100 patients from those admitted for a planned CD due to placenta previa with variable degrees of accretion. To include this number in the study,

the sample size was prepared before starting as the authors conducted a pilot study using uterine exteriorization with mean ± SD of the estimated intraoperative blood loss was 550 ± 250 ml. Assuming alpha = 0.05 and beta = 0.2 (power = 80%) and using the 2-tailed Student t-test, 45 subjects were required in each group to detect a difference of 150 ml between groups which are considered to be the least clinically significant effect. To allow for subject dropouts, 50 subjects were assigned to each group. Allocated patients were divided randomly using a computer-generated table into two equal groups. Group 1 [G1], where the bladder was dissected early before uterine incision, and group 2 [G2], in whom the bladder was dissected late after uterine incision and baby extraction. All patients included were those having previous one or more CDs, gestational age of at least completed 37 weeks with the viable fetus and normal fetal heart rate tracing, and PAS with anteriorly located placenta previa. All patients were judged clinically for exclusion of evidence of active labor. Moreover, an ultrasound was performed for fetal well-beginning the day before or on the morning of surgery. On the other hand, patients who were hemodynamically unstable before the skin incision (admitted with severe bleeding, operated as an emergency, coagulation defects, hemoglobin level <9gm/dl), placenta separated spontaneously, the previous history of bladder injury, posteriorly located placenta, and those with no evidence of gross placental invasion at the time of surgery were already excluded. Patients who had any type of medical disorders or evidence of active labor were also excluded. Patients' demographic data were gathered from both groups including mainly, full history, thorough clinical examination, routine laboratory investigations, data of 2D ultrasound, and color doppler for features suggestive of PAS. Caesarean deliveries were performed under general anesthesia by the same senior obstetrician after consulting a senior anesthetist. General anesthesia was decided in all cases as viewed by the consultant anesthetist as it would be better for patients' control of general parameters where a long time is expected with more manipulation of the bowel or expected urinary tract complications. In the first group, the bladder was dissected before uterine incision from lateral to medial to improve the line of cleavage followed by a uterine incision higher than the previous scar. In the second group, the bladder was dissected from lateral to medial after the uterine incision was done above the level of the placenta and after the delivery of the baby. In each group we looked for blood loss and if there were any urinary tract injuries. The uterus in both groups was repaired with a continuous unlocked suture in 2 layers using Vicryl 1 suture (Johnson & Johnson, USA). The peritoneum was left un-sutured while the muscle layer was opposed and approximated with Vicryl 0. The rectus sheath was closed by Vicreyl 1, and finally, the skin was closed with sub-cutical suture by Proline double zero in both groups of patients. Estimation of blood loss started after skin incision by two trained nurses, one for each group. They were responsible for blood and amniotic fluid collection in two separate suction sets and weighing the surgical towels before and after the operation. Those with documented intraoperative urinary complications were urgently managed by a senior consultant urologist on duty and their postoperative care was followed up according to his surgical advice. Some cases with severe lacerations of the lower uterine segment and difficult repair or complicated by severe intractable intraoperative bleeding were urgently secured by salvage hysterectomy. Post-partum blood loss during the first 24 hours after the operation was estimated by weighing soaked napkins and blood accumulated in the intraperitoneal drains when applied. Preoperative hemoglobin was measured 2 hours before surgery and again 24 hours after the operation. Urinary tract injuries and the need for a hysterectomy were counted in both groups. Neonatal outcomes

including APGAR score, admission to the neonatal intensive care unit (NICU), and neonatal deaths were also evaluated in the two groups. Data were collected, tabulated, and statistically analyzed by IBM computer using SPSS v25 (IBM©, Chicago, IL, USA).

Statistical Analysis

Statistical analysis was done by SPSS v25 (IBM©, Chicago, IL, USA). Shapiro-Wilks test and histograms were used to evaluate the normality of the distribution of data. Quantitative parametric data were presented as mean + standard deviation (+SD) and were analyzed by unpaired student t-test. Quantitative non-parametric data were presented as the median and interquartile range (IQR) and were analyzed by the Mann-Whitney test. Qualitative data were presented as numbers and percentages and were compared by chi-square (X2) or Fisher's Exact test when appropriate. A two-tailed P value <0.05 was considered statistically significant.

Results

A total of 238 patients with elective CD were enrolled in the study, of them 138 patients were excluded due to failure to fulfill the inclusion criteria (figure 1). Baseline patients' characteristics are shown in Table (1); there were no significant differences between both groups regarding maternal age, gravidity, parity, body mass index, fetal gestational age, number of previous CD(s), and preoperative hemoglobin levels, history of early obstetric complications including mainly abortion or ectopic pregnancy as well as intrauterine manipulation specifically myomectomy, curettage or hysterotomy [p>0.05]. Also, the type of placenta previa did not show any statistically significant change in both groups [p>0.05] as presented in table (1).

The mean estimated blood loss during and after cesarean delivery was significantly lower in group 2 compared to group 1 (2654.12 ± 1412.48 ml vs. 3356.2 ± 1906.63, p=0.039). Similarly, the need for additional packed RBCs and plasma were significantly higher in group 1 compared to group 2 (3.98 ± 1.80 vs 2.84 ± 1.65, p =0.001 and 1.86 ± 1.77vs 1.22 ± 1.36, p =0.046 respectively), as shown in table (2). Also, there was more liability for bladder injuries and emergent hysterectomy in group 1 compared to group 2 (10 vs 4 cases, p =0.04 and 12 vs 5 cases, p =0.02 respectively). Therefore, the mean operative time/minutes ± SD is found significantly longer in group 1 compared to group 2 (86.5 + 10.2 vs 55.4 + 8.2, p = 0.02) as described in table (2). On the other hand, there were irrelevant differences regarding the need for platelet or Voluven transfusion between both groups together with postoperative Hb level as well as maternal or neonatal ICU admission and postpartum maternal complications including PPH, fever or prolonged hospital stay time (p values >0.05) as evidenced in table (2).

Discussion

The main findings of the study confirmed that, the bladder dissection after uterine incision and fetal delivery is much less liable to be accompanied with bladder injuries, intraoperative bleeding and emergent hysterectomy than it would be done earlier. Furthermore, the operative time and the need for blood and blood products transfusion is much decreased.

Recently, PAS is deemed as a well-known serious obstetric situation with significant maternal morbidity and sometimes mortality. The principal hazards emerging with any type of PAS comes mainly from heavy obstetric bleeding that is mostly managed by unplanned surgeries. Therefore these patients are commonly put in danger, in addition to surgical risks, for hazards of blood and blood elements transfusion up to disseminated intravascular coagulopathy, adult respiratory distress syndrome and even renal failure in some occasions [10, 24]. This makes

some authors to publish at some time that caesarean hysterectomy is considered as the gold standard management for PAS [12,13]. But, according our opinion, it is really a catastrophe in female who do not complete her family and the time may come soon to change this notion. The results of the current study demonstrated blood loss in large amounts in both groups but still significantly lower in group 2 than group 1 (p=0.039) with less usage of intra and postoperative transfusion of packed RBCs and plasma (p =0.001 and 0.046 respectively). This could be explained by the fact that dissection of the urinary bladder before uterine incision takes more time due to stretch of the lower uterine segment with adherent bladder. Another explanation is that when the bladder is dissected before uterine incision and delivery of the fetus, it led to increase blood loss from varicosities and engorged vessels caused by compression and stretch of the lower uterine segment by the presenting part and implanted lower down placenta. Moreover, many of these patients (12 cases) had emergent salvage hysterectomies which prolonged more and more the operative time and increased patients' susceptibility for intraoperative bleeding. This comes in accordance with facts proved by other authors [11, 14 and 15].

Also, the data of this study evidenced that bladder dissection and mobilization were observed easier when done after uterine incision, baby extraction and more and easier when the placenta is completely removed with less liability for bladder injury or the need for postoperative urological care and follow up. Logically, this is again is clarified by easy manipulation of the tissues after delivery of the fetus and retraction of lower uterine segment and regaining of the bladder tissues to its normal size with better control of the bleeding beds. This comes in agreement with some authors [15, 16] who demonstrated a challenging surgery to do bladder dissection prior to uterine incision and newborn delivery with more association of severe bleeding. The problem is raised more and more when the placental invasion reaches the percreta type, so they advised some modifications of the surgical maneuvers to preserve the uterus, maintain integrity of the bladder and before deciding to hysterectomy. So, if bladder invasion was expected in such situations, the bladder was dissected away from the uterus with clamping of any blood vessels, devascularization of the area and the placental bed and preserving the bladder wall as much as possible. Similar maneuvers were presented by some local and international authors for the same purpose [16-19] but the dome of the bladder was opened by some to secure the vasculature form inside [16]. According to our experience from this work, when such situations met as suspected by preoperative Doppler ultrasound study or MRI, or assured intraoperatively, the bladder was opened only in presence of senior urologist to remove the invading placental tissues, then close the uterus or did hysterectomy according to our decision and left the bladder to be repaired by the urologist. An advice which we should highlight for all obstetricians, when suspecting placenta percreta and bladder invasion, the obstetrician should consult a urologist to attend the operation. Our advice was raised earlier by some surgeons to decrease urinary complication during the management of PAS [20, 21]. On the other hand, data from some previous published results cannot come in accordance with our findings because they verified that bladder dissection before uterine incision and baby delivery gained good results in terms of decreased blood loss, intraoperative blood transfusion and urinary tract injuries [22, 23].

As mentioned, caesarean hysterectomy was considered by some as the only solution for PAS [12,13] but the decision was very difficult for the obstetricians attending the cases of this study and resorted to only after failure of all other conservative surgical and medical

measures on an attempts to preserve the uterus in our patients and after discussion with other members of the surgical team in the theatre. Our results appeared satisfactory regarding this point, as in group 2 we achieved to preserve the uterus in 90% of cases, salvage hysterectomy in 5 cases only, meanwhile, in the group 1 hysterectomy was the solution in 24% of cases. Here the authors can state that most case from both groups [4 from group 2 and 9 from group 1] had percreta type of placental invasion. Surprising to us was the postoperative data, as the authors did not find any significant difference in both groups regarding Hb level, hospital stay time, mean (+SD) of blood loss, need for blood or circulation correcting fluids as well as maternal and neonatal outcome. This might be explained by the fact that the management of patients was in a tertiary care hospital with well-equipped staff members at operating theatre and all available facilities for intra and postoperative care. These findings were contrary to data observed earlier by some other authors [17, 18, 24].

Unquestionably, this study had some limitations including a relatively small sample size compared to thousands admitted yearly in tertiary place of the study, being unicentric and lack of long follow up for the patients to estimate remote urinary morbidities and the fertile function of the preserved uteri.

Table [1]: Patients' epidemiological data in both groups.

Variable	Group 1 (n = 50)	Group 2 (n = 50)	P value
Age/years (± SD)	31.8 ± 6.14	30.74 ± 4.49	0.327
Gravidity	4	5	0.744
Parity	3	3	0.153
BMI	26.7 ± 2.02	27.5 ± 1.82	0.67
Previous CD(s)	50 (100%)	50 (100%)	1
Hx of Abortion	18 (36%)	19 (38%)	0.836
Ectopic	2 (4%)	2 (4%)	1
Gestational age in weeks	37.68 ± 1.62	37.76 ± 0.72	0.750
Hx of myomectomy Hx of D&C Hx of Hysterotomy	1 (2%) 10 (20%) 2 (4%)	1 (2%) 11 (22%) 1 (2 %)	1 1 0.495
Preoperative Hb (+ SD)	11.43 + 1.2	11.84 + 1.3	0.46
Types of the placenta Grade1 Grade2 Grade3A Grade3B	 19 (38%) 21 (42%) 8 (16%) 2 (4%)	 14 (28%) 18 (36%) 17 (34%) 1 (2%)	 0.207

Data were presented as mean (± SD) or frequency (%). CD: cesarean delivery, Hx; history, D&C; dilatation and curettage. P value was set as significant when <0.05.

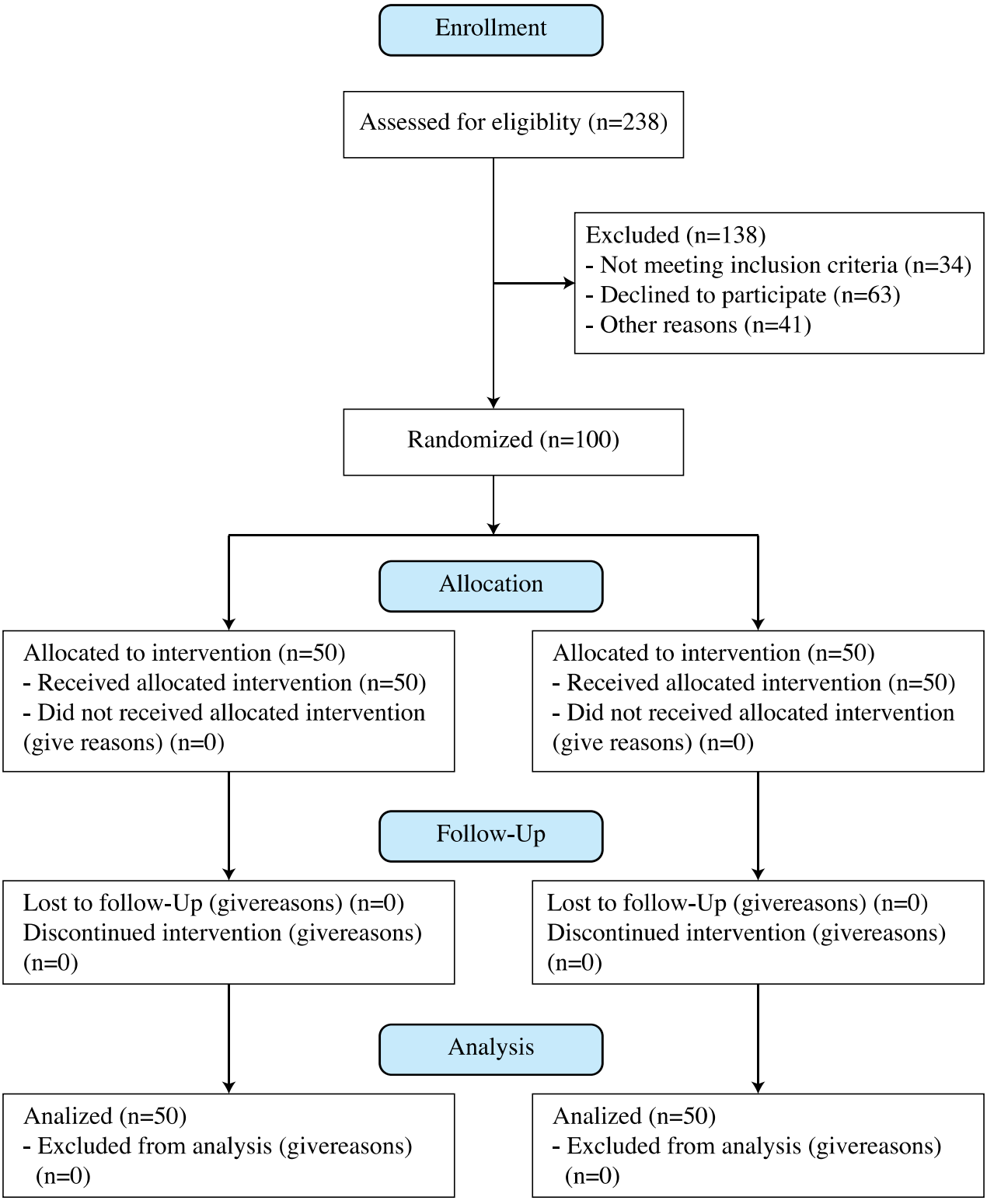
Table [2]: Operative and postoperative data in the two studied groups.

Variables	Group 1 (n = 50)	Group 2 (n = 50)	P value
Blood loss (Mean ± SD)	3356.2 ± 1906.63	2654.12 ± 1412.48	0.039*
Bladder injury			
NO	40 (92%)	46 (80%)	0.04*
yes	10 (20%)	4 (8%)	
Cesarean hysterectomy	12 (24%)	5 (10%)	0.02*
Operative time/minutes (Mean ± SD)	86.5 + 10.2	55.4 + 8.2	0.02*
Parameters (Mean ± SD)			
RBCS	3.98 ± 1.80	2.84 ± 1.65	0.001*
Plasma	1.86 ± 1.77	1.22 ± 1.36	0.046*
Platelet	0.20 ± 0.78	0.08 ± 0.27	0.309
Voluven	0.14 ± 0.40	0.08 ± 0.27	0.387
Postoperative Hb	11.04 ± 1.15	10.85 ± 1.22	0.397
Hospital-stay time	6.24 ± 4.54	7.5 ± 4.25	0.278
Maternal ICU admission	0 (0%)	0 (0%)	-----
Postpartum hemorrhage	1 (2%)	1 (2%)	1
Postpartum fever	1 (2%)	0 (0%)	1
Neonatal outcome			
APGAR score at 5 minutes	9.1 + 0.8	8.9 + 0.9	0.368
ICU admission	0 (0%)	0 (0%)	-----

Data were presented as mean ± SD or frequency (%). ICU; intensive care unit. P value is statistically significant when <0.05.

Conclusions: bladder dissection after uterine incision and fetal extraction is better than if done before uterine incision and fetal delivery, as the latter is commonly accompanied with more bleeding, blood transfusion as well as bladder injuries with more liability for emergent hysterectomy and affection of the future fertility.

Patients' Flow Diagram



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Tables' legend:

Table [1]: Patients' epidemiological data in both groups.

Table [2]: Operative and postoperative data in the two studied groups.

Figure [1]: Patient's flow chart.