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Original Research Article

Manual removal versus spontaneous delivery of the placenta at caesarean section: a randomized controlled trial

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ABSTRACT

Background: Cesarean section (CS) is a life-saving surgery when certain complications occur during pregnancy and childbirth. The method of placental removing is one such procedure that can affect outcomes of cesarean delivery, such as the amount of bleeding during intraoperative and postoperative, the time of operation, the occurrence of postoperative endometritis, and may contribute to an increase or decrease in the incidence of CS. The objective of the study was to compare the manual removal of the placenta and spontaneous placental delivery at caesarean section.

Methods: One hundred twenty six consented to participate and divided randomly into two groups: Group A: included 63 pregnant women underwent elective caesarean section, the placental left in situ and the uterus massaged waiting spontaneous placental separation and Group B: included 63 pregnant women underwent elective caesarean section in which placenta was removed manually.

Results: We found that women who had manual removal of the placenta lost significantly more blood than those who had spontaneous separation. A significant drop in hemoglobin was observed in manual separation group compared to spontaneous separation group. The median duration of placental delivery was shorter in manual separated group than spontaneously separated group. There was a statistically significant difference between both groups was found as regard the need for blood transfusion. There was a statistically significantly longer hospital stay with manual delivery of the placenta.

Conclusions: Spontaneous separation of the placenta during cesarean section is more beneficial than manual separation.

Keywords: Manual removal, Spontaneous delivery, Placenta, Caesarean section

INTRODUCTION

The rate of cesarean section CS has consistently increased worldwide, to reach a peak of 30%. Being one of the most commonly performed obstetric procedures doesn't mean that it's not without risk. Operative morbidity arising from the procedure includes hemorrhage, infection, anemia, blood transfusion, and related risks for receiving donor products. In severe cases major obstetric hemorrhage resulted in hysterectomy, intensive care unit ICU admission, and in some instances maternal mortality.¹

Caesarean section is the most common major operation performed on women. Some of the short-term morbidities of caesarean section include hemorrhage, need for blood transfusion, post-operative fever and endometritis.^{2,3} Long term morbidities include placenta previa, placenta accrete and ectopic pregnancy. Some of complication mentioned increased by different ways of performing caesarean section operation and variation in techniques.⁴

By the end of the third trimester, the uterus is perfused by 500–700 ml blood/min. This physiological hyper

perfusion leads to an estimated loss of approximately 1 liter of blood at CS.⁵ Estimation of blood loss during CS is paramount for reducing morbidity arising from the procedure.⁶ The method of removing the placenta is one such procedure that may increase or decrease in the morbidity of the caesarean section.⁷

The process of placental separation starts immediately after delivery of the baby by contraction and retraction of uterine muscle which result in reduction in the size of the uterus consequently the placental bed to which the placenta attached become smaller than the incompressible placenta, the placenta sheared off and blood vessel supplying the denuded placental bed are compressed by continued contraction and retraction of uterine muscle to reduce the bleeding and oxytocin is given after delivery of the baby to minimize blood loss.⁸

The mode of placental delivery may contribute to an increase or decrease in the morbidity associated with CS, and many studies have shown it to be a key role in determining the blood loss during CS.⁹

Placental delivery types at caesarean section have been described as, placental drainage with spontaneous delivery, cord traction with spontaneous placental separation and manual removal.¹⁰

The aim of the present study was to compare the risk of significant blood loss associated with spontaneous and manual removal of the placenta during caesarean section and duration of the surgery, need for blood transfusion and duration of hospital stay.

METHODS

Study design

This was a randomized clinical study conducted on 126 women underwent elective caesarean section, at department of Obstetrics and Gynecology, Aswan University hospital, during period from 1st of January 2020 to 1st of January 2021.

Divided randomly into two groups

Group A included 63 pregnant women underwent elective caesarean section, the placental left in situ and the uterus massaged waiting spontaneous placental separation.

Group B included 63 pregnant women underwent elective caesarean section in which placenta was removed manually.

Inclusion criteria

Women aging from 18 years to 35 years, normal fetal heart rate tracing, singleton pregnancy, and pregnant at term 37-40wks.

Exclusion criteria

Gestational age less than 37 weeks and more than 40 weeks. Abnormality adherent placenta whether placenta accreta, percreta or placenta previa. Suspected chorioamnionitis and polyhydramnios by U/S. Rupture of membrane for more than 12 hours. Bleeding diathesis. Previous history of postpartum hemorrhage. Women with multiple pregnancy. Women with medical illness example: anemia Hb less than 10.5 gm/dl, DM, cardiac, hepatic, renal etc. Tears or extensions into the lower uterine segment >1 cm, or uterine artery injury were also excluded. Presence of adhesion intra operative lead to prolongation of CS duration. Suspected or proven placental abruption. Obesity BMI >35. Retained placental tissues. big baby > 4 kg, and presence of uterine fibroids.

An approval of the study was obtained from Aswan University academic and ethical committee. Every patient signed an informed written consent for acceptance of the operation.

All patients were subjected to the following

History

Personal age, duration of marriage, present any current medical or surgical diseases and any current medication, Past history of any medical disorder or surgical history with particular emphasis on especially for bleeding tendency and obstetric history (including parity, gestational age, obstetric complications.

Clinical examination

General examination: assessment of vital data pulse, blood pressure, temperature, cardiac and chest auscultation.

Abdominal examination: assessment of fundal level, fetal lie and presentation, liquor volume and previous scar if present.

Ultrasound examination: to assess fetal viability, determine gestational age exclude major anomalies.

Basic laboratory investigations

Complete blood count: which was done twice, before the operation, 12 hours and 24 hours after the operation, also hematocrit Hct % value will be recorded. Coagulation profile. Renal functions. Liver functions.

Methods of randomization

A total of 197 women were assessed for eligibility in this trial, 136 were enrolled, 68 were randomized to each group, and finally 63 women were analyzed in each group. Randomization conducted using a computer-generated table of random numbers; Allocation was done using

serially numbered closed opaque envelope, counseling for participation had been done before recruitment.

Intervention

This study included 126 patients underwent elective caesarean section at the department of Obstetrics and Gynecology, Aswan University hospital, patients were divided into two groups:

Group A included 63 pregnant women underwent elective caesarean section after the cord clamping, following fetal extraction the placental left in situ and the uterus massaged waiting spontaneous placental separation, Combined with the use of oxytocin by intravenous drib 20 unit after delivery of the baby.

Group B included 63 pregnant women underwent elective caesarean section in which placenta was removed manually following fetal extraction by the use of the primary surgeon dominant hand, and he introduced his hand into the uterine cavity and cleavage plane created between the placenta and the decidua basalis then the placenta grasped and removed. Combined with the use of oxytocin by intravenous drip 20 unit after delivery of the baby.

The blood loss measured by recording the fluid in the suction apparatus before and after placental separation, keeping in mind that most fluid in the apparatus before fetal extraction was amniotic fluid and therefore deducted from the total, and the number of towels used during delivery of the placenta and to which degree they were soaked. Where each soaked towel = 150 cc, and semi-soaked towel = 75 cc. Estimation of blood loss had begun after suction of amniotic fluid and discarding it. Blood from the uterine incision, soaked towels and blood in suction bottle before placental delivery had not been added to the blood measurements. NB Soaked towel = 150 cc. Semi-soaked towel = 75 cc.

Postoperative care

Vital signs of the patients measured four times daily during hospitalization. 12 hours and 24 hours postoperatively complete blood count was done.

Statistical analysis

Data were collected, revised, coded and entered to the Statistical package for social science (SPSS) IBM version 25. The qualitative data were presented as number and percentages while quantitative data were presented as mean, standard deviations and ranges when their distribution found parametric. The comparison between two groups with qualitative data were done by using Chi-square test and/or Fisher exact test was used instead of Chi-square test when the expected count in any cell was found less than 5. The comparison between two independent groups with quantitative data and parametric

distribution was done by using Independent t-test. The confidence interval was set to 95% and the margin of error accepted was set to 5%. P<0.05 was considered significant.

RESULTS

A total of 126 women were randomized, 63 in the spontaneous placenta delivery group and 63 in the manual removal group. Preoperatively, there were no statistically significant differences between the two groups regarding baseline demographic characteristics (Table 1).

Table 1: Patients' demographic characteristics.

Variable	Group A (Spontaneous delivery) (n=63)		Group B (Manual removal) (n=63)		P value
	No.	%	No.	%	
Maternal age (years)					
20–29	35	55.5	36	57.1	0.850*
30–40	28	44.5	27	42.9	
Mean±SD (Range)	28.17±6.16 (22-36)		29.47±7.19 (22-39)		0.355#
Gestational age at delivery (weeks)					
Mean±SD (Range)	38.05±1.09 (37-40)		38.9±2.07 (37-40)		0.224#
Residence					
Urban	23	36.5	20	31.7	0.511
Rural	40	63.5	43	68.3	#
Parity group					
Primigravida	19	30.2	15	23.8	
Multigravida	28	44.4	30	47.6	0.055*
Grand multigravida	16	25.4	18	28.6	
Number of deliveries					
Median (interquartile range),	2 (0-3)		2 (0-3)		0.097^
BMI‡ (kg/m2)					
Mean±SD (95% CI)	28.1±2.6 (27.7-28.4)		28.0±2.5 (27.7-28.3)		0.738#

BMI= body mass index; †Values are expressed as mean ± standard deviation, number (% percentage) or median (interquartile range), as appropriate; ‡Calculated as weight in kilograms divided by the square of height in meters. #: Independent t test ^: Mann Whitney test *: Chai square test **: Fisher Exact test. Statistical significance different between the two groups was indicated as p<0.05.

Preoperatively, there were no statistically significant differences between the two groups regarding preoperative HB and Hct values. There were no statistically significant differences between women of both groups concerning the

studied preoperative vital signs (example: temperature and blood pressure). In this table, there were no significant differences between the two groups regarding indications

for CS (p=0.0711), previous cesarean section and presence of history of laparotomy (Table 1).

Table 2: Pre-operative data.

Variable	Group A (Spontaneous delivery) (n=63)		Group B (Manual removal) (n=63)		P value
	No.	%	No.	%	
Preoperative Hb level (gm/dL)					
Mean±SD	11.44±1.80		11.22±1.19		0.153 [#]
Preoperative Hct level (%)					
Mean±SD	35.62±2.08		36.13±1.78		0.054 [#]
Temperature (°C)					
Mean±SD	37.03±0.25		37.09±0.24		0.741 [#]
Systolic blood pressure (mmHg)					
Mean±SD	114.89±8.06		116.14±7.27		0.663 [#]
Primary indication for caesarean section					
Previous caesarean	24	38.0	21	34.0	0.0711*
Malpresentation	14	22.0	15	23.0	
Dystocia	10	16.0	9	14.0	
Infertility	7	11.0	9	14.0	
Fetal distress	2	3.0	1	2.0	
Others	6	10.0	8	13.0	
Previous caesarean section(s)					
Yes	32	50.8	33	52.2	0.287*
No	31	49.2	30	47.6	
Number of previous caesarean section(s) Median (interquartile range),	1 (0-2)		1 (0-3)		0.853 [^]
Membranes ruptured					
Yes	0	0.0	1	1.7	0.063***
No	63	100.0	62	98.3	
History of laparotomy					
Yes	1	1.7	1	1.7	1.00***
No	62	98.3	62	98.3	
ANC status					
Yes	48	76.2	44	69.8	0.084*
No	15	23.8	19	30.2	

Hb = haemoglobin; = haematocrit; †Values are expressed as mean ± standard deviation, number (% percentage) or median (interquartile range), as appropriate.; #Independent t test ^: Mann Whitney test *: Chai square test ***: Fisher Exact test . Statistical significance different between the two groups was indicated as p<0.05.

Table 3: Operative data.

Variable	Group A (Spontaneous delivery) (n=63)		Group B (Manual removal) (n=63)		P value
	No.	%	No.	%	
Type of caesarean section (CS)					
Emergency	4	6.4	3	4.8	0.300***
Elective	59	93.6	60	95.2	
Mode of anesthesia					0.080***

Continued

Variable	Group A (Spontaneous delivery) (n=63)		Group B (Manual removal) (n=63)		P value
	No.	%	No.	%	
Spinal	61	96.8	62	98.4	
General	2	3.2	1	1.6	
Visually estimated blood loss, ml Median (interquartile range)	622.2 (613.3-645.9)		685.9 (640.8-715.9)		<0.001 [^]
Duration of placental delivery, seconds Median (interquartile range)	80 (66-100)		49 (46-66)		<0.001 [^]
Duration of caesarean section, minutes Median (interquartile range)	55 (44-66)		50 (44-66)		0.052 [^]
Neonatal birth weight, gm Mean±SD	3070.0±480.3		3025.0±487.0		0.421 [#]

†Values are given as mean± standard deviation, number (percentage) or median (interquartile range), as appropriate. #:Independent t test
[^]: Mann Whitney test * : Chai square test. *** Fisher Exact test Statistical significance different between the two groups was indicated as p<0.05.

Table 4: Postoperative data and main outcome measures.

Variable	Group A (Spontaneous delivery) (n=63)		Group B (Manual removal) (n=63)		p-Value
	No.	%	No.	%	
Postoperative 12 h Mean ± SD					
HB, gm/dl	11.00±1.70		10.60±1.50		<0.001 [#]
HB deficit, gm/dl	0.46±0.10		1.04±0.19		0.033 [#]
Hematocrit	33.38±2.04		31.11±1.42		<0.001 [#]
Hematocrit drop	2.24±0.04		5.02±0.36		<0.001 [#]
Postoperative 24 h Mean ± SD					
HB, gm/dl	10.70±1.40		10.20±1.14		0.021 [#]
HB deficit, gm/dl	0.74±0.40		1.02±0.05		<0.001 [#]
Hematocrit	32.35±2.02		31.06±1.40		<0.001 [#]
Hematocrit drop	3.27±0.06		5.07±0.38		<0.001 [#]
Temperature (oC)					
Mean±SD	37.05±0.41		38.06±0.52		<0.001 [#]
Systolic blood pressure (mmHg)					
Mean±SD (Range)	115.5±11.54		113.2±11.3		0.721 [#]
Use of extra ecbolics					
IV Oxytocin	11	17.5	13	20.6	0.089 [*]
Rectal Misoprostol	3	4.8	4	6.3	
Non	49	77.7	46	73.1	
Blood Transfusion					
Yes	2	3.2	4	6.4	0.043 ^{***}
No	61	96.8	59	93.6	
Duration of hospital stay, hours Median (interquartile range)					
	2 (2-4)		3 (3-4)		0.033 [^]

HB, hemoglobin. †Values are given as mean ± standard deviation, number (percentage) or median (interquartile range), as appropriate.;
[‡]Deficit = (preoperative value – postoperative value). #:Independent t test [^]: Mann Whitney test * : Chai square test. *** Fisher Exact test . Statistical significance different between the two groups was indicated as p<0.05

Intraoperative, there were no statistically significant differences between the two groups regarding type of CS,

mode of anesthesia, CS duration and neonatal birth weight p>0.05 (Table3).

Table 5: Effect on pregnancy outcome.

Variable	Group A (Spontaneous delivery) (n=63)		Group B (Manual removal) (n=63)		P value
	No.	%	No.	%	
Birth weight/kg					
Low	5	7.9	4	6.4	0.226*
Normal	55	87.3	58	92.0	
Macrosomia	3	4.8	1	1.6	
Neonatal birth weight, gm Mean±SD	307±480.3		3025.0±487.0		0.421*
Fetal complications					
Alive/well	59	93.6	57	90.5	0.086*
Perinatal death	1	1.6	2	3.2	
Neonatal intensive care admission	3	4.8	4	6.3	
Blood loss					
Normal	58	92.0	53	84.0	0.013*
PPH	3	4.8	6	9.6	
Severe PPH (≥1500 ml)	2	3.2	4	6.4	
Post-partum pyrexia (≥38.5C° on two occasions)					
Yes	4	6.4	6	9.6	0.032*
No	59	93.6	57	90.4	
ICU admission					
Yes	0	0.0	3	4.8	0.035*
No	63	100.0	60	95.2	
Duration of hospital stay					
1–3 days	60	95.2	58	92.0	0.041*
>3 days	3	4.8	5	7.9	
Duration of hospital stay, hours Median (interquartile range)	2 (2-4)		3 (3-4)		0.033^

ICU: intensive care unit. #:Independent t test ^: Mann Whitney test *: Chai square test. ** Monte Carlo probability test. *** Fisher Exact test Statistical significance different between the two groups was indicated as p<0.05

However, it has been indicated that group B had a statistically significant rise in the median of blood loss in women who had their placenta manually removed compared to the women in group A with spontaneous placental delivery 685.94 (640.8-715.9) ml and 622.12 (613.3-645.9) ml respectively; p<0.001.

Table 6: The effect of the practice e of placental delivery on total blood loss: association between mode of placental delivery and blood loss.

Variable	Group A (Spontaneous delivery) (n=63)		Group B (Manual removal) (n=63)		P value
	No.	%	No.	%	
Blood loss					
Normal	58	92.0	53	84.0	0.013
PPH	3	4.8	6	9.6	
Severe PPH (≥1500 ml)	2	3.2	4	6.4	
Significant drop in Hb% i.e. >2 g/dl.					
Yes	5	7.9	12	19.0	0.02*
No	58	92.1	51	81.0	
Visually estimated blood loss, ml Median (interquartile range)	622.12 (613.3-645.9)		685.94 (640.8-715.9)		<0.001^
Blood Transfusion					
Yes	2	3.2	4	6.4	0.043###
No	61	96.8	59	93.6	
Duration of hospital stay, hours Median (interquartile range)	2 (2–4)		3 (3–4)		0.033^

#:Independent t test ^: Mann Whitney test *: Chai square test *** Fisher Exact test. Statistical significance different between the two groups was indicated as p<0.05

Although the median time interval between delivery of the fetus and placental separation was significant (p<0.001); group B had significantly shorter placental delivery time, the total operative time overall was not statistically different (p 0.052), it was similar between spontaneous delivery group and manual removal group (Table 3).

The results for the postoperative data and main outcome for the whole sample and various subgroups. There was a significant drop in postoperative HB in both 12 hours and 24 hours readings (p=0.003 and p≤0.001 respectively) and HCT levels in both 12 hours and 24 hours readings (p≤0.001). There were no statistically significant differences between women of both groups concerning postoperative blood pressure. However, there were statistically significant differences regarding postoperative temperature as it was higher in women who had manual separation of placenta. There was a significantly higher risk of blood Transfusion as detected on performing CS in women who had their placentae manually separated than those who wait spontaneous separation. There were no

statistically significant differences between both groups as regards the use of additional ecbolics (Table 4).

There was statistical difference in the incidence of postpartum pyrexia (p 0.032) between the two groups. There were more women with severe PPH (≥ 1500 ml) (p=0.013) in the manual separation group. There were only a total of three patients that had ICU admission among manual separation group with statistically different (p 0.035). There were statistically significant differences between both groups regarding duration of hospital stay with increase among Group B (p 0.033). There were no cases of endometritis during the postnatal hospital stay (Table 5).

There were more women with severe PPH (≥ 1500 ml) (p 0.013) and blood transfusion after CS (p 0.043) in the manual separation group. We found significant difference in the duration of hospital stay, hours between the two groups (Table 6).

DISCUSSION

Caesarean section is a common operation and needs to be made as safe as possible. Caesarean section rates are rising worldwide and becoming a cause of concern as it has been shown to be positively associated with maternal mortality and severe morbidity, even after adjusting for risk factors.¹¹

The mode of placental delivery may contribute to an increase or decrease in the morbidity associated with CS, and many studies have shown it to be a key role in determining the blood loss during CS.¹²

There are two main methods for placental delivery during CS. Some obstetricians practice manual removal of the placenta as they believe it to be quicker than awaiting spontaneous placental delivery.¹³

Immediately after fetal extraction, the uterine muscles start a process of contraction and retraction, thereby reducing the size of the uterus. As the uterus grows smaller, the size of the placental bed decreases dramatically in comparison with the incompressible placenta. This causes a shearing movement that leads to placental separation, and the newly denuded blood vessels feeding the placental bed are compressed, thereby decreasing blood loss. This mechanism can explain why blood loss is less in spontaneous placental separation.¹⁴

The demographic data of the two groups were compared using chi square test and p value was found to be > 0.05 . This findings were found in the most of relevant studies.^{14, 15}

In this study, women who waited for the placenta to separate spontaneously had a significantly lower estimated intraoperative blood loss than women who had their placenta separated manually (p<0.001). The median

amount of blood loss in spontaneous placental separation group was (622.2 (613.3-645.9)) but in manual separation group was (685.9 (640.8-715.9)), These results were similar to that obtained by other studies.^{5,14,15} They have found that Women who had manual removal of the placenta lost significantly more blood than those who had spontaneous separation.

Postoperative Hg and postoperative Hg drop were significantly lower in women who had spontaneous placental separation when compared to women who had manual separation. The Postoperative Hg drop (0.46 ± 0.10 vs 1.04 ± 0.19), respectively, A significant drop in hemoglobin was observed in manual separation group compared to spontaneous separation group.¹⁴

For the result data reported here, the median duration of placental delivery was shorter in manual separated group than spontaneously separated group (49 (46–66) and 80 (66–100) seconds respectively), p<0.001). This findings were agreed with.^{14,15,16}

In the other side there were no statistically differences between the two groups concerning duration of whole CS .In contrary to the findings of our study, Ramadani found the operating time to be significantly shorter in the manual removal group, which are also opposite to several studies.¹⁵⁻¹⁷ They found no significant difference in the duration of operation as the duration of operation depends on several factors with time taken to deliver the placenta being just one of them. However, it is possible that time saved by manual removal of the placenta may be counteracted by delays in closure of the uterus related to increased bleeding.

In concueernt with El-behiedy et al the current study shows that no statistically significant difference between both groups regarding the use of additional ecbolics drugs.¹⁵

A statistically significant difference between both groups was found as regard the need for blood transfusion . There were four patients in manual separation group and two patients in spontaneous separation group had been taken blood transfusion postpartum. These results were in opposite to that obtained by Ramadani, Kamel et al and El-behiedy et al as there was no significant difference in the rate of transfusion when the placenta was delivered by manual removal or by spontaneous delivery.^{5,14,15}

Our study reported a statistically significantly longer hospital stay with manual delivery of the placenta. Some authors agreed with our finding, while other authors disagreed with US.^{14,17}

A study by El-behiedy et al had similar finding to our own in regard to ICU admission, while no statistically significant difference between two studied groups had been detected by Kamel et al.^{14,15}

Limitations of the study

The limitations of the study included variability in the skill of obstetrician performing the CS. Even though all obstetricians performing the procedure had the same training and had the same hospital ranking, it is difficult to quantify talent and speed. Also, there is no single set standardized method to quantify blood loss; however, we did all possible methods to account for known variables.

CONCLUSION

In this randomized study a statistically significantly increased amount of blood loss with manual removal of the placenta compared to the spontaneous placental separation group with shorter time of placental delivery, while the duration of surgery was statistically not significantly differs in both groups. Postoperative hematocrite and postoperative hematocrite drop, Postoperative Hg and Postoperative Hg drop were significantly lower in women who had there placenta spontaneous separation when compared to women who had manual separation. Spontaneous separation of the placenta during cesarean section is more beneficial than manual separation. As it has the following advantages: Decrease intraoperative blood loss, decrease hematocrite drop after CS and decrease time of hospital stay.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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