Efficacy and Safety of the Mobius Retractor® In Elective Caesarean Section for Obese Pregnant Women

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Abstract: Objective: to test the efficacy and Safety of a plastic self retaining retractor (Mobius retractor®) in elective caesarean section (C/S) for obese women. **Design**: Randomized prospective single – blinded case control study. **Setting**: Tertiary–care University hospital in Cairo, Egypt and a tertiary maternity hospital in Bristol, UK. **Population**: 300 pregnant women with age between 18 and 40 and BMI ≥ 35 undergoing elective C/S at or near term. Patients with anticipated excessive blood loss, abnormal coagulation profile, substance abuse or with extensive intra-operative adhesions were excluded. **Methods**: The study population was randomly divided into cases (n=135) in which the Mobius retractor® was used and controls (n=131) in which the conventional retractors were used. 34 women were excluded from the study due to extensive intra-operative adhesions. **Outcome measures**: Primary outcome included the operative time. Secondary outcomes included intra-operative blood loss, intra-operative injury, extra need for assistance, need for uterine exteriorization, assistant satisfaction, length of hospital stay, extra need for postoperative analgesia, postoperative fever, time of resumption of intestinal motility, wound infection and need for blood transfusion. **Results**: Using the Mobius retractor® was associated with a significant shorter operative time, higher assistant satisfaction, less extra need for assistance, less need for uterine exteriorization and less need for postoperative analgesia. The use of the Mobius retractor® was not associated with significant reduction in the operative blood loss, duration of hospital stay, time of resumption of intestinal motility, intra operative injury, postoperative fever, wound infection and need for blood transfusion. No injuries were reported from the Mobius retractor® in all cases. **Conclusion:** The Mobius retractor® is an efficient and safe retractor that can be used to improve the outcome and reduce morbidity in elective caesarean section for obese pregnant women.
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1. Introduction:

With about one in three babies born surgically, caesarean section (C/S) is one of the most common operating room procedures done worldwide[1]. Over the past two decades, its rate has significantly increased. This increase was among women with and without prior C/S, in both preterm and term pregnancies, in low risk and high risk women and across all age groups, races and ethnicities [2].

C/S are not without risks to the mother and the baby. Risks include haemorrhage, infection, ileus, pulmonary embolism, complications of anaesthesia, bladder injury, formation of adhesions, uterine rupture and placenta accreta in subsequent pregnancies and transient tachypnea of the newborn. Moreover feeling of inadequacy and guilt among the couple should not be underestimated [3].

Maternal obesity has become one of the most commonly accusing risk factors in obstetric practice. It is defined as BMI ≥ 30 Kg/m^2 in the first antenatal consultation [4]. It is associated with a series of adverse outcomes including miscarriage, thrombo-embolism, gestational diabetes, pre-eclampsia, dysfunctional labor, postpartum haemorrhage and stillbirth [5,6]. It is also associated with a higher rate of C/S together with a higher rate of all of C/S complications [7].

Several key technical issues should be considered while delivering an obese woman by C/S to decrease the risk of complications. These include adequate dose of pre-operative intra-venous antibiotics, consider Trendelenburg position, use of absorbable sutures in both subcutaneous layer and the skin, minimal disturbance of the fat layer, consider use of a negative pressure skin dressing system and proper post-operative heparin dose[8]. One of these issues is to use a suitable self retaining retractor.

The Mobius retractor® is composed of an elastic membrane attached to an external and internal ring. It is postulated that it creates a less traumatic, circular and completely self- retaining area of abdominal retraction.

The aim of this study is to examine the efficacy and safety of the use of this retractor in elective caesarean section for obese women.

2. Patients and Methods:

This was a prospective randomized single-blinded case control study that was conducted in a tertiary Maternity hospital in the UK and a tertiary University hospital in Egypt in the period from January 2010 till September 2014. 300 pregnant women with age between 18 and 40 years, BMI ≥ 35 and scheduled for elective C/S for term or near term babies were

randomly divided. Randomization was established using a computer generated list in a 1: 1 ratio into 2 groups: Group 1 (150 cases) in which the Mobius retractor® was used and Group 2 (150 controls) in which conventional retractors were used. Each woman in the study received a closed envelope which contains a random number that is corresponding to which group she will be enrolled to in the randomization table. The envelope will be opened by the surgeon immediately before the operation. The numbers were reduced to 135 cases and 131 controls as some of them did not meet the intra-operative inclusion criteria (i.e absence of intra-operative adhesions as positive adhesions might obstruct the insertion of the Mobius retractor®).

Patients undergoing emergency C/S or undergoing C/S with anticipated excessive blood loss or patients with abnormal coagulation profile or women on substance abuse or with positive intra-operative adhesions were excluded from the study. The study was conducted after approval of the local ethical committee in both hospitals according to the World Medical Association Declaration of Helsinki and all patients agreed to participate in the study signed a formal written consent. All C/S were conducted by the same surgeon.

Mobius retractor® (created by Apple Medical Corporative, Marlborough, MA,USA) is composed of an elastic membrane attached to an external and internal flexible plastic ring creating a cylinder of 10.6 inches height. After opening the parietal peritoneum and ensuring that there are no adhesions preventing the insertion of the ring between the uterus and the anterior abdominal wall, the internal ring is manually collapsed and inserted through the abdominal incision where it is allowed to spring open against the parietal peritoneum. The external ring is then pulled upward placing the cylindrical sleeve in tension then the operator rolls the external ring down the sleeve (reducing the height of the sleeve by 1.5 inches/ rotation) until the external ring sits firmly against the skin. The radial force of the two rings acts to retract the abdominal wall to the desired circular geometry. All through the insertion procedure, the surgeon has to be sure that no intestines are trapped between the internal ring and the parietal peritoneum of the anterior abdominal wall. In the controls we used the conventional metal retractors.

Apart from the step of retraction we used the same technique of C/S in both cases and controls. The uterine lower segment was closed in 2 layers using Vicryl®1 sutures, the parietal peritoneum was left open, the rectus sheath was closed by vicryl® 1 suture as a continuous layer,the subcutaneous layer was closed by interrupted inverted vicryl® 2-0 sutures and the skin was closed by prolene® 2-0 subcuticular stitch. No drains were inserted in all cases.

The primary outcomes included the operative time. The secondary outcomes included intra-operative blood loss, intra-operative injury, extra need for assistance, need for uterine exteriorization, assistant satisfaction, length of stay in hospital, extra need for postoperative analgesia, post operative fever, time of resumption of intestinal motility, wound infection and need for blood transfusion.

The amniotic fluid index (AFI) was estimated by abdominal U/S in all cases and controls prior to the C/S. Amniotic fluid volume (ml) was estimated by multiplying AFI (cm) by 30 [9]. The surgical towels were weighed in (gm) before and after the operation using a highly accurate digital balance (National Xiamen Yukexiang Trading Co. LT. D, China) ® and the difference in weight between dry and soaked towels was calculated. Blood loss during the operation was calculated as follows: Volume of the contents of the suction bottle (mls) (A) + difference in weight of surgical towels (B)- amniotic fluid volume (ml) (C) [(A+B)- C][9]. Hemoglobin (Hb) difference (preoperative Hb-24 hrs. Postoperative Hb) was taken into consideration in cases of major blood loss for the decision of blood transfusion.

Assistant satisfaction was measured by a 10 point-likert scale. Resumption of intestinal motility was confirmed by passage of flatus +/- stools.

All cases and controls received spinal anaesthesia for the C/S and a self retaining urinary catheter was inserted at the start of the procedure and removed 6 hours later. At the end of the C/S the wound was injected with 20 ml of local anaesthetic (2% Lidocaine) after its closure. Postoperatively the patient received 1grm of Paracetamol I.V/ 6 hours and 1 dose of 50mg of pethidine (synthetic opioid analgesic) slowly intravenous in the first 24 hours. Any extra doses of analgesics needed as requested by the patient were considered extra post-operative analgesia. All cases and controls received the same dose of prophylactic antibiotic.

Statistical Analysis:

The collected data was revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (SPSS 15.0.1 for windows; SPSS Inc, Chicago, IL, 2001). Data was presented and suitable analysis was done according to the type of data obtained for each parameter. Continuous variables are expressed as mean and standard deviation. Categorical variables are expressed as frequencies and percents. Student t test was used to compare quantitative variables between both groups. Chi-square test was used to compare qualitative variables between both groups. Statistical significance was considered positive if the P-value was less than 0.05.

3. Results:

Fifteen out of the 150 cases and 19 out of the 150 controls did not meet the inclusion criteria and were excluded from the study due to extensive intra-operative adhesions.

Both cases and controls were matched as regards to maternal age, body mass index (BMI) and gestational age at which C/S was done. 61.48% were primary C/S in the cases in comparison to 62.6% in the controls with no significant difference. 38.52% were repeat C/S in the cases in comparison to 37.4% with no significant difference.

There were no significant differences between the cases and controls as regards the indications of C/S. This is shown in Table 1.

There was significantly shorter operative time and significantly higher assistant satisfaction in cases as compared to controls. Operative blood loss, duration of hospital stay and time of resumption of intestinal motility were all reduced in cases as compared to controls but the differences were not statistically significant.

There was significant more extra need for assistance, uterine exteriorization and extra postoperative analgesia in controls in comparison to cases. No significant differences were found in the intra-operative injury, postoperative fever, wound infection or blood transfusion between cases and controls although they were all higher in the controls (Table 2).

Table (1) : Indications of C/S in both cases and controls

Indication		Cases (n= 135)		Controls(n=131)		X^2	*P* Value
		n	%	n	%		
Previous C/S	Total	52	38.52	49	37.4	0.004	> 0.05
	Previous 1 C/S	18	13.33	21	16.03	0.201	> 0.05
	Previous 2 C/S	20	14.81	15	11.45	0.397	> 0.05
	Previous 3 C/S	10	7.41	7	5.34	0.191	> 0.05
	Previous 4or more C/S	4	2.96	6	4.58	0.138	> 0.05
Breech		18	13.33	13	9.92	0.456	> 0.05
Maternal request		13	9.63	9	6.87	0.353	> 0.05
Multiple pregnancy		12	8.89	8	6.1	0.394	> 0.05
Previous shoulder dystocia		11	8.15	9	6.87	0.026	> 0.05
Previous 3rd or 4th degree perineal tear		7	5.19	6	4.58	0.003	> 0.05
Maternal Diabetes + fetal macrosomia		6	4.44	8	6.1	0.111	> 0.05
Hypertensive disorder +/- IUGR*		4	2.96	7	5.34	0.445	> 0.05
Others	Total	12	8.89	22	16.79	3.051	> 0.05
	Previous myomectomy	2	1.48	4	3.05	0.203	> 0.05
	Previous IUFD*	1	0.74	5	3.81	1.629	> 0.05
	Poliomyelitis	2	1.48	1	0.76	0.001	> 0.05
	Lumber disc prolapse	2	1.48	1	0.76	0.001	> 0.05
	Fetal hydrocephalus	1	0.74	1	0.76	0.474	> 0.05
	Retinal detachment	1	0.74	1	0.76	0.474	> 0.05
	Previous facture pelvis	1	0.74	0	0	0	> 0.05
	Contracted pelvis	0	0	1	0.76	0	> 0.05
	Tight Aortic stenosis	0	0	1	0.76	0	> 0.05
	Pelvic kidney	0	0	1	0.76	0	> 0.05
	Transverse lie	1	0.74	0	0	0	> 0.05
	Cervical fibroid	1	0.74	0	0	0	> 0.05
	Vulv. & vag. Varicosities	0	0	2	1.53	0.535	> 0.05
	Myathenia gravis	0	0	1	0.76	0	> 0.05
	Previous Sling, T.O.T*, Burch colposuspension.	0	0	3	2.29	1.410	> 0.05

*IUFD=Intrauterine fetal death,*TOT=Transobturator tape procedure, *IUGR=Intrauterine growth retardation

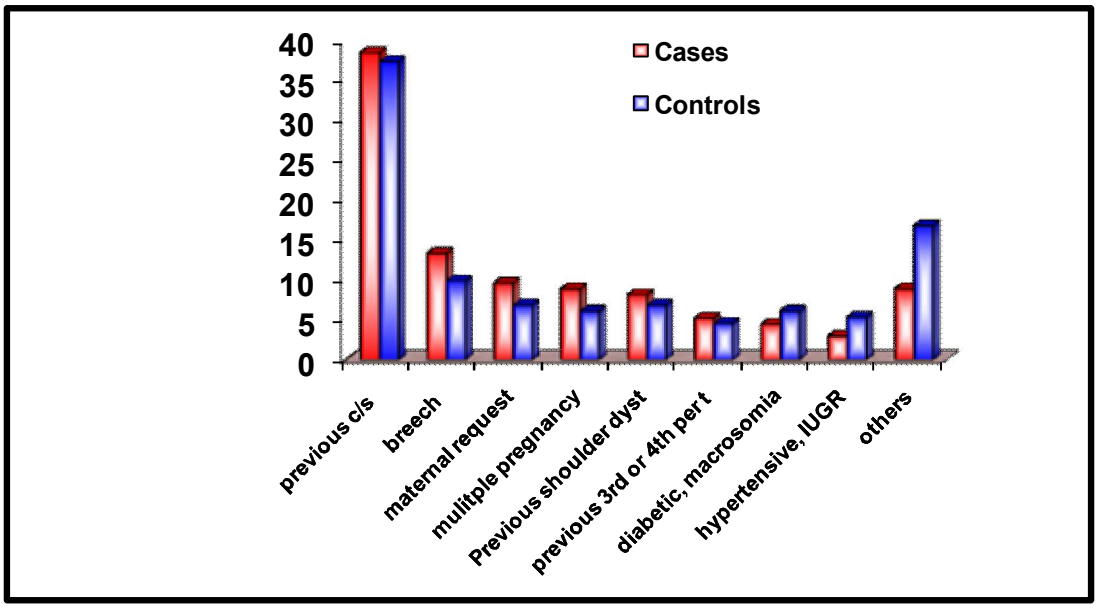


Fig 1: The indications of C/S in both cases and controls.

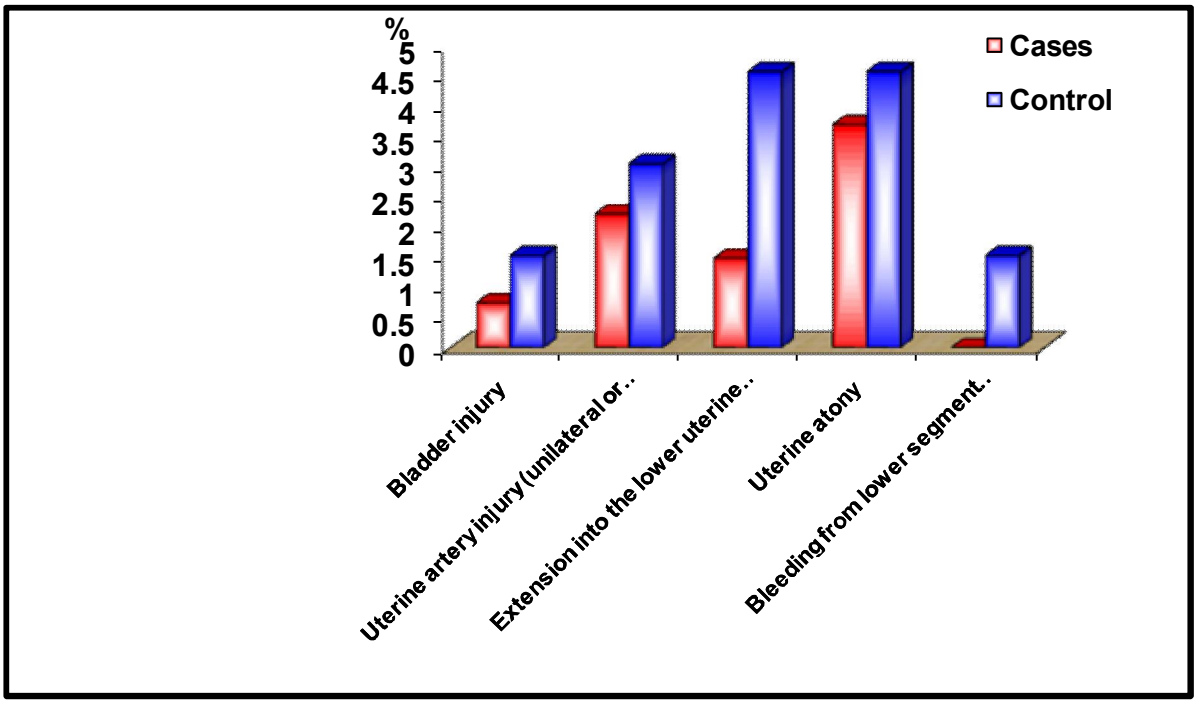
Table 2 : Comparison between the cases & controls regarding the demographic data, operative data & post operative parameters

	Cases(n=135) Mean ± S. D (range)		Controls(n=131) Mean ± S. D (range)		T – test	*P* value
Age (y)	30.17 ± 5.5 (19-41)		30.67 ± 5.5 (18-41)		- 0.745	> 0.05
*** wt. (Kg)**	107.63 ± 15.2 (84-154)		108.79 ± 11.9 (89-142)		-0.693	> 0.05
*** ht. (cms)**	163.76 ± 5.2 (150-174)		165.21 ± 5.4 (148-178)		0.534	> 0.05
BMI	40.05 ± 4.6 (35.1-55.2)		39.83 ± 3.7 (35-52.9)		0.428	> 0.05
*** GA (wks)**	38.63 ± 0.7 (36.3-41)		38.59 ± 0.9 (36.6-41)		0.490	> 0.05
Operative time (min.)	52.42 ± 9.3 (35-80)		61.13 ± 10.7 (45-95)		-7.082	<0.001*
Blood loss (mls)	860.74 ± 180.4 (500-1300)		860.69±217.1 (550-1650)		0.002	> 0.05
*** Assistant satisfaction**	9.67 ± 0.9 (5-10)		8.19 ± 2.1 (2-10)		7.514	<0.001*
Hospital stay (hrs)	33.96 ± 15.6 (24-96)		37.19 ± 19.3 (24-120)		-1.503	> 0.05
Time of resumption of intestinal motility (hrs)	14.84 ± 7.7 (4-48)		15.97 ± 8.2 (6-48)		-1.164	> 0.05
	N	**%**	**N**	**%**	**X^2**	***P* value**
Primary C/S	83	61.48	82	62.6	0.004	> 0.05
Repeat C/S	52	38.52	49	37.4		
Intra-operative injury	11	8.15	20	15.27	3.310	> 0.05
Extra need for assistance	0	0	16	12.21	17.544	< 0.001*
Need for uterine exteriorization	4	2.96	29	22.14	22.494	< 0.001*
Extra post-operative analgesia	10	7.41	26	19.85	8.792	< 0.05*
Post-operative fever	7	5.19	14	10.69	2.768	> 0.05
Wound infection	7	5.19	11	8.4	1.087	> 0.05
Blood transfusion	5	3.7	9	6.87	1.337	> 0.05

wt. = weight, ht. = height, GA = gestational age, Assistant satisfaction is measured on a ten point likert scale.

Table 3 & Fig.2: Distribution of various types of intra-operative injuries or complications among cases and controls.

Groups / Type of operative injury or complication	Cases (n= 135)		Controls (n= 131)		X^2	*P* value
	N	%	N	%		
Bladder injury	1	0.74	2	1.53	0.001	> **0.05**
Uterine artery injury (unilateral or bilateral)	3	2.22	4	3.05	0.002	> **0.05**
Extension into the lower uterine segment	2	1.48	6	4.58	1.255	> **0.05**
Uterine atony	5	3.70	6	4.58	0.003	> **0.05**
Bleeding from lower segment varicosities	0	0	2	1.53	0.535	> **0.05**



4. Discussion:

Although caesarean section is one of the most common operations done worldwide, sometimes it might be very challenging. One of these distressing challenges is maternal obesity especially that this problem has risen relentlessly across the world. The risk of performing a C/S in patients with BMI $\geq$ 35 may exceed 50% simply because of suspected macrosomia and its anticipated complications.

Several technical modifications has been tried over the years in an attempt to decrease the risks to the mother and the baby. One of these measures is the use of a suitable retractor.

The apple Medical OB/ Mobius® elastic retractor has been marketed and used since 2005. Its idea is to provide 360° of self retaining radial retraction, thus providing greater exposure. It was designed as well to line the incision thus hypothized to protect the wound from contamination while keeping the wound edges moist. It comes in a range of sizes.

The aim of this study was to examine the efficacy and safety of the use of this retractor in elective C/S for obese women (BMI $\geq$ 35 at the time of the operation).

To our knowledge and after reviewing the literature no published data is still available although there are 2 clinical trials still ongoing. The first is in Thomas Jefferson University. It is a randomized controlled trial comparing the use of Mobius® retractor to the use of traditional metal retraction instruments in non-urgent caesarean deliveries of obese women[10]. The second study is in Dartmouth- Hitchock medical center and it concentrated on the effect of the Mobius® retractor in decreasing the post- operative pain after C/S in comparison to the conventional retractor use[11].

The assessment of the pain in the latter study was by using a 7 item pain scale questionnaire completed by the patient each post- operative day for 3 days (until discharge).In our study we used a more objective parameter for pain assessment which is the need for more doses of analgesics than the usual protocols.

Our study showed that using the Mobius® retractor is associated with a significantly shorter operative time, higher assistant satisfaction, less extra need for assistance, less need for uterine exteriorization and less need for postoperative analgesia. The use of Mobius® retractor was not associated with significant reduction in the operative blood loss, duration of hospital stay, time of resumption of intestinal motility, intra-operative injury, postoperative fever, wound infection and need for blood transfusion.

No injuries were reported from the Mobius® retractor in all cases.

Conclusion:

The Mobius® retractor is an efficient and safe retractor that can be used to improve the outcome and reduce morbidity in elective caesarean section for obese pregnant women.

Conflict of interest: None

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