Journal of Cardiovascular Disease Research

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

Evaluation of the Effects of Vacuum Extraction Device in Assisted Vaginal Delivery on Both Mother and Fetus

Khaled ElShamy[1], Taha Abdelfattah[1], Ahmed ElMaasarawy[1]& Hussein Abdeldayem[1]

[1]Department of Obstetrics and Gynecology, Faculty of Medicine, Zagazig University, Egypt.

Correspondence: Khmm3elshamy@gmail.com

ABSTRACT

Background: Numerous vaginal delivery techniques have been recognized as significant risk factors for fetal morbidity and mortality, as well as early and late mother morbidity, particularly pelvic floor disease. Such techniques were mostly utilized for nulliparous deliveries .Although long-term follow-up indicates no variation in pelvic floor function between women who delivered using vacuum and those who delivered with forceps, the vacuum is regarded the preferred tool due to a hypothesized reduction in maternal injury**.**

Aim of the Study: To evaluate the use of vacuum extraction device for assisted vaginal delivery and its effects on mother and neonate.

Patients and Methods: a prospective cohort studyincluding 141 Pregnant females who need assisted vaginal deliveries (AVD). All patients were subjected to complete history taking in addition to general physical examination including whole abdominal and vaginal examination like Vertex presentation; if Cervix was fully dilated, and the membranes ruptured, if the exact position of the head was readily determined to achieve proper placement of the instrument, assessment of caput and molding if the pelvis was deemed adequate.Vacuum cup application: fulfilled follow-up criteria number of pulls: 3 or a smaller number of applications: 2 Duration of procedure: less than 15 min assessment of anterior rotation from OT/OP

Results:The overall outcome exhibited that complicated cases were 38.3% of the studied group. Complicated cases are significantly associated with older maternal age; Lower GA is also significantly associated with 1-2 parity and no analgesia. Complicated cases were significantly associated with longer duration of cup application and severe maternal effort and traction, the higher number of pull also with no episiotomy and with Vacuum detachment.

Conclusion: Assisted delivery with a vacuum extractor rather than forceps seems to minimize fetal morbidity and mortality in addition to early and late maternal morbidity, including pelvic floor disease. Hence, applying a vacuum extraction device is a potential procedure for achieving favorable outcomes on mothers and neonates.

Key words: Vacuum Extraction Device, Assisted Vaginal Delivery, forceps delivery**.**

1. Introduction

Several procedures for operative vaginal delivery have been identified as major risk factors for fetal morbidity and mortality as well as early and late maternal morbidity including pelvic floor disease. These procedures were used mostly for nulliparous deliveries [1].

The vacuum is considered the instrument of choice due to a posited reduction in maternal injuries, although long-term follow-up suggests no difference in pelvic floor function between women who have undergone vacuum delivery and those who have had forceps delivery [2].

Clinical guidelines and protocols have been introduced in many labor ward settings to reduce complications and ensure optimum outcomes for both mothers and neonates [3]. The FDA introduced recommendations that were designed to reduce the risks associated with vacuum delivery, which included the need for more education and training for the correct use. The American Colleague of Obstetricians and Gynecologist (ACOG) also supported the FDA recommendations [4].

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

Many different types of vacuum extractors and cups, including metal cups, semi-rigid cups and soft cups, have been introduced into clinical use [5].

The basic premise of any vacuum device is that a suction cup, made of silastic or metal material, is connected, via tubing, to a vacuum source. Traction is then applied to the presenting part, the fetal vertex, to expedite delivery, either directly through the tubing or using a traction chain [4].

Determination of the flexion point is vital for successful vacuum extraction. In an average term infant, this point is located on the sagittal suture 3 cm anterior to the posterior fontanelle, and thus 6 cm posterior to the anterior fontanelle. However, not all vacuum cup designs allow easy positioning over the flexion point, especially when the fetal head adopts an occipito-posterior or lateral position [6].

Operative vaginal delivery using the vacuum cup is one of the most common instrument procedures used in obstetrics [7].

2. Patients & Methods

2.1. Technical Design:

2.1.1. The Setting of the Study:

This study was conducted in the Department of Obstetrics and Gynecology, Faculty of Medicine, Zagazig University, Zagazig, Egypt.

2.1.2. Study Population

Pregnant females who need assisted vaginal deliveries (AVD)

2.1.3. Sample Size:

Assuming the total number of pregnant women attending Zagazig university hospitals for Vaginal delivery was 500 women and the failure rate 15%. At design effect=1 and 95% contraindicated, the estimated sample equals 141 women open Epi.

2.2. Indications for Assisted Vaginal Deliveries include:

1. **Fetal:** Presumed fetal compromise.
2. **Maternal:** To shorten and reduce the effects of the second stage of labor on medical conditions (e.g., cardiac disease Class III or IV, hypertensive crises, myasthenia gravis, spinal cord injury patients at risk of autonomic dysreflexia, proliferative retinopathy)
3. **Inadequate Progress:**
   - Nulliparous women lack continuing progress for 2 hours (total of active and passive second-stage labor).
   - Multiparous women lack continuing progress for 1 hour (total of active and passive second stage labor).
   - There were extra one hour for nulliparous women and multiparous women for epidural analgesia (Hung et al., 2015)
   - Maternal fatigue/exhaustion

2.3. Selection of Study Subjects

2.3.1. Inclusion Criteria:

All included participants had been characterized by the following:

1. Singleton pregnancies.
2. More than 36 weeks of gestation.
3. Cephalic presentation with the highest point of the skull is at station +2 and more.

2.3.2. Exclusion Criteria:

All individuals characterized by the following had been excluded from our study:

1. Gestational age is less than 36 completed weeks.

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

2. Cephalopelvic disproportion.
3. Non-engagement of the head.
4. Incomplete cervical dilatation.
5. Excessive Molding of the fetal head, large caput, and unknown position of the fetal head.
6. BMI is higher than 30.

2.4. Operational Design:

2.4.1. Study Design:

This study is a prospective cohort study.

All patients were subjected to complete history taking in addition to general examinations.

Prerequisites for Operative Vaginal Delivery.

A- Whole abdominal and vaginal examination

- Vertex presentation.
- Cervix was fully dilated, and the membranes ruptured.
- The exact position of the head was readily determined, so proper placement of the instrument was easily achieved.
- Assessment of caput and Molding.
- The pelvis was deemed adequate. Irreducible Molding indicated cephalopelvic disproportion.
- Head was ≤1/5th palpable per abdomen.

B- Preparation of Mother

- A clear explanation was given, and informed consent was obtained.
- Analgesia and local anesthesia were administered.
- The maternal bladder has been emptied.
- Aseptic technique.

C- Preparation of staff

- Adequate facilities were available (appropriate equipment was used for performing the assisted vaginal delivery-, bed, lighting).
- Back-up plan in place in case of failure to deliver where there was no evidence of progressive descent with moderate traction during each contraction or where delivery was not imminent following three contractions of the correctly applied instrument, theatre staff was immediately available to allow a cesarean section to be performed without delay (less than 30 minutes).
- Personnel present that was trained in neonatal resuscitation

2.5. The Vacuum Extraction Procedure

Vacuum cup application: fulfilled follow up criteria, Number of pulls: 3 or less, Number of applications: 2, Duration of procedure: less than 15 min and assessment of anterior rotation from OT/OP.

2.6. Outcome Measures:

2.6.1. Primary Outcome Results:

Favorable outcome on mother and neonate.

2.6.2. Secondary Outcome Results:

A. Maternal outcomes:

- Third- and fourth-degree perineal tears.
- Postpartum hemorrhage.
- Postpartum fever.
- Prolonged hospitalization.

B. Neonatal outcomes

- Scalp lacerations.

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

- Subgaleal hematoma (**SGH**).
- Cephalohematomas.
- Intracranial bleeding, Intraocular bleeding and Shoulder dystocia.

2.7. Administrative Design:

Approval was obtained from Zagazig University Institutional Review Board (IRB).

2.8. Statistical Analysis of the Data:

Data collected throughout history, basic clinical examination, laboratory investigations, and outcome measures coded, entered, and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis. According to the type of data qualitative represent as number and percentage, quantitative continues group represented by mean ± SD, the following tests were used to test differences for significance. Difference and association of qualitative variable by Chi-square test (X^2). Differences between quantitative independent groups by t-test. Data were collected and submitted to statistical analysis.

2.8.1. Level of Significance:

The significance of test results was quoted as two-tailed probabilities. For all the tests mentioned above, the level of significance was tested, expressed as the probability of (p-value), and the results were explained as follows:

- Non-significant if the p value is > 0.05
- Significant if the p value is ≤ 0.05.
- Highly significant if the p value < 0.001

3. Results

3.1. Basic Demographic and clinical data distribution

Age was distributed as 28.48±4.38 with minimum 20 and maximum 38 years, regard BMI it was distributed as 28.87±1.25, gestational age was distributed as 38.85±0.81, regard parity majority were 1-2 with 51.0%

Table 1. Basic Demographic and clinical data distribution among studied group (N=141)

Maternal age	Mean± SD	28.48±4.38	
	Median (Range)	29.0 (20-38)	
BMI	Mean± SD	28.87±1.25	
	Median (Range)	29.0 (27.8-29.9)	
GA	Mean± SD	38.85±0.81	
	Median (Range)	39.0 (38-40)	
		N	%
Parity	PG	56	39.7
	1-2	72	51.0
	3-4	13	9.3
	Total	141	100.0

3.2. Pre procedure characters distribution

Majority were anterior then posterior regard position, 54.6% regard indication majority were Fetal distress then Mother exhaustion and finally Prolonged 2nd stage of labor, 42.6% had Epidural analgesia.

Table 2. Pre procedure characters distribution among studied group (N=141)

		N	**%**
Position	**Anterior**	**72**	**51.1**
	Posterior	**57**	**40.4**
	Pregma	**12**	**8.5**

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

Indication	**Fetal distress**	**64**	**45.4**
	Maternal exhaustion	**50**	**19.1**
	Prolonged 2nd stage of labor	**27**	**35.5**
Epidural analgesia	**-VE**	**81**	**57.4**
	+VE	**60**	**42.6**
	Total	**141**	**100.0**

3.3. Procedure characters distribution

Duration of delivery was distributed as 28.47±8.7 minutes and regard Duration of cup application it was distributed as 10.55±3.78 minutes, regard maternal effort and Traction majority were mild, majority had one pull and 43.3% had Episiotomy, Vacuum detachment happened in 18.4% and Failure of vacuum happened only in 3.5% (5 cases).

Table 3. Procedure characters distribution among studied group (N=141)

Time delivery	**Mean± SD**	**28.47±8.7**	
	Median (Range)	**25.0 (15-45)**	
Duration of cup application	**Mean± SD**	**10.55±3.78**	
	Median (Range)	**10.0 (5-20)**	
		N	**%**
Maternal effort	**Mild**	**62**	**44.0**
	Moderate	**29**	**20.6**
	Sever	**50**	**35.5**
Traction	**Mild**	**65**	**46.1**
	Moderate	**27**	**19.1**
	Sever	**49**	**34.8**
Number of pulls	**I**	**82**	**58.2**
	II	**43**	**30.5**
	III	**16**	**11.3**
Episiotomy	**-VE**	**80**	**56.7**
	+VE	**61**	**43.3**
Vacuum detachment	**No**	**115**	**81.6**
	Yes	**26**	**18.4**
Failure of vacuum	**No**	**136**	**96.5**
	Yes	**5**	**3.5**
	Total	**141**	**100.0**

3.4. Outcome distribution

Maternal outcome distribution showed 22% had Perineal Tears, 17% had Post-partum Hg and 17% had blood transfusion (table 9). Neonatal outcome distribution showed that baby weight was distributed as **3278.72±153.95** grams regard APGAR 5 & 10 were distributed as **7.43±1.0** and **8.60±1.13**respectively, 12.1% had Shoulder dystocia and 7.8% had **Neonatal injury** (table 10). Overall outcome distribution among studied group showed that complicated cases were 38.3% of studied group (table 11).

Table 4. Outcome distribution among studied group (N=141) for maternal outcome.

		N	**%**
Perineal Tears	**-VE**	**110**	**78.0**
	+VE	**31**	**22.0**
Post-partum Hg	**-VE**	**117**	**83.0**
	+VE	**24**	**17.0**
Blood transfusion	**-VE**	**117**	**83.0**
	+VE	**24**	**17.0**
	Total	**141**	**100.0**

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

Table 5. Outcome distribution among studied group (N=141) for neonatal outcomes

		Value	
Baby weight	**Mean± SD**		**3278.72±153.95**
	Median (Range)		**3300.0 (2450-3550)**
APGAR 5	**Mean± SD**		**7.43±1.0**
	Median (Range)		**8.0 (5-9)**
APGAR 10	**Mean± SD**		**8.60±1.13**
	Median (Range)		**9.0 (5-10)**
		N	**%**
Shoulder dystocia	**-VE**	**124**	**87.9**
	+VE	**17**	**12.1**
Neonatal injury	**-VE**	**130**	**92.2**
	+VE	**11**	**7.8**
	Total	**141**	**100.0**

Table 6. Overall outcome distribution and relation with complication.

		N	%
Overall outcome	**Non complicated**	**87**	**61.7**
	Complicated	**54**	**38.3**
	Total	**141**	**100.0**

3.5. Relation of complication with basic characters and pre procedure characters

Complicated cases significantly associated with older maternal age, Lower GA also significantly associated with 1-2 parity and no analgesia.

Table 7. Relation of complication with basic characters and pre procedure characters

			Non complicated outcome (N=87)	Complicated outcome (N=54)	t/ X^2	P
Maternal age			**27.55±4.39**	**30.01±3.95**	**3.313**	**0.001 ****
BMI			**33.62±1.43**	**33.30±2.37**	**0.983**	**0.328**
GA			**39.03±0.79**	**38.55±0.76**	**3.510**	**0.001 ****
Parity	**PG**	**N**	**48**	**8**		
		%	**55.2%**	**14.8%**		
	1-2	**N**	**30**	**42**	**24.36**	**0.00* ***
		%	**34.4%**	**77.8%**		
	3-4	**N**	**9**	**4**		
		%	**10.4%**	**7.4%**		
Epidural analgesia	**-VE**	**N**	**37**	**44**		
		%	**42.5%**	**81.5%**		
	+VE	**N**	**50**	**10**	**20.68**	**0.00* ***
		%	**57.5%**	**18.5%**		
Position	**Anterior**	**N**	**43**	**29**		
		%	**49.4%**	**53.7%**		
	Posterior	**N**	**37**	**20**	**0.42**	**0.808**
		%	**42.5%**	**37.0%**		
	Bregma	**N**	**7**	**5**		
		%	**8.0%**	**9.3%**		

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

Indication	Fetal distress	N	43	21		
		%	49.4%	38.8%		
	Maternal exhaustion	N	30	20	1.98	0.39
		%	34.4%	37.0%		
	Prolonged second stage		14	13		
			16.2%	24.2%		
Total		N	87	54		
		%	100.0%	100.0%		

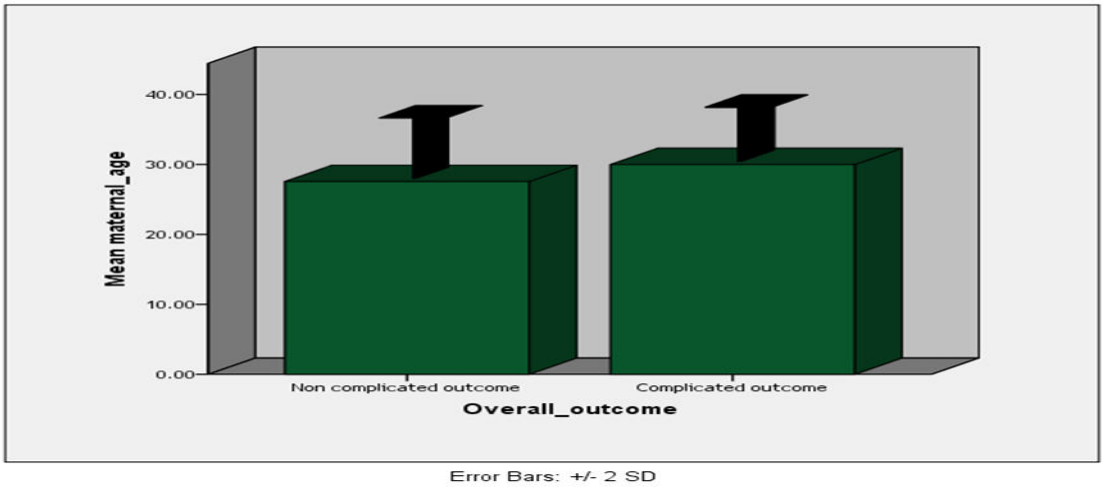

Figure 1. Relation between mean maternal age and complication outcome

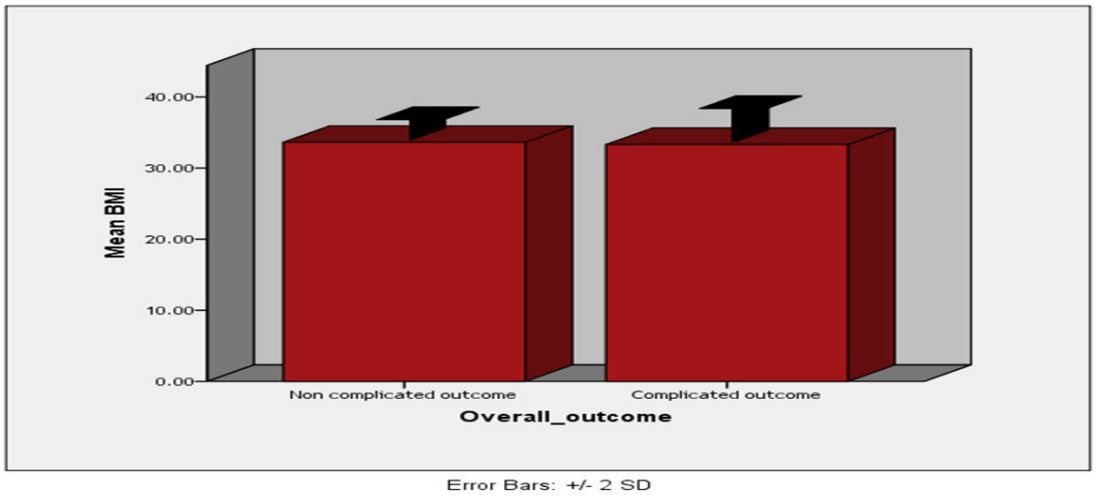

Figure 2. Relation between BMI and complication outcome

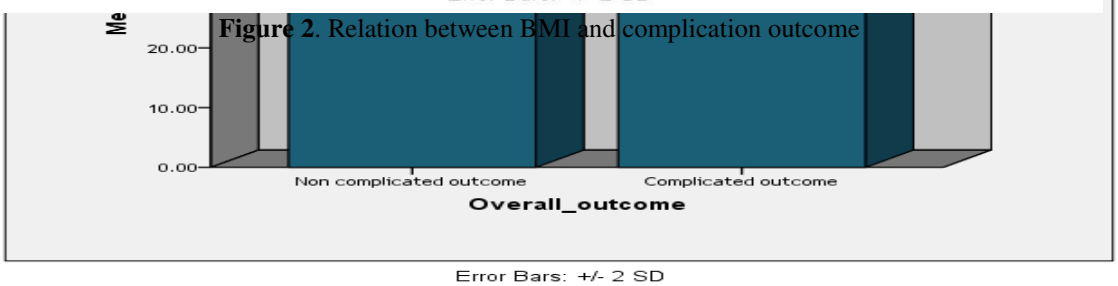

Figure 3. Relation between mean GA and complication outcome

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

3.6. Relation of complication with procedure characters

Complicated cases were significantly associated with longer duration of cup application and sever maternal effort and traction, higher number of pull also with no episiotomy and with vacuum detachment.

Table 8. relation of complication with procedure characters

			Non complicated outcome (N=87)	complicated outcome (N=54)	t/ X^2	P
Time of delivery			**29.59±9.04**	**26.66±7.39**	**1.955**	**0.053**
Duration of cup application			**9.62±3.05**	**12.05±3.75**	**3.900**	**0.00****
Maternal effort	**Mild**	**N**	**57**	**5**		
		%	**65.5%**	**9.3%**		
	Moderate	**N**	**21**	**8**		
		%	**24.1%**	**14.8%**	**65.8**	**0.00****
	Sever	**N**	**9**	**41**		
		%	**10.3%**	**75.9%**		
Traction	**Mild**	**N**	**55**	**10**		
		%	**63.2%**	**18.5%**		
	Moderate	**N**	**21**	**6**		
		%	**24.1%**	**11.1%**	**49.34**	**0.00****
	Sever	**N**	**11**	**38**		
		%	**12.6%**	**70.4%**		
Number of pulls	**I**	**N**	**58**	**24**		
		%	**66.7%**	**44.4%**		
	II	**N**	**20**	**23**	**7.22**	**0.027***
		%	**23.0%**	**42.6%**		
	III	**N**	**9**	**7**		
		%	**10.3%**	**13.0%**		
Episiotomy	**-VE**	**N**	**34**	**46**		
		%	**39.1%**	**85.2%**		
	+VE	**N**	**53**	**8**	**28.85**	**0.00****
		%	**60.9%**	**14.8%**		
Vacuum detachment	**-VE**	**N**	**85**	**30**		
		%	**97.7%**	**55.6%**		
	+VE	**N**	**2**	**24**	**39.35**	**0.00****
		%	**2.3%**	**44.4%**		
Failure of vacuum	**-VE**	**N**	**86**	**50**		
		%	**98.9%**	**92.6%**		
	+VE	**N**	**1**	**4**	**3.81**	**0.051**
		%	**1.1%**	**7.4%**		
Total		**N**	**87**	**54**		
		%	**100.0%**	**100.0%**		

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

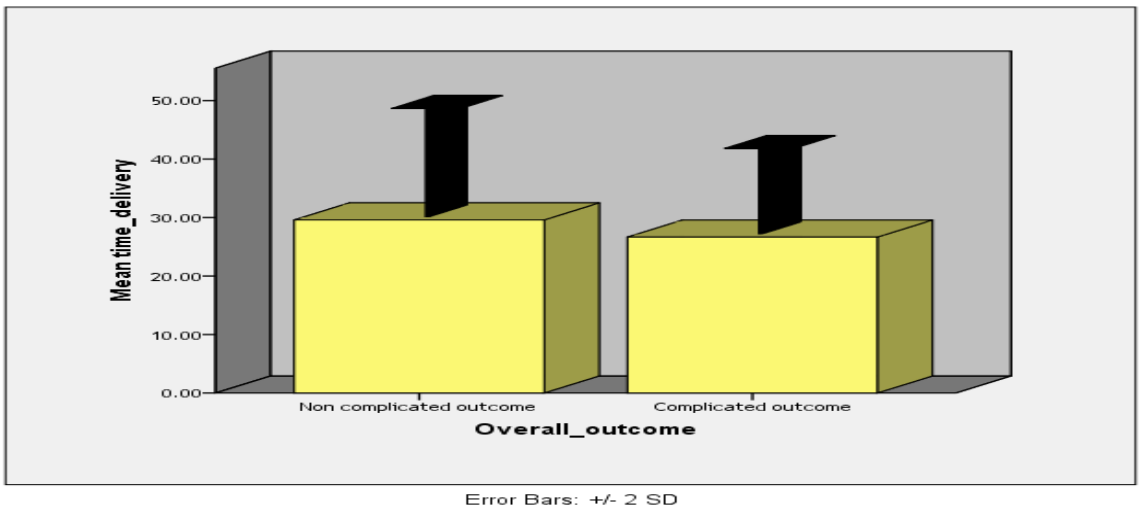

Figure4. Relation between mean delivery time and complication outcome

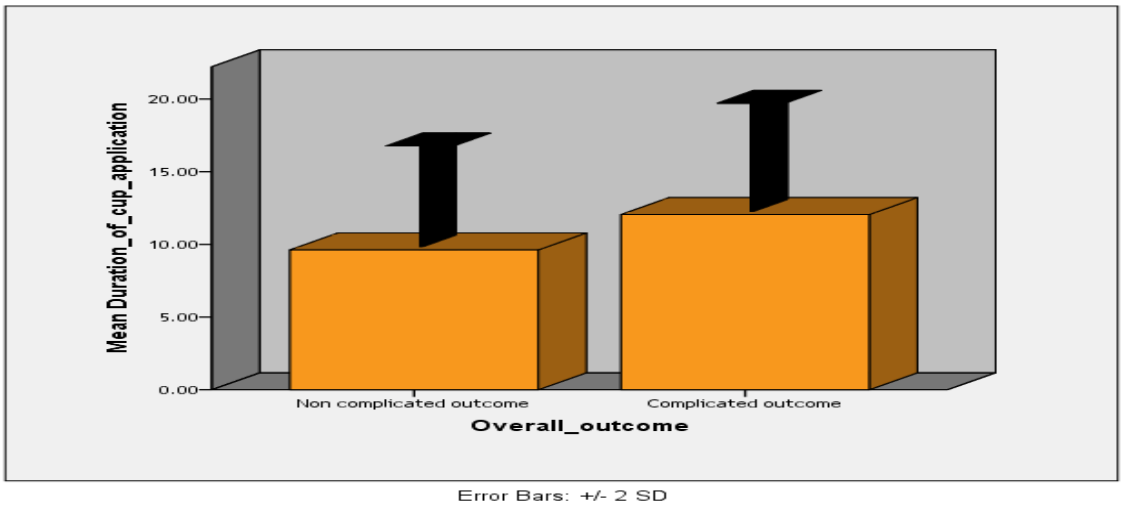

Figure 5. Relation between duration of cup application and complication outcome

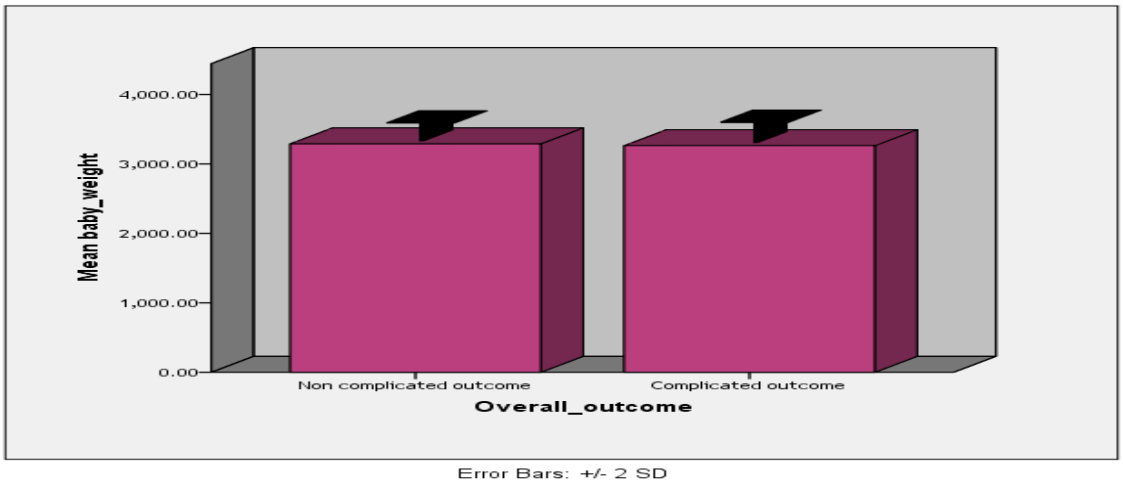

Figure 6. Relation between mean baby weight and complication outcome

4.Discussion

In the current study, the total number of studied women was 141 and the age was distributed as 28.48±4.38 with minimum 20 and maximum 38 years, BMI was distributed as 28.87±1.25,

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

gestational age was distributed as 38.85±0.81 while parity majority were 1-2 with 51.0%. During the basic selection we avoided cases that have Contraindications for Vacuum-Assisted Vaginal Delivery. The main contraindications were described byAlcolea Santiago et al. [8]. The absolute contraindications were nominated as the following; fetal bleeding disorders, fetal demineralizing diseases, failure to fulfill all the requirements for operative vaginal delivery and estimated gestational age less than 36 weeks or estimated fetal weight less than 2500 g.

Our basic maternal demographics was closely related to another study that assessed neonatal and maternal short-term outcome parameters in instrument-assisted vaginal delivery Polkowski et al. In that study, the total number of studied women was 149 and the age was distributed as 30.6 (17.2–42.6), BMI was distributed as 29.9 (21.5–48.3) and gestational age was distributed as 39.3 (33.7–42.3). Another study that analyzed predictors for failure of vacuum-assisted vaginal delivery (Verhoeven et al. 2016) conducted the study on a large number of women 618, BMI was distributed in a range between 20 and 30 while gestational age was distributed as 40 (37–42).

Moving to the point of pre procedure characters distribution among studied group, the current study demonstrated that the majority were occiput anterior then occiput posterior regarding head position and for indication, majority were fetal distress then mother exhaustion and finally prolonged 2nd stage of labor. These findings were closely related to another study on risk for cerebral complications in term newborn infants for vacuum assisted birth Ekéus et al. [9] where the majority were also anterior then posterior for position and for indication, most of cases were fetal distress then mother exhaustion came in the second place.

Procedure characters distribution among studied group of the current study showed that, the mean time of delivery was 28.47±8.7 and the duration of cup application was 10.55±3.78.

Moving to another point, the current study demonstrated mild maternal effort in the majority of cases. Traction was mild or moderate in 65 and 27 cases respectively which represents a percentage of 66% as a sum. Majority of cases had one pull while only 11.3% had three pulls. About 43.3% had episiotomy and vacuum detachment happened in 18.4% of cases while failure of vacuum happened only in 3.5% (5 cases) as the majority, 136 cases, did not experienced that failure.

To correlate the above data of the current study, parameters of a published study that questioned about neonatal complications in vacuum-assisted vaginal delivery and their association with number of pulls, cup detachments, and duration of vacuum application Ghidini et al. [10]. In that study total number of cases that showed no head injury was 483 (more than 90% of cases), the maternal age was 29.0 ± 6.0 and gestational age at delivery (weeks) was 39.6 ± 1.1. The Type of vacuum was Kiwi in 460 cases (95.2 %), the duration of vacuum application (in seconds) was 45

(30–75). About 215 cases (44.5 %) experienced episiotomy and the number of pulls was 2 (1-2).Another study that analyzed the impact of clinical practice guidelines for vacuum-assisted delivery on maternal and neonatal outcomes in Japan Egami et al.[11] studied 184 cases between 2015 and 2019. This study showed that the number of consecutive tractions was only one in 93 cases, 2-5 in 89 cases and more than five in only two cases.

Maternal outcome distribution among the studied group of the current study showed that 22% of cases had Perineal Tears, 17% had Post-partum hemorrhage and 17% had required blood transfusion. The literature has made clear that, compared to forceps,

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

vacuum-assisted delivery causes less maternal genital tract trauma, less blood loss, and requires less maternal analgesia. Recently, obstetric morbidity relating to postpartum pelvic floor damage and fecal incontinence has gained increasing attention Wang et al. [12]. In 2003, in a prospective, randomized clinical trial Fitzpatrick.[13] compared differences in anal sphincter function following vacuum- and forceps-assisted deliveries. Their results showed that, in the short term, significantly more women complained of altered continence following forceps delivery when compared with vacuum delivery. These findings were also echoed in the study Chaliha et al. [14] which found that 80% of women delivered by forceps developed sub-clinical sphincter defects, while no defects were identified after vacuum extraction.

An important study that analyzed the maternal outcome from vacuum, forceps and caesarean based delivery Polkowski et al. [15] showed that vacuum assisted delivery is a better option more that forceps assisted and caesarean based delivery regarding mother safety after delivery.

A valuable study that support vacuum assisted delivery regarding the maternal outcome is Chang et al. [16]. During that study period, 100 vacuum applications were performed on laboring women complicated with prolonged second stage of labor. Mean maternal age was 23.8 ± 6.4 years (range14–41 years) with 57% of patients were nulliparous. Left anterior and right posterior fetal positions were the most frequent (85% and 11%, respectively). Maternal complications included need for blood transfusion (1%), shoulder dystocia (1%) and perineal tears (first degree 6%, second degree 5%). Vaginal delivery was successful in 97% of cases.

Another study Levin et al. [17] confirmed the preference of vacuum assisted delivery regarding maternal outcomes. In that study, a small percentage of studied cases suffer from post-partum complications such as blood transfusion, hemorrhage, vaginal tears or perineal tears.

Another significant factor to judge the outcome of vacuum assisted delivery is fetal outcome distribution among studied group. In the current study, Baby weight was distributed as 3278.72±153.95 grams. Regarding APGAR 5 & 10, they were distributed as 7.43±1.0 and 8.60±1.13 respectively. Shoulder dystocia was found only in 17 cases (about 12.1%) while the other 124 cases did not experienced that. Another assessment had been occurred to neonatal injury, where only 11 cases were positive for this assessment while the remaining 130 cases did not experienced that and actually they were the majority of cases (92.2%).

Regarding the neonatal output of other studies, Among 913 successful vacuum-assisted in Simonson et al. [18], full-term deliveries, 25.7% were admitted to the neonatal intensive care unit. Scalp edema, cephalhematoma, and skull fracture were assessed by cranial radiography and were present in, respectively, 18.7%, 10.8%, and 5.0% of cases.

Vacuum procedures were attempted in 183 cases in Egami et al. [11] where Phototherapy for neonatal hyperbilirubinemia was performed in 75 (41%) of 183 deliveries with vacuum procedure, cephalohematoma occurred in 35 (19%), and umbilical artery pH <7.10 was observed in 10 (5.5%).

A total of 787 patients were studied for neonatal outcomes in Abbas et al. [19]. Cephalohematoma occurred in 23 (14.6%), Scalp laceration occurred in 6 cases and Subgaleal hematoma occurred only in two cases (1.3%).

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

A total of 1779 women attempted vacuum assisted delivery during study period of Krispin et al. [20]. Of them, in 146 (8.2%), the cup detached prior to delivery; 130/146 (89%) had a single detachment. After detachment, 4 (2.7%) delivered by cesarean section, 77 (52.7%) delivered after cup reapplication, and 65 (44.6%) delivered spontaneously. Neonates in the detachment group had higher rates of subarachnoid hematoma and composite neonatal birth trauma (2.7 vs. 0.1% and 4.8 vs. 1.8%, respectively).

As a final point of assessment in the current study, overall outcome distribution among studied group where analyzed. Complications occurred in 54 cases which represented 38.3% of the total number of cases. On the other hand, the majority of cases (61.7%) did not show any complications.

Another important analysis of the current study was the connection between complications with basic characters. Maternal age distribution of non-complicated outcome was 27.55±4.39 while that of complicated outcome was 30.01±3.95. Moving to the point of gestational age, age distribution of non-complicated outcome was 39.03±0.79while that of complicated outcome was 38.55±0.76. From these data, we can conclude that complicated cases significantly associated with older maternal age and lower gestational age.

In the current study, we also made a connection between complication and procedure characters. Complicated cases were significantly associated with longer duration of cup application and sever maternal effort and traction. Regarding duration of cup application, it was distributed as 9.62±3.05 and 12.05±3.75 for non-complicated and complicated cases respectively. Moving to the point of sever maternal effort, it was 9 and 41 for non-complicated and complicated cases respectively. And as a final point, traction severity was directly proportional with the complication occurrence in the studied cases as traction was mild in only 10 cases with complications and it was severe in 38 cases with complications. To explain that point, traction was mild in 55 cases with no complications and in 10 cases with complications. On the other hand, traction was severe in 11 cases with no complications and in 38 cases with complications.

5. Conclusion

Assisted delivery with a vacuum extractor rather than forceps seems to minimize fetal morbidity and mortality in addition to early and late maternal morbidity, including pelvic floor disease. Hence, applying a vacuum extraction device is a potential procedure for achieving favorable outcomes on mothers and neonates.

Funding: No funding was received for this study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. **Franz H, Erxleben C, Franz A, Hofmann R. (2012)** Prevention of labour-associated pelvic floor injuries-what is known for sure. Geburtshilfe und Frauenheilkunde.72(09):804-8.
2. **Baskett TF, Fanning CA, Young DC. (2008).** A prospective observational study of 1000 vacuum assisted deliveries with the OmniCup device. Journal of Obstetrics and Gynaecology Canada. 30(7):573-80.

ISSN:0975-3583,0976-2833 VOL12,ISSUE05,2021

3. **Spector JM, Lashoher A, Agrawal P, Lemer C, Dziekan G, Bahl R, et al. (2013).** Designing the WHO Safe Childbirth Checklist program to improve quality of care at childbirth. International Journal of Gynecology & Obstetrics.122(2):164-8.
4. **Nasir F, Hashim N, Hussain R, Soomro N. (2016).** Clinical evaluation of Kiwi omni cup: a new vacuum extraction device. Rawal Medical Journal.41(1):68-71.
5. **Wanyonyi SZ, Achila B, Gudu N. (2014).** Factors contributing to failure of vacuum delivery and associated maternal/neonatal morbidity. Int J Gynaecol Obstet. 115: 157-160.
6. **McQuivey RW, Block JE. (2017).** vacuum-assisted cesarean section. International journal of women's health. 9:151.
7. **Baskett TF. (2019).** Operative vaginal delivery-An historical perspective. Best Practice & Research Clinical Obstetrics & Gynaecology.56:3-10.
8. **Alcolea Santiago, J., Romero Nieto, I., Duro Gómez, J., Arenas Farrona, B., Guerra Vilches, V., Duro Gómez, J., De La Torre González, A. J., & Marín Martín, M. E. (2015).** Operative vaginal deliveries results in a reference hospital. Period 2006-2013. Journal of Perinatal Medicine.
9. **Ekéus, C., Högberg, U., & Norman, M. (2014).** Vacuum assisted birth and risk for cerebral complications in term newborn infants: A population-based cohort study. BMC Pregnancy and Childbirth.
10. **Ghidini, A., Stewart, D., Pezzullo, J. C., & Locatelli, A. (2017).** Neonatal complications in vacuum-assisted vaginal delivery are they associated with number of pulls, cup detachments, and duration of vacuum application Archives of Gynecology and Obstetrics.
11. **Egami, N., Muta, R., Korematsu, T., & Koga, H. (2020).** Mild neonatal complications following guideline-compliant vacuum-assisted delivery in Japan: improvements still needed. Journal of Maternal-Fetal and Neonatal Medicine.
12. **Wang, L. H., Seow, K. M., Chen, L. R., & Chen, K. H. (2020).** The health impact of surgical techniques and assistive methods used in cesarean deliveries: A systemic review. In International Journal of Environmental Research and Public Health.
13. **Fitzpatrick, M., Behan, M., O'Connell, P. R., & O'Herlihy, C. (2003).** Randomised clinical trial to assess anal sphincter function following forceps or vacuum assisted vaginal delivery. BJOG: an international journal of obstetrics and gynaecology, 110(4), 424-429.
14. **Chaliha, C., Sultan, A. H., Bland, J. M., Monga, A. K., & Stanton, S. L. (2001).** Anal function: Effect of pregnancy and delivery. American Journal of Obstetrics and Gynecology.
15. **Polkowski, M., Kuehnle, E., Schippert, C., Kundu, S., Hillemanns, P., & Staboulidou, I. (2018).** Neonatal and Maternal Short-Term Outcome Parameters in Instrument-Assisted Vaginal Delivery Compared to Second Stage Cesarean Section in Labour: A Retrospective 11-Year Analysis. Gynecologic and Obstetric Investigation.
16. **Chang, X., Chedraui, P., Ross, M. G., Hidalgo, L., & Peñafiel, J. (2007).** Vacuum assisted delivery in Ecuador for prolonged second stage of labor: Maternal-neonatal outcome. Journal of Maternal-Fetal and Neonatal Medicine.
17. **Levin, G., Rottenstreich, A., Shapira, M., Cahan, T., Yagel, I., Tsur, A., & Meyer, R. (2021).** Neonatal and maternal outcome of small-for-gestational-age neonates delivered by vacuum-assisted delivery. International Journal of Gynecology and Obstetrics.
18. **Simonson, C., Barlow, P., Dehennin, N., Sphel, M., Toppet, V., Murillo, D., & Rozenberg, S. (2007).** Neonatal complications of vacuum-assisted delivery. In Obstetrics and Gynecology.
19. **Abbas, R. A., Qadi, Y. H., Bukhari, R., & Shams, T. (2021).** Maternal and Neonatal Complications Resulting From Vacuum-Assisted and Normal Vaginal Deliveries. Cureus.
20. **Krispin, E., Aviram, A., Salman, L., Chen, R., Wiznitzer, A., & Gabbay-Benziv, R. (2017).** Cup detachment during vacuum-assisted vaginal delivery and birth outcome. Archives of Gynecology and Obstetrics.