VACUUM DELIVERY AT THE MATERNITY HOSPITAL KUALA LUMPUR: A COMPARISON OF METAL AND SILICONE CUPS

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ABSTRACT

Objective: To compare the advantages and disadvantages of the New Bird metal cups and silicone cups in terms of maternal and foetal outcome. To study the adverse effects and factors associated with failed vacuum deliveries.

Design: A prospective randomised study of all vacuum deliveries from 1 December 1991 to 31 April 1992. The Hanshin electrical vacuum pump was used.

Setting: A large obstetric unit - The Maternity Hospital Kuala Lumpur (MHKL).

Subjects: Seventy-two consecutive patients where vacuum deliveries were indicated. Forty had metal and 32 had silicone cups. Another 7 vacuum deliveries using the manual vacuum pump were excluded.

Main outcome measures: Success rate of vaginal delivery, birth canal injuries, post-partum haemorrhage, duration of hospital stay, Apgar score, foetal injuries (scalp-ecchymosis, haematomas) neonatal jaundice, the rate of special care nursery (SCN) admission and neonatal mortality rate.

Results: Failure to deliver with silicone cups alone was 21.9% compared to 10% for metal cups alone. Maternal morbidities and serious foetal scalp injuries were almost the same in both cups. However, minor foetal scalp injuries were significantly lower with silicone cups. Maternal height and baby's weight had no independent predictive values for successful vacuum delivery. When the foetal head was palpable per abdomen, the failure rate was 54.5% compared to 8.2% when it was not. Failed vacuum deliveries were associated with increased maternal and foetal morbidities.

Conclusion: Silicone cups and metal cups can be equally dangerous to the baby. Although our sample size was small, we recommend that vacuum delivery be avoided if the foetal head is palpable per abdomen.

Keywords: vacuum delivery, metal versus silicone cups

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INTRODUCTION

The original vacuum extractor was designed by Malmstrom and first used in Sweden in 1954[1]. The instrument quickly gained popularity until 1962 when Aguero and Alvarez reported cases of severe foetal scalp injuries associated with its use[2].

Following that, the Malmstrom vacuum extractor was extensively reevaluated[3-6] and various modifications were introduced. Soft cups were reported to have less foetal scalp injuries[7-10] whereas rigid cups were found to have higher success rates[7,8,11].

At the MHKL, both the rigid (metal) and the soft (silicone) cups were available. However, the choice was a matter of individual preference. No study has been done to compare the advantage of one cup over another in the local setting.

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MATERIALS AND METHOD

This prospective randomised study involved all patients scheduled for vacuum delivery from 1 December 1991 to 31 April 1992. Only singleton term pregnancies with vertex presentations were included. The accoucheurs were all registrars in training.

Allocation of vacuum cups was randomised by drawing a sealed envelope from a box. Hanshin electrical vacuum pump was used with either the New Bird 5 or 6cm diameter metal cup or the 6cm silicone cup.

The patient was put in the lithotomy position and the bladder was catheterised. The perineum was infiltrated with lignocaine 1% and a vaginal examination was done before the vacuum cup was inserted. As far as possible the vacuum cup was applied close to the posterior fontanelle in the midline.

An initial vacuum of 20cmHg was applied for 1 minute and the vaginal examination was repeated to rule out the inclusion of maternal tissues. The vacuum pressure was then taken up directly to 45 - 50cmHg.

A continuous and even traction (in synchrony with uterine contraction), using the accoucheur's body weight, was applied with the pulling elbow fully extended. The non-pulling fingers were applied on the foetal scalp to detect any leakage of seal. Episiotomy was done when the perineum threatend to tear.

The procedure was limited to 15 minutes or 2 vacuum cup reattachments or 4 pulls. When vacuum deliveries failed, forceps or Caesarean deliveries would be the alternatives depending on the individual case as decided by the accoucheur.

Immediately after delivery, details of the procedure were recorded in the study protocol. Antenatal and labour information

such as age, race, parity, height, cervical prostin ripening, liquor colour, vaginal examination findings were collected.

Apgar score and condition of the baby were assessed by the paediatrician on standby and blood loss was estimated by the attending midwife. Both the mother and the baby were followed up until discharge.

Epi Info version 5.01a March 1991 software was used for statistical analysis.

RESULTS

General

A total of 79 vacuum deliveries were done during the five-month period and these constituted 1.2% of the total deliveries (6,423). Seven cases using the manual vacuum pump (when the electrical one was not functioning) were excluded. Of the 72 cases analysed, 40 used metal cups and 32, silicone cups.

Indication - Table I

The commonest indication for vacuum deliveries was prolonged second stage, 91% of which were due to poor maternal effort. Foetal distress as an indication constituted 12.5% and 22% for metal and silicone cups respectively. The difference was not significant.

Table I – Indications for vacuum delivery

Indication	Metal (n=40)	Silicone (n=32)	p value
Prolonged 2nd stage	32 (80 %)	24 (75%)	NS
Foetal distress	5 (12.5%)	7 (22%)	NS
Pre-eclampsia	3 (7.5%)	1 (3%)	NS

NS - Not significant (p>0.05)

Maternal characteristics - Table II

Mean maternal age and height were similar for the two cups. The proportion of primigravida was slightly higher in the silicone group but statistically it was not significant.

Table II – Maternal characteristics

Variable	Metal (n=40)	Silicone (n-32)	p value
Race			
Malay	27 (67.5%)	15 (46.9%)	NS
Chinese	5 (2.5%)	5 (15.6%)	
Indian	6 (15.0%)	6 (18.0%)	
Others	2 (5.0%)	6 (18.0%)	
Mean age (years)	27 ± 5.4	26.6 ± 5.6	NS
Mean height (cm)	154.1 ± 5.5	155.6 ± 5.6	NS
Primigravida	23 (57.5%)	21 (65.6%)	NS

NS - Not significant (p>0.05)

Labour characteristics - Table III

Mean gestational age was almost 40 weeks for both and there was no significant difference in the onset of labour, use of prostin for cervical ripening and the finding of clear amniotic fluid at amniotomy in both the groups. More than 90% of the cases had full cervical dilatation when vacuum deliveries were done.

Twenty-five percent of patients in the silicone cup group had one-fifth palpable foetal head per abdomen compared to 7.5% in the metal cup group. The odds ratio of finding a palpable foetal head in the silicone cup group was 4.11 and the difference fell on the significance level itself (p=0.05).

Table III – Labour characteristics

	Metal (n = 40)	Silicone (n = 32)	p value
Mean period or gestation (weeks)	39.5 ± 1.5	39.6 ± 1.2	NS
Labour			
Spontaneous	31 (77.5%)	29 (90.6%)	NS
Induced	9 (22.5%)	3 (9.4%)	
Prostin ripening	2 (5.0%)	2 (6.3%)	NS
Clear liquor	31 (77.5%)	26 (81.3%)	NS
Full cervical dilataion	37 (92.5%)	30 (93.8%)	NS
Palpable foetal head per abdomen	3 (7.5%)	8 (25%)	0.05

NS = Not significant (p>0.05)

Foetal characteristics - Table IV

No significant difference was found in any of the variables although patients in the silicone cup group appeared to have less favourable station. None of the patients had caput of moulding of more than 2+. Vacuum cup attachment on the occipital region was achieved in 75% of the cases.

Table IV – Foetal characteristics

Variable	Metal (n =40)	Silicone (n = 32)	p value
Mean birthweight (kg)	3.14 ± 0.4	3.28 ± 0.4	NS
Station §			
0 or higher	2 (5.0%)	3 (9.4%)	NS
+1	15 (37.5%)	15 (46.9%)	
+2	23 (57.5%)	13 (40.6%)	
+3	0	1 (3.1%)	
Caput #			
2+	4 (10%)	1 (3.1%)	NS
1+	26 (65%)	26 (81.3%)	
0	10 (25%)	5 (15.6%)	
Moulding *			
2+	2 (5.0%)	1 (3.1%)	NS
1+	31 (77.5%)	22 (68.8%)	
0	7 (17.5%)	9 (28.1%)	
Site of chignon			
Anterior	1 (2.5%)	3 (9.4%) }	NS
Middle	9 (22.5%)	5 (15.6%) }	
Posterior	30 (75.0%)	24 (75.0%) }	

NB:§ Station - Distance of the foetal head below the ischial spine in cm.
Caput - 0 No caput
1+ < 3cm diameter
2+ 3-6cm diameter
3+ > 6cm diameter
* Moulding - 0 No moulding
1+ Narrowing of sutures
2+ Overriding of parietal bones but separable
3+ Overriding of parietal bones but not separable
NS = Not significant (p>0.05)

Procedure - Table V

Large metal cups (6cm) were used in only 7.5% of patients. Patients in the silicone cup group received more number of pulls and cup detachment was more common than in the metal cups group although statistically it was not significant. More than 90% of patients received local perineal infiltration with lignocaine 1% and episiotomy. The maximum vacuum pressure allowed in the protocol was used in 97% and 90% of silicone and metal cup groups respectively.

Table V – Procedure characteristics

Variable	Metal (n = 40)	Silicone (n = 32)	p value
Cup size			
Large (6cm)	3 (7.5%)	32 (100%)	< 0.005
Medium (5cm)	37 (92.5%)	0	
Episiotomy	39 (98%)	29 (91%)	NS
Local analgesia	37 (93%)	31 (97%)	NS
Traction Force *			
Mild	8 (20.0%)	9 (28.1%) }	NS
Moderate	31 (77.5%)	20 (62.5%) }	
Strong	1 (2.5%)	3 (9.4%) }	
No. of pulls applied			
3 or 4	6 (15%)	10 (31.2%)	NS
2	12 (30%)	7 (21.9%)	
1	22 (55%)	15 (46.9%)	
Median number of pulls applied	1	2	NS
Cup detachment			
Once or more	8 (20%)	8 (25%)	NS
Maximum vacuum pressure (50cmHg)	36 (90%)	31 (97%)	NS

* Accoucheur's subjective report.
NS = Not significant (p>0.05)

Procedure outcome - Table VI

The accoucheur subjectively reported that the procedure was easier with metal cups. The mean time taken to deliver the baby was comparable in the two groups.

Failure rate was 10% and 21.9% in the 2 groups with metal and silicone cups respectively.

Of the 4 cases where the metal cup had failed to deliver vaginally, 3(75%) required Caesarean sections. Following the failed metal cup delivery, 2 patients were subjected to forceps extraction. One was delivered vaginally whereas the other failed and required a Caesarean section. Forceps failure in this group was 50%.

On the other hand, of the 7 patients in whom silicone cup had failed to deliver, 5(71.4%) patients could still deliver vaginally (with the obstetric forceps). Six of the 7 patients had subsequent forceps extraction and vaginal delivery was achieved in 5 of them giving a forceps failure rate of 16.7%. Forceps delivery was only attempted in suitable cases decided by the accoucheur on clinical grounds.

Table VI – Procedure outcome

Variable	Metal (n = 40)	Silicone (n = 32)	p value
Subjective report*			
Easy procedure	32 (80%)	22 (69%)	NS
Difficult procedure	8 (20%)	10 (31%)	
Mean duration in mins. taken to deliver the baby (range)	7 (2 - 24)	6 (1 -13)	NS
Final delivery			
Vacuum	36 (90.0%)	25 (78.1%)	NS
Forceps	1 (2.5%)	5 (15.6%)	
LSCS	3 (7.5%)	2 (6.3%)	

* Accoucheur's subjective report on the vacuum delivery
LSCS = Lower segment Caesarean section
NS = Not significant (p>0.05)

Maternal outcome - Table VII

Maternal morbidities like birth canal injury, post-partum haemorrhage, post-partum pyrexia and prolonged hospitalisation did not differ significantly with the two cups. However, vaginal mucosal tears were higher (28.1%) with silicone cups than with the metal cups (17.5%).

There were two patients with third degree tears. Both the patients had metal cups for vacuum extraction. One of them was delivered by Neville Barnes forceps after a failed vacuum.

Two patients in the metal cup group had post-partum haemorrhage and both sustained birth canal injuries. One had a successful vacuum delivery whereas the other was delivered by Neville Barnes forceps. The third patient with post-partum haemorrhage was from the silicone cup group. There was no birth canal injury but vacuum delivery failed and Caesarean section was done.

Post-partum pyrexia of 38°C or more was present in two patients in the silicone cup group 24 hours after delivery. Both had Caesarean sections after failed vacuum deliveries. Mean hospital stay was comparable for the two cups. Sixty-eight percent of patients in the silicone cup group were discharged in less than 48 hours compared to 63% in the metal cup group. The difference was not significant.

Table VII – Maternal outcome

Variable	Metal (n = 40)	Silicone (n = 32)	p value
Vaginal mucosal tear	7 (17.5%)	9 (28.1%)	NS
Perineal extension/tear	12 (30.0%)	8 (25.0%)	NS
Anal tear	2 (5.0%)	0	NS
Post-partum haemorrhage (≥ 500 ml)	2 (5.0%)	1 (3.1%)	NS
Pyrexia (38°C) > 24 hrs	0	2 (6.3%)	NS
Hospital stay			
Mean (day)	1.7	1.8	NS
< 48 hrs	27 (67.5%)	20 (62.5%)	
48 - 72 hrs	10 (25.0%)	9 (28.1%)	
> 72 hrs	3 (7.5%)	3 (9.4%)	

NS = Not significant ((p>0.05)

Foetal outcome - Table VIII

Irrespective of the cup used, about one-third of the babies required some form of resuscitation at birth. Fifteen percent of the babies in the metal cup group developed neonatal jaundice compared to 6% in the silicone cup group. However, none of the babies required exchange transfusion.

There were two deaths and both were associated wth traumatic vacuum deliveries. One was a fresh stillbirth weighing 2.8 kg. It was delivered by Caesarean section after a failed silicone cup delivery. The baby was given three pulls and the attempt was abandoned after 13 minutes. The baby was found to have a subaponeurotic haematoma measuring 5cm x 5cm on the right parietal region.

The other death was a 3.2 kg baby delivered after four pulls with the metal cup. The indication was for prolonged second stage and intrapartum cardiotocograph was reactive. Apgar score was 6 at 1 minute and 8 at 5 minutes. There was a subaponeurotic haematoma measuring 4cm x 4cm over the right occipital region. The baby was pale at birth and was scheduled for blood transfusion but succumbed 3 hours later. A post-mortem lumbar puncture showed heavily blood stained cerebrospinal fluid suggestive of intraventricular haemorrhage.

Four babies in the metal cup group and one from the silicone

cup group were admitted to the special care nursery (SCN). All the five babies had either cephalhaematoma or subaponeurotic haematoma. Except for the neonatal deaths described above,the rest were discharged well from the SCN after 5-14 days.

Foetal scalp ecchymosis or abrasion was significantly more common with babies delivered by metal cups. However, they all healed well without treatment.

Incidence of cephalhaematoma or subaponeurotic haematoma was 15% with metal cups and 12% with silicone cups respectively.

Table VIII – Foetal outcome

Variable	Metal (n = 40)	Silicone (n = 32)	p value
Neonatal resuscitation*	14 (35.0%)	10 (31.0%)	NS
Neonatal jaundice	6 (15.0%)	2 (6.3%)	NS
5-min Apgar $\leq$ 6	0	1 (3.1%)	NS
Laryngeal intubation	1 (2.5%)	0	NS
SCN admission	4 (10.0%)	1 (3.1%)	NS
Scalp ecchymosis/ abrasion	24 (60.0%)	9 (28%)	0.013
Cephalhaematoma/ subaponeurotic haematoma	6 (15.0%)	4 (12.0%)	NS
Number of death	1 (2.5%)	1 (3.1%)	NS

* Face oxygen, bagging or intubation
NS = Not significant ((p>0.05)

Successful versus failed vacuum cases (Tables IXa, b, c)
Comparing successful and failed vacuum deliveries, we found no significant difference in maternal height and the baby's weight (Table IXa). The mean maternal height and the baby's weight were comparable irrespective of the foetal head engagement (Table IXb). However foetal head engagement was highly significant in relation to a successful vacuum delivery. On the other hand, a palpable foetal head was not related to the failure or success of vaginal delivery as a whole.

Patients with failed vacuum delivery had significantly higher frequency of a palpable foetal head per abdomen and a higher station. The failure rate was 54.5% when the foetal head was one-fifth palpable and 8.2% when it was not palpable at all.

Babies of failed vacuum deliveries received a higher number of scalp tractions (pulls) and the incidence of cup detachment was significantly higher.

Apgar score at one minute of less than 7 was significantly more frequent when vacuum deliveries failed. However at five minutes there was no difference in Apgar score.

Incident of cephalhaematoma or subaponeurotic haematoma was very much increased, from 6.6% to 54.5% when vacuum deliveries failed. There were two foetal deaths and both were attributable to traumatic deliveries. Neonatal jaundice and SCN admission were also increased although not statistically significant.

Maternal morbidities like birth canal injuries or post-partum haemorrhage were about the same irrespective of the outcome. However, post-partum pyrexia of 38°C or more and maternal hospitalisation of more than 48 hours were increased with failed vacuum deliveries.

DISCUSSION

Vacuum deliveries with silicone cups appear to be a more difficult skill to master. Various reports have shown that its failure rate is

Table IXa – Successful versus failed vacuum cases – Maternal, foetal and labour characteristics

Variable	Successful (n=61)	Failed (n=11)	p value
Maternal			
Mean height (cm)	154.8 ± 5.5	154.6 ± 5.7	NS
Primigravida	35 (57.4%)	9 (81.8%)	NS
Labour			
Prolonged 2nd stage as indication	46 (75.4%)	8 (72.7%)	NS
Spontaneous	51 (83.6%)	9 (81.8%)	NS
Cervical os < 10cm	3 (4.9%)	2 (18.2%)	NS
Palpable foetal head per abdomen	5 (8.2%)	6 (54.5%)	0.02
Foetal			
Mean birth weight (kg)	3.21 ± 0.4	3.20 ± 0.4	NS
Male sex	36 (59.0%)	5 (45.5%)	NS
Station O or higher	1 (1.6%)	4 (36.4%)	0.0014
Caput > 2+	5 (8.2%)	0	NS
Moulding > 2+	3 (4.9%)	0	NS
Position §			
OA or OP	11 (18.0%)	2 (18.2%) }	
Oblique	12 (19.7%)	2 (18.2%) }	
OT	36 (59.0%)	5 (45.4%) }	NS
uncertain	2 (3.3%)	2 (18.2%) }	

§ OA- Occipito - anterior
OP - Occipito - posterior
OT - Occipito - transverse
NS = Not significant ((p>0.05)

Table IXb – Maternal height and baby's weight in relation to foetal head engagement

	foetal head	
	non palpable (n=61)	palpable (n=11)
Mean maternal height (cm)	154.4 ± (5.5)	156.6 ± (5.7)
Mean baby's weight (kg)	3.2 ± (0.4)	3.2 ± (0.5)

1.5 to 12 times higher than metal cups[7,8,11] (Table X).

This could be attributed to the tenting effect of the cup on traction. Besides, traction force allowed by the soft cup has also been found to be significantly lower than that permitted by the metal cup[7]. Consequently, cup detachment and failure to achieve vaginal delivery occur more commonly.

Failure of vacuum vaginal deliveries - Table X
In this study we found that failure rate with silicone cups was 21.9%, twice the rate of metal cups (10%). This finding appears to conform to previous reports. However detailed analysis revealed that 25% of the patients in the silicone cup group had palpable foetal heads as compared to only 7.5% in the metal cup group despite randomisation.

Hofmeyr in 1990[7] and Hammarmstrom in 1986[11] had not mentioned the amount of palpable foetal head per abdomen when they reported that soft cups had a higher failure rate.

In this study we have analysed it in addition to station, moulding, caput, and numerous other factors (Table IXa) which could possibly affect the outcome of a successful vaginal delivery.

Contrary to popular belief, foetal weight and maternal height analysed separately, were found to have no bearing on a successful vacuum delivery.

Table IXc – Successful versus failed vacuum cases – Procedure and outcome

Variable	Successful (n=61)	Failed (n=11)	p value
Procedure			
Large cup (6 cm)	28 (45.9%)	7 (63.6%)	NS
Traction force (Moderate to strong)	44 (72.1%)	11 (100%)	NS
2 pulls or more	10 (16.4%)	6 (54.5%)	0.001
Cup detachment	7 (11.5%)	9 (81.8%)	< 0.001
Max vacuum (50cmHg)	56 (91.8%)	11 (100%)	NS
Outcome			
Maternal			
Vaginal tear	12 (19.7%)	4 (36.4%)	NS
Perineal tear	19 (31.1%)	1 (9.1%)	NS
Anal tear	1 (1.6%)	1 (9.1%)	NS
PPH* (≥ 500 ml)	1 (1.6%)	2 (18.2%)	NS
Pyrexia #	0	2 (18.2%)	0.02
Hosp. stay < 48 hrs	57 (93.4%)	6 (54.5%)	0.003
Foetal outcome			
Apgar 1 min < 7	6 (9.8%)	4 (36.4%)	0.039
Apgar 5 min < 7	0	1 (9.1%)	NS
Neonatal jaundice	6 (9.8%)	2 (18.2%)	NS
SCN admission	3 (4.9%)	2 (18.2%)	NS
Cephalhaematoma/ Subaponeurotic haematoma	4 (6.6%)	6 (54.5%)	0.0005
Death	1 (1.6%)	1 (9.1%)	NS

* PPH - Post-partum haemorrhage
# Pyrexia of at least 38°C and 24 hours after delivery
NS = Not significant ((p>0.05)

The only factor of predictive value was the foetal head engagement which was measured by the amount of palpable foetal head per abdomen and station. A palpable foetal head per abdomen was associated with a 54.5% failure rate compared to 8.2% when it was not (p=0.02).

With a higher number of women having palpable foetal heads in the silicone cup group, the higher failure rate observed may not be true. It appears that randomisation of patients alone without taking into consideration the amount of palpable foetal heads per abdomen might not be adequate, especially with small sample size.

A recent study in Nepal where metal and silicone cup patients had statistically similar foetal engagement reported their failure rate as 13% and 15% respectively. However, the author cautioned that when there was excessive caput, the silicone cup tended to fail more frequently[9].

Although the incidence of cup detachments was about the same for both, there was evidence that traction force allowed by the silicone cup was lower. This probably explains why using the same standard protocol, 71% of failed silicone cup deliveries could still be delivered vaginally (by forceps) in contrast to only 25% when the metal cup failed.

There was no significant difference in maternal morbidities with the two cups although vaginal mucosal injury was higher with silicone cups (28.1%) compared to metal cups (17.5%). This is probably due to its larger diameter.

Significant foetal scalp injuries - Table XI

Foetal scalp ecchymosis or abrasion was significantly higher with metal cups, due to their rigid edges and the stronger traction force permitted. SCN admission was higher with metal cups and more babies developed neonatal jaundice although statistically they were not significant.

Table X – Failure of vacuum vaginal deliveries

Study	Metal cup (n)	Metal cup (%)	Soft cup (n)	Soft cup (%)
1986 Hammarmstrom[11]	1/50	2	9/50	18
1989 Cohn el al[8]	13/127	10	21/131	16
1990 Hofmeyr et al[7]	0/18	0	3/13	23
1991 Present study	4/40	10	7/32	21.9

Contrary to previous reports[7-9, 11] (Table XI), we found silicone cups could be equally dangerous to the foetus. They were equally capable of causing cephalhaematomas, 12% compared to 15% with metal cups. It was unfortunate that there were two foetal deaths associated with the vacuum delivery, one in each group.

Table XI – Significant foetal scalp injuries (Cephalhaematoma, subaponeurotic haematoma or serious lacerations)

Study	Metal cup (n)	Metal cup (%)	Soft cup (n)	Soft cup (%)
1986 Hammarmstrom[11]	6/50	12	2/50	4
1989 Cohn el al[8]	23/127	18	18/131	14
1990 Hofmeyr et al[7]	1/18	6	0/13	0
1992 Rashna et al[9]	37/98	38	22/101	22

CONCLUSION

Both the silicone and metal cups had comparable maternal morbidities except that silicone cups had a slightly higher incidence of vaginal mucosal tears, probably due to its larger diameter.

While silicone cups might have a lower incidence of minor foetal scalp injuries (scalp ecchymosis or abrasion), they did not save babies from serious injuries. Incidence of cephalhaematoma or subaponeurotic haematoma was comparable to metal cups.

Unlike Berkus et al[12], we found that failed vacuum deliveries are not without risk to the baby and mother. Table XI showed that our results support the finding of Cohn et al[8] and Rashna et al[9] that silicone cups can also result in significant foetal morbidity.

Although the number of subjects in this study was only 72, we feel that vacuum delivery is best avoided when the foetal head is palpable per abdomen. If the head is palpable, the possibility of failure is very high and following a failed vacuum delivery, both the maternal and foetal morbidities are significantly increased.

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