Vacuum Extraction: A Comparison Of The Performance Of Instruments

R Aapkes, I van der Tweel, K Deurloo

Citation

R Aapkes, I van der Tweel, K Deurloo. *Vacuum Extraction: A Comparison Of The Performance Of Instruments*. The Internet Journal of Gynecology and Obstetrics. 2017 Volume 21 Number 1.

DOI: 10.5580/IJGO.47001

Abstract

The aim of this study is to retrospectively compare the effectiveness of three vacuum extractors, Mystic pump (MP) (Coopersurgical Inc), Kiwi omnicup (Clinical Innovations Inc) (soft cups), and the conventional metal cup (Medela Inc).

All women requiring a ventouse delivery in our hospital, from October 2012 to January 2014 were included. Demographics and labor details were collected. Primary we analyzed successfulness of the instruments, secondary maternal and neonatal morbidity.

We included 278 vacuum deliveries with conventional cup, 34 with Kiwi omnicup and 51 with MP. We found no significant differences in failure rates (conventional 7.6%, Kiwi 14.7%, MP 3.9%, p= 0.19). In the MP group, the number of tractions is significantly less. Rates of maternal or neonatal morbidity were very low and similar in both groups.

In conclusion, all three vacuum extractors have high effective rates, although MP seems to require a lower number of tractions for successful delivery.

INTRODUCTION

Vacuum extraction is indicated when vaginal delivery needs to be assisted or accelerated in the second stage of labor (Chalmers and Chalmers 1989). The rate of instrumental vaginal delivery (ventouse and forceps) in different countries varies between 10 and 13% (Bahl et al. 2010). In the Netherland, the rate of instrumental vaginal delivery by woman delivering in a secondary hospital was 12,2% in 2013 (Brouwers et al. 2015).

Since the development, the vacuum extractor (or ventouse) is more frequently used for assisted vaginal delivery, due to its decreased risk of maternal morbidity compared with forceps (Miksovsky and Watson 2001). More recently, the soft cup vacuum extractors were developed and introduced in a clinical setting. There is contradicting evidence regarding the benefits of soft cups in comparison with metal cups. Some literature reports present higher success rates of the metal cups (OR 1.63, 95% CI 1.17-2.28) (O'Mahony et al. 2010). However, the soft cups seem potentially safer than metal cups, especially looking at fetal morbidity as cephalhaematoma or scalp injury (O'Mahony et al. 2010).

The number of studies comparing effectiveness of different kinds of soft cups is limited.

Therefore, the aim of this study was to compare three different and frequently used types of vacuum extractors, two soft cups (the Mystic pump, mushroom cup (MP) (Coopersurgical Inc, Trumbull) and the Kiwi omnicup (Clinical Innovations Inc, Salt Lake City) and the conventional metal cup (Medela Inc, MCHenry). Primary outcomes were the failure rate of the instruments. Secondary we compared the maternal and neonatal morbidity between the different instruments.

MATERIAL AND METHODS

This retrospective research was performed in the Diakonessenhuis Utrecht, a large secondary teaching hospital. Data was collected using our validated hospital medical database. Informed consent for anonymous use of medical data was obtained from all included patients at first contact. The ethical committee of the Diakonessenhuis stated that the current study did not fall within the purview of the Medical Research Involving Human Subjects Act.

Therefore, it was possible to conduct the study without approval by an accredited research ethics committee. All data were double checked by comparing them to the actual medical status. All deliveries from October 2012 till January 2014 were collected.

All deliveries were performed by trained and skilled obstetricians. Vacuum extraction was performed to accelerate delivery, when necessary for maternal or fetal wellbeing, such as non-progressive labour. Three instruments could be chosen for assisted vaginal delivery: the Mystic pump and Kiwi omnicup, both soft cups, or a conventional metal cup. The instrument of choice was based upon experience, preference and clinical assessment of the obstetrician.

Three instruments for vacuum delivery were used. The MP is a relatively recent handheld vacuum device, with a mushroom-shaped cup and a flexible stem, which flexes up to 90º in any direction to facilitate use in non-occiput anterior positions. It reaches a 580mmHg negative pressure. The kiwi omnicup is a more well-known device, a handheld model with flexible stem and a low-profile cup, reaching a 600mmHg negative pressure. The conventional cup is a device developed in the 50's, with a metal cup connected to a pump system, reaching an 600mmHg negative pressure.

All instruments were used according to the manufacturer's guidelines. The bladder was emptied and patient was placed in dorsal lithotomy position. Position and the station (at least Station 0) of the fetal head were assessed, after which the cup was placed as close as possible at the flexion point. After verification of the correct placement of the cup, vacuum was created gradually by increasing suction until a negative pressure of 600 mmHg for the conventional cup, 580 mmHg for the MP and 600 mmHg for the Kiwi was reached. Traction was given simultaneously with the uterus extraction and pushing of the mother. Routine use of medio lateral episiotomy was advocated (Jango et al. 2014). The maximum number of tractions was three. After three pulls ceasarion section was strongly considered according to the guidelines of the dutch gynaecologist and obstretrian board (NVOG). Only in highly exceptional cases, more tractions were done. Extraction failed when the cup was detached 2 times or no progress was made.

In- and exclusion criteria

Data were identified and collected by one researcher (RA). In a few cases, there was a change of instrument during the vacuum extraction procedure, due to a prompt instrument defect. When there was a multiple use of instruments during the delivery, only the first used instrument is taken in to account, and noted as a failed vacuum extraction. We excluded premature deliveries (GA < 37 weeks) and multiple pregnancies.

BACKGROUND AND OUTCOMES

Patient characteristics were assessed: parity, maternal age, obstetrical history, BMI, gestational age at time of delivery, birth weight and specifics about the delivery (anaesthetics, spontaneously onset or induction, oxytocin use). Characteristics of the vacuum extraction, type, position of the head, number of tractions, cup detachments and failure rate) were included. Failure rate is described as no successful delivery with de chosen instrument, leading to a caesarean delivery. Perineal lacerations, as classified by Sultan et al (Sultan and Thakar 2002) were described: moderate lacerations includes grade 1 and 2 lacerations (rupture of skin or skin and perineum) and severe laceration includes grade 3 and 4 lacerations (perineum and anal sphincter of perineum, anal sphincter and anal mucosa). Neonatal complications includes Apgar scores, pH value umbilical cord artery, trauma and clinical admittance.

Statistics

Statistical analysis was performed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA). Results were analysed using the Chi-square test, Kruskal-Wallis test and ANOVA test. A two-sided p-value less than 0.05 was considered statistically significant.

RESULTS

A total of 2825 deliveries were identified. After exclusion, 363 (13%) vacuum extractions were included in our analysis: 278 in the conventional metal cup group, 34 in the Kiwi group and 51 in the Mystic Pump group. In three cases, there has been a switch of vacuum extraction instrument, twice from Kiwi to conventional, once from MP to Kiwi. In all the three cases the reason for replacement by another instrument was a defect instrument, there was no suspected cephalopelvic disproportion. All three times delivery was successfully performed by the second instrument tried with. Only the vacuum extraction with the first instrument is taken in to account.

There were no significant differences in demographics (Table I) or in labor details between the three groups of the study population (Table II). Most of the included patients are

nulliparous, with normal body mass indices who were in spontaneous labor.

No statistically significant differences in the failure rates of the vacuum extraction between the groups were found (Table III). The highest failure rate is in the Kiwi group, with also the highest detachment percentage, although both not significant. The number of tractions is significantly decreased in the MP group.

There were four cases of neonatal trauma, two clavicular fractures, one scalp injury and one small subdural hematoma. All neonates recovered without any long-term injury. There were no casus of subgaleal hemorrhage or cephalohematoma. There were no significant differences in maternal and neonatal outcome variables (Table IV).

Table 1

Demographics details of study population

Patient characteristics	Conventional cup N=278	Kiwi Omnicup N=34	Mystic Pump N=51	p- value
Parity % nulliparous % multiparous	 89.6 10.4	 80.0 20.0	 96.1 3.9	 0.05
Mean maternal age	31.8 SD 4.0	31.8 SD 4.0	31.6 SD 3.9	0.94
Mean maternal BMI (%) <18.5 18.5-25 25-30 30-40 >40	(N=207/278) 28,1 48,9 13,3 9,0 0,7	(N=23/34) 38,2 47,1 8,8 5,9 0	(N=34/51) 33,3 56,9 9,8 0 0	 0,4
Obstetrical history % Cesarean delivery % Vacuum extraction	 5.7 2.1	 2.9 3.8	 2.0 2.0	 0.44 0.08
Mean gestation at delivery (days)	281.3 SD 8.5	281.4 SD 9.8	283.1 SD 8.3	0.39

Missing data are described as N= (nr identified/ total nr of chosen instrument)

Table 2

Labor details of study population

Delivery characteristics	Conventional cup N=278	Kiwi Omnicup N=34	Mystic Pump N=51	p- value
Mean birth weight (gram)	3508 SD 428	3640 SD 498	3447 SD 431	0.13
Median duration of 2nd stage of labor (minutes) (IQR)	67 31-96	63 39-90	53 34-89	0.44
Reason for ventouse % fetal distress % maternal conditions	 52.5 47.5	 55,9 44,1	 52.9 47.1	 0.93
Analgesia used (%)	60.4	50.0	45.1	0.08
Spontaneously start of labor (%)	83.1	82.9	78.4	0.65
Use of oxytocine (%)	74.8	70.6	68.6	0.60
Caput position at moment of cup application* % occiput anterior % occiput posterior % other	(N=143/278) 62.9 25.2 11.9	(N=19/34) 73.7 10.5 15.8	(N=16/51) 50.0 31.3 18.7	 0.51

Missing data are described as N= (nr identified/ total nr of chosen instrument)
*determined by transcervical examination

Table 3

Primary outcomes

Vacuum extraction – Primary outcomes	Conventional N=278	Kiwi Omnicup N=34	Mystic Pump N=51	p-value
% Failure rate (no delivery by chosen instrument)**	7.6	14.7	3.9	0.19
Number of tractions % ≤ 2 tractions % >2 and <4 tractions % ≥ 4 tractions	(N=276/278) 63.8* 27.9* 8.3*	(N=34/34) 73.5 17.6 8.8	(N=49/51) 89.8* 10.2* 0*	 0.01
% Detachments	10.4	14.7	13.7	0.65
% Other problems**	6.8	5.7	5.9	0.95

Missing data are described as N= (nr identified/ total nr of chosen instrument)
* Significant difference in mean number of tractions between Conventional cup and MP, p= 0.001
** Slipping of the cup, or defect or incomplete instrument

Table 4

Secondary outcomes: maternal and neonatal morbidity

Vacuum extraction – Secondary outcomes	Conventional N=278	Kiwi Omnicup N=34	Mystic Pump N=51	p-value
Perianal trauma % none % moderate % severe	 68.7 24.1 7.2	 73.5 11.8 14.7	 68.6 25.5 5.9	 0.32
Apgar score % ≤7 1 minute after delivery % ≤7 5 minutes after delivery	 16.5 5.8	 17.6 5.9	 7.8 0	 0.27 0.21
Blood gas analyses % venous <7.1 % arterial <7.1	 4.7 (N=240/278) 6.8 (N=209/278)	 5.9 (N=32/34) 14.7 (N=26/34)	 3.9 (N=44/51) 9.8 (N=39/51)	 0.94 0.22
Need for neonatal admittance (%)	9.4	11.8	5.9	0.62

Missing data are described as N= (nr identified/ total nr of chosen instrument)

DISCUSSION

This is the first report comparing the effectiveness of three commonly used vacuum extractors, including a relatively knew and unknown soft cup, the Mystic Pump. No significant differences are found between the three different cups concerning failure rate, cup detachments, and maternal or fetal morbidity. All of the extractors seem to be highly successful in achieving successful assisted vaginal delivery, although MP requires a lower number of tractions.

The lower amount of tractions required in het MP group is remarkable and has not been described before. This suggests that the MP is a more preferable instrument, due to its comparable success rate with significantly less traction needed. However, due to the retrospective nature of this study, we cannot rule out the influence of the station of the caput at the moment of cup application on the number of tractions or success rate.

Success rates described in this article are similar or higher compared to other literature (O'Mahony et al. 2010). Attilakos et al. and Groom et al. studied the effectiveness of the ‘standard vacuum cup’ to the newer rigid plastic cup (Kiwi omnicup in both studies)in a randomized setting (Attilakos et al. 2005;Groom et al. 2006). In the Attilakos study, among 194 deliveries, the failure rates were 34% for the ‘standard vacuum cup’ versus 21% for the kiwi omnicup

(adjusted OR 2.3 (1.01–5.0))(Attilakos et al. 2005). These are higher rates than our data (3.9-14.3%), but most of the cups were placed when the fetal caput was still high in the birth-canal, at spines (kiwi ommicup 13%, standard cup 11%) or at station spine+1 (out of three) (kiwi omnicup 61%, standard cup 55%).

Groom et al., also noticed a significant difference in failure rate in favour of the standard vacuum cup, 30.1% (standard cup) versus 19.2% (Kiwi omnicup) (RR 1.58; 95% CI 1.10–2.24)(Groom et al. 2006), in a study including 404 patients. The higher failure rate is related to a higher number of cup detachments in the Kiwi omnicup group. Remarkable, only looking at the vacuum extractions from a station ≥ 2, in Grooms et al the failure rates are comparable (20.3 Kiwi omnicup group, 20.9 standard vacuum group, RR 0.97 (95% CI 0.51–1.84)).

Turkmen shows in a retrospective cohort study, as well as our data, no difference in maternal and fetal outcomes and failure rates between Kiwi and Metal cup (Turkmen 2014), even as Ismael et al. They have a vacuum extraction success rate of 100% in both groups (Ismail et al. 2008), possible partly by a lower overall rate of assisted vaginal delivery (8.2%) and a higher forceps rate (27%).

The only study found which included an instrument of mitysoft, as our mystic pump, was the study performed by Bothuyne-Queste (Bothuyne-Queste et al. 2009). It shows a smaller success rate of the mitysoft bellcup compared with the Kiwi omnicup (failure rates 31.3% versus 12.8%) (Bothuyne-Queste et al. 2009). Instead of a bellcup we used a mushroom cup, which could explain the improved success rate in our study. A mushroom style cups generate a greater traction force than Bellcups (Muise et al. 1993). Therefore, they are less likely to slip or release of the fetal head, which is related to failure of the vacuum extraction.

In interpreting our results, we acknowledge the fact that the retrospective design of this study did not enable us to reveal the true motivation by the clinician to choose the allocated instrument.

There is only a small trend to a higher maternal BMI in the conventional group (p=0.06), caused by a few outlying BMI values: two women had a BMI of 50, five women had a BMI higher than 35. In labor details, there are a lot of missing data in the variable ‘caput position at moment of cup application’ (occiput anterior, occiput posterior etc.) (table II). All three vacuum extraction instruments are suitable for the different caput positions.

This study includes the MP, a new design vacuum extractor. Little research had been done with this tool and only few data is available. A variety of possible important variables were taken in to account. The well-trained obstetricians strengthen this research, especially because of the high rates of inappropriate placement of the cup mentioned in literature (Sau et al. 2004).

CONCLUSION

In conclusion, the conventional metal cup, the kiwi omnicup and the mystic pump seem to be very safe instruments with high success rates in vacuum assisted vaginal delivery. MP seems to be slightly more effective in terms of number of tractions with very low failure rates as well. Randomized controlled trials and long term research should further elucidate the advantages and disadvantages of vacuum extractors, which is the aim of future research. For the moment, we advise that the instrument of first choice should be determined by the preference and experience of the obstetrician and individualized according to the current clinical situation.

References

1. Attilakos G, Sibanda T, Winter C, Johnson N, Draycott T. 2005. A randomised controlled trial of a new handheld vacuum extraction device. BJOG 112: 1510-1515
2. Bahl R, Strachan BK, Murphy DJ. 2011. Royal College of Obstetricians and Gynaecologists. RCOG. Operative vaginal delivery. Green-top Guideline No. 26.
3. Bothuyne-Queste E, Deruelle P, Closset E, Depret S, Subtil D. 2009. Comparative study of two single-use vacuum extractor. J.Gynecol.Obstet.Biol.Reprod 38: 149-154
4. Brouwers HAA, Bruinse HW, Dijs-Elsinga J, van Huis AM, de Miranda E, Tamminga P. 2013. Perinatale Zorg in Nederland. http://www.perinatreg.nl/uploads/150/153/PRN_jaarboek_2013_09122014.pdf (19-2-2016)
5. Chalmers JA, Chalmers I. 1989. The obstetric vacuum extractor is the instrument of first choice for operative vaginal delivery. Br.J.Obstet.Gynaecol. 96: 505-506
6. Groom KM, Jones BA, Miller N, Paterson-Brown S. 2006. A prospective randomised controlled trial of the Kiwi Omnicup versus conventional ventouse cups for vacuum-assisted vaginal delivery. BJOG 113: 183-189
7. Ismail NA, Saharan WS, Zaleha MA, Jaafar R, Muhammad JA, Razi ZR. 2008. Kiwi Omnicup versus Malmstrom metal cup in vacuum assisted delivery: a randomized comparative trial. J.Obstet.Gynaecol.Res. 34: 350-353
8. Jango H, Langhoff-Roos J, Rosthoj S, Sakse A. 2014. Modifiable risk factors of obstetric anal sphincter injury in primiparous women: a population-based cohort study. Am.J.Obstet.Gynecol. 210: 59-66
9. Miksovsky P, Watson WJ. 2001. Obstetric vacuum extraction: state of the art in the new millennium. Obstet.Gynecol.Surv. 56: 736-751

10. Muise KL, Duchon MA, Brown RH. 1993. The effect of artificial caput on performance of vacuum extractors. Obstet.Gynecol. 81: 170-173
11. O'Mahony F, Hofmeyr GJ, Menon V. 2010. Choice of instruments for assisted vaginal delivery. Cochrane.Database.Syst.Rev. 11: CD005455
12. Sau A, Sau M, Ahmed H, Brown R. 2004. Vacuum extraction: is there any need to improve the current training in the UK? Acta Obstet.Gynecol.Scand. 83: 466-470
13. Sultan AH, Thakar R. 2002. Lower genital tract and anal sphincter trauma. Best.Pract.Res.Clin.Obstet.Gynaecol. 16: 99-115
14. Turkmen S. 2015. Maternal and neonatal outcomes in vacuum-assisted delivery with the Kiwi OmniCup and Malmstrom metal cup. J.Obstet.Gynaecol.Res 41: 207-13

Author Information

R.R. Aapkes, MD
Department of Gynecology and Obstetrics, Diakonessenhuis Utrecht
Utrecht, The Netherlands

I. van der Tweel, PhD
Department of Biostatistics and Research Support, Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht
Utrecht, The Netherlands

K.L. Deurloo, MD PhD
Department of Gynecology and Obstetrics, Diakonessenhuis Utrecht
Utrecht, The Netherlands