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ORIGINAL ARTICLE

Influence of introducing a maneuverable vacuum extractor cup on maternal hospital stay after instrumental birth. Retrospective cohort study

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Abstract
Objectives: The aim of our study is to evaluate the impact of the introduction of a maneuverable vacuum extractor cup on the length of hospital stay after assisted vaginal birth in nulliparous women in a hospital where no vacuum devices were used.
Methods: This single center retrospective analytical study included two groups of nulliparous women who had undergone an assisted vaginal birth. The 2 groups differ according to the availability or not of a maneuverable vacuum extractor cup. The first group includes the last 54 instrumental births until May 2017, when only obstetric forceps and Thierry's spatulas were available in our center; the second group includes the first 54 instrumental births since May 2018 in our center, when obstetric forceps, Thierry's spatulas and maneuverable vacuum extractor cup were available. Maneuverable vacuum extractor cups had been available for 12 months in the second group.
Results: In the no vacuum cup group, Kjelland forceps and Thierry's spatulas were used in 29 (53.7%) and 25 (46.3%) of the 54 assisted vaginal births, respectively. In the vacuum available group, a vacuum cup was chosen in 30 (55.6%), Kjelland forceps were used in 18 (33.3%) and Thierry's spatulas in 6 (11.1%) of the assisted vaginal births. 22 women (40.7%) had a postpartum hospital stay longer than 3 days in the group with no maneuverable vacuum extractor cup availability, versus 3 women (5.6%) in the group with availability of a maneuverable vacuum extractor cup, $p < 0.001$. Average postpartum hospital stay length was 3.17 ± 0.803 days versus 2.81 ± 0.585, $p < 0.001$. There was also a significant reduction in the number of episiotomies.
Conclusion: The introduction of a maneuverable vacuum extractor cup in a center where only forceps and Thierry's spatulas had been used resulted in a decrease in postpartum hospital stay in nulliparous women.

Abbreviations: OASIS, obstetric anal sphincter injuries; BMI, body mass index.

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PALABRAS CLAVE
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Ventosa obstétrica;
Desgarros perineales obstétricos

Repercusión de la introducción de la ventosa obstétrica maniobrable en un centro hospitalario sobre la estancia materna tras parto instrumental. Estudio de cohortes retrospectivo

Resumen
Objetivos: El objetivo de nuestro estudio es evaluar el impacto de la introducción de una ventosa obstétrica con cazoleta maniobrable en la duración de la estancia hospitalaria tras parto instrumental en mujeres nulíparas en un hospital donde no se utilizaban ventosas obstétricas.
Métodos: Este estudio de cohortes retrospectivo unicéntrico incluyó 2 grupos de mujeres nulíparas sometidas a parto instrumental. Los 2 grupos se diferencian según la disponibilidad o no de ventosa obstétrica en el centro. El primer grupo se compone de las últimas 54 mujeres a las que se les asistió un parto instrumental hasta mayo del 2017, cuando solo había disponibilidad de fórceps obstétricos y espátulas de Thierry en nuestro centro; el segundo grupo se compone de las primeras 54 mujeres a las que se les asistió un parto instrumental desde mayo del 2018 en nuestro centro, cuando había disponibilidad de fórceps obstétricos, de espátulas de Thierry y de ventosa obstétrica con cazoleta maniobrable (esta última desde hacía 12 meses).
Resultados: En el grupo sin disponibilidad de ventosa obstétrica, se utilizaron fórceps de Kjelland y espátulas de Thierry en 29 (53,7%) y 25 (46,3%) de los 54 partos instrumentales, respectivamente. En el grupo con disponibilidad de ventosa, se usó la ventosa en 30 (55,6%), fórceps de Kjelland en 18 (33,3%) y espátulas de Thierry en 6 (11,1%) de los partos instrumentales; 22 mujeres (40,7%) tuvieron una estancia hospitalaria tras el parto mayor de 3 días en el grupo sin disponibilidad de ventosa, frente a 3 mujeres (5,6%) en el grupo con disponibilidad de ventosa, $p < 0{,}001$. La duración media de la estancia hospitalaria tras el parto fue de $3{,}17 \pm 0{,}803$ días frente a $2{,}81 \pm 0{,}585$, $p < 0{,}001$. También hubo una reducción significativa en el número de episiotomías.
Conclusión: La introducción de una ventosa obstétrica con cazoleta maniobrable en un centro donde solo se usaba fórceps y espátulas de Thierry resultó en una disminución de la estancia hospitalaria tras el parto en mujeres nulíparas.

Introduction

A major goal in current obstetrics is to decrease the rate of primary cesarean births.[1] The increase in the rate of primary cesarean births depends on many factors such as the increase in planned cesarean births, advanced maternal age and the increase in comorbidities.[1] Assisted vaginal birth is occasionally an alternative to cesarean birth when indicated, thus it is used in 5–26% of nulliparous women.[2] However, as the rate of cesarean birth has increased over the past decades, the rate of assisted vaginal birth has decreased.[3] Nevertheless, assisted birth remains an important part of current obstetric care and can be used to safely avoid cesarean births.[4,5] Instrument choice is generally influenced by clinical circumstances, operator experience, and availability.[6]

The preference for vacuum-assisted births has increased during the last decades.[6] The main reason for this change is less maternal perineal trauma with vacuum-assisted births, when compared to forceps-assisted births.[6–9] The advantages for vacuum over forceps also include: simpler technique to learn, intrinsic limitation to the amount of force which can be applied and that it can be used to promote flexion of a deflexed fetal head.[10] Disadvantages include: cannot be used for face presentation, aftercoming head of the breech or preterm births; it is dependent on maternal expulsive efforts; it is not recommended for gestational age less than 34 weeks and it has been associated with neonatal complications such as bruising, abrasion, cephalohematoma, jaundice or retinal hemorrhage.[4]

After an assisted vaginal birth, a longer maternal hospital stay due to maternal trauma is common, especially after rotational forceps compared to rotational vacuum, but also after non-rotational forceps.[11–13] Many early postnatal discharge protocols (discharge in less than 48 h after birth) have assisted vaginal birth with forceps as an exclusion criterion.[14] Despite knowing that forceps are more damaging to the maternal perineum, there are no adequate studies on the days of hospital stay after birth based on obstetric instruments.

A significant reduction in hospital stay has been observed in our center since the introduction of vacuum devices. The aim of our study is to assess whether adding a vacuum device as an option, along with forceps and Thierry's spatulas as available devices, can reduce the length of hospital stay in nulliparous women after assisted vaginal birth.

Materials and methods

This unicenter retrospective analytical study included two groups of nulliparous women who have undergone an assisted vaginal birth. The 2 groups differ according to the

availability or not of a maneuverable vacuum extractor cup. The no vacuum available group included the last cases of assisted vaginal births in nulliparous women, when obstetric forceps and Thierry's spatulas were the only available instruments before the introduction of the maneuverable vacuum extractor cup (Kiwi Omnicup®) in our center. The vacuum available group included the first cases after exactly one year of use of the maneuverable vacuum extractor cup in our center, when obstetric forceps, Thierry's spatulas and maneuverable vacuum extractor cup were available. The one-year period that differs both groups was decided after evaluating the evolution of the proportion of the different instruments used in assisted vaginal births in our center and observing a stabilization in the curves.

The inclusion criteria included nulliparous women after assisted vaginal birth from May 2017 backwards and from May 2018 onwards until completing the estimated sample size. Only assisted vaginal births due to prolonged second stage of labor or concern for fetal compromise were included. Exclusion criteria were twin pregnancies, antepartum fetal death, multiparous women, preterm births, uncomplete medical records, fetal malformations, pregnant women under 18 or over 45 years old and women with previous uterine surgeries.

According to departmental policy, the attending obstetrician decides to assist a vaginal birth after complete evaluation of fetal head position and station, adequacy of the maternal pelvis, adequate analgesia, emptying of the maternal bladder, consent of the woman, willingness to abandon the procedure and an alternative method of birth (cesarean section) if the instrumental attempt fails. Afterwards, hospital discharge is decided by the obstetrician in charge of the postpartum ward. Early postnatal discharge after assisted vaginal birth is not recommended and there are not different protocols for the different instruments.

Each attempt at an assisted vaginal birth is fully documented. Episiotomy is not performed routinely during assisted vaginal birth, but depends on the decision of the attending obstetrician, based on subjective evaluation of the likelihood of a severe perineal tear. If it is decided to perform an episiotomy, the right mediolateral episiotomy is used.

Clinical characteristics were recorded, including maternal age, height, pre-pregnancy body mass index, gestational age, obstetric history, perineal tears, obstetric anal sphincter injuries (OASIS), diabetes, obstetric instrument, episiotomy and indication, postpartum hospital stay, need of red blood cells concentrates, need of intravenous iron infusion, umbilical cord blood gas analysis, Apgar's test, neonatal weight and neonatal injuries related to instrumental birth in the initial assessment by neonatologists.

We estimated the necessary sample size with a confidence level of 0.95 ($1-\alpha$) and a statistical power of 0.80 to demonstrate a difference of at least 20% in the proportion of nulliparous women who require an extension of their hospital stay in the postpartum ward beyond 72 h. Starting from a possible 6% that would require more than 3 days of hospital stay after the introduction of the maneuverable vacuum extractor cups, the necessary sample size would be 54 women for each group.

The distribution of the variables was verified by the Kolmogorov–Smirnov test and by visual assessment of histograms. Numerical variables were expressed as mean (standard deviation) or median (interquartile range, IQR) as appropriate and qualitative variables were expressed as proportions (absolute and relative frequencies). Comparisons between groups were performed by the Student's t-test, Mann–Whitney U-test, two-tailed χ^2-test or two-tailed Fisher's exact test as appropriate. Level of significance was set at 0.05. All analyses were performed using SPSS version 22.0 (SPSS Inc., Chicago, IL, USA).

Ethical clearance was obtained from our institutional ethics committee (PI-4694).

Results

108 women were enrolled in the study. 54 women were enrolled in each group of the study, from May 2017 backwards (from April 27 to February 18) in the no vacuum available group and from May 2018 onwards (from May 1 to June 15) in the vacuum available group.

No statistically significant differences were observed between both groups in terms of demographic data, gestational diabetes, indication of the assisted vaginal birth, head station prior to the assisted vaginal birth and onset of labor (induction or spontaneous) (Table 1).

Vacuum was chosen as instrument in 30 out of 54 (55.6%) of the assisted vaginal births in the vacuum available group, versus 0 out of 54 (0%) in the no vacuum available group ($p < 0.001$). In the no vacuum available group, Kjelland forceps and Thierry's spatulas were used in 29 (53.7%) and 25 (46.3%) of the 54 assisted vaginal births, respectively. In the vacuum available group, Kjelland forceps were used in 18 (33.3%) assisted vaginal births and Thierry's spatulas in 6 (11.1%). There were no cases of failed assisted vaginal births. There were no cases of neonatal injuries related to instrumental birth in the initial assessment of the newborn in both groups.

There were statistically significant differences between both study groups in hospital stay, in rate of women with postpartum hospital stay longer than 72 h and in episiotomy rate (Table 2). There was an excess of 38 days of hospital stay in the no vacuum available group. There were only births without episiotomy among vacuum-assisted births.

There were no differences in OASIS, umbilical cord pH, need of red cell blood concentrates or intravenous iron therapy. There were statistically significant differences in the neonatal weight (Table 2).

Discussion

Our results show that there is a reduction in the length of postpartum hospital stay after assisted vaginal birth in nulliparous women after the introduction of a maneuverable vacuum extractor cup. This reduction could be due to fewer perineal damage in the mother with a better recovery. As it has been observed, there was a significant decrease in the number of episiotomies, and these can be related to less postpartum pain. Although a significant decrease in OASIS was not observed, it must be noted that lesions of the levator ani muscles as well as OASIS can be unnoticed and are known to be more frequent after forceps-assisted births.[6,9,15] In general, the use of vacuum devices has been related to less

Table 1 Pre-birth data.

	No vacuum available	Vacuum available	*p*
Maternal age (years)	33 (30.75; 36.0)	32 (29.75; 35.0)	0.217
Gestational age (weeks)	40.1 ± 1.19	39.75 ± 1.13	0.107
Maternal height (m)	1.62 (1.59; 1.68)	1.62 (1.59; 1.66)	0.552
BMI (kg/m^2)	25.68 (24.24; 27.5)	25.22 (23.87; 28.77)	0.803
Gestational diabetes	7/54 (13.0%)	5/54 (9.3%)	0.54
Labor induction	24/54 (44.4%)	21/54 (38.9%)	0.558
Head station +2	39/54 (72.2%)	35/54 (64.8%)	0.407
Head station >+2	15/54 (27.8%)	19/54 (35.2%)	0.407
Concern for fetal compromise	26/54 (48.1%)	22/54 (40.7%)	0.439
Prolonged 2nd stage of labor	28/54 (51.9%)	32/54 (59.3%)	0.439
Vacuum as chosen instrument	0/54 (0%)	30/54 (55.6%)	**≤0.001**

Data are presented as means ± (standard deviations) for normally distributed continuous variables, medians (interquartile range) for not normally distributed continuous variables, and absolute and relative frequencies for qualitative variables.
BMI, body mass index.
The fetal head station is described according to DeLee's stations. A fetal head station of +2 corresponds approximately with the third plane of Hodge.

Table 2 Post-birth data.

	No vacuum Available	Vacuum available	*p*
Episiotomy	54/54 (100%)	44/54 (81.5%)	**≤0.001**
OASIS	2/54 (3.7%)	1/54 (1.9%)	0.388
Neonatal weight	3407 ± 399	3245 ± 375	**0.032**
Umbilical cord pH	7.23 ± 0.07	7.23 ± 0.08	0.710
Days of postpartum hospital stay	3.17 ± 0.803	2.81 ± 0.585	**≤0.001**
>3 Days of postpartum hospital stay	22/54 (40.7%)	3/54 (5.5%)	**≤0.001**
Blood transfusion	2/54 (3.7%)	1/54 (1.9%)	0.604
Intravenous iron therapy	14/54 (25.9%)	14/54 (25.9%)	1

Data are presented as means ± (standard deviations) for normally distributed continuous variables and absolute and relative frequencies for qualitative variables.
OASIS, obstetric anal sphincter injuries.

postpartum pain than forceps, probably because the diameter of the fetal head is not increased by the use of vacuum devices.[6]

Generally, women are admitted for 2 days in the postpartum ward after a vaginal assisted birth.[14] Like other studies we used the 3-day limit to define a prolonged postpartum hospital stay.[12,16] In our study, we decided to use the 3-day limit, because in our center pediatricians can extend the stay up to 3 days before proceeding to admit the baby. Once the 3 days have passed, the woman can remain hospitalized in the postpartum ward only for reasons of her health.

The main differences between vacuum and forceps lie in their physical principles. The ideal application of forceps is biparietal and bimalar to exert lever mechanisms on the fetal head.[17] The forces exerted by forceps are a combination of traction, compression and friction, which makes it impossible to ascertain the exact amount of force exerted.[18] While in vacuum-assisted births, traction force is exerted on the area of the flexion point at the fetal scalp, as an addition to the normal forces of labor.[19] Concerning the perineum, these differences in physical principles between the instruments carry 2 points in favor of the maneuverable vacuum devices. The first point is an increase in the fetal biparietal diameter of approximately 2–3 cm due to the curvature and thickness of the forceps; while the diameters do not increase with the maneuverable vacuum devices.[20] The second point is the use of a lower traction force with vacuum devices than with forceps, in fact, a traction force of up to 11.5 kg with vacuum and up to 23 kg with forceps is accepted.[21]

There was a statistically significant reduction in episiotomies in the vacuum available group. In our center it does not exist a policy of mandatory episiotomy during forceps, it lays in the assisting obstetrician experience. Mediolateral episiotomy is the one used in our center when indicated. Mediolateral episiotomy reduces the risk of OASIS compared to midline episiotomy, although it has been linked to an increased chance of long-term perineal pain and dyspareunia.[22] There is an international trend toward the reduction of use of episiotomies.[23] Routine episiotomy with assisted vaginal birth is not recommended due to poor healing and prolonged discomfort with mediolateral episiotomy.[22] Episiotomy has also been associated with an increase of postpartum hemorrhage, perineal infection, stronger analgesia, neonatal birth trauma and length of hospital stay.[16] It should be noted that there were only births without episiotomy among vacuum-assisted births in our study.

It has been widely studied in the literature that forceps-assisted births have a greater perineal trauma and OASIS risk compared with vacuum-assisted births.[6,8] It is known that injuries to the levator ani muscles are more frequent after forceps-assisted birth, but they may not be identified in the labor ward.[9] We did not observe any statistically significant differences between both groups concerning to OASIS in our study. A meta-analysis that included 12 studies, including 3129 women, comparing forceps versus vacuum-assisted births, concluded that forceps use was associated with a higher rate of OASIS (RR, 1.83; 95% [CI], 1.32−2.55).[6] The same meta-analysis did not find differences in perineal pain between forceps and vacuum (only two studies with 315 women were selected for this comparison).[6] We believe that we did not find statistically significant differences due to the low number of women included in our study, since the sample size was calculated to demonstrate a reduction in hospital stay, not in OASIS.

Although in our study no failed assisted vaginal births were observed, the use of vacuum has been reported to be more likely to fail compared with forceps.[4] In case of failed vacuum birth, sequential use of instruments (vacuum followed by forceps) has been associated with significantly higher rates of subdural or cerebral hemorrhage, subarachnoid hemorrhage, retinal hemorrhage, facial nerve injury, brachial plexus injury, feeding difficulties low umbilical artery pH and OASIS.[24] The sequential use of instruments should be avoided if possible.[4,25]

As described in the results, there was a statistically significant difference in neonatal weight between the studied groups. In the group studied before the maneuverable vacuum extractor cup was introduced in our center, neonatal average weight was 162 grams higher. Although forceps-assisted births with neonatal weights greater than 4000 g have been related to an increase in neonatal injuries,[4] we do not believe that the difference in weight found in our study to be of clinical relevance as the average weight was far from 4000 g in both groups.

Our study was not designed to assess costs within the primary outcomes. However, it stands out that there was an excess of 28 days in hospital stay in the group without vacuum. Estimating costs after birth is very complicated, since an earlier postnatal discharge can lead to an increase in later costs that are difficult to quantify.[25] Despite this, considering that the average cost per day in the postpartum ward in our center in 2019 was 492 euros, we estimate that about 346 euros were saved per woman in the vacuum available group.

The greatest strength of our study is that, as an observational study, it is carried out based on real clinical practice. The originality of the study lies in showing how the incorporation of a maneuverable vacuum extractor cup in an obstetric service influences real practice. As happened in our center, many centers in the world do not have maneuverable vacuum extractor devices. We believe that this study provides information that can be of aid to centers that are in similar situations to ours before May 2017.

The main weaknesses of our study are the lack of randomization and the lack of neonatal follow-up. About the lack of randomization, having collected all consecutive assisted vaginal births in nulliparous women in time order from the introduction of the maneuverable vacuum extractor cup, both backwards and forwards after one year of use, and having verified the homogeneity of both groups about the indication of assisted vaginal birth, gestational age, body mass index, maternal age, gestational diabetes and head station, we believe that the two groups are fairly comparable. Regarding the fact that the inclusions were not performed in parallel, it could be a bias due to the greater experience of the obstetricians in the second group (one year greater), but since the forceps and Thierry's spatula protocols have not changed in our center since 2014 (year in which the presence of a companion was allowed), we do not believe that it may have influenced the results.

Regarding the lack of neonatal follow-up, although no injuries due to instrumental deliveries were observed in the initial assessment. We do not know if other problems such as jaundice were more frequent in one of the groups. In this regard, it is important that the NICU admission rate of our center has not increased since the introduction of the maneuverable vacuum extractor cup. Furthermore, this study was not designed to detect differences in neonatal problems beyond the initial neonatal assessment, such as jaundice, which occurs in 3% of vacuum-assisted births.[19]

Another limitation is that we have only studied nulliparous pregnant at term. Therefore, our results may not apply to other types of assisted vaginal births.

In conclusion, the introduction of a maneuverable vacuum extractor cup resulted in a decrease in postpartum hospital stay in nulliparous women. Furthermore, we can conclude that the introduction of a maneuverable vacuum extractor cup had an impact on reducing the rate of episiotomies in assisted vaginal births in nulliparous women, reducing the perineal trauma.

Ethical responsibilities

Protection of people and animals. The authors declare that the procedures followed were in accordance with the ethical standards of the responsible human experimentation committee and in accordance with the World Medical Association and the Declaration of Helsinki.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the corresponding author.

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Conflict of interest

The authors declare that they have no conflicts of interest.

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