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A randomized study of two cups for vacuum extraction

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1 Introduction

MALMSTRÖM designed the first "genuine" vacuum extractor in 1953 [8]. In Europe, as in most parts of the Third World, the **ventouse** is now a popular extraction device that has replaced obstetric forceps in many clinics.

Two imperfections have been ascribed to the Malmström instrument: (a) its lack of maneuverability and (b) its relative ineffectiveness if pulled obliquely. These drawbacks have prompted numerous investigators to modify the design of the traditional cup in an attempt to overcome these alleged inconveniences [13].

Lack of maneuverability: If Malmström's cup is positioned in the conventional way [9], i. e., applied to the most accessible part of a deflexed and/or asynclytic head, the extraction force tends to fix the head in this unfavorable attitude, thus maintaining the relative disproportion [2]. If, on the contrary, the cup is positioned over the posterior fontanelle in the midline (flexing median or "ideal" application according to BIRD [2]), the chances are good that the initial pull(s) will correct any postural deviation and thus make extraction easier and safer. Because the centrally attached suction pipe may hinder ideal application of the Malmström cup, Bird [1] connected the traction chain to the center of the cup and moved the pipe excentrically. However, the laterally placed tube still impeded ideal cup application when the position of the occiput was posterior or lateral, and therefore the author moved the suction pipe to the flange of the cup [2]. Bird called one of his models the anterior cup (OA) and the other the posterior (OP) cup.

Direction of pull: When the operator pulls in an oblique direction the effective tractional force is reduced proportionally to the angle of traction [6]. As a result, the cup tends to tilt and may even become detached from the fetal scalp [7], thus decreasing the efficiency of the procedure and increasing the risk of damage to the fetal head. Because neither of the Bird models substantially neutralizes the effects of the tilting phenomenon (figure 1), O'NEIL et al. [11] devised a highly imaginative rotating traction collar (figure 2) that allows two planes of movement and ensures that within a 70-degree range of pull the line of traction is always through the center of the vacuum surface and the effective traction remains constant (figure 1). By combining the principle underlying Bird's modified cups with that of the rotating collar, O'Neil created a set of cups (OA and OP) which theoretically would overcome the two main drawbacks of the Malmström device (figure 3).

To check these claims we conducted a randomized controlled trial comparing the efficiency and safety of the conventional instrument with those of the O'Neil models.

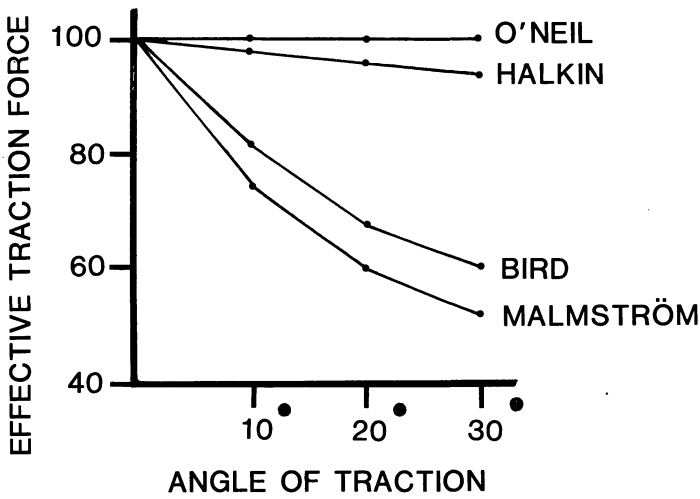

Figure 1. Effective traction force according to angle of traction for a variety of suction cup models (Reproduced, with permission, from Thiery 1985).

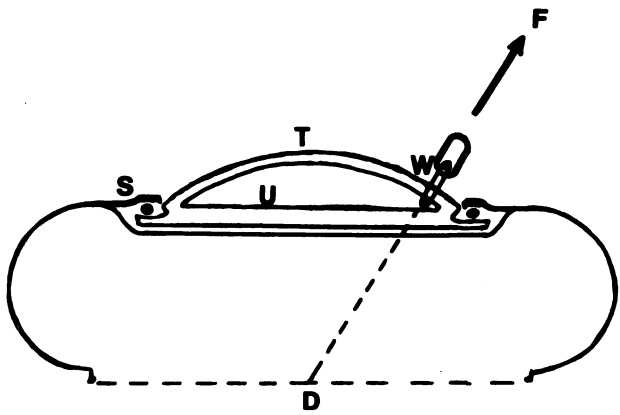

Figure 2. Cross-section of O'Neil's cup. Metal rod (T) curved to form the perimeter of a circle about D. This rod is mounted on a circular plate (U) which rotates against its bearing (S). A ring of the traction chain (W) slides on T along the perimeter of the circle with its center at D. This mechanism allows two planes of movement and ensures that the line of traction is always through D. (Reproduced, with permission, from O'Neil et al. 1981).

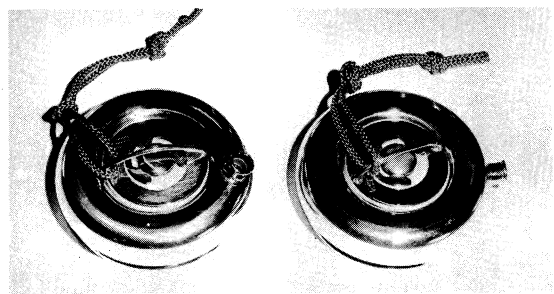

Figure 3. O'Neil's OP (left) and OA cups with cord attached to rotating collar (Courtesy of GO Medical Industries, Subiaco, Western Australia).

2 Methods and subjects

Between January 30, 1984 and September 30, 1985, 410 elective vacuum extractions were attempted with either a 50-mm diameter Malmström cup (n = 210) or the standard 55-mm diameter OA or OP O'Neil cup (n = 200). Allocation of cup type was on the basis of randomization. When planning the extraction procedure, the operator received from the midwife either a conventional ventouse or a set of O'Neil cups. In the latter instance it was up to the operator to make the appropriate choice between the OA and the OP cup on the basis of the findings of the pelvic examination: OP for a fetus in the occipito-posterior of occipito-lateral position, OA for other positions.

Operators with various degrees of expertise participated in the trial, 49% of the procedures being performed by junior staff. Operators were free to enter candidates provided the woman was a normal term ($\geq$ 38 full gestational weeks) gravida, fully dilated, and carrying an apparently healthy singleton fetus in cephalic presentation.

For assessment of the condition of the fetus immediately prior to the attempted extraction a scalp blood sample was collected before application of the suction cup. Evaluation of the infant's status at birth was based on clinical and biochemical parameters. The head of all of the newborns was inspected by two of us (MT and HVK) between 24 and 48 hours post-delivery.

For the evaluation of cup position, two values were used: the degree of flection, expressed as the distance (cm) between the edge of the cup and the anterior fontanelle and the degree of synclitism, as the difference between the distances (cm) from cup edge to sagittal suture (figure 4).

Currently accepted standards were applied for the extraction procedure. The highest possible level of negative pressure (usually -0.8 kg/cm^2) was obtained in a single step, usually requiring 1–2 minutes, with an electric vacuum pump controlled by a foot pedal. After the operator had made certain that no soft tissue or any

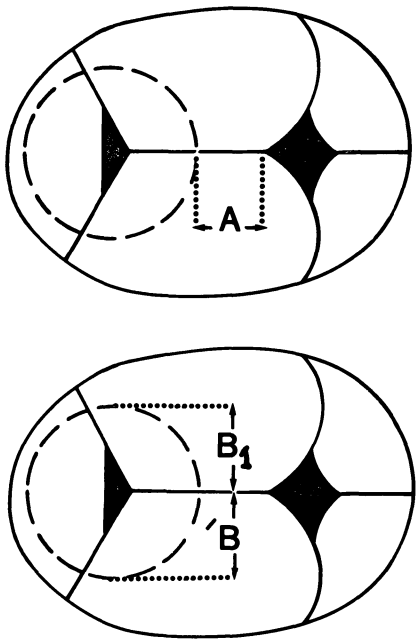

Figure 4. Determinations for assessment of cup position. Top: distance between cup edge and anterior fontanelle (A). Bottom: difference between distances from cup edges to sagittal diameter ($B-B_1$ or B_1-B).

foreign body (e. g., scalp electrode or intrauterine pressure recording catheter) was present between the rim of the cup and the fetal scalp, a trial traction was performed to confirm proper cup attachment. During the extraction proper, the operator had to respect the following rules of thumb [10]: synchronization of pulling with uterine contractions; adjustment of traction direction to pelvic axis; pressing of the fetal head toward the sacrum during pulls using the Dreifingergriff [5]; and, most important of all, restriction of the number of pulls and the duration of the extraction. According to departmental policy, a "freshman" is asked to stop the procedure after 3 to 4 full pulls have failed to complete the ventouse delivery, and to call on a senior staff member for reevaluation.

Immediately after the delivery, details of each procedure were recorded by the operator on specially designed charts. Neonatal and puer-

peral data were entered on the same document and completed at discharge. For inter-group comparison, the Student t test and chi-square tests were used.

The two instrument groups were comparable as to patient characteristics and management, operator skill, and obstetric and fetal conditions at cup application (table I).

3 Results

Efficiency: Seven (1.7%) of the intended vacuum extractions were to be considered failures because the patient was not delivered with the cup model allocated, and the failure rate did not differ significantly between the two models investigated (table II). Most of the failures were overcome by switching to the other suction cup model. One patient was delivered abdominally (section rate 0.2%) after three pulls with the O'Neil cup were unsuccessful, probably because of cephalo-pelvic disproportion; the infant (3,100 g) was in good condition at birth (5-min Apgar score = 7; pH in umbilical-artery blood 7.16).

No significant inter-group differences were found for other parameters related to efficiency of the extraction procedure (table III). The incidence of occipito-posterior position at birth was similar in the two groups and there were no significant differences in the distribution of flexing or median positions (table IV).

Table I. Comparison of instrument groups (mean ± SD).

Variable	Malmström cup* (n = 210)	O'Neil cups* (n = 200)
Patient characteristics		
age	26.6 ± 4.3	26.0 ± 4.5
parity	1.5 ± 0.9	1.5 ± 0.7
weight (kg)	69.3 ± 9.3	70.2 ± 12.9
height (cm)	163.5 ± 5.9	163.5 ± 7.7
Patient management		
episiotomy (number)	210	199
epidural block (number)	101	91
paracervical block	3	1
Operator skill		
junior (number)	102	98
senior (number)	108	102
Obstetric condition		
dilatation (number)		
10 cm	208	197
9 cm	2	3
station (Hodge plane)		
−3 and −2	14	12
−1 to +1	148	144
+2 and +3	48	44
Fetal condition		
scalp pH	7.31 ± 0.08	7.37 ± 0.07
Birthweight (g)	3313 ± 468	3304 ± 433

* None of the differences are statistically significant

Table II. Failures and final method of delivery.

Method	Malmström cup* (n = 210)	O'Neil cups* (n = 200)
N failures	1	6
Final method of delivery		
other type of cup	1	5
spontaneous vaginal	0	0
forceps	0	0
cesarean section	0	1

* No statistically significant differences

Safety: Serious maternal complications were not observed and the two groups were similar as to estimated total blood loss and puerperal pyrrhexia. In 3 (1.5%) of the subjects delivered with one of the O'Neil models a linear midline incision of the perineum caused by the nylon traction cord was observed.

Neonatal mortality was nil. Condition of the infant and neonatal evolution were comparable in the two groups and there was no significant difference as to rate or pattern of head trauma (table V).

Table III. Efficiency of extraction procedure.

Variable	Malmström cup** (n = 210)	O'Neil cups** (n = 200)
Force applied (n patients)		
mild	80	70
moderate	71	66
strong	59	64
Number of pulls (mean ± SD)	2.0 ± 1.3	1.8 ± 1.2
Leakage/detachment (n patients)*	28	17

* Including incidents related to equipment failure, i. e., rupture of traction chain of the Malmström cup (n = 1) and fracture of the metal rod of the O'Neil cup (n = 1)
** None of the differences are statistically significant

Table IV. Internal rotation and position of cup application.

Variable	Malmström cup* (n = 210)	O'Neil cups* (n = 200)
Persistent OP position (n cases)	6	8
Flexing position		
> 3 cm	124	109
2–3 cm	53	58
< 2 cm	33	33
Median position		
0–1.5 cm	111	119
2–3.5 cm	70	60
4–5.5 cm	29	21

* No statistically significant differences

Table V. Neonatal condition and morbidity.

Neonatal outcome	Malmström cup*** (n = 210)	O'Neil cups*** (n = 200)
Neonatal condition		
Low Apgar scores (n cases)		
one-min score < 4	6	7
five-min score < 7	5	3
Acid-base status (mean ± SD)		
pH umbilical artery	7.27 ± 0.08	7.27 ± 0.07
ΔXL_{fm}*	7.8 ± 11.2	8.1 ± 10.6
Head trauma (n cases)		
Laceration/abrasion	7	4
Subcutaneous hematoma	0	0
Cephalhematoma	4	6
Subgaleal hematoma	0	0
Fracture	0	0
Neonatal morbidity		
Intubation	3	4
Non-physiologic jaundice**	43	38

* Fetal-maternal difference in excess lactate (mEq/l)
** Total serum bilirubin level > 12 mg/100 ml within first 5 days of neonatal life
*** No statistically significant differences

4 Discussion

Our groups are large enough to make comparison between the two types of suction cup a valid exercise. That the diameter of the standard O'Neil cup is 0.5 cm larger than that of the conventional instrument implies that at the same vacuum level the adhesiveness of the O'Neil cup will probably be somewhat greater [12], a difference which, in contrast with the actual results, should have been to the advantage of the O'Neil instrument. However, it cannot be excluded that greater familiarity of the operator – especially the senior staff – with the Malmström cup may in fact have neutralized this effect. All extractions were performed on an elective basis, i. e., to shorten and facilitate the second stage of labor. Cases in which the ventouse was indicated, either for fetal of for maternal reasons, were excluded. Hence, our results are valid only for what might be expected to become an uncomplicated vacuum extraction.

We know of only two studies that compared suction cup models randomly [3, 4]. CARMODY et al. [3] compared the original Bird cup with its most recent modification, i. e., the New Generation or "string" cup [13], the design of which is based on principles not unlike those underlying the O'Neil cup. These authors found "little evidence that the use of the New Generation cup is associated with a reduction of cup detachment and scalp trauma ...", and the frequencies of correct application (i. e., flexing median position) for "original" and "string" cups were similar (74% and 72% of the cases, respectively). We do not know which criteria they applied for the assessment of "correct" application, but if we add up our "ideal" and "acceptable" applications (flexing position 2 to > 3 cm; median position 0–3.5 cm) our incidences of "correct" flexing median positions amount to 87% for either the Malmström or the O'Neil cup.

Summary

O'Neil [11] designed a set of suction cups which, because of more efficient lateral pull and greater maneuverability, were claimed to be more efficient and perinatally safer than the Malmström model. These claims were checked by comparing the two instruments in a randomized controlled trial comprising 410 attempted elective extractions. The two instrument groups were comparable at entry and the operators had a similar degree of experience, the sole inter-group difference being the 0.5 cm larger diameter of the O'Neil cups. No significant differences were found between the two types of instrument as to failure rate, incidence of correct cup positioning, and capacity of eliciting internal rotation nor was there a significant divergence in neonatal safety. In a few cases the perineum was lacerated by the traction cord affixed to the O'Neil instrument. The results of this study indicate that the relative advantages and disadvantages of the two cup models are unremarkable.

Keywords: Malmström suction cup, O'Neil suction cup, vacuum extraction.

Zusammenfassung

Eine randomisierte Studie zweier Glocken für die Vakuumextraktion

O'Neil [11] hat einen Set von Saugglocken entwickelt, der auf Grund besseren seitlichen Zuges und größerer Beweglichkeit größere Effizienz und Sicherheit als die Malmström Ausführung besitzen soll. Diese Behauptungen wurden geprüft, indem die beiden Instrumente in einer randomisierten Studie mit 410 Vakuumextraktionen eingesetzt wurden. Die beiden Gruppen waren zu Beginn vergleichbar. Die Operateure hatten einen vergleichbaren Grad an Erfahrung. Der einzige Unterschied zwischen den beiden Gruppen war der um 0,5 cm größere Durchmesser der O'Neil Glocken. Bezüglich der Versagensrate, des Zustandekommens einer korrekten Glockenpositionierung und der Möglichkeit einer internen Rotation wurden keine Unterschiede gefunden, auch war kein deutlicher Unterschied bezüglich neonataler Sicherheit festzustellen. In einigen Fällen wurde durch die am O'Neil Instrument befestigte Zugschnur der Damm verletzt. Die Ergebnisse dieser Studie zeigen, daß die relativen Vorteile und Nachteile der beiden Glockenausführungen sich in etwa entsprechen.

Schlüsselwörter: Malmström Saugglocke, O'Neil Saugglocke, Vakuumextraktion.

Résumé

Étude randomisée de deux types de ventouse

O'Neil [11] a mis au point un jeu de ventouses qui, en raison d'une traction latérale plus efficace et d'une manœuvrabilité plus grande, ont été présentées comme plus efficaces et moins dangereuses sur le plan périnatal que le modèle de Malmström.

On a fait le bilan de ces prétentions en comparant les deux instruments par un essai controlé et randomisé comprenant 410 extractions. Les deux groupes étaient comparables lors du tirage au sort et les opérateurs avaient le même niveau d'expérience, la seule différence entre les deux groupes étant le diamètre plus grand de 0,5 cm des ventouses de O'Neil. On n'a pas trouvé de différence significative entre les 2 types d'instruments quant au taux d'échec, à l'incidence des bons positionnements des ventouses et quant à la réalisation de rotations; il n'y a pas de différence significative non plus en ce qui concerne l'inocuité néonatale. Dans quelques cas il y a eu des lacérations périnéales provoquées par le cordon de traction de la ventouse de O'Neil. Les résultats de cette étude indiquent qu'on ne peut pas mettre en évidence d'avantages ni d'inconvénients pour ces deux types de ventouses.

Mots-clés: Extraction par ventouse, ventouse de Malmström, ventouse de O'Neil.

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