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Malmström's vacuum or Kielland's forceps: what causes more damage to the pelvic floor?

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Contribution

What does this work add to what is already known?

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We present the first study designed to evaluate the differences in the rates of avulsion of the levator ani muscle (LAM) between Malmström's vacuum delivery (MVD) and Kielland's forceps delivery (KFD), according to the characteristics of instrumentation

What are the clinical implications of this work?

We failed to find a significantly different avulsion rate between KFD and MVD when the characteristics of instrumentation are considered in the evaluation

Abstract:

Objectives: To determine whether differences exist in the rates of avulsion of the levator ani muscle (LAM) between Malmström's vacuum delivery (MVD) and Kielland’s forceps delivery (KFD), according to the characteristics of instrumentation, at different hospital centers.

Methods: Prospective, observational, in two different hospital centersstudy that included 414 nulliparous women after instrumental delivery with Malmström's vacuum extractor or Kielland's forceps. The instrumentation characteristics analyzed were fetal head position (anterior position or other position) and fetal head station (low instrumentation and mid instrumentation). Avulsion was defined as an abnormal insertion of the LAM in the three central sections from the plane of minimal dimensions (PMD).

Results: In all, 414 patients completed the study (212 MVD and 202 KFD). We observed a higher rate of LAM avulsion in KFD (MVD 32.6% vs. KFD 49.5%; p= 0.001). When the results were evaluated according to the mode of instrumentation (head position and station), we observed no differences in LAM avulsion. The crude OR for avulsion between KFD and MVD was 2.03 (95%CI: 1.36, 3.03), and the adjusted OR was 2.14 (95%CI: 0.95, 4.85) (p=0.068) (adjusted by the 2nd stage of labor and fetal head circumference and instrumentation height).

Conclusions: We failed to find a significantly different avulsion rate [adjusted OR: 2.14 (95%CI: 0.95, 4.85) (p=0.068) between KFD and MVD when the characteristics of instrumentation are considered in the evaluation

INTRODUCTION

Instrumental delivery results in an increase in neonatal morbidity (subdural or cerebral hemorrhage, seizures, and need for mechanical ventilation)[1-3] and maternal morbidity (hemorrhage, perineal injuries)[3-5]. However, these are not the only injuries that occur during labor; there are other types of muscle trauma, such as levator ani muscle (LAM) avulsion, which can influence the future occurrence of pelvic floor dysfunction[6-14]. Actually, LAM injury caused during childbirth causes an increase in levator hiatus[6-8], decreases muscle strength, as well as its contraction speed and resistance[9], and is associated with lower strain[10]. In addition, LAM injury is related to the development of pelvic organ prolapse[11-13], urinary incontinence[14], and fecal incontinence during the postpartum period[15]. LAM avulsion is defined as the disconnection of LAM muscle fibers from their insertion in the inferior pubic ramus[16] and represents the primary hazard during vaginal delivery[17]. The most vulnerable moment in LAM avulsion is that of maximum distension of the levator hiatus area (when the fetal head is in Hodge's 4th plane)[18]. Risk factors associated with the development of avulsion have been described, such as forceps delivery (FD)[19] with a relative risk (RR) of 3.4[20]. However, in vacuum delivery (VD), published data on LAM injury are contradictory. Some authors report a higher rate of injuries in VD than in normal vaginal deliveries[21], which has not been confirmed in other studies[22-23]. However, these studies[20,24-26] included a small sample size, which makes it difficult to establish a direct association.

In addition, other factors might influence instrumental delivery, such as the characteristics of instrumentation (head station and position). Therefore, the aim of this study is to determine any differences in LAM injury (avulsion) between VD and FD, according to the characteristics of instrumentation in different hospital centers.

METHODS

A prospective, observational, was planned and included 414 nulliparous women who presented between January 2015 and January 2017. The following hospitals participated in the study: Virgen de Valme University Hospital of Seville, and University Healthcare Complex of León. The study was approved by the Biomedical Ethics Committee of the Junta of Andalusia (1153-N-15).

Patients were recruited after delivery during their hospital stay. Consecutive patients who met the inclusion criteria were invited to participate in the study. The inclusion criteria for our patients were nulliparous, full-term pregnancy, cephalic presentation, instrumental delivery with Malmström's vacuum extractor or Kielland's forceps, and previous written informed consent. Excluded patients were those with prior pelvic floor pathology, those who underwent delivery by cesarean section after failed instrumentation or who required a change in instrumentation during delivery to complete it, and those with severe maternal or fetal pathology.

Instrumental deliveries were performed by qualified obstetricians with over five years of experience who worked at different hospitals participating in the study. Assessment of fetal head station (low or mid instrumentation) was defined based on the criteria of the American College of Obstetricians and Gynecologists[27]. Transabdominal ultrasound was performed to establish fetal head position as described in previous studies[28]. The choice of instrument for delivery was made by each obstetrician based on what was considered the most appropriate according to the conditions of delivery and on the obstetrician’s experience in using each instrument[27].

Instrumentation (Malmström's vacuum or Kielland’s forceps) was used during uterine contraction and was associated with active maternal pushing. Moreover, two to three tractions per contraction were applied without application of the Kristeller maneuver (to avoid confounding factors[29]). Restrictive episiotomy was performed, and protection of the maternal perineum was performed in all cases at the time of fetal head bulging.

The following obstetric parameters were collected: maternal age, gestational age, induction of labor, epidural analgesia, duration of epidural analgesia, duration of the second stage of labor, episiotomy and perineal tear according to Sultan's classification of perineal tears[30], fetal head position (anterior, posterior, and transverse), fetal head station [low instrumentation (vertex at +2 station) and mid instrumentation (head is engaged but leading part above +2 station)][27], fetal weight, and head circumference.

Ultrasound assessment was performed 3-6 months after delivery (after the recovery period[31]) by examiners with over three years of experience in 4D pelvic floor ultrasound (JAGM, EGA). The examiners were blinded to the obstetric data related to the delivery. The ultrasound machines used were a Toshiba® 500 Aplio (Toshiba Medical Systems Corp., Tokyo, Japan) with a PVT-675MV 3D abdominal probe and a Voluson E8 (GE Medical Systems, Zipf, Austria) ultrasound system with an 8-4 MHz volume transducer, covered with a sterile glove.

The acquisition and offline analysis of the volumes were performed as described in previous studies[21], and the volumes were acquired in the midsagittal plane of the pelvic floor and in the lithotomy position after voiding. During the examination, three dynamic 4D volumes were acquired for each patient: one at rest, another during maximum contraction, and the other during the Valsalva maneuver (for at least 6 seconds)[32]. Hiatus measurements were obtained in the plane of minimal dimensions (PMD), which is the minimum distance between the hyperechoic posterior part of the pubic symphysis and the hyperechoic anterior border of the LAM just posterior to the anorectal muscle[26]. Levator hiatus measurements[33,34], transverse diameter, and antero-posterior diameter and area were studied in the plane of minimal hiatal dimensions, as described in previous publications[35]. The integrity of the levator ani muscle was assessed at maximum contraction using the multislice mode, as previously described[36,37]. Complete avulsion was diagnosed when an abnormal LAM insertion was observed in the three central sections (Figure 1). In unclear cases, a levator-urethra gap ≥ 2.5 cm was used to define an abnormal insertion.

Statistical analysis

The statistical analysis was performed using the IBM SPSS Statistics program version 24 (IBM, Armonk, NY, USA). For quantitative variables, the normality of the data was contrasted (Shapiro-Wilk test) in the groups defined by the type of delivery; an analysis of variance (ANOVA) test for independent samples or a nonparametric Kruskal-Wallis test was applied, followed by a multiple comparison test if the variable was significant. For the analysis of qualitative variables, either contingency tables and Chi-square tests or the non-asymptotic methods of Monte Carlo and exact tests were performed. We used a univariate binary logistic regression analysis to determine crude ORs and a multivariate binary logistic regression analysis to control for possible confounding factors. These results were complemented with 95% confidence intervals (CIs) for the ORs. $P<0.05$ was considered statistically significant.

Power analysis

To detect a 30% difference in the percentage of levator ani muscle injuries between the two types of instrumental deliveries (40% in Kielland's forceps deliveries (KFD) vs. 10% in Malmström's vacuum deliveries (MVD), we determined that 42 women were needed in each study group to achieve a power of 90% and a significance level of 5%.

If we assumed a minor difference in the percentage of levator ani muscle injuries (45% of KFD versus 25% of MVD), we needed a sample of 89 women in each study group to obtain a statistically significant and clinically relevant difference among the study groups, with a power of 80% and a significance level of 5%.

In addition to the type of delivery, we also considered the fetal head position before instrumentation (occipito-anterior vs. 'other position'). To detect a 20% difference in the rate of injuries between the two fetal head position groups, we needed to include 80

MVD (40 with the head in the occipito-anterior position and 40 with the head in some 'other position') and 80 KFD (40 with the head in the occipito-anterior position and 40 with the head in some 'other position'). To reach these sample sizes, we estimate that we need 2 years of studies.

RESULTS

During the study period, 414 nulliparous women with instrumental delivery (Malmström's vacuum or Kielland's forceps) were included. In the recruitment diagram (Figure 2), we show the causes, classified by the participating hospitals, of exclusion of nulliparous women from instrumental delivery (Malmström's vacuum or Kielland's forceps). The study was completed by 414 patients of which 212 were in the MVD and 202 KFD in the groups. The general obstetric data of the 414 participants are shown in Table 1. Regarding the obstetric conditions, statistically significant differences were detected between MVD and KFD. In MVD, 2^{nd} stage of labor was greater than that in KFD (116.6 vs. 99.6, p=0.008).

Table 2 shows the conditions under which instrumentation was applied. No differences were found regarding fetal head position between MVD and KFD, and the occipito-anterior position was the most common. No differences were found regarding height at instrumentation between MVD and KFD.

The ultrasound study showed that avulsion was more common in KFD (MVD 32.6% vs. KFD 49.5%; p= 0.001) (Table 3). We also found no difference in the rate of avulsion according to the fetal head position and station, based on the type of the instrument used for delivery, either for MVD or KFD (Table 3). The crude OR for avulsion between KFD and MVD was 2.03 (95%CI: 1.36, 3.03), and the adjusted OR was 2.14 (95%CI: 0.95, 4.85) (p=0.068) (adjusted by the 2^{nd} stage of labor and fetal head circumference and instrumentation height). Regarding the levator hiatus area, we only found significant differences during the realization of the Valsalva (18.5 ± 5.3 vs. 20.2 ± 6.1, p= 0.001) (videoclip 1).

DISCUSSION

In our study in which we analyzed 414 patients who underwent labor with Malmström's vacuum or Kielland's forceps delivery, we found no stadistically significant differences in the rate of LAM avulsion (adjusted OR of 2.14 (95%CI: 0.95, 4.85) (p=0.068) for KFD vs. MVD) when the characteristics of instrumentation are considered in the evaluation.

Here, we present the first study designed to compare LAM injuries after instrumental deliveries and to evaluate the characteristics of the instrument used. To date, the aim of different authors[22] has been to identify the different factors associated with the appearance of LAM injury during vaginal delivery. In fact, most published studies agree that VD does not increase the rate of LAM injury[19]. This finding could be explained by the way in which instrumentation was performed, which was not specified in these studies. Nonetheless, using forceps is considered the most important risk factor for the occurrence of these injuries[19].

Different rates of LAM injury have been described according to the time at which ultrasound was performed, and presentation rates have ranged from 40-66% in FD[24,26,38-41] and 9-33% in VD[24,26,38-41] before the end of the first postpartum year. In this period, ORs have been estimated in favor of FD versus VD for avulsion and have ranged between 3.42 and 10[24,26,38-41]. However, when LAM avulsion rates were compared after the first year postpartum, values ranged from 55 to 89% after FD[42-45] and 18-41% after VD[44,45]; ORs are higher in FD and ranged from 5.3 to 11.4[44,45]. These LAM avulsion rates decreased when FD and VD were compared 10 years after delivery, and an OR of 4.2-5 was determined[20,46]. Based on these data and according to the studies mentioned[23-26,38,40,47-51], using forceps seems to lead to an increased risk of LAM avulsion compared with the vacuum extractor. However, none of these studies included approach that has evaluated the conditions under which each instrument was used at the time of delivery. Previously, a study indicated that vacuum was applied to all positions of the fetal head and in the upper part of the birth canal, while forceps delivery was only used when the fetal head was in an occiput anterior or posterior position on the pelvic floor[23], which can be a confounding factor when interpreting the results. On the other hand, we present a population in which either Malmström's vacuum or Kielland's forceps was indiscriminately applied, according to the head position and station, with the aim of reducing these confounding factors regarding avulsion (Table 2), possibly explaining our higher LAM avulsion rate in VD.

Currently, the use of forceps, especially rotational forceps, has increased, which has reduced the rate of cesarean section[19]. Following the indications of the ACOG practice bulletin for operative vaginal births[27], using rotational forceps is the procedure indicated in cases of transverse presentation. Therefore, some authors argue that this increase in forceps use could cause an increase in maternal morbidity[52]. It has been established that using forceps is the most important risk factor for LAM injury and surpasses the risk of using a vacuum extractor[19]. For this reason, the use of forceps as a rotator in some centers is very rare, and intrapartum cesarean section is the preferred option for difficult instrumental deliveries[26]. However, we must consider that the studies that have compared both types of instrumental deliveries and their relation to LAM trauma have not considered the conditions under which each instrument is applied[20,22-26], and thus, we believe their findings might be insufficient. In this study, as in previous studies[53], we have evaluated the characteristics of each instrumentation to minimize the confounding factors that different instrumental techniques might cause. We did not find stadistically significant differences in the LAM avulsion rate between the different types of operative deliveries (avulsion rate of MVD was 32.6% vs 49.5% for KFD with an adjusted OR of 2.14 (95%CI: 0.95, 4.85) (p=0.068). However, in our study we have only included Malmström's vacuum extractor and Kielland's forceps and can explain why we have found higher avulsion rate after vacuum delivery as compared to other studies[54]. In addition, Malmström's vacuum extractor, as compared to soft cups, allows more force to be used for extraction[1,3]. On the other hand Kielland's forceps, compared to Neville-Barnes forceps, increase the fetal circumference less as compared to Neville-Barnes (1.04 cm for Kielland's forceps, and 1.64 cm for Neville-Barnes forceps)[54].

The advantage of our study is that it is prospective in which we have homogenized the population according to the characteristics of instrumentation. In addition, we have included a large number of patients greater than what has been previously published[55], which adds to the strength of our results. We have even included more patients of the required sample size because we initially calculated to need 2 years of study to reach the required sample size

The drawbacks are that only Malmström's vacuum and Kielland's forceps were used, the patients were not randomly selected, and the evaluation of BMI and the indication for instrumentation—which could be confounding factors—were not included in our assessment. Another possible criticism may be the assessment of the fetal head position and station by digital examination since this method could provide poor reliability[56]. To reduce a possible error, we used intrapartum ultrasound to determine the fetal head position; in addition, the obstetricians performing instrumental delivery, who defined the instrumentation height, had over 5 years of experience in obstetric surgery.

In summary, we failed to find a significantly different avulsion rate [adjusted OR: 2.14 (95%CI: 0.95, 4.85) (p=0.068) between KFD and MVD when the characteristics of instrumentation are considered in the evaluation

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Figure legends:

Figure 1. Multiview display of levator ani muscle bilateral complete avulsion (arrows).

Figure 2. Recruitment diagram. H1. Virgen de Valme University Hospital of Seville. H2. University Healthcare Complex of León. Reasons for exclusion. 1. Instrumentation delivery performed by personnel with less than 5 years of experience. 2. Delivery completed by C-section, or the instrument changed during delivery. 3. Severe maternal or fetal disease. 4. Participation in the study could not be offered (recruitment failure). 5. Candidates did not accept to participate in the study. 6. Participants did not undergo postpartum ultrasound. 7. Ultrasound not suitable to assess LAM avulsion.

Videoclip 1 Pelvic floor damage caused by instrumental delivery. Malmström's vacuum or Kielland’s forceps?

Table 1. General obstetric and intrapartum characteristics (n:414).

	Mean (SD) or n (%)		p
	Malmströn´s Vacuum delivery (n=212)	Kielland´s Forceps delivery (n=202)	
Maternal age (years)	31.5 ±5.2	31.5 ±5.6	0.902
Gestational age (weeks)	39.7 ±1.3	39.5 ±1.3	0.110
Induced labor	51/212 (24.1 %)	45/202 (22.3 %)	0.755
Epidural	210/212 (99.1%)	201/202 (99.5%)	1
Epidural period (min)	409.3±231.5	417.8 ±193.3	0.270
2nd stage of labor (min)	116.6±73.6	99.6 ±70.2	0.008
Episiotomy	208/212 (98.1%)	201/202 (99.5%)	0.373
Perineal tear	43/212 (20.3 %)	55/202(27.2%)	0.206
Grade III	43/212 (20.3%)	69/202 (26.2%)	
Grade IV	0/ 212 (0%)	2/202 (0.9%)	
Newborn weight (kg)	3396.0 ±399.7	3334.2±440.8	0.136
Fetal head circumference (cm)	34.7 ±1.2	34.4 ±1.3	0.133

Data are given as mean (Standard deviation) or number (%)

Table 2: Malmströn´s Vacuum Deliveries and Kielland´s Forceps Deliveries according to the characteristics of the instrumentation.

	Mean (SD) or n (%)		p
	Malmströn´s Vacuum delivery (n=212)	Kielland´s Forceps delivery (n=202)	
Fetal head position			
Anterior	130/178 (73.0%)	131/201(65.2 %)	
Posterior	33/178 (18.5%)	42/201 (20.9%)	0.163
Transverse	15/178 (8.4%)	28/201 (13.9%)	
Height at instrumentation			
Low instrumentation	116/162 (71.6%)	58/89 (65.2%)	0.360
Mid instrumentation	46/162 (28.4%)	31/89 (34.8%)	

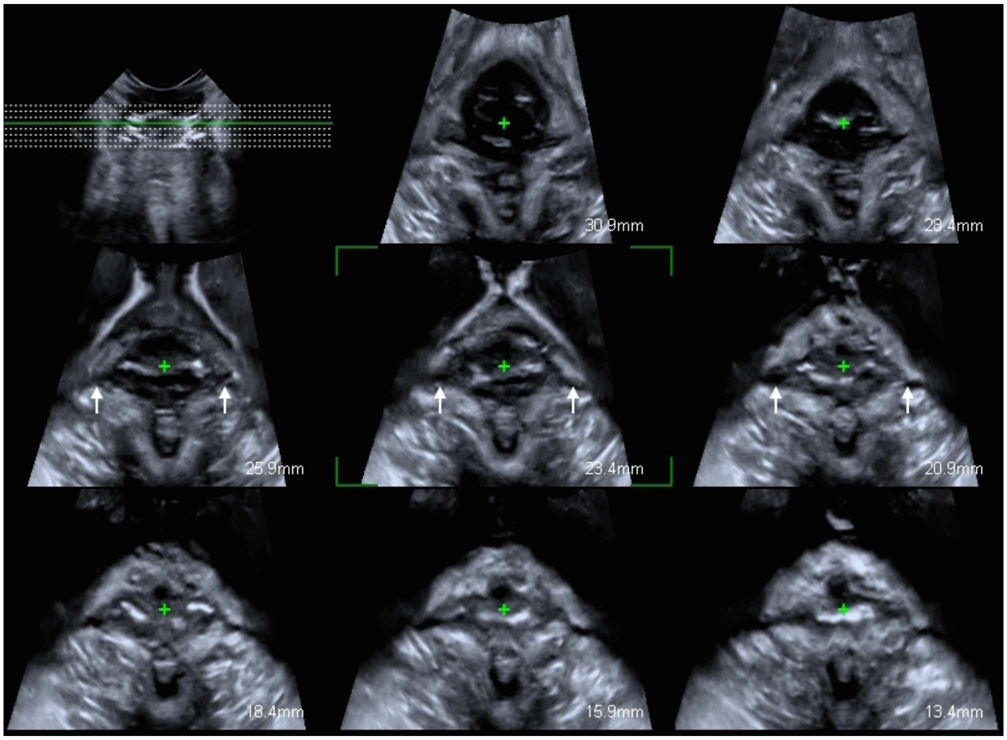
When assessing the influence of the fetal head position and instrumentation height, we excluded cases wherein the data collected in the study did not include these parameters. Data are given as mean (Standard deviation) or number (%)

Table 3: Levator Ani Muscle injury and general levator hiatus ultrasound measurements.

	Mean (SD) or n (%) Malmströn´s Vacuum delivery (n=212)	Kielland´s Forceps delivery (n=202)	p	Crude OR	Adjusted OR
Avulsion	69/212 (32.6%)	100/202 (49.5%)	0.001	2.03 (95%CI: 1.36, 3.03)	2.14 (95%CI: 0.95, 4.85) (p=0.068)
Avulsion in H1	51/162 (31.5%)	47/89 (52.8%)	0.605		
Avulsion in H2	18/50 (36.0%)	53/113 (46.9%)	0.479		
Avulsion in A-LS	22/72 (30.6%)	10/26 (38.5%)	0.474		
Avulsion in T-LS	4/9 (44.4%)	14/21 (66.7%)	0.418		
Avulsion in P-LS	4/15 (26.7%)	4/15(26.7%)	0.419		
Avulsion in A-MS	7/25 (28.0%)	11/19 (57.9%)	0.066		
Avulsion in T-MS	1/3 (33.3%)	2/6 (33.3%)	1		

Avulsion in P-MS	2/5 (40.0%)	5/6 (83.3%)	0.242
Levator hiatus area (cm2)			
Rest	14.6±4.3	14.7±4.1	0.417
Valsalva	18.5±5.3	20.2±6.1	0.001
Maximum contraction	13.6±4.9	12.9±4.2	0.229

H1. Virgen de Valme University Hospital of Seville. H2. University Healthcare Complex of León. A-LS. Operative delivery in the anterior fetal head position and low station. T-LS. Operative delivery in the transverse fetal head position and low station. P-LS. Operative delivery in the posterior fetal head position and low station. A-MS. Operative delivery in the anterior fetal head position and mid station. T-MS. Operative delivery in the transverse fetal head position and mid station. P-MS. Operative delivery in the posterior fetal head position and mid station. Data are given as mean (Standard deviation) or number (%).


30.9mm
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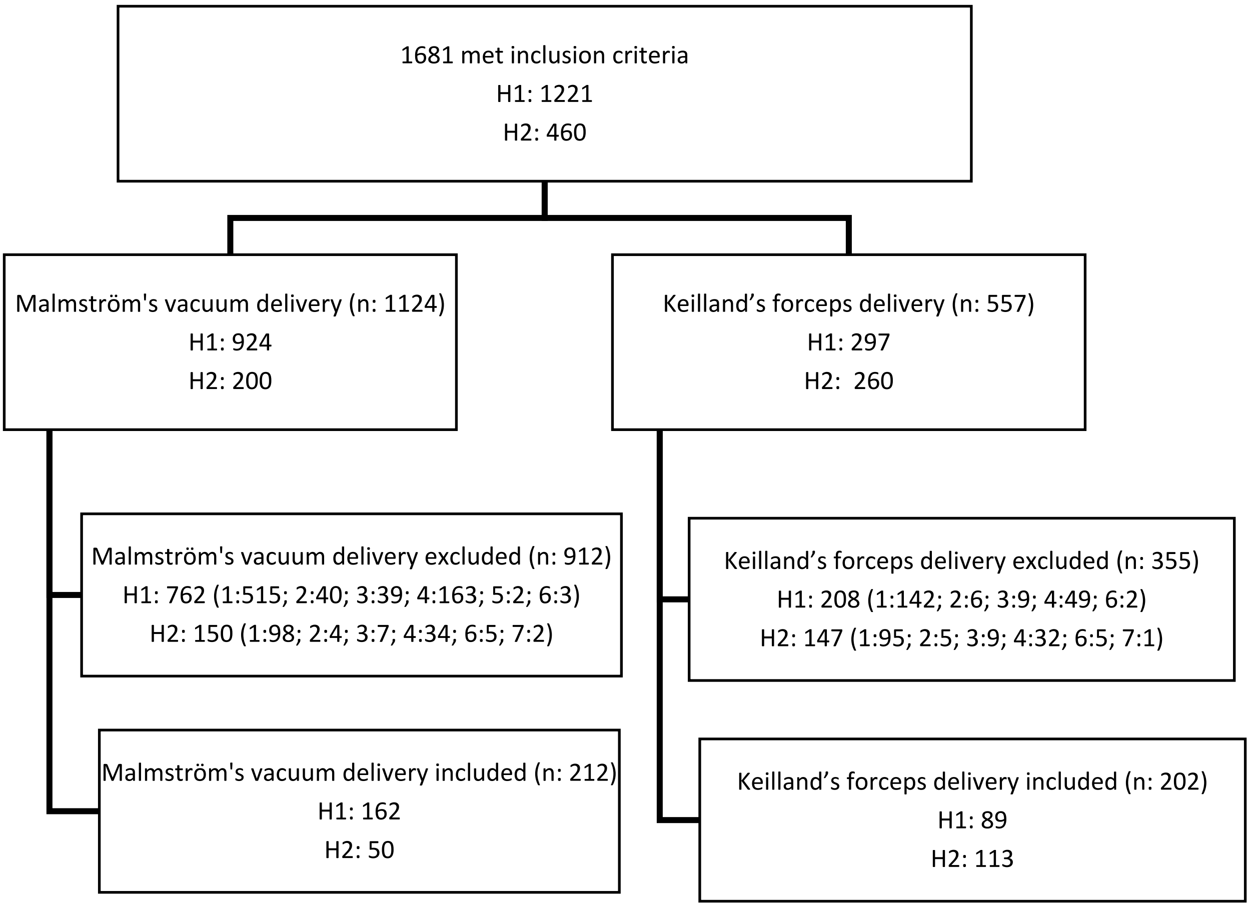
1681 met inclusion criteria
H1: 1221
H2: 460
Malmström's vacuum delivery (n: 1124)
H1: 924
H2: 200
Keilland’s forceps delivery (n: 557)
H1: 297
H2: 260
Malmström's vacuum delivery excluded (n: 912)
H1: 762 (1:515; 2:40; 3:39; 4:163; 5:2; 6:3)
H2: 150 (1:98; 2:4; 3:7; 4:34; 6:5; 7:2)
Keilland’s forceps delivery excluded (n: 355)
H1: 208 (1:142; 2:6; 3:9; 4:49; 6:2)
H2: 147 (1:95; 2:5; 3:9; 4:32; 6:5; 7:1)
Malmström's vacuum delivery included (n: 212)
H1: 162
H2: 50
Keilland’s forceps delivery included (n: 202)
H1: 89
H2: 113