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Is directed open-glottis pushing more effective than directed closed-glottis pushing during the second stage of labor? A pragmatic randomized trial – the EOLE study

Chloé Barasinski[a,*], Anne Debost-Legrand, MD, MPH[a,b], Françoise Vendittelli, MD, PhD[a,b,c]

[a] Université Clermont Auvergne, CHU, CNRS, SIGMA Clermont, Institut Pascal, F-63000, CLERMONT-FERRAND, France
[b] Réseau de Santé en Périnatalité d'Auvergne, F-63000, Clermont-Ferrand, France
[c] AUDIPOG (Association des Utilisateurs de Dossiers Informatisés en Pédiatrie, Obstétrique et Gynécologie), RTH Laennec Medical University, 7 rue Guillaume Paradin, 69372, Lyon Cedex 08, France;

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ABSTRACT

Objective: To compare the effectiveness of directed open-glottis and directed closed-glottis pushing.

Design: Pragmatic, randomised, controlled, non-blinded superiority study.

Settings: Four French hospitals between July 2015 and June 2017 (2 academic hospitals and 2 general hospitals).

Participants: 250 women in labour who had undergone standardised training in the two types of pushing with a singleton fetus in cephalic presentation at term (≥37 weeks) were included by midwives and randomised; 125 were allocated to each group. The exclusion criteria were previous caesarean birth or fetal heart rate anomaly. Participants were randomised during labour, after a cervical dilation ≥ 7 cm.

Interventions: In the intervention group, open-glottis pushing was defined as a prolonged exhalation contracting the abdominal muscles (pulling the stomach in) to help move the fetus down the birth canal. Closed-glottis pushing was defined as Valsalva pushing.

Measurements: The principal outcome was "effectiveness of pushing" defined as a spontaneous birth without any episiotomy, second-, third-, or fourth-degree perineal lesion. The results in our intention-to-treat analysis are reported as crude relative risks (RR) with their 95% confidence intervals. A multivariable analysis was used to take the relevant prognostic and confounding factors into account and obtain an adjusted relative risk (aRR).

Findings: In our intention-to-treat analysis, most characteristics were similar across groups including epidural analgesia (>95% in each group). The mean duration of the expulsion phase was longer among the open-glottis group (24.4 min ± 17.4 vs. 18.0 min ± 15.0, p=0.002). The two groups did not appear to differ in the effectiveness of their pushing (48.0% in the open-glottis group versus 55.2% in the closed-glottis group, for an adjusted relative risk (aRR) of 0.92, 95% confidence interval (CI) 0.74–1.14) or in their risk of instrumental birth (aRR 0.97, 95%CI 0.85–1.10).

Key conclusions: In maternity units with a high rate of epidural analgesia, the effectiveness of the type of directed pushing does not appear to differ between the open- and closed-glottis groups.

Implications for practice: If directed pushing is necessary, women should be able to choose the type of directed pushing they prefer to use during birth. Professionals must therefore be trained in both types so that they can adequately support women as they give birth.

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Introduction

Valsalva breathing was introduced by childbirth professionals in the 1950s to overcome the disadvantages of the lithotomy position and to hasten birth (Simkin et al., 2017). Since then, epidural anal-

* Corresponding author.
E-mail address: cbarasinski@chu-clermontferrand.fr (C. Barasinski).

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gesia has become increasingly widespread throughout the industrialised world; it is currently used by more than 80% of women in France, 58% in the USA, and 30% in the United Kingdom (40% of nulliparas)(Anim-Somuah et al., 2018; INSERM and DRESS, 2017; The Epidural and Position Trial Collaborative Group, 2017). This analgesia appears to affect the management of pushing efforts by reducing the "bearing down" reflex (Anim-Somuah et al., 2018; Lemos et al., 2017; Osborne and Hanson, 2012). For this reason, despite the advice of some professionals against directed pushing, it is widely used in high-income countries, especially among women with epidural analgesia (Colciago et al., 2019; Lee et al., 2018; Macfarlane et al., 2014; Osborne and Hanson, 2012).

A meta-analysis of randomised controlled trials (RCTs) reported no difference between spontaneous and directed pushing for the duration of the second stage of labour, perineal lacerations, duration of pushing, mode of birth, or neonatal outcomes (8 studies, 884 women) (Lemos et al., 2017). The authors concluded that further well-designed and properly conducted RCTs are needed. We searched for studies comparing “directed Valsalva” pushing vs. “directed open-glottis” pushing, given that these are the two practices used most often with epidural analgesia in France. The only published study (Ahmadi et al., 2017) we found had notable methodological problems: numerous exclusion criteria, no data about women's mode of birth or adherence, no intention-to-treat analysis, exclusions after randomisation, and the use of pharmacological pain reduction methods (Ahmadi et al., 2017).

Although 139 million children are now born annually worldwide, we still do not know what type of pushing to recommend during labour, especially for women with epidural analgesia, because the type of pushing associated with the least maternal-fetal morbidity has not yet been determined (Committee on Obstetric Practice, 2017; de Tayrac and Letouzey, 2016; Lemos et al., 2017). Current obstetric practices must thus be assessed so that academic training of perinatal professionals and counselling of women during pregnancy and labour can be appropriately modified on the basis of evidence.

The hypothesis of our study was that closed-glottis pushing might be associated with more risks to mother and child, for two reasons. First, its use of high abdominal pressure might induce pressure on the perineum, which in turn would respond by bulging and contracting, due to the myotatic reflex to stretching (Shafik et al., 2003). This perineal pressure may increase the risk of perineal lacerations. Second, closed-glottis Valsalva type breathing might reduce maternal blood pressure and thereby diminish placental perfusion and fetal oxygenation (Barnett and Humenick, 1982).

The principal objective of our study was to assess the effectiveness of directed open-glottis (i.e., pushing while exhaling) and directed closed-glottis pushing (i.e., Valsalva pushing). Our secondary objectives were to compare, according to the type of pushing, the following outcomes: immediate maternal morbidity, early neonatal morbidity, and uncomplicated births.

Methods

The EOLE study was a randomised, controlled, non-blinded multicentre superiority intention-to-treat trial with two parallel groups, intended to assess the effectiveness of directed open-glottis pushing compared with directed closed-glottis pushing during the active phase of the second stage of labour. We conducted the study in four French centres: two university hospitals and two general hospitals. This study was approved by a French Institutional Review Board on May 21, 2015 (Patient Protection Committee Southeast VI, AU 1168). The protocol is available online (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5223691/) (Bara)(Barasinski and Vendittelli, 2016).

Women of any parity with a singleton pregnancy in cephalic presentation, between 37–42 weeks of gestation, with a planned vaginal birth after spontaneous or induced labour, were eligible for the trial if they had taken an antenatal class that included the specific training developed for the study in the types of pushing. Exclusion criteria were an age younger than 18 years, a previous caesarean birth or other uterine surgery, a disease contraindicating pushing or that might justify emergency delivery (haemolysis-elevated-liver-enzyme-low-platelet [HELLP] syndrome, abruptio placentae, etc.), or any of the following: severe genital haemorrhage, major fetal malformation, polyhydramnios, oligohydramnios, intrauterine growth restriction diagnosed in utero (i.e., below the 5th percentile for gestational age and sex), a fetal heart rate anomaly according to the French guidelines before randomisation (Martin, 2008), or in utero fetal death.

Participants were enrolled in the study by the midwives-investigators during labour, after verification of the inclusion and exclusion criteria, thorough information, and collection of the signed informed consent. They could then randomise the women once cervical dilation reached 7 cm and then guide them with the allocated type of pushing during the expulsion phase. All participants in the trial provided written informed consent before randomisation. Women could be included by the investigating midwives (n=156) at any moment of the day or night.

Randomisation (1:1 allocation) was performed according to a randomisation list created by a computer program designed by an independent group at the hospital's clinical research centre. It was in blocks of four to six and stratified by maternity ward and within maternity wards by both parity (nulliparous vs parous) and epidural analgesia use at randomisation. Both randomisation and data collection took place at a website available 24 hours a day.

There was no conceivable way to conduct this study on either a double- or single-blinded basis. The principal investigator, who had no knowledge of the women's allocation groups, subsequently abstracted maternal and neonatal outcomes from the participants' medical files.

In France, pushing techniques are taught at antenatal childbirth and parenting preparation classes, available free to all pregnant women (Haute Autorité de Santé, 2005). As part of this study, the types of pushing were standardised for both the women and the professionals, with prenatal training for both. All participating staff – that is, all professionals teaching antenatal classes who agreed to support the study and the midwives-investigators who recruited and randomised the women and then managed the birth – were trained in advance in both pushing techniques. A video intended specifically for professionals was developed for the study to standardise the information they provided to women. During pregnancy, women received information about the study and instruction about the types of pushing during antenatal classes, between 29 and 37 weeks of gestation. During one session of prenatal classes, pregnant women saw a video specifically created for the potential study participants, describing and illustrating both types of directed pushing. Those who had completed this session received a card attesting to this instruction, which they were asked to keep with their blood group cards and bring to the labour ward.

In the intervention group, directed open-glottis pushing (with prolonged exhalation) was explained as follows: “After inhaling deeply, you should exhale while pulling in your stomach so that you can use the contraction of your abdominal muscles to help the fetus descend through the birth canal. You should push as long as possible”. In the control group, directed closed-glottis pushing (pushing while holding one's breath) was explained as follows: “After inhaling deeply, you should push very hard downwards to the perineum, while holding the inhaled breath in your lungs. You should push as hard and as long as possible”.

During the birth, both techniques were directed by the attending midwife. Women in both groups were directed to push three times per contraction, as usual in France, if possible. After each birth, the midwife-investigator responsible for it completed a brief summary in the women's electronic case report file, describing, among other things, compliance with the allocated intervention, fetal station at the start of pushing (that is, of the expulsive efforts), the techniques of perineal protection used, etc.

Monitoring of labour and any associated interventions (analgesia, oxytocin, maternal position, etc.) were identical to standard management in the participating maternity units. The onset of the second stage was identified by the midwife with a vaginal examination (routinely practiced hourly in France at the time of the study, or if the woman asked for it). The midwife determined when active pushing began, as delayed pushing during the passive descent phase of the second stage of labour is recommended and practised in France. The direction to push actively normally does not begin until the fetal station has reached at minimum the low pelvis – station +2 to +3. Fetal heart rate and frequency of uterine contractions were nonetheless monitored continuously with an external tocodynamometer throughout labour and during the pushing period. The occurrence of a fetal heart rate anomaly during labour was evaluated by the midwife-investigator or the obstetrician in accordance with French guidelines (Martin, 2008).

Investigators concluding after 20 minutes of active pushing that the allocated type of pushing appeared ineffective could, if they thought it useful, ask mothers to switch to the other type. If fetal heart rate abnormalities or other obstetric emergencies occurred, the midwife and/or the supervising obstetrician were to be the sole decision-makers, jointly with the mother to the extent possible, for the ensuing management (change in pushing technique, or instrumental or caesarean birth). Standard French practices allow an expulsion phase of approximately 30 minutes, when fetal heart rate is normal (Dupuis and Simon, 2008). An operative vaginal delivery should be considered after 30 minutes of adequate active pushing, if birth does not appear imminent (Vayssière et al., 2011).

Our primary outcome was a composite criterion defining effectiveness: spontaneous birth with no perineal lesion (more precisely, no episiotomy or second-, third-, or fourth-degree lacerations). Our secondary outcomes were immediate maternal morbidity, defined by an episiotomy or a third- or fourth-degree perineal laceration or an immediate postpartum haemorrhage (blood loss >500 mL in the 24 hours after birth); immediate neonatal morbidity, defined by a 5-minute Apgar score <7 or an umbilical artery pH <7.10 or need for resuscitation in the birth room (defined by one or more of the following events: aspiration by laryngoscope, mask ventilation, oxygenation by nasal cannula or hood mask, tracheal intubation, endotracheal ventilation, or cardiac massage), or transfer to a neonatology department. Finally, a composite secondary outcome for mother and child, considered to be a quality indicator, was uncomplicated birth, defined by birth with a 5-min Apgar ≥9 and with none of the following: caesarean birth, operative intervention, or obstetric manoeuvers, postpartum haemorrhage (blood loss >500 mL), second-, third-, or fourth-degree perineal lacerations.

The onset of any serious adverse event to mother or child (death or transfer to adult or neonatal intensive care unit) was to be immediately reported on a special form to the study investigators. An independent monitoring committee was set up at the beginning of the study and available for consultation by the sponsor.

For α=0.05 and a power of 90%, based on data from the French Audipog database (http://www.audipog.net/interro-choix.php) that 49.6% of all parturients give birth spontaneously, without any perineal lesion (that is, with neither an episiotomy nor a spontaneous second-, third-, or fourth-degree laceration), the investigators estimated that a two-sided test showing an absolute difference between groups of 20% (that is, 49.6% vs. 69.6%, a relative difference on the order of 40%) would require 125 women per group.

The analysis of the primary outcome included all women who were randomised and assigned to the interventional (directed open-glottis pushing) or the control group (directed closed-glottis pushing) on an intention-to-treat basis (except as otherwise specified), after a description of the baseline characteristics of the women and children (age, weight, parity, adherence, etc.) in both groups. Adherence to the allocated intervention was defined by the number of uterine contractions for which pushing complied with allocated group over the total number of uterine contractions with pushing and characterised in three qualitative categories. Thus adherence category 1 included women with 100% compliance, that is, 100% of whose pushes were of the allocated type. Adherence category 2 comprised those with compliance ≥ 80%, and adherence category 3 those whose compliance was ≥ 50%.

The principal results are reported as crude relative risks (RR) with their 95% confidence intervals (CI). A multivariate analysis (generalised linear model with a manual backwards stepwise procedure) was used to take the relevant prognostic and confounding factors into account and obtain an adjusted relative risk (aRR) with its 95% CI. Because the publications assessing the types of pushing at birth have not reported any confounding factors, and no authors have published a multivariate analysis, we chose the clinically relevant confounding factors identified by the univariate analyses ($p \leq 0.20$) and prepregnancy body mass index (BMI), suggested in the literature (Deruelle et al., 2017). We also looked for clinically relevant interactions between the type of pushing and other factors. The same procedure was used to analyse the secondary outcomes. When the prevalence was low, however, we sought to calculate a crude odds ratio (OR) and an adjusted OR (aOR) if possible. The threshold for statistical significance was set at 5%. One per protocol and one subgroup analysis were also performed for the principal outcome: one considering women with adherence level 3 for each group and one for the women with an epidural analgesia only. The statistical analysis was conducted with SAS software (Statistics Program for Public Health on IBM-compatible Microcomputer, version 9.4).

The EOLE trial was registered at clinicaltrial.gov (NCT02474745).

Findings

The study took place from July 9, 2015, through June 14, 2017, when we reached the predetermined sample size. Of the 255 women randomised during this period, five were excluded, all by the next day: four for non-adherence to the protocol (two did not meet the eligibility criteria and two had midwives who were not listed as investigators, as required by the protocol and French law), and one decided not to participate before the intervention (Fig. 1). The number of eligible women is not available because the women were required to have taken the one-session training course in the types of pushing planned by the protocol, to be conducted during a standard antenatal course offered to all women receiving antenatal care in France. These sessions take place mainly in private practice, outside French hospitals. No data were missing for any of the maternal or neonatal outcomes.

Baseline characteristics, neonatal data and characteristics of participants' labour and birth are detailled in Table 1 and in Table 2.

The mean compliance of the open-glottis group (61.7 %±31.0) was significantly lower than that of the closed-glottis group (98.6%±8.5, $p<0.0001$) (Table 3). Only 65.6% of the women in the open-glottis group adhered to the allocated type of pushing for at least half the contractions during their pushing.

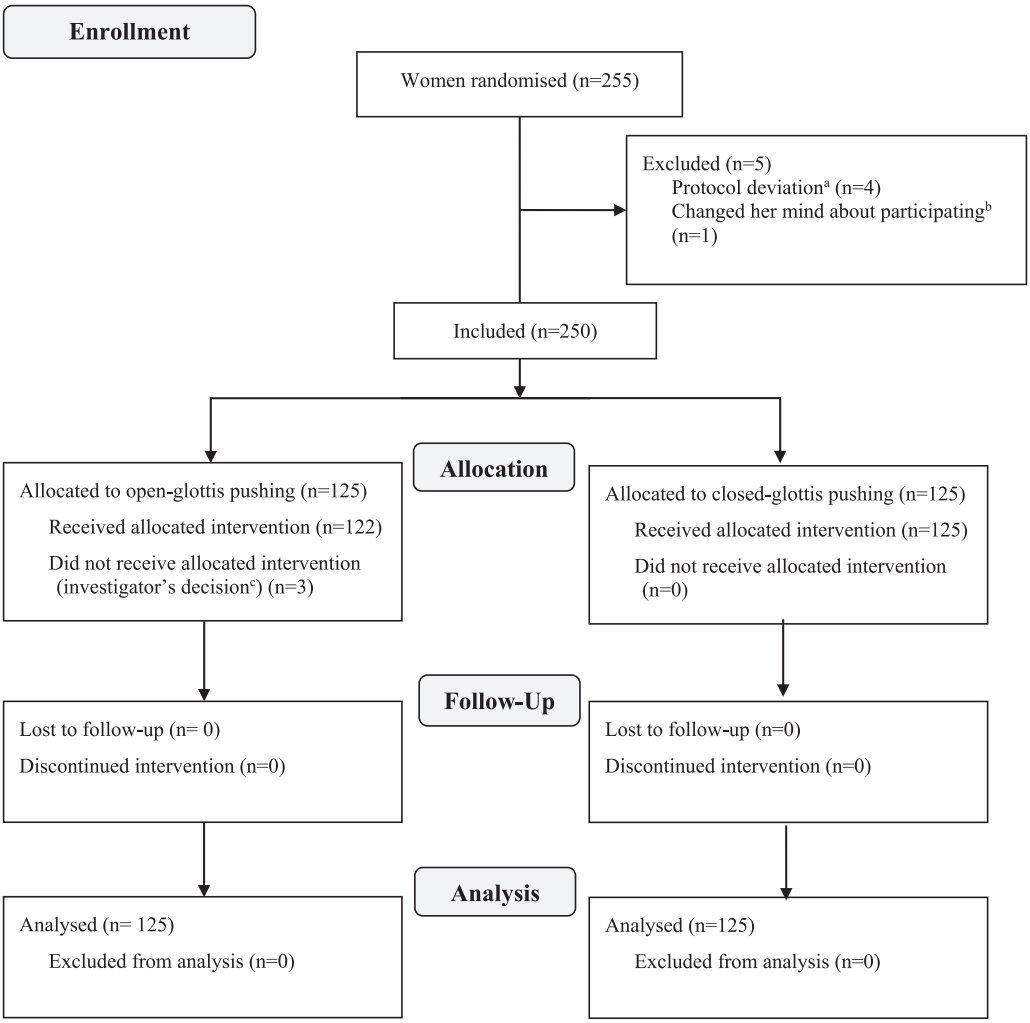

Fig. 1. EOLE trial profile.
This figure describes the flow chart of our randomised study.
[a]2 births were supervised by midwives who were not study investigators and 2 failed to comply with inclusion criteria.
[b]Refusal after randomisation and before intervention (pushing).
[c]Fetal heart rate abnormalities were associated with posterior positions in two cases and in one case with a fetus suspected of macrosomia.

We found no statistically significant difference for the effectiveness of the pushing between the two groups: 48% in the open-glottis and 55.2% in the closed-glottis group; crude RR 0.87, 95% CI 0.68–1.11 (Table 4).

After adjustment for the confounding factors (prepregnancy BMI and station at start of pushing) and the clinically relevant prognostic factors (parity, fetal head position at start of pushing, fetal heart rhythm [FHR] at risk of acidosis (Martin, 2008), and birth weight), we again found no statistically significant difference in the effectiveness of pushing between the two groups: aRR 0.92, 95% CI 0.74–1.14 (Table 4). We found an interaction with parity but the analysis stratified by parity found no difference between the two groups (Table 4). The per protocol analysis (of women who adhered to the allocated pushing for at least 50% of their contractions) found open-glottis pushing was more effective, with a crude RR 1.41, 95% CI 1.12–1.78; after adjustment, the difference was no longer statistically significant: aRR 1.18, 95% CI 0.94–1.47 (data not shown). The results did not change when we limited our intention-to-treat analysis to the women who had epidural analgesia (n=240): crude RR 0.86, 95% CI 0.67–1.11; aRR 0.92, 95% CI 0.73–1.16 (data not shown).

Immediate maternal morbidity included the eight women who had caesarean sections: six in the open-glottis and two in the closed-glottis group. Of the six caesareans in the former group, three took place during the active expulsion phase: forceps-assisted delivery failed for one, and two others had a caesarean for non-engagement at full dilation. The other three took place before expulsive efforts began: one for failure to progress to seven centimetres of dilation and two for non-engagement. Both caesareans in the closed-glottis group took place before expulsive efforts began: one for lack of progress in dilation to seven centimetres and one for non-engagement at full dilation. We found no statistically significant difference for operative birth between the two groups (24% in the open-glottis and 20% in the closed-glottis group) for either the crude or adjusted RRs: RR 1.24, 95% CI 0.78–1.98 and aRR 0.97, 95% CI 0.85–1.10 (Table 4).

We found no statistically significant difference for the onset of immediate postpartum haemorrhage (Table 4) or the mean volume of blood loss after birth, with 255.8±300.1 ml lost in the open-glottis and 232.6±214.5 ml in the closed-glottis group (p=0.48), or for the rate of uncomplicated births: 44.8% in the open-glottis and 49.6% in the closed-glottis group, aRR 0.97, 95% CI 0.76–1.23

Table 1
Baseline characteristics of the trial participants.

Baseline characteristics	Open-glottis pushing (n=125)	Closed-glottis pushing (n=125)
Age (y)	30.1 ± 4.0	30.5 ± 3.7
Body mass index (kg/m^2)	22.5 ± 3.4	22.9 ± 4.2
Lives with partner	120 (96.0)	119 (95.2)
Geographic origin		
Metropolitan France	121 (96.8)	115 (92)
Educational level		
Post-secondary education	96 (76.8)	94 (75.2)
Worked during pregnancy	105 (84)	110 (88)
Obstetric history		
Nulliparous	87 (69.6)	85 (68)
Parous	38 (30.4)	40 (32)
Previous child with BW> 4000 g	1/38 (2.6)	3/40 (7.5)
Smoked at the beginning of pregnancy	25 (20)	17 (13.6)

Data are expressed as means ± standard deviation, n or n/n (%).
Abbreviation: BW, birth weight.

Table 2
Characteristics of participants' labour and birth, by treatment group.

Characteristics of labour and birth	Open-glottis pushing (n=125)	Closed-glottis pushing (n=125)
Gestational age at birth (weeks)	40.1 ± 1.0	40.1 ± 1.0
Spontaneous labour	101 (80.8)	106 (84.8)
Epidural analgesia	121 (96.8)	119 (95.2)
Duration of labour		
Active phase of first stage[a] (min)	325.6 ± 183.1	310.2 ± 162.4
Passive descent of second stage[b] (min)	n=122[c]113.3 ± 74.4	n=123[c]94.3 ± 72.2
Abnormalities during labour	89 (71.2)	83 (66.4)
Fetal heart rate abnormality[d]	72 (80.9)	70 (84.3)
Obstructed labour[e]	18 (20.2)	15 (18.1)
Use of oxytocin	70 (56.0)	60 (48.0)
Maternal position at birth[c]		
Dorsal decubitus position with stirrups or footholds	117/122 (95.9)	119/123 (96.7)
Fetal station at start of pushing[c]		
High – station -5 to -1	4/122 (3.3)	1/123 (0.8)
Mid – station 0 to +1	37/122 (30.3)	25/123 (20.3)
Low – station +2 to +3	67/122 (54.9)	68/123 (55.3)
Outlet – station +4 to +5	14/122 (11.5)	29/123 (23.6)
Fetal head position at start of pushing[c]		
Anterior (OA, LOA, ROA)	112/122 (91.8)	111/123 (90.2)
Transverse (LOT, ROT)	0/122 (0)	2/123 (1.6)
Posterior (OP, LOP, ROP)	10/122 (8.2)	9/123 (7.3)
Not determined	0/122 (0)	1/123 (0.8)
Technique of perineal protection		
Perineal massage[c]	36/122 (29.5)	35/123 (28.5)
Warm compresses[c]	27/122 (22.1)	30/ 123 (24.4)
Maintenance of the fetal head		
Hands-on[f]	86/89 (96.6)	94/ 98 (95.9)
Neonatal data at birth		
Fetus in occiput anterior position at birth	122[g](99.2)	119[g](96.8)
Weight (g)	3316.4 ± 395.8	3332.0 ± 409.7
Head circumference (cm)	n=125 34.5 ± 1.5	n=124[h] 34.6 ± 1.4

Data are expressed as means ± standard deviation, n or n/n (%).
Abbreviation: FHR, fetal heart rate; OA, occiput anterior; LOA, left occiput anterior; ROA, right occiput anterior; LOT, left occiput transverse; ROT, right occiput transverse; OP, occiput posterior; LOP, left occiput posterior; ROP, right occiput posterior.
[a] Duration from 3 cm of dilation or from admission to full dilation or until caesarean birth if dilation is not completed.
[b] Time from full dilation until the start of pushing.
[c] Only women with (or after a trial of) vaginal birth.
[d] All types of abnormalities (early, late, or variable decelerations or bradycardia or tachycardia or abnormal variability, or any combination).
[e] Abnormal progression of cervical dilation speed or abnormal progression of the fetal head.
[f] Only during spontaneous vaginal births.
[g] In the open-glottis group: 1 LOA and 1 ROA in the closed-glottis group: 1 ROP and 3 OP.
[h] One missing data item.

(Table 4). Similarly, perineal outcomes (intact perineum or first-degree tears; perineal lacerations or episiotomy; severe perineal lacerations or episiotomy) did not differ between the groups in either the crude or multivariate analyses (Table 4).

No significant difference was found between the groups for mean umbilical artery and venous pH (respectively p=0.73 and p=0.62) or for umbilical artery pH <7.10: OR 1.98, 95% CI 0.28–22.26 (Table 4). No newborn had a 5-minute Apgar <7 in the study and only two newborns in the open-glottis and one in the closed-glottis group were transferred to the neonatology department after birth.

We encountered no adverse effects attributable to maternal pushing in our trial.

Table 3
Adherence to the allocated type of pushing and duration of the expulsion phase.

	Open-glottis pushing (n=119[a])	Closed-glottis pushing (n=123[a])	*P*-value
Adherence to the allocated intervention[b]			
All women (%)	61.7 ± 31.0	98.6 ± 8.5	<0.0001
By parity			
Nulliparous (%)	55.5 ± 29.6	99.0 ± 7.7	<0.0001
Parous (%)	75.1 ± 30.1	97.8 ± 10.0	<0.0001
Adherence to the allocated pushing type			
Adherence 1[b]	34 (28.6)	118 (95.9)	<0.0001
Adherence 2[b]	43 (36.1)	120 (97.6)	<0.0001
Adherence 3[b]	78 (65.6)	122 (99.2)	<0.0001
If compliance not total (<100%)			
woman's decision	9/85 (10.6)	2/5 (40.0)	0.18
practitioner's decision	62/85 (72.9)[c]	3/5 (60.0)[d]	
both	14/85 (16.5)[e]	0/5 (0)	
Duration of the expulsion phase (min)	24.4 ± 17.4	18.0 ± 15.0	0.002
< 15 min	40 (33.6)	63 (51.2)	0.006
< 30 min	77 (64.7)	98 (79.7)	0.01
≥ 30 min	42 (35.3)	25 (20.3)	0.01

Data are expressed as means ± standard deviation, n or n/n (%).
[a] Number of women with a vaginal birth.
[b] Number of uterine contractions for which pushing complied with allocated group/total number of uterine contractions with pushing. Adherence Category 1 included women with 100% compliance; adherence category 2 comprised those with compliance ≥ 80%, and adherence category 3 those whose compliance was ≥ 50%.
[c] Detailed reasons are: obstructed labour (34 women), fetal heart rate abnormalities (19 women), clinical need (7 women), no detailed reason (2 women).
[d] Detailed reason is obstructed labour (3 women).
[e] Detailed reasons are: obstructed labour (12 women) and fetal heart rate abnormalities (19 women).

Discussion

Our randomised controlled trial found no statistically significant difference in the adjusted risk of the effectiveness of directed open-glottis vs. directed closed-glottis pushing: aRR 0.92, 95% CI 0.74–1.14 (48% of the women in the open-glottis and 55.2% of those in the closed-glottis group). Nor did our study find differences for severe perineal lacerations, episiotomies, immediate postpartum hemorrhages, uncomplicated births, or adverse neonatal outcomes, as assessed by low umbilical cord pH or the need for neonatal special care.

One of the strengths of our study is that, unlike most studies on this topic, we standardised the training for both pregnant women and professionals with a specific training session and two separate films specifically created for the study (Barasinski et al., 2016). Our study was pragmatic, that is, conducted by all maternity unit midwives and including all eligible women regardless of whether they gave birth during weekday day shifts, with broad inclusion criteria (all women, regardless of parity, with a planned vaginal birth, whether or not labour was spontaneous, as long as they had attended the relevant session of the antenatal birth and parenting class) to facilitate recruitment and ensure the good internal and external validity of our results. Our study is also the only one to include mostly women using epidural analgesia (>95%). This inclusion rate is an important strength in view of the need for evidence-based practices for the increasing number of women with epidural analgesia (82.2% in France in 2016) (INSERM and DRESS, 2017). Only one prior study, by Low et al., had a significant percentage of patients with epidural analgesia—around 60% (directed vs. spontaneous pushing; n=39 vs. 34) (Low et al., 2012). Finally, we looked for confounding factors and took them into account in the multivariate analysis, unlike earlier studies (Barasinski et al., 2016).

One limitation of this multicentre study is that finally it took place mainly at a single centre, which prevented us from identifying a centre effect. A second limitation is the less than optimal compliance in the open-glottis group (61.7±31.0% vs. 98.6±8.5%). Adherence, if defined as compliance with the allocated type of pushing for ≥50% of the pushes, was observed among 65.6% of the women in the open-glottis group and 99.2% in the closed-glottis group. However, among the published randomised trials, only two specified adherence to the allocated intervention as defined by a threshold ≥50% (Barasinski et al., 2016). Parnell et al. (1993) reported adherence rates of 34.4% in their open-glottis group and 75.5% for closed-glottis pushing, and Low et al. (2012) 76.4% and 65% respectively. Our percentage of adherence is thus better in the Valsalva group than in either of these studies, and adherence in the open-glottis pushing group is better than that in the study by Parnell et al. (1993) and slightly lower than in the study by Low et al. (2012) The practice of open-glottis pushing, even when directed, may be hampered by the use of epidural analgesia, which may reduce the desire to push (Lemos et al., 2017). Some authors even consider that this point alone justifies the use of Valsalva pushing (Lemos et al., 2017; Roberts and Hanson, 2007; Roberts, 2002).

In any case, our per protocol analysis to take into account the non-optimal compliance did not find a statistically significant difference in adjusted risk for the principal outcome. A third limitation is that we lacked the power to assess neonatal rare outcomes and other secondary outcomes. Although one retrospective trial (Lee et al., 2019) reports that directed pushing is associated with increases in resuscitation and nursery admission, the Cochrane review on this topic included all randomised controlled trials and was unable to conclude that any particular type of pushing was preferable for neonatal outcomes (Lemos et al., 2017).

In our study, we found that pushing was effective for 48% of the women in the open-glottis group and 55.2% of those in the closed-glottis group, but our composite endpoint has not previously been used in the literature. When we look specifically at mode of birth our results are consistent with those in the literature, since no randomised trial has found that any type of pushing affects the mode of birth (Bloom et al., 2006; Low et al., 2012; Thomson, 1993). Similarly, the meta-analysis by Lemos et al. (2017) did not observe any significant difference in the mode of birth (RR=1.01, 0.97-1.05; 5 studies; 688 women). Only one other study has found a significant difference in perineal outcomes: Ahmadi et al. (2017) found more women with an intact perineum in the open-glottis than in the Valsalva group (p=0.002). Nonetheless, their study had no-

Table 4
Maternal and neonatal outcomes according to trial group.

	Open-glottis pushing (n=125)	Closed-glottis pushing (n=125)	Crude RR (95% CI)*Crude OR (95% CI)*	Adjusted RR (95% CI)*Adjusted OR (95% CI)*
Maternal outcomes				
All women				
Effectiveness of pushing	60 (48.0)	69 (55.2)	0.87 (0.68–1.11)	0.92 (0.74–1.14)[a]
Nulliparous	30/87 (34.5)	38/85 (44.7)	0.77 (0.53–1.12)	0.81 (0.57–1.15)[b]
Parous	30/38 (79.0)	31/40 (77.5)	1.02 (0.81–1.29)	1.07 (0.85–1.34)[b]
Mode of birth				
Spontaneous vaginal birth	89 (71.2)	98 (78.4)	1	1
Operative vaginal birth[c]	30 (24.0)	25 (20.0)	1.24 (0.78–1.98)[d]	0.97 (0.85–1.10)[a,d]
Caesarean	6 (4.8)	2 (1.6)	–	–
Immediate postpartum hemorrhage	11 (8.8)	8 (6.4)	*1.41 (0.50–4.19)*	*1.27 (0.44–3.84)*[e]
Uncomplicated birth	56 (44.8)	62 (49.6)	0.90 (0.69–1.17)	0.97 (0.76–1.23)[f]
Women with vaginal births				
Intact perineum or first-degree perineal tears	69/119 (58.0)	76/123 (61.8)	0.94 (0.76–1.15)	0.96 (0.79–1.16)[g]
Nulliparous	38/81 (46.9)	44/83 (53.0)	0.89 (0.65–1.20)	0.91 (0.68–1.22)[h]
Parous	31/38 (81.6)	32/40 (80.0)	1.02 (0.82–1.27)	1.08 (0.87–1.33)[h]
Perineal tears and lacerations[i]	84/119 (70.6)	89/123 (72.4)	0.98 (0.83–1.14)	0.98 (0.83–1.14)[h]
First-degree	64/84 (76.2)	68/89 (76.4)	1	1
Second-degree	15/84 (17.9)	20/89 (22.5)	0.84 (0.46–1.52)	0.82 (0.44–1.53)[g]
Third-degree	5/84 (6.0)	1/89 (1.1)	–	–
Episiotomy[i]	31/119 (26.1)	27/123 (22.0)	1.19 (0.76–1.86)	1.08 (0.74–1.59)[h]
Severe perineal lacerations or episiotomy	36/119 (30.3)	27/123 (22.0)	1.38 (0.90–2.12)	1.26 (0.85–1.86)[h]
Neonatal outcomes				
Arterial pH	n=119[j] 7.24 ± 0.07	n=122[j] 7.23 ± 0.07	–	–
< 7.10	2/119 (1.7)	4/122 (3.3)	*1.98 (0.28–22.26)*	–
Venous pH	n=115[j] 7.30 ± 0.06	n=114[j] 7.29 ± 0.07	–	–
Resuscitation in the birth room[k]	2 (1.6)	3 (2.4)	–[l]	–
Transfer to neonatology department	2 (1.6)	1 (0.8)	–[l]	–

Data are expressed as n, n/n (%) or mean ± standard deviation unless otherwise specified.
Abbreviation: RR, Relative risk; CI, Confidence interval; OR, Odds Ratio.
[a] RR adjusted for confounding factors (prepregnancy BMI and station at start of pushing) and clinically relevant predictive factors (parity, fetal head position at start of pushing, FHR at risk of acidosis as defined in the 2007 French guidelines [www.cngof.fr], birth weight).
[b] RR adjusted for confounding factors (prepregnancy BMI and station at start of pushing) and clinically relevant predictive factors (fetal head position at start of pushing, FHR at risk of acidosis, birth weight).
[c] 24 had a birth assisted by vacuum in the open-glottis group and 19 in the closed-glottis group, and respectively, 3 and 1 by forceps, 1 and 3 by vacuum and forceps, 1 and 1 by vacuum and spatulas, and 1 and 0 by spatula; finally 0 and 1 had a manoeuver for shoulder dystocia.
[d] RR and adjusted RR calculated with caesareans excluded.
[e] RR adjusted for clinically relevant predictive factors (parity, induction of labour, oxytocin use, mode of birth, duration of the active phase of the first stage of labour, birth weight).
[f] RR adjusted for confounding factors (prepregnancy BMI and fetal head station at start of pushing) and clinically relevant predictive factors (parity, induction of labour, oxytocin use, fetal head position at start of pushing, FHR at risk of acidosis, duration of the active phase of the first stage, birth weight).
[g] RR adjusted for confounding factors (prepregnancy BMI and fetal head station at start of pushing) and clinically relevant predictive factors (parity, fetal head position at start of pushing, FHR at risk of acidosis, mode of birth, birth weight).
[h] RR adjusted for confounding factors (prepregnancy BMI and fetal head station at start of pushing) and clinically relevant predictive factors (fetal head position at start of pushing, FHR at risk of acidosis, mode of birth, birth weight).
[i] There were no fourth-degree perineal lacerations in the study and no parous woman had an episiotomy.
[j] Data missing because pH could not be assessed.
[k] Aspiration by laryngoscope and/or mask ventilation and/or oxygenation by nasal cannula, or hood mask and/or tracheal intubation, and/or cardiac massage.
[l] No statistical test because of lack of power for this outcome.

table methodological problems, as mentioned above. Finally, we included a composite endpoint that can be considered a quality indicator for maternity units: uncomplicated births. These occurred in half the women in each group (aRR = 0.97, 95% CI 0.76-1.23). Like Lemos et al. (2017), we found no statistically significant differences in neonatal outcomes. Our results therefore do not support the theory of Barnett and Humenick (1982), who suggested that Valsalva-type pushing might lead to a decrease in fetal pH and therefore in cord blood pH at birth.

Some authors recommend against the use of Valsalva pushing, but neither our results nor those of the literature support such advice (King and Pinger, 2014; Roberts and Hanson, 2007). The alternation of the types of pushing while giving birth (mixed pushing with open- and closed-glottis, directed or not) may be the optimal practice for some women, but this has never been scientifically proven. Moreover, our study might have shown a positive effect of the type of pushing if an expulsion phase >30 min with directed pushing and a normal fetal heart rate had been practiced. So long an expulsion period was, however, contrary to standard French practices and national guidelines (Dupuis and Simon, 2008).

In our study, the duration of the active phase of the second stage was 24.4 ± 17.4 min in the open-glottis group vs 18.0 ± 15.0 min in the closed-glottis group (p=0.002). Nonetheless, the two groups did not differ in their use of epidural analgesia. The meta-analysis of Lemos et al. (2017), including a few women with epidural analgesia, failed to find a difference between the groups for either mode of birth or duration of the second stage of labour (mean difference: -10.26 minutes (95% CI: -1.12; +21.64) in favour of directed pushing; n= 667). It should also be noted that the maternity wards in our study applied French recommendations for delayed pushing for women with epidural analgesia (Vayssière et al., 2011). The caesarean rate was low in both of our groups (4.8% vs. 1.6%) because of the late randomisation during labour but also because the policy of the maternity units participating was to keep the caesarean rate (20% in France) from rising, in accordance with French guidelines (Haute Autorité de Santé, 2012; INSERM and DRESS, 2017). Inversely, the rate of instrumental births was high.

In view of the apparent lack of difference in maternal and neonatal outcomes according to the type of directed pushing (open-glottis vs. closed-glottis), women with epidural analgesia

during birth, if directed pushing is necessary, should be able to choose the type of directed pushing they want, according to their preferences and their experience. Professionals must therefore be trained in both types so that they can adequately support women as they give birth. Other studies are needed to assess the perineal outcome in the intermediate or even long term according to the type of pushing for women with epidural analgesia. Future studies might also consider the possibility of other strategies of pushing without directed management.

Ethical Approval

This study was approved by a French Institutional Review Board on May 21, 2015 (Patient Protection Committee Southeast VI, AU 1168).

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Clinical Trial Registry and Registration number

The EOLE trial was registered at clinicaltrial.gov (NCT02474745).

Declaration of Competing Interest

The authors declare no conflict of interest.

CRediT authorship contribution statement

Chloé Barasinski: Conceptualization, Methodology, Software, Investigation, Writing - original draft, Project administration, Visualization. **Anne Debost-Legrand:** Formal analysis, Data curation, Writing - review & editing. **Françoise Vendittelli:** Funding acquisition, Conceptualization, Methodology, Formal analysis, Supervision, Writing - review & editing, Visualization.

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