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Abstract

Introduction: The breech presentation represents 4,7% of deliveries at term. There is a method of external cephalic version (ECV) performed from 36 weeks of gestation. French guidelines for the clinical practice of ECV were published in 2020.

Objective: To evaluate the national practices of ECV in French maternity units, especially on the use of tocolysis, 1 year after publication of the French clinical recommendations guidelines by the French national college of obstetricians and gynecologists (CNGOF).

Methods: Data self-reported for this national descriptive study were collected from March to May 2021 by an online questionnaire distributed to all French maternities. The 25 items of the questionnaire collected information of maternity units, the general practice of ECV, use or not of tocolysis for ECV attempt and the relevance of a prospective study.

Results: Of the 517 French maternity units, 150 (29%) responded to the online survey. 95,3% systematically performed ECV. A Kleihauer test was routinely performed in 71 units (49.7%). A tocolysis was associated with ECV attempt in 52.4% of cases. The drugs used were intravenous atosiban (30,7%), mainly in levels 2b and 3 maternity units, intravenous salbutamol (24%), other mode of administration of salbutamol (14,7%) and oral nifedipine (22,6%) mainly in levels 1 and 2a maternity units. Adverse effects were described in 20%, mainly with the use of salbutamol (73,3%).

Conclusions: 52.4% of the French maternity units surveyed used tocolysis for the ECV attempt, although it is systematically recommended. The choice of tocolytic drug differed according to the maternity units.

Keywords: breech presentation, external cephalic version, ECV attempt, tocolysis, atosiban, salbutamol

Introduction

In France, the breech presentation at term represents 4.7% of deliveries according to the latest national perinatal survey of 2016 [1]. The caesarean section rate is 81% for breech presentation and 12% for cephalic presentation [1]. Compared to vaginal delivery, caesarean section is associated with a lower quality of life for women [2,3] and greater maternal-foetal complications, especially respiratory complication [4–6].

There is a method of external cephalic version (ECV), performed from 36 weeks of gestation [7], which aims to exert a direct manual force on the foetus, in order to facilitate its rotation to a cephalic presentation, in order to reduce the rate of caesarean sections. Its safety has already been demonstrated [8–10]. The success rate of ECV in the literature is between 39 and 65% [11]. In France, it is between 16 and 24% [12–14]. The predictive factors for successful ECV are multiparity, transverse presentation, gestational age <38 SA [14,15] and the absence of maternal obesity [16]. In 2020, the French guidelines of French national college of obstetricians and gynecologists (CNGOF) recommended to systematically purpose ECV attempt to the women with non-cephalic presentation of the foetus and in the absence of contraindication [17].

International [18,19] and French [17] guidelines recommend the use of a drug with a tocolytic action (Intravenous beta-mimetic or intravenous atosiban, an oxytocin antagonist) which will improve uterine relaxation during ECV attempt. Indeed, in relaxed women, the success rate would be higher [20].

The French national guidelines of ECV seem to be heterogeneous and sometimes not very protocolized. The objective of this descriptive study was to collect the different information concerning the practice of ECV in French maternity units, and to compare them with the new guidelines of the CNGOF in 2020, particularly on the use and means of tocolysis.

Methods

This national multicentre descriptive study, carried out as an online self-report survey, made it possible to collect data and carry out a status report concerning the practice of ECV in France and more specifically on the use of tocolysis.

All French maternity units, public or private, including the French overseas departments and regions (DROMs), were targeted, i.e., 517 health facilities according to the last perinatal survey of 2016 [1]. Metropolitan France was divided into five geographic areas: northwest, northeast, southwest, southeast, and Ile de France. The legal status of the maternity units was defined in two categories: public (general hospitals and university hospitals) or private (also with mission of public service).

Data were collected from March 16th, 2021, to May 12th, 2021, and were stratified by level of perinatal care. Level of perinatal care was defined according to the classifications in the French regulations on the safety of childbirth published in 1998 : level 1, level 2a, level 2b and level 3 [21].

An online survey was created at the "Google Forms" site and distributed by e-mail to the various practitioners responsible for the birth room, through the perinatal networks or directly to business email addresses (Appendix 1). The link to the questionnaire was sent to each maternity a maximum of three times.

The survey comprised 9 parts including 25 items: the first part collected informations on the maternity units (7 items). Parts 2, 3, and 4 reported information on the performance of ECV in general (7 items: number of ECV attempts per year, success rate, operator, complications). Parts 5 and 6 concerned the use or not of tocolysis for ECV attempt (5 items: drug, time between administration and performance of the procedure, adverse effects). Parts 7 and 8 discussed the relevance of a possible prospective study. The ninth part allowed for any remarks or comments on the study.

Responses were short open-ended, single or multiple choice. Only one response per maternity unit was retained. For centers that replied multiple times, we retained the first one.

A data table was produced with the Google Forms platform as well as on the Excel software. Calculations were performed with Excel software (version 16.49).

Results

Among the 517 French maternities surveyed, 150 (29%) participated in the study by completing the online questionnaire (Figure 1).

Table 1 summarizes the characteristics of the participating centers according to their level of perinatal care. The different levels of perinatal care units were evenly distributed. All regions of France were represented, including the DROMs. The number of reported births per year increased proportionally with the level of maternity unit (level 1: 1,002 +/- 704, level 2a: 1,595 +/- 939, level 2b: 2,077 +/- 784, level 3: 3,208 +/- 1,030). The health professionals who responded were obstetricians-gynaecologists in 88.7% of cases and midwives in 10.7%.

Among the 143 maternity hospitals (95.3%) that systematically offered ECV attempt to affected women, the number of annual ECV attempts seemed to increase with the level of maternity unit, with an average number of ECV attempts per year, across all levels of care combined, of 55 (Table 2). We note that 4.7% of the hospitals participating in the study (n=7) did not perform ECV, in particular following a complication, lack of practice from the doctor or in order to perform vaginal breech delivery. The versions were performed by a senior physician in most cases, or by a resident with a second attempt by a senior in case of failure, or by 4 hands (Figure 2). Half of the hospitals surveyed (n=71, i.e. 49.7%) systematically performed a Kleihauer test after carrying out an ECV attempt. Twenty eight percent declared that they had already performed emergency caesarean sections after an ECV attempt, mainly in level 3 maternity units (n=24/40 or 60%). The approximate number of C-sections reported was 1 or less. Regarding the use of tocolysis, 75 maternities (52.4%) stated that they regularly used them for ECV attempt, with a median time between administration and ECV attempt of 30 minutes. The main drugs administered for tocolytic purposes were salbutamol (38.7%, all routes of administration combined), intravenous atosiban (30.7%) and oral nifedipine (22.6%). Intravenous atosiban is mostly used in level 2b and 3 maternity units, as opposed to level 1 and 2a which prefer intravenous salbutamol and/or oral nifedipine. Twenty percent had adverse effects, for which salbutamol seemed to be the most frequently involved drug (n=11/15, 73.3%). In majority of cases, the side effects described were maternal tachycardia, nausea-vomiting or arterial hypotension.

Half of the participants were convinced of the value of tocolysis in ECV attempt, particularly in level 2 and 3 maternity units (n=64, 88.9%) (Table 3).

Seventy-six percent would be interested in participating in a possible study evaluating the value of tocolysis in ECV attempt in France. Of the 114 positive responses to a possible participation in a new study, 112 detailed their choices concerning the different study arms. While 70.5% (n=79) would accept a placebo arm, 65.2% (n=73) an intravenous atosiban arm, 38.4% (n=43) an arm without placebo or tocolysis and 25% (n=28) an intravenous salbutamol arm (Figure 3).

Discussion

This national survey was conducted one year after French clinical guidelines (CNGOF) concerning breech foetuses [17].

The number of average annual ECV attempts increased with the level of care of maternity unit (n=26 for level 1, n=33 for level 2a, n=55 for level 2b, and n=81 for level 3), in proportion to the number of deliveries reported. However, the success rate does not seem to vary with the number of ECV attempts and therefore with practice (level 1: 42% success for 26 ECVs/year, level 2a: 38% for 33 ECVs/year, level 2b: 40% for 55 ECVs/year, level 3: 36% for 81 ECVs/year). In our study, the success rate varied between 10 and 70% with a median of 40%, whether performed by a senior, a resident, or four hands. A study published in 1997 by Teoh et al [23] found no significant difference between the success rate and the experience of the operator.

According to the latest French guidelines, tocolysis should be systematically used to increase the success of ECV [17].

Among the practitioners, 52.4% surveyed used tocolysis for ECV attempt. The tocolytic agents recommended in France are atosiban or intravenous Beta mimetics. A 2015 Cochrane review [8] stated that tocolysis with IV Beta mimetics significantly decreased the failure rate compared to placebo (45.7% vs. 65.4%; RR=0.70; CI95% 0.60-0.82) as well as the caesarean section rate (51.5% vs. 67.0%, RR 0.77 CI95 0.67-0.88) [19]. Velzel's randomized trial comparing fenoterol with atosiban during ECV attempt found an immediate success rate with atosiban of 34% versus 40% with fenoterol (RR=0,73; CI95 0.55-0.93) [24]. There was no difference in the rate of cephalic presentation at entry into labour and the rate of caesarean

delivery. Furthermore, in a recent meta-analysis comparing IV atosiban with other tocolytics, specially Beta mimetics, Riemma et al. concluded that atosiban did not increase the success rate of ECV compared with Beta agonists (36.7% vs. 45.3%, RR 0.78, CI95 0.6-0.98) [25]. The results were non-significant regarding the mode of delivery between the 2 groups.

In our study, intravenous atosiban was the most used drug (30.7%), although it does not have marketing authorization (MA) for this indication, followed by intravenous salbutamol (24%). The MA for atosiban exists to date in France for threats of preterm delivery, and not for ECV attempt. These practices varied according to the level of care of the institutions. Indeed, the use of atosiban was more important in levels 2b and 3 in contrast to salbutamol in levels 1 and 2a because of side effects. Oral nifedipine was still utilized in 22.6% of cases, although it is not recommended [26–28]. In fact, Wilcox et al. in 2011 in a meta-analysis [29], showed a decrease in the success rate with oral nifedipine compared to IV terbutaline (36.8% vs 55.0% respectively, CI95% 0.48-0.93) and no significant difference between oral nifedipine and a placebo (41.6% vs 37.2% respectively, p=0.43).

In the 68 maternities declaring not to use tocolysis for ECV attempt, some justify this by the cost of the drugs, particularly atosiban, or by a large number of maternal adverse effects with salbutamol.

Although it was not specified in the French clinical practice guidelines [17], time between administration of tocolysis and performance of ECV seems to be relatively similar in all maternities with an average delay declared at 28 minutes. This figure is arbitrary and may vary according to activity in the delivery room.

A descriptive study of German practices published in 2020 [30], similar to our study, showed a greater use of tocolysis (70.2%), mainly with fenoterol (95.5%). Nifedipine and atosiban were rarely used. The adverse effects reported were relatively similar to those described in our study (maternal tachycardia, nausea, arterial hypotension). Usually, ECV was performed by a senior physician (78.3%). The participation rate in the study was 37.2%.

The side effects encountered during the administration of tocolytics were mostly found with salbutamol, regardless of the mode of administration. It represented 73.3% of the side effects (n=11/15). Atosiban was involved in 13.3% of cases (n=2/15). These results are consistent with the literature. Velzel et al [24] and Riemma et al [25] observed that atosiban was significantly less responsible for side effects than Beta mimetics (30% vs. 75.7%, RR 0.4 CI95 0.33-0.48 and

16% vs. 42.9%, RR 0.38, CI95 0.31-0.47). They did not correspond to serious adverse events. Palpitations were the most common. In our study, 28% of participants reported having performed less than one emergency caesarean section per year after an ECV attempt, i.e., an estimated caesarean section rate of 1.8% (1/55). The cause was not specified. In the German study by Kohls et al. [30], 85% reported an emergency caesarean rate of <1% and the most commonly reported indication was pathological cardiotocography.

Among the limitations of this study, the response rate was 29%. This result was expected for a study with an online survey, although it was higher than for a study of the same size [22]. Extrapolating from the 324,444 deliveries reported by the 150 maternities, this represents almost 44% of children born in 2020 (740,000 births). Equal participation of all levels of maternity units, as well as public and private institutions, relatively similar to the perinatal survey of 2016 [1], resulted in a representative sample.

This sample is similar to or slightly larger than a study based on the same model [22].

The reported figures for success rates, emergency caesarean section rates and side effects should be treated with caution as participants were only asked about their personal assessment and no verifiable figures were available.

It should be interested to assess the management of the failure of the ECV attempt because according to the maternities, it is different. In fact, for some maternities, breech presentation at term induce a caesarean section or for other teams, the delivery route is systematically discussed.

Nevertheless, at this time, there is no study in the French population comparing the different tocolytics in this indication and its consequences in terms of costs and consequences for mothers and newborns.

In addition, 57.3% of the maternity hospitals that participated think that other studies would be necessary to confirm the interest of tocolysis for ECV attempt. 76%, i.e. 114 centres, would be interested in participating in this study with the possible arms in order of choice: a placebo, intravenous atosiban or an arm without placebo or tocolysis.

Conclusion

Among the French maternity units surveyed, 52.4% use of tocolysis for the performance of ECV, although it is systematically recommended. The choice of tocolytic drug differs according to the level of maternity units.

Declaration of interests

Any authors have financial competing interests. Vincent Dochez is a regular reviewer of the editorial board. Norbert Winer and Thibault Thubert are associate editors of this journal. The other authors have no non-financial competing interests.

Author Contributions:

Conceptualization, L.H., V.-P.R. and V.D.; methodology, M.L.; validation, T.T. and N.W.; investigation, A.C.-D. and I.B.; writing—original draft preparation, L.H. and V.D..; writing—review and editing, M.L. and V.-P.R.; visualization, C.A.; supervision, T.T. and N.W.; project administration, A.D. and I.B. All authors have read and agreed to the published version of the manuscript

Ethics statement

No ethical approval required, given the study design.

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Figure 1: Flowchart

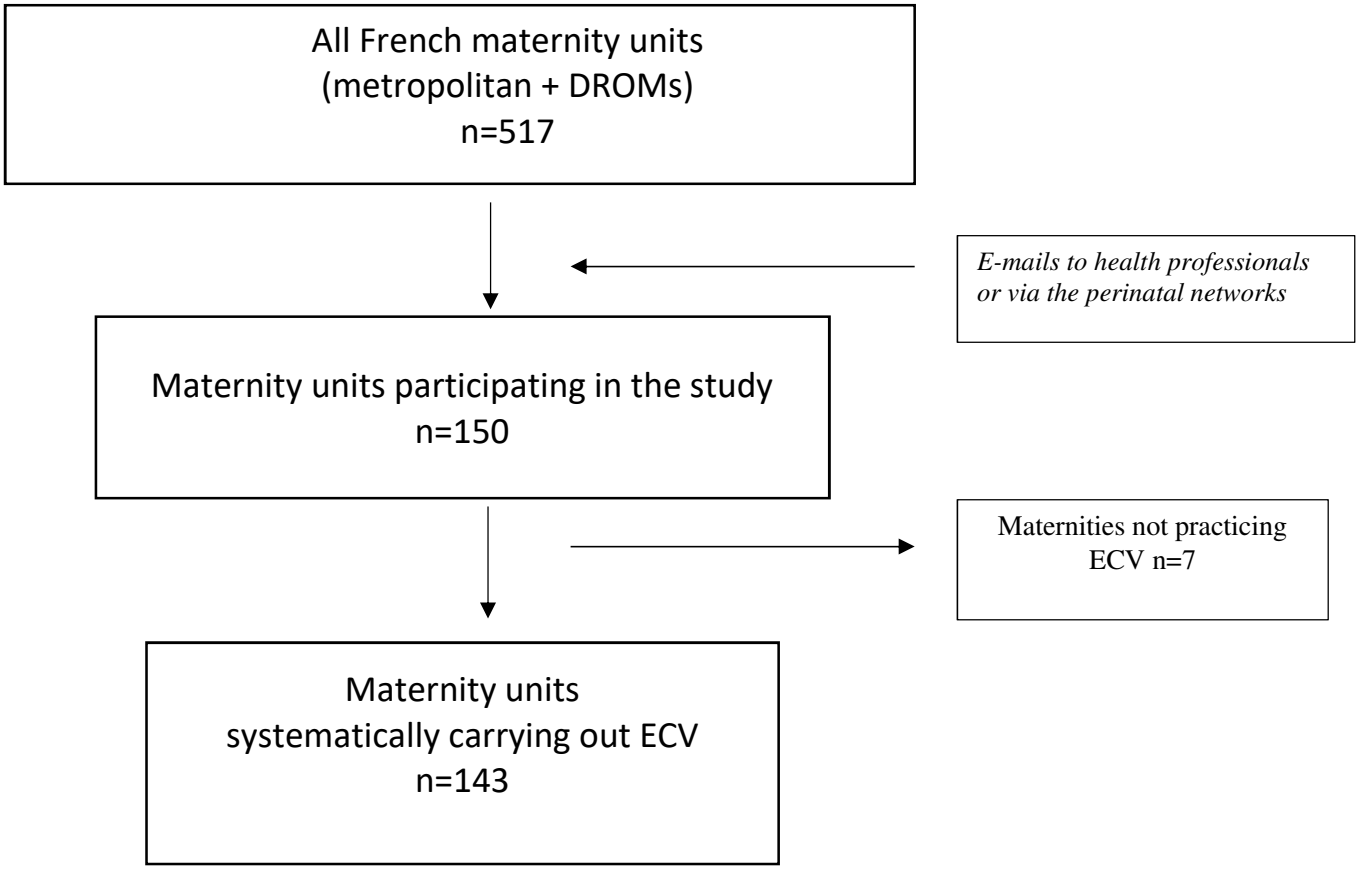

Figure 1: Distribution of operators performing External Cephalic Version

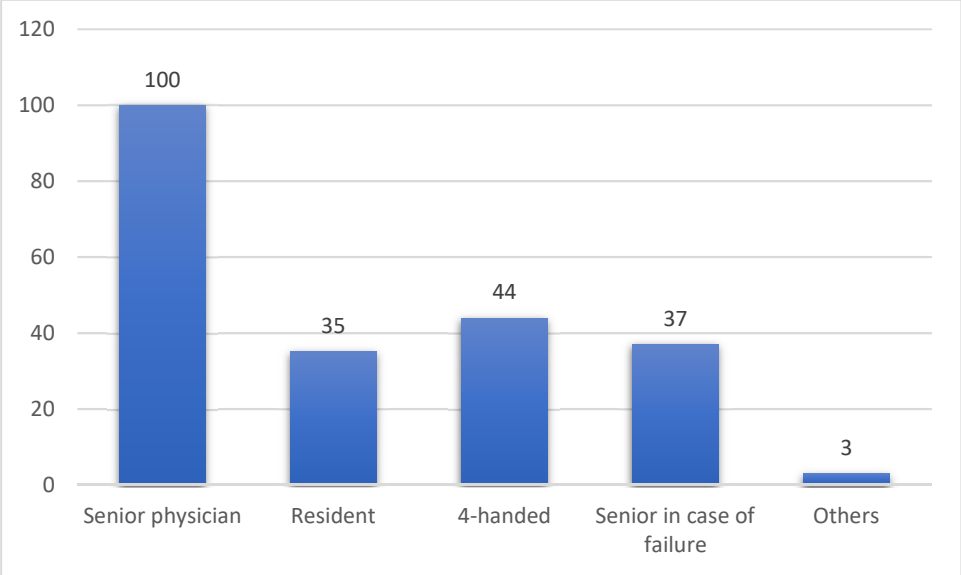

Figure 3: Distribution of the choices of the different arms of the study

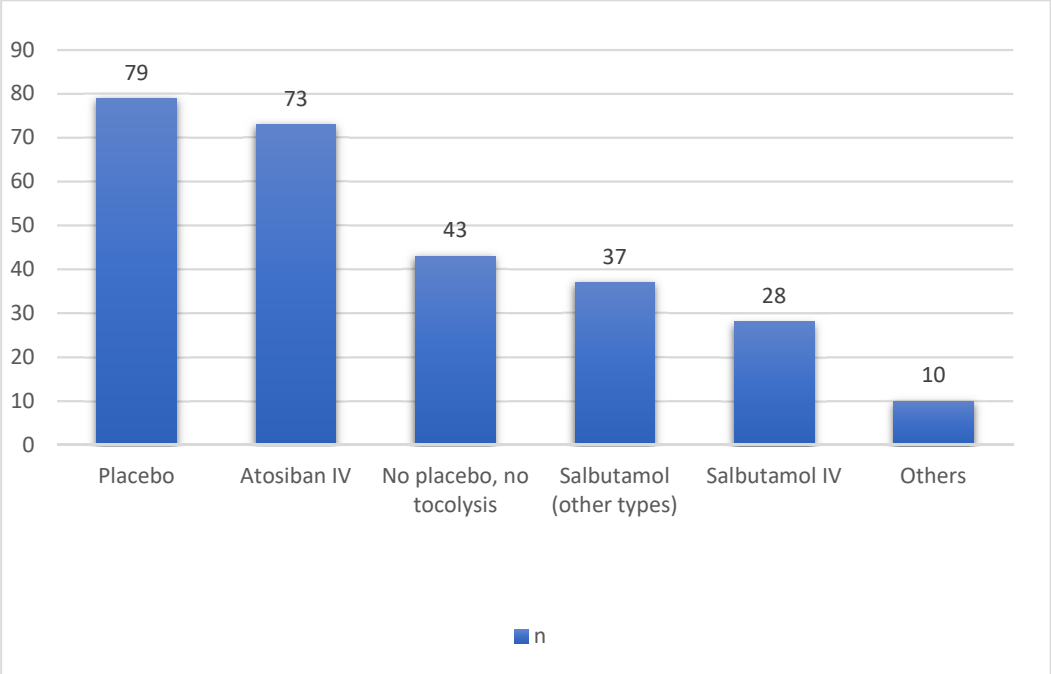

Table 1 : Characteristics of participating maternity units according to level of care

	Level 1	**Level 2a**	**Level 2b**	**Level 3**	**Total**
Participating centers, *n* (%)	24 (16,0)	37 (24,7)	39 (26,0)	50 (33,3)	150 (100)
Geographic origin, *n* (%)					
Ile de France	7 (29,2)	5 (13,5)	6 (15,4)	9 (18,0)	27 (18,0)
Northwest	13 (54,1)	13 (35,1)	15 (38,5)	13 (26,0)	54 (36,0)
Northeast	1 (4,2)	7 (19,0)	9 (23,1)	9 (18,0)	26 (17,3)
Southwest	0 (0)	3 (8,1)	2 (5,1)	6 (12,0)	11 (7,3)
Southeast	2 (8,3)	5 (13,5)	6 (15,4)	10 (20,0)	23 (15,4)
DROM	1 (4,2)	4 (10,8)	1 (2,5)	3 (6,0)	9 (6,0)
Public/Private, *n* (%)					
Public (general and teaching hospitals)	13 (54,2)	27 (73,0)	36 (92,3)	50 (100,0)	126 (84,0)
Private and PSPH	11 (45,8)	10 (27,0)	3 (7,7)	0 (0)	24 (16,0)
Number of reported deliveries per year, *n* (%)					
Total	24 047 (7,4)	59 005 (18,2)	81 002 (25,0)	160 390 (49,4)	324 444 (100,0)
Public	12 125 (50,4)	41 645 (70,6)	73 702 (91,0)	160 390 (100,0)	287 862 (88,7)
Private and PSPH	11 922 (49,6)	17 360 (29,4)	7 300 (9,0)	0 (0)	36 582 (11,3)
Number of reported deliveries per year					
Mean +/- SD	1 002 +/- 704	1 595 +/- 939	2 077 +/- 784	3 208 +/- 1 030	2 163 +/- 1 208
Median	808	1400	2000	3100	2000
Q1-Q3	600-1 079	1 000-1 950	1 456-2 600	2 500-3 730	1 162,5-3 100
Status of respondents, *n* (%)					
Obstetrician-gynecologist	21 (87,5)	32 (86,5)	36 (92,3)	44 (88,0)	133 (88,7)
Midwife	3 (12,5)	5 (13,5)	2 (5,1)	6 (12,0)	16 (10,7)
Health care manager	0 (0)	0 (0)	1 (2,6)	0 (0)	1 (0,6)

DROM: French overseas departments and regions
PSPH: private establishments participating in the public hospital service
Q1: 1st quartile
Q3: 3rd quartile
SD: standard deviation

Table 1: Practices related to ECV and tocolysis according to level of care

	Level 1 (*n* = 22)	Level 2a (*n* = 33)	Level 2b (*n* = 38)	Level 3 (*n*= 50)	Total (*n* = 143)
Number of reported ECVs per year					
mean +/- SD	26 +/- 34	33 +/- 33	55 +/- 45	81 +/- 60	55 +/- 51
median (Q1-Q3)	20 (9-23)	20 (17-40)	40 (25-81)	45 (45-100)	20 (20-71)
Reported success rate of ECV (%)					
mean +/- SD	42 +/- 18	38 +/- 17	40 +/- 17	36 +/- 13	38 +/- 16
median (Q1-Q3)	50 (30-50)	30 (30-50)	40 (25-50)	32 (30-50)	40 (30-50)
Systematic performance of a Kleihauer test after ECV attempt, *n* (%)	14 (63,6)	18 (54,5)	15 (39,5)	24 (48,0)	71 (49,7)
Have you ever performed emergency cesarean section after ECV attempt ? *n* (%)					
Yes	3 (13,6)	4 (12,1)	9 (23,7)	24 (48,0)	40 (28,0)
No	18 (81,8)	29 (87,9)	28 (73,7)	25 (50,0)	100 (70,0)
Don't know	1 (4,6)	0 (0)	1 (2,6)	1 (2,0)	3 (2,0)
Regular use of tocolysis for ECV attempt, *n* (%)	11 (50,0)	17 (51,5)	22 (57,9)	25 (50,0)	75 (52,4)
Tocolytic drug used, *n* (%)					
Atosiban IV	2 (18,1)	3 (17,6)	9 (40,9)	9 (36,0)	23 (30,7)
Salbutamol IV	3 (27,3)	5 (29,4)	5 (22,7)	5 (20,0)	18 (24,0)
Salbutamol other mode of administration (IM, SC, oral, suppository)	3 (27,3)	2 (11,8)	2 (9,1)	4 (16,0)	11 (14,7)
Oral nifedipine	3 (27,3)	5 (29,4)	4 (18,2)	5 (20,0)	17 (22,6)
Others	0 (0)	2 (11,8)	2 (9,1)	2 (8,0)	6 (8,0)
Time between administration of tocolysis and ECV attempt (in minutes)					
mean +/- SD	24 +/- 10	29 +/- 16	26 +/- 8	30 +/- 21	28 +/- 15
median (Q1-Q3)	20 (20-30)	30 (20-30)	30 (20-30)	30 (20-30)	30 (20-30)
Have you observed any side effects des with the use of tocolysis ? *n* (%)					
Yes	3 (27,3)	2 (11,8)	4 (18,2)	6 (24,0)	15 (20,0)
Atosiban IV	1 (33,3)	0 (0)	0 (0)	1 (16,7)	2 (13,3)
Salbutamol (any mode of administration)	2 (66,7)	2 (100,0)	3 (75,0)	4 (66,6)	11 (73,3)
Oral nifedipine	0 (0)	0 (0)	0 (0)	1 (16,7)	1 (6,7)
Others	0 (0)	0 (0)	1 (25,0)	0 (0)	1 (6,7)
No	8 (72,7)	14 (82,4)	18 (81,8)	19 (76,0)	59 (78,7)
Don't know	0 (0)	1 (5,8)	0 (0)	0 (0)	1 (1,3)

ECV: External Cephalic Version
IM: intramuscular
IV: intravenous
SC: subcutaneous
Q1: 1st quartile
Q3: 3rd quartile
SD: standard deviation

Table 3: Evaluation of the relevance of a new study on tocolysis and ECV

	Level 1 (n=24)	**Level 2a (n=37)**	**Level 2b (n=39)**	**Level 3 (n=50)**	**Total (n=150)**
Would you consider changing your practice according to the new CNGOF guidelines and using tocolysis for ECV ? n (%)					
Yes	9 (37,5)	13 (35,1)	18 (46,2)	25 (50,0)	65 (43,3)
No	8 (33,3)	9 (24,3)	15 (38,5)	16 (32,0)	48 (32,0)
Don't know	7 (29,2)	15 (40,5)	6 (15,3)	9 (18,0)	37 (24,7)
Are you personally convinced of the value of tocolysis for ECV ? n (%)					
Yes	8 (33,3)	20 (54,1)	24 (61,5)	20 (40,0)	72 (48,0)
No	10 (41,7)	11 (29,7)	13 (33,3)	19 (38,0)	53 (35,3)
Don't know	6 (25,0)	6 (16,2)	2 (5,2)	11 (22,0)	25 (16,7)
Do you think more studies are needed to confirm the value of tocolysis for ECV ? n (%)					
Yes	12 (50,0)	17 (45,9)	24 (61,5)	33 (66,0)	86 (57,3)
No	5 (20,8)	9 (24,3)	11 (28,2)	12 (24,0)	37 (24,7)
Don't know	7 (29,2)	11 (29,8)	4 (10,3)	5 (10,0)	27 (18,0)
If a study evaluating the value of tocolysis for ECV were to be conducted, would you be interested in participating in it ? n (%)					
Yes	15 (62,5)	24 (64,9)	35 (89,7)	40 (80,0)	114 (76,0)
No	9 (37,5)	13 (35,1)	4 (10,3)	10 (20,0)	36 (24,0)
Don't know	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

CNGOF: French national college of obstetricians and gynecologists.
ECV: External cephalic version