

Evaluation of adherence to French clinical practice guidelines in the management of pregnancy loss issued by the French College of Obstetricians and Gynecologists, one year after publication: A vignette-based study.

Evaluation of adherence to French RPC in the management of pregnancy loss

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Introduction

The management of pregnancy loss in the first trimester is a significant part of the activity of obstetricians/gynecologists, and particularly consultations for gynecological emergencies. It is the most common complication of pregnancies, with an estimated incidence of approximately 12% (1).

The French College of Obstetrician Gynecologists (CNGOF) published recommendations for clinical practice (RCP) for the management of pregnancy loss in 2014 (2). Previously, the term pregnancy loss grouped missed early miscarriage and incomplete early miscarriage. Three alternative therapeutic treatments were used for both situations: misoprostol, watching-and-waiting, and surgical treatment by aspiration (3, 4).

The RCP introduced precise definitions for types of fetal loss, including definitions of missed early miscarriage and incomplete early miscarriage, to standardize practice. Missed early miscarriage is defined as the arrest of development (stagnation of the size of the gestational sac and/or cranio-caudal length and/or the disappearance of cardiac activity) before 14 weeks of amenorrhea. Incomplete early miscarriage is defined as an early miscarriage with persistent intrauterine material on ultrasound. Two decision algorithms for determining uterine vacuity are recommended. In the event of a missed early miscarriage, the two recommended treatment options are surgical aspiration or misoprostol medication, as watching-and-waiting is not recommended. In cases of incomplete early miscarriage, the two recommended treatment options are surgical aspiration or watching-and-waiting, and misoprostol is not recommended.

The adherence of French obstetricians/gynecologists to these national recommendations in their daily practice has not been evaluated. Thus, the objective of this study was to assess the adherence of French obstetricians/gynecologists to the RCP of pregnancy loss one year after their publication.

Materials and Methods

This study was a survey of professional practices in the form of a questionnaire sent by email on January 25, 2016 to French obstetricians/gynecologists who were on a national mailing list. A reminder was sent one month later. The inclusion criteria were: being an obstetrician/gynecologist and working in France.

The questionnaire was anonymous. Practitioners responded concerning their type of practice (university hospital (CHU), regional hospital (CHR), or private practice), their field of specialization (gynecological surgery, obstetrics, mixed activity, medical gynecology, or medically assisted procreation), and the year they obtained their medical qualification. The number of years of professional experience was calculated based on the year of their medical qualification and classified into five categories: less than five years, between 6 and 10 years, between 11 and 20 years, between 21 and 30 years, and more than 31 years of experience.

The questionnaire focused on the RCP chapter on ensuring uterine vacuity following a first trimester pregnancy loss (5). We used clinical vignettes (6) to evaluate the professional practices of the obstetricians/gynecologists. A review of the literature showed that there were no clinical vignettes related to the management of pregnancy loss in the first trimester.

We thus constructed two clinical vignettes with an unequivocal diagnosis according to the 2014 RCP: incomplete early miscarriage and missed early miscarriage. We created two vignettes for each of these two situations: one in 2012, before the RCP and one in 2016, after the RCP. Each vignette indicated that the patient had no allergy or comorbidity and that this was the first loss of a first-trimester pregnancy in a primigravida nulliparous patient (Appendix 1). The doctors stated whether they felt they had changed their practices since the release of the RCP.

For each vignette, the responding physician selected the intended medico-surgical management from among watching-and-waiting, misoprostol, endo-uterine aspiration, and operative hysteroscopy. For misoprostol, the dose, route, and duration of administration were

specified. When aspiration was chosen, the physician indicated whether or not the aspiration product was sent out for analysis.

The primary outcome measure was the percentage of responses conforming to the RCP before and after 2014. A proposal to treat the patient by aspiration and/or misoprostol for missed miscarriage early and surgical treatment and/or watching-and-waiting for incomplete early miscarriage conformed to the RCP and were scored as correct.

Secondary outcome measures focused on three points in the RCP: the avoidance of watching-and-waiting for the management of missed early miscarriage; the non-use of misoprostol for the treatment of incomplete early miscarriage; and the prescribing modalities of misoprostol. The rate of watching-and-waiting for the management of missed early miscarriage, the use of misoprostol for the management of incomplete early miscarriage, and the number of correct prescriptions of misoprostol before and after 2014 were compared. We also investigated the rate of pathology analysis of the aspiration products.

We analyzed the influence of the type of practice and work experience on adherence to the RCP. The management of missed early miscarriage and incomplete early miscarriage according to type of practice and the amount of experience were compared before and after the release of the RCP. We also analyzed the correct management of missed early miscarriage and incomplete early miscarriage.

We performed a matched descriptive statistical analysis for each vignette using R statistical software: we compared ordinal variables before and after RCP using the McNemar test and the means using the nonparametric Mann Whitney test. A p value < 0.05 was considered to be significant.

Résultats

An e-mail was sent to 404 obstetricians/gynecologists working in metropolitan France and Réunion. The response rate was 35.4%. The main demographic characteristics are presented in Table 1.

Among the responding practitioners, 43% reported that they had changed their practices in the management of pregnancy loss since the RCP were issued in 2014. Self-reported adherence to the RCP for the management of missed early miscarriage is summarized in Table 2 and that for incomplete early miscarriage in Table 3.

There was moderate adherence to the RCP for the management of missed early miscarriage (53% correct cases) by responding practitioners as a whole. There was a significant difference before and after the publication of the RCP ($p = 0.01$). Adherence to the RCP was better in the subgroup of practitioners reporting a change in their practices, with 72% reporting correct management of the cases versus 46% before the release of the RCP; this change was significant ($p = 0.001$).

Adherence to the RCP for incomplete early miscarriages was low (43% correct management of the cases post-RCP), although there was a significant improvement since publication ($p < 0.001$). Adherence was better in the subgroup of practitioners reporting a change in their practices since publication of the RCP (62% correct management after versus 23% before the RCP, $p < 0.001$).

Misoprostol prescription was described by 138 physicians: 21.7% prescribed it only vaginally before the RCP and 36.9% after, a statistically significant difference ($p < 0.001$). The oral route remained the most commonly used with 68.1% of prescriptions before 2014 and 52.2% after ($p < 0.001$). Five % of physicians prescribed it sublingually alone or had no preferential route of administration (random sublingual, oral, or vaginal administration), both before and after the release of the RCP. The prescribed dose of misoprostol was correct in 28% of cases before the RCP and 38% after, a statistically significant difference ($p = 0.003$).

Anatomopathological analysis of the aspiration product was requested by 82.5% of practitioners before release of the RPC versus 78% after, a statistically significant difference ($p = 0.02$).

In secondary analysis, we investigated whether the type of professional practice or work experience influenced adherence to the RCP (Table 3 for the management of missed early miscarriage and Table 4 for incomplete early miscarriage). Comparison of the pre-/post-RCP treatment of missed early miscarriage and incomplete early miscarriage did not reveal any significant difference according to type of professional practice. Adherence to the recommendations for the management of incomplete early miscarriages varied depending on professional experience: Adherence to the RCP was better for practitioners with work experience of less than 20 years.

Discussion

The rate of adherence to the RCP was moderate (53% correct) for the vignette involving missed early miscarriage. It was low (43%) for incomplete early miscarriage. There was a tendency to less watching-and-waiting for the management of missed early miscarriages since the publication of the RCP. Watch-and-wait management exposes patients to an increased risk of the absence of spontaneous expulsion, unscheduled surgical treatment, and blood transfusion (7).

The use of misoprostol was less frequent for cases of incomplete early miscarriage. Misoprostol does not improve the rate of complete evacuation over watching-and-waiting after two weeks and has no benefit concerning infections or hemorrhage (2).

The national RCP were the result of extensive review of available data, involving systematic analysis of the literature concerning a generally controversial subject for which there was no indisputable reference. RCP help practitioners in their medical decisions by informing them of the best practices.

These national RCP are known to French obstetricians/gynecologists: 43% of responders reported having changed their practices since their publication. Our study did not show a difference in conformity to RCP for missed early miscarriage according to experience or type of professional practice. However, adherence to the RCP for the management of incomplete early miscarriage was better among practitioners working in University hospitals and those whose professional experience did not exceed 20 years.

The typical profile of responders was an obstetrician/gynecologist with between 20 and 30 years of professional experience with predominantly surgical or mixed activity. Our survey included physicians working in university hospitals, regional hospitals, and private practice. The subgroup of practitioners declaring that they have integrated the RCP into their practices had less professional experience (13.14 years on average versus 20.11 years for non-members, $p = 0.0001$), and a mixed or

surgical activity in a university medical center (33 practitioners or 54% of those who integrate the RCP into their daily practices).

These findings confirm the need to promote continuing medical education outside of university hospitals and the importance of continuing professional development, which is now facilitated by financial compensation for doctors in private practice.

Among the 61 practitioners reporting a change in practices since the RCP were published, 65.6% actually changed the way they manage incomplete early miscarriage, 57% missed early miscarriage, and a lower frequency the mode of misoprostol administration. Five practitioners reported changing their professional practices since publication of the RCP but without any modification of their practices as assessed by our survey. However, our survey evaluated only one chapter of the RCP: the change in practice reported by these practitioners may involve another part of the RCP. Finally, the poor adherence to the RCP for the management of incomplete early miscarriage may have been in part due to unfamiliarity with this term, which was defined only one year ago in France.

Clinical vignettes are a simple and useful tool for evaluating professional practices (8-10). They are cheap and adapted to all types of professional exercises (11). The gold standard for the evaluation of professional practices is based on the use of "standardized patients" (professional actors who simulate a clinical presentation) with an analysis of the interview, clinical examination, and prescriptions given by health professionals during the consultation (12, 13). There are two validated alternatives: peer-reviewed medical records or the use of clinical vignettes. Clinical vignettes reliably reflect the variations of professional practice, and perform well in comparison to other approaches. The review of medical records is mainly reserved for the forensic setting. The retrospective study of cases treated in emergency departments is not identified in the literature as a valid tool for the evaluation of professional practices, although it is common. A national study evaluating the case management of hundreds of practitioners before and after the publication of the RCP could be informative, but it would be costly and difficult to implement.

The validity of written clinical vignettes and their computerized use have been confirmed (6). The computerization of surveys has the advantage of being cheaper and less time-consuming than written versions or the gold standard. Finally, clinical vignettes can be used in specialties such as obstetrics/gynecology and pediatrics, specialties for which the use of standardized patients would be difficult: the invasive nature of the gynecological examination severely limits the use of actors.

Our study confirms the utility of clinical vignettes for the evaluation of professional practices in gynecology. This approach allowed us to detect a change of practices in favor of adherence to the RCP among practitioners who stated that they had changed their behavior since the RCP were published.

The number of respondents in our study is equivalent to that of comparable published studies in various specialties (14-16) including obstetrics/gynecology (17, 18). Our results demonstrate a moderate change in professional practice. Adherence to the RCP was higher than reported by comparable studies in France (19) and other countries (20, 21). However, these findings must be qualified. According to the literature, the adherence of practitioners to national and international recommendations declines after more than one year following their publication (22).

This work has some limitations: it focused on the chapter of the RCP concerning therapeutic management to ensure uterine vacuity. We considered this chapter to be the best to evaluate, because of the frequency of the pathology and the simple treatment algorithm for the two measurable situations. Consequently, adherence of practitioners to these recommendations is relatively straightforward to evaluate. Knowledge and application of the diagnostic criteria in the RCP are necessary for the diagnosis of missed early miscarriage and incomplete early miscarriage but were not evaluated in this study. The number of actual correct responses for overall patient management (diagnostic and therapeutic) in everyday practice is therefore probably lower than the values we report here. In addition, our findings based on vignettes to evaluate the management of first trimester fetal losses in 2012 are subject to memory bias.

Responding practitioners were probably those most interested in the subject and/or concerned about the quality of their care, favoring a selection bias for responders. The participation of responding practitioners in emergency settings was not evaluated; this would have indicated how many of the responders regularly manage first-trimester fetal loss.

Information on membership in the French College of Obstetricians and Gynecologists was not sought: members have easy access to the national RCP and constitute a subgroup more aware of the benefits of continuing medical education.

Finally, a study of non-responding practitioners and those who do not adhere to the RCP may reveal more about the reluctance of practitioners to modify their practices in the light of evidence-based medicine and participate in surveys assessing professional practices.

Conclusion

Adherence to the national recommendations for clinical practice promoted by the CNGOF to French obstetricians/gynecologists is uneven: moderate for the management of missed early miscarriages and low for the management of incomplete early miscarriages. Continuing professional training should be promoted to reach as many practitioners as possible, irrespective of their type of practice or professional experience.

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Table 1

Demographic characteristics of responding obstetricians/gynecologists

Demographic characteristics	Total responders (n = 143)
<i>Years of experience</i>	
1 to 5 years, n (%)	33 (23.1%)
6 to 10 years, n (%)	25 (17.4%)
11 to 20 years, n (%)	26 (18.2%)
21 to 30 years, n (%)	30 (21.0%)
> 31 years, n (%)	29 (20.3%)
<i>Specialty</i>	
surgical gynecology, n (%)	60 (42%)
obstetrics, n (%)	16 (11%)
mixed activity, n (%)	56 (39%)
medically assisted procreation, n (%)	10 (7%)
medical gynecology, n (%)	1 (1%)
<i>Type medical practice</i>	
university hospital, n (%)	52 (36.3%)
regional hospital, n (%)	45 (31.5%)
private practice, n (%)	46 (32.2%)
<i>Distribution of hospital practitioners by status:</i>	
university professor or associate	10/97 (10%)
professor [n/N (%)]	62/97(64%)
hospital practitioner [n/N (%)]	
specialized assistant or hospital clinical	25/97 (26%)
head [n/N (%)]	

Table 2

Adherence to the RCP for the management of missed early miscarriage before and after their publication.

	Correct management n (%)	Incorrect management: watch- and-wait n (%)	p
<i>Total responders (n = 143)</i>			
- before the RCP	60 (42)	83 (58)	
- after the RCP	76 (53)	67(47)	0.001
<i>Responders declaring a change in practices (n = 61)</i>			
- before the RCP	28 (46)	33 (54)	
- after the RCP	44 (72)	17 (28)	0.001

Table 3

Adhesion to the RCP for the management of incomplete early miscarriage before and after their publication

	Correct management n (%)	Incorrect management: misoprostol n (%)	p
<i>Total responders (n = 143)</i>			
- before the RCP	38 (27)	105 (73)	
- after the RCP	62 (43)	81 (57)	< 0.001
<i>Responders declaring a change in practices (n = 61)</i>			
- before the RCP	14 (23)	47 (77)	
- after the RCP	38 (62)	23 (38)	< 0.001

Table 4

Adherence to the RCP for the management of missed early miscarriage before and after their publication depending on the type of practice and experience of the practitioners.

	correct proposed management	
	N (%)	p
<i>Depending on the type of practice</i>		
<i>(total responders = 143)</i>		
<i>Before the RCP</i>		
- university hospital (n = 52)	18 (34.6)	0.2
- regional hospital (n = 45)	18 (40)	
- private practice (n = 46)	24 (52)	
<i>After the RCP</i>		
- university hospital (n = 52)	25 (48)	0.6
- regional hospital (n = 45)	26 (58)	
- private practice (n = 46)	25 (54)	
<i>Depending on experience</i>		
<i>(total responders = 143)</i>		
<i>Before the RCP</i>		
- 1 to 5 years (n = 33)	7 (21)	0.03
- 6 to 10 years (n = 25)	9 (36)	
-11 to 20 years (n = 26)	11 (42)	
- 21to 30 years (n = 30)	17 (57)	
- > 30 years (n = 29)	16 (55)	
<i>After the RCP</i>		
- 1 to 5 years (n = 33)	15 (46)	0.6
- 6 to 10 years (n = 25)	15 (60)	
-11 to 20 years (n = 26)	12 (46)	
- 21to 30 years (n = 30)	19 (63)	
- > 30 years (n = 29)	15 (52)	

Table 5

Adherence to the RCP for the management of incomplete early miscarriage before and after their publication depending on the type of practice and experience of the practitioners.

	correct proposed management	
	n (%)	p
<i>Depending on the type of Practice (total responders = 143)</i>		
<i>Before the RCP</i>		
- university hospital (n = 52)	14 (27)	0.07
- regional hospital (n = 45)	7 (15.6)	
- private practice (n = 46)	17(36.9)	
<i>After the RCP</i>		
- university hospital (n = 52)	29(55.8)	0.05
- regional hospital (n = 45)	14(31.1)	
- private practice (n = 46)	19(41.3)	
<i>Depending on experience (total responders = 143)</i>		
<i>Before the RCP</i>		
- 1 to 5 years (n = 33)	9 (27.2)	0.3
- 6 to 10 years (n = 25)	7 (28)	
- 11 to 20 years (n = 26)	5 (19.2)	
- 21 to 30 years (n = 30)	12 (40)	
- > 30 years (n = 29)	5 (17.2)	
<i>After the RCP</i>		
- 1 to 5 years (n = 33)	17(51.6)	0.03
- 6 to 10 years (n = 25)	12 (40)	
- 11 to 20 years (n = 26)	12(42.3)	
- 21 to 30 years (n = 30)	16(46.7)	
- > 30 years (n = 29)	5 (17.2)	

Appendix 1

Clinical vignettes given to the obstetricians/gynecologists by email

The following questions are divided into two parts:

- your management of the case before 2015, the year in which the recommendations for clinical practice for the management of pregnancy losses were published
- your management of the case after 2015

Vignette 1

It is 2012.

A patient consults for slight metrorrhagia since the beginning of the pregnancy. This is a first pregnancy. She has no history of medico-surgical treatment.

Pelvic ultrasound finds a 28-mm gestational sac with a vitelline vesicle and an 8-mm embryo with no cardiac activity. The diagnosis of missed early miscarriage is thus established with certainty.

What would be your first choice for treatment? (Several choices are possible)

- watch-and-wait
- medical treatment with misoprostol (Cytotec ©)
- surgical treatment by aspiration
- surgical treatment by operative hysteroscopy

You decide to prescribe misoprostol (Cytotec ©). By which route do you prescribe misoprostol (Cytotec ©)?

- intravaginally
- orally
- sublingually
- Any of the three with no preference

What dose (number of tablets)?

If you opt for aspiration.

Do you send the aspiration product to pathology?

- yes
- no

Vignette 2

It is still 2012.

A patient consults for slight metrorrhagia since the beginning of the pregnancy. She has no history of medico-surgical treatment. This is a first pregnancy.

Pelvic ultrasound finds a 28-mm gestational sac with a vitelline vesicle and an 8-mm embryo with cardiac activity.

Today's examination: There is retention of trophoblastic debris of 20 mm without a gestational sac.

What would be your first choice for treatment? (Several choices are possible)

- watch-and-wait for 7 to 10 days
- medical treatment with misoprostol (Cytotec ©)
- surgical treatment by aspiration
- surgical treatment by operative hysteroscopy

It is now December 2015.

Have you changed your practices since the 2015 recommendations?

- yes

- no

Vignette 3

A patient consults for slight metrorrhagia since the beginning of the pregnancy. She has no history of medico-surgical treatment. This is a first pregnancy.

Pelvic ultrasound finds a 28-mm gestational sac with a vitelline vesicle and an 8-mm embryo with no cardiac activity. The diagnosis of missed early miscarriage is thus established with certainty.

What would be your first choice for treatment? (Several choices are possible)

- watch-and-wait for 7 to 10 days
- medical treatment with misoprostol (Cytotec ©)
- surgical treatment by aspiration
- surgical treatment by operative hysteroscopy

Vignette 4

A patient consults for slight metrorrhagia since the beginning of the pregnancy. Pelvic ultrasound finds a 28-mm gestational sac with a vitelline vesicle and an 8-mm embryo with cardiac activity.

Today's examination: There is retention of trophoblastic debris of 20 mm without a visible gestational sac.

What would be your first choice for treatment? (Several choices are possible)

- watch-and-wait for 7 – 10 days
- medical treatment with misoprostol (Cytotec ©)
- surgical treatment by aspiration
- surgical treatment by operative hysteroscopy

You decide to prescribe misoprostol (Cytotec ©). By which route do you prescribe misoprostol (Cytotec ©)?

- intravaginally
- orally
- sublingually
- Any of the three with no preference

What dose (number of tablets)?

If you opt for aspiration.

Do you send the aspiration product to pathology?

- yes
- no

We have no Conflict of Interest.

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Keywords: vignette-based study, pregnancy loss, clinical practice guideline, missed early miscarriage, incomplete early miscarriage.

Abstract

Objectives - To assess the adhesion of French obstetricians and gynecologists to the French clinical practice guidelines for pregnancy loss, issued by the French College of Obstetricians and Gynecologists, one year after publication.

Methods – An online vignette-based study was emailed to a sample of French obstetricians and gynecologists to compare their management of women with missed early miscarriage and incomplete early miscarriage. A descriptive statistical analysis was performed comparing the rates of appropriate management for these two indications before and after the release of the guidelines.

Results - Of the 404 specialists contacted, 143 completed the questionnaire. Forty-three percent stated that they had changed their practices following the release of the guidelines. The rate of adhesion was moderate for the management of missed early miscarriage (53% after publication of the guidelines versus 42% before, $p = 0.001$) with a trend to avoid watching-and-waiting management. The rate of adhesion was poor for the management of incomplete early miscarriage (43% after the publication of the guidelines versus 27% before, $p < 0.001$) with a lower use of misoprostol.

Conclusion - Adhesion to the French guidelines appears to be moderate for the management of missed early miscarriage and low for the management of incomplete early miscarriage.