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Iatrogenic late preterm birth: when is it recommended? A Delphi survey promoted by the Italian Society of Perinatal Medicine

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ABSTRACT

Background: The rate of iatrogenic Late Preterm (LP) Birth varies in different settings. This is due to the lack of strong evidence/guidelines on the management of the different maternal, fetal and placental complications affecting pregnancy in the LP window. Steroid prophylaxis is also under discussion. Aim: To build recommendations about the management of main medical complications (pregestational diabetes, placenta previa, preeclampsia, cholestasis, p-PROM, intrauterine growth restriction -IUGR-) occurring in the LP period to reduce clinical heterogeneity.
Methods: A group of Italian Perinatal experts were identified by Scientific Societies. A Delphi consensus methodology was used to reach agreement on different clinical sceneries. Two rounds of consultation by using a purpose built on-line survey and a third open panel discussion were performed.
Results: The panel of 50 experts reached agreement for the vast majority of clinical sceneries (Placenta Previa, Preeclampsia, Diabetes, Cholestasis). Overall, there was agreement to be conservative at 34 weeks and in favor of delivery at 36 weeks. The management of p-PROM and mostly of IUGR were characterized by a minor degree of consensus. Corticosteroids were found necessary at the 34th week and unnecessary at the 36th week.
Conclusions: Besides providing some guidance on clinical indications for LP iatrogenic delivery, these results represent a stimulus for designing future trials investigating the grey areas in this field.

Background

Late preterm (LP) births range between 5% and 7% of all births and account for about 70% of prematurity in Europe [1]. An increasing rate of LP has been reported in different countries in recent years, while the occurrence of early preterm birth remains stable [2–4].

Although at less risk than those born before 34 weeks of gestation, infants born late preterm remain at higher risk than term infants for pulmonary, metabolic, and neurologic disorders [1]. Cognitive deficits and learning issues at school age, as well as small but measurable negative effects in adult age groups have been reported [5,6].

With the exception of spontaneous preterm labor, most of late preterm births rely upon a medical decision. The reported rate of iatrogenic causes on the total population of LP varies in different settings (from 8 to 46.1%); this variability is due to different approaches in the decision to anticipate the date of delivery [7–9]. The balance between the harm to be born and the risk in the prosecution of pregnancy is often difficult to reach. Indeed, guidelines on the management of the different maternal, fetal and placental complications affecting pregnancy in the LP window are heterogenous due to the absence of strong evidence for many of the related clinical issues. Thus, clinical practice differs in various clinical settings and countries.

Both doctors and patients anxiety seems to prevail in most circumstances, as reported in the retrospective Canadian cohort study where 25.2% of LP births were iatrogenic in absence of evidence-based indications, namely when women had experienced a previous stillbirth [10].

Another hot topic in this field is RDS prophylaxis, since only one randomized-controlled trial is available at present over the use of steroids in the LP period [11].

Thus, through the Delphi method, this study was aimed at collecting the common practice of opinion leaders in the management of several medical complications occurring in the LP period. This would serve to build recommendations, in order to reduce clinical heterogeneity in the management of complicated pregnancies before 37 weeks of gestation.

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Methods

In this study a Delphi consensus methodology was adopted. This technique is used to obtain a consensus in a panel of experts, regarding the appropriateness of medical procedures in specific fields [12]. The experts express their opinion about the procedures referring to specific categories of patients described in different "clinical sceneries".

The first phase of this study consisted in a review of the scientific literature that served as a reference, in the case of disagreement among the panelists.

In the second phase different clinical sceneries were built-up. They consist in detailed descriptions of specific patients with pregnancy conditions as to simulate a real scenery of everyday clinical practice. In particular, we proposed the following sceneries, subdivided according to the week of gestation (34, 35 or 36): pregestational Diabetes mellitus (both type I and II, not gestational diabetes), preterm pre-labour rupture of membranes (pPROM), cholestasis, Intrauterine growth restriction (IUGR), placenta previa, and preeclampsia. The two main questions were about the timing of delivery and RDS prophylaxis. Moreover, in case of preeclampsia, antihypertensive treatment and Mg Sulphate prophylaxis were also investigated. The variables used for building the sceneries are shown in Table 1.

For each scenery the panelists were asked to indicate their level of agreement with each statement via a nine-point Likert scale (1 = Strongly inappropriate; 5 = not sure; 9=Strongly agree). When the agreement of the panelists about each question reached more than 70% of consensus, the scenery was considered solved with agreement.

As part of this technique, we undertook three consultation rounds with responses in each round aggregated and feed-back to the group [12].

Table 1
Variables used to build the Delphy sceneries.

Diabetes	Variable
Gestational age	34, 35, 36
Glycemic diary not under control	Yes, No
Ultrasound signs of metabolic failure (AC >95° centile and/or miocardic hypertrophy and/or large for gestational age)	Yes, No

Cholestasis	Variable
Gestational age	34, 35, 36
Bile acids 40 mmol/UI	<, >
Symptoms under control	Yes, No

pPROM	Variable
Gestational weeks at preterm rupture of membranes	32, 33, 34, 35, 36
Inflammation markers	altered, not altered
Antibiotics prophylaxis <7 days	Yes, No

IUGR (intrauterine growth restriction)	Variable
Gestational weeks at diagnosis	34, 35, 36
Arrest of fetal growth	Yes, No
Presence of umbilical A-RED (absent or reverse end diastolic blood flow in umbilical artery)	Yes, No
Short term variability (STV) ≤ 3 msec	Yes, No

Preeclampsia	Variable
Gestational weeks of onset	34, 35, 36
Blood pressure (BP) ≥160/100 mmHg	<, >
Presence of Associated Symptoms (at least one between visual, epigastralgia, thrombocytopenia, AST doubling, ALT, creatinine> 1.1, pulmonary edema, neurological symptoms)	Yes, No

Placenta previa	Variable
Gestational age	34, 35, 36
Vaginal bleeding	Moderate, severe
number of bleeding episodes	First, second or more

Assembling of expert panel

Panel members were selected based on their scientific and clinical expertise in perinatology. The board of SIMP (Società Italiana di Medicina Perinatale) asked the boards of the 3 main italian Ob/Gyn scientific societies, namely AGUI (Associazione Ginecologi Universitari Italiani), AOGOI (Associazione Ostetrici Ginecologi Ospedalieri Italiani) and SIGO (Società Italiana di Ginecologia e Ostetricia) to nominate 10 experts each one, to be part of the panel. Then, also based on a geographical representation, SIMP identified twenty-two additional members. Panel members were initially contacted via e-mail introducing the study and inviting them to participate. Two invited panelist never answered to solicitation, therefore 50 members formed the Panel. The software Google Drive was employed to submit the survey.

Data collection

Data were collected by using Google Drive. We adopted a 'quasi-anonymous' Delphi technique [12], where each panel member was aware of the members forming the panel, but individual responses were kept anonymous.

Procedures

Consultation round 1

The first consultation round took place from 16th December 2017 to 31 st January 2018. One hundred ninety questions were posed, grouped in different sceneries.

Responses were collected and summarized in Microsoft Excel. The answers were grouped in three ranges: not appropriate (answers 1–3), uncertain (answers 4–6), appropriate (answers 7–9).

Consultation round 2

The sceneries that received discordant results from the experts, (< 70% agreement), were resubmitted in the second consultation round. This occurred in the period from 19th February 2018 to 9th April 2018. Attached to the mail containing the Google drive link for answer, a box plot of answer distribution of the first round was also added.

Consultation round 3

The third consultation round consisted in an open panel discussion occurring in Milan, on 21 st September 2018, during a SIMP congress where panelists were invited. 27 out of the 42 panelists of the previous consultation rounds participated.

Panel members were asked to provide their opinion about the sceneries still unsolved at the end of the second round. Their opinion was expressed by hand raise when asked if the scenery was "strongly not appropriate" or "very appropriate". Panelists who did not answer were considered as "uncertain".

Results

The number of panel members participating in rounds 1 and 2 were 44 and 42, respectively (88% and 84%).

At the end of the first round the solved sceneries were 95 out of a total of 196 questions (48.4%). They were so divided among topics: 9 out of 24 of the diabetes sceneries (37.5%), 24 out of 40 of

Table 2
DIABETES MELLITUS type 1 and 2 (not GDM).

Sceneries	Glycemic diary under control and Absence of ultrasound signs of metabolic failure		Altered glycemic diary and Absence of ultrasound signs of metabolic failure		Glycemic diary under control and Presence of ultrasound signs of metabolic failure ***		Altered glycemic diary **** and Presence of ultrasound signs of metabolic failure	
	Delivery*	RDS prophylaxis**	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis
34 weeks	No	No	No	No	No	No	No	No
35 weeks	No	No	No	No	No	No	No	No
36 weeks	No	No	No	No	No	No	Yes	Not sure

* Delivery: the decision of timing of birth by 48 h.
** RDS prophylaxis: Two doses of Bentelan 12 mg IM die every 24 h.
*** Ultrasound signs of metabolic failure: CA > 95°centile, miocardic hypertrophy, large for gestational age.
**** Altered glycemic diary: repeated measurement of blood sugar over 90 mg/dl fasting, or over 140 mg/dl 1 h after meals.

the pPROM sceneries (60%), 6 out of 24 of the cholestasis sceneries (25%), 20 out of 36 of the IUGR sceneries (55.5%), 10 out of 24 of placenta previa sceneries (41.7%) and 26 out of 48 of the preeclampsia sceneries (54.2%).

Out of the 101 unsolved questions, only 20 reached more than 70% agreement among the panelists, at the end of round 2. Therefore, a total of 58.7% questions became solved at this stage. The remaining 81 unsolved questions were therefore discussed in the open round 3. After this stage, only 11 questions remained unsolved. The final round 3 together with the previous 2 rounds are summarized in Tables 2–7.

Pre-gestational Diabetes: For every scenery proposed neither delivery, nor steroids were considered appropriate at 34 and 35 weeks, while the presence of both an altered glycemic diary and ultrasound signs of metabolic failure indicate delivery at 36 weeks of gestation. Even for this latter scenery there are doubts over the implementation of RDS prophylaxis (Table 2).

pPROM: In the LP period, once inflammation indices are altered, delivery is considered the best option, independently from a completed antibiotic prophylaxis or not. In the case of earlier alteration of inflammation indices (occurring at 32–33 weeks) a complete antibiotic prophylaxis is required before indicating delivery. RDS prophylaxis is recommended at the 32th and 33th week and often at 34th week (Table 3).

Cholestasis: Experts generally agreed for a conservative management at 34 and 35 weeks. Only for women presenting at 35–36 weeks with bile acids >40 mmol/UI and uncontrolled symptoms, delivery was considered an option. Accordingly, RDS prophylaxis was never adviced (Table 4).

Placenta previa: There is an agreement towards conservative management at first episode of a moderate, self-limiting bleeding. Delivery, on the contrary, is always indicated either with a severe bleeding and at the second bleeding episode when occurring at 35–36 weeks. RDS prophylaxis is always recommended at 34 weeks while at 35 weeks only when bleeding is severe (Table 5).

Preeclampsia: Delivery is always recommended in the presence of associated symptoms, as well as MgSO4 and corticosteroids (not advised at 36th). On the contrary, the presence of solely high blood pressure values (≥160/100 mmHg) is considered to be manageable, and delivery is indicated only at 36th week. On the opposite, there is agreement that only antihypertensive treatment should be used in the milder scenery (BP < 160/100 mmHg, no symptoms) accompanied with a conservative management (Table 6).

Table 3
pPROM.

Sceneries	Negative inflammation markers and Antibiotics prophylaxis <7 days		Altered inflammation markers and Antibiotics prophylaxis >7 days		Negative inflammation markers and Antibiotics prophylaxis >7 days		Altered inflammation markers and Antibiotics prophylaxsis < 7 days	
	Delivery *	RDS prophylaxis**	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis
32 weeks	No	Yes	Yes	Yes	No	Yes	Not sure	Yes
33 weeks	No	Yes	Yes	Yes	No	Yes	Not sure	Yes
34 weeks	No	Yes	Yes	Yes	No	No	Yes	Not sure
35 weeks	No	No	Yes	No	Not sure	No	Yes	No
36 weeks	Yes	No	Yes	No	Yes	No	Yes	No

* Delivery: the decision of timing of birth within 48 h.
** RDS prophylaxis: Two dose of Bentelan 12 mg IM die every 24 h.

Table 4
Cholestasis.

Sceneries	Bile acids < 40 mmol/UI and Symptoms under control		Bile acids < 40 mmol/UI and Symptoms not under control		Bile Acids > 40 mmol/UI and Symptoms under control		Bile Acids > 40 mmol/UI and Symptoms not under control	
	Delivery*	RDS prophylaxis**	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis
34 weeks	No	No	No	No	No	No	No	No
35 weeks	No	No	No	No	No	No	Not sure	No
36 weeks	No	No	No	No	No	No	Yes	No

* Delivery: the decision of timing of birth by 48 h.
** RDS prophylaxis: Two doses of Bentelan 12 mg IM die every 24 h.

Table 5
Placenta previa.

Sceneries	Moderate bleeding and first episode****		Moderate bleeding and second or more episode		Severe bleeding and first episode		Severe bleeding and second or more episode	
	Delivery*	RDS Prophylaxis**	Delivery	RDS Prophylaxis	Delivery	RDS Prophylaxis	Delivery	RDS Prophylaxis
34 weeks	No	Yes	No	Yes	No	Yes	Yes	Yes
35 weeks	No	No	Yes	No	Yes	Yes	Yes	Yes
36 weeks	No	No	Yes	No	Yes	No	Yes	No

* Delivery: the decision of timing of birth until 48 h.
** RDS Prophylaxis: Two doses of Bentelan 12 mg IM die every 24 h.
**** Episode of vaginal bleeding.

Table 6
Preeclampsia.

Sceneries (1)	Arterial pressure ≥160/100 mmHg and Absence of associated symptoms*****				Arterial pressure ≥ 160/100 mmHg and Associated symptoms			
	MgSO4 prophylaxis	Antihypertensive therapy	RDS prophylaxis**	Delivery*	MgSO4 prophylaxis***	Antihypertensive therapy	RDS prophylaxis	Delivery
34 weeks	Yes	Yes	Yes	Not Sure	Yes	Yes	Yes	Yes
35 weeks	No	Yes	No	No	Yes	Yes	Yes	Yes
36 weeks	Yes	Yes	No	Yes	Yes	Yes	No	Yes

sceneries (2)	Arterial pressure ≤ 160/100 mmHg and Absence of associated symptoms				Arterial pressure ≤ 160/100 mmHg and Associated symptoms			
	MgSO4 prophylaxis	Antihypertensive therapy	RDS prophylaxis	Delivery	MgSO4 prophylaxis	Antihypertensive therapy	RDS prophylaxis	Delivery
34 weeks	No	Yes	No	No	Yes	Yes	Yes	Yes
35 weeks	No	Yes	No	No	Yes	Yes	Yes	Yes
36 weeks	No	Yes	No	No	Yes	Yes	Yes	Yes

* Delivery: the decision of timing of birth by 48 h.
** RDS Prophylaxis: two doses of Bentelan 12 mg im die every 24 h.
*** MgSO4 prophylaxis: infusion of attack dose (3 vials = 3gr = 30 ml in 100 ml of physiological solution at 390 ml/h=20 min) following a maintenance dose (10 fiale = 10 g = 100 ml in 400 ml of physiological solution at 1gr/h=40 ml/h = 12 h).
***** Associated symptoms: one among visual symptoms, epigastralgia, thrombocytopenia, GOT doubling, GPT, creatinine> 1.1, pulmonary edema, neurological symptoms.

IUGR: At every gestational age delivery is recommended in the presence of suspected fetal distress (short term variability STV < 3 m/s) while RDS prophylaxis is recommended only at the 34th week. In the presence of abnormal blood flow in the umbilical artery (A-RED) a conservative management is suggested at 34 weeks while there was disagreement at later gestational ages. Finally, with normal Doppler indices, delivery is never recommended if fetal growth shows only a reduction, while there was disagreement if fetal growth is arrested. Corticosteroid prophylaxis is never recommended at 35 and 36 weeks (Table 7).

Discussion

This study addresses a very relevant clinical issue in perinatal medicine, i.e. medical indications for a late preterm delivery. Many pregnancy disorders still not have an effective treatment and therefore timing of delivery represents the only therapeutic choice, and one of the main challenges in perinatal medicine. Although each case may have a specific medical history, general indications should be provided to avoid excessive heterogeneity interventions, namely in the late preterm period, when most preterm deliveries occur. In view of the lack of sufficient evidence and guidelines, a Delphi procedure was adopted to provide clinicians help.

Strengths and limitations

The strength of a Delphi procedure is largely attributable to the experience, representativeness and independence of the panelists. In fact, the main weakness of a Delphi procedure is the potential for selection bias by gathering together a group of individuals that share the same interests and opinions and attrition of contributors with successive rounds.

We have included experts identified by the Italian Society of Perinatal Medicine as well as experts indicated by the three main Italian Scientific Societies of Obstetrics and Gynecology, societies which are generalists, in nature. Moreover, the experts represent all the geographic areas (North, Centre and South of Italy). All participants were blinded to the individual expert opinions of their colleagues, thus lowering pressure from the more authoritative experts.

The participation to the first two rounds was practically total among the 42 panelists who agreed to participate however only 27 panelist took part to the round 3 due to organizative problems. Panelists who did not participate to the meeting agree with the final recommendations we send them, later on.

Predefined rules regarding acceptance or rejection of parameters were strictly adhered to, with the opportunity of considering different interpretations of the answers in subsequent rounds. This allowed the participants to change their opinion in light of feedback from results of previous rounds.

We have not included in the panel epidemiologists or methodologists, but only clinicians. This choice may be a cause of bias but provides recommendations adherent to clinical practice.

Recommendations of the panelists

Pre-gestational Diabetes. Neither delivery, nor steroids were considered appropriate at 34 and 35 weeks. Delivery was

Table 7
IUGR.

Sceneries (1)	Arrest of fetal growth [***] and STV ≥ 3 msec and Umbilical A-RED [******]		Fetal growth restriction [****] and STV ≥ 3 msec and Normal doppler UA		Arrest of fetal growth and STV ≤ 3 msec and [*****] and Normal doppler UA	
	Delivery [*]	RDS prophylaxis [**]	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis
34 weeks	No	No	No	No	Yes	Yes
35 weeks	Not sure	No	No	No	Yes	No
36 weeks	Not sure	No	No	No	Yes	No

Sceneries (2)	Fetal growth restriction and STV ≤ 3 msec and Umbilical A-RED		Arrest of fetal growth and STV ≥ 3 msec and Normal doppler UA		Fetal growth restriction and STV ≤ 3 msec and Normal doppler UA	
	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis
34 weeks	Yes	Yes	Yes	Yes	Yes	Yes
35 weeks	Yes	No	Yes	No	Yes	No
36 weeks	Yes	No	Yes	No	Yes	No

Sceneries (3)	Fetal growth restriction and STV ≥ 3 msec and Umbilical A-RED		Arrest of Fetal Growth and STV ≤ 3 msec and Umbilical A-RED	
	Delivery	RDS prophylaxis	Delivery	RDS prophylaxis
34 weeks	No	No	Yes	Yes
35 weeks	Not sure	No	Yes	No
36 weeks	Not sure	No	Yes	No

[*] Delivery: the decision of timing of birth by 48 h.
[**] RDS Prophylaxis: two doses of Bentelan 12 mg im die every 24 h.
[***] Arrest of fetal growth: absence of growth of AC (abdominal circumference) at the ultrasound measurement after 2 weeks of each other.
[****] Fetal Growth Restriction: first diagnosis of AC < 10° centile or reduction of the growth of AC at the ultrasound measurement after 2 weeks of each other.
[*****] STV ≥ 3 msec is normal; STV ≤ 3 msec is pathologic.
[******] Umbilical A-RED: absent or reverse end diastolic blood flow in umbilical artery.

recommended only in case of an altered glycemic diary and ultrasound signs of metabolic failure, at 36 weeks of gestation. Therefore, our panelists seem more conservative than the current US recommendations [8,13], while agreeing more with the Canadian and NICE Guidelines that suggest delivery before 37–38 weeks, only in case of poor glycemic control or metabolic and/or fetal complications [14,15].

pPROM: The inflammation indices seem a decisive factor for choosing timing of delivery. These results are in contrast with ACOG recommendations [13] that suggest "benefits for immediate delivery in pPROM occurring from 34 weeks and above". Indeed, panelists are in line with the results of the PROMEXIL trial (which was performed in an European population) concluding that induction of labour substantially does not improve pregnancy outcomes compared with expectant management [16]. The only advantage of induction of labour was the reduction in the risk of chorioamnionitis which however is not associated with benefits in neonatal outcome [16]. Moreover, our results suggested RDS prophylaxis only until 34 weeks in contrast with the recent NEJM trial that recommends "administration of betamethasone to women with high probability of delivery in the LP period, such as pPROM" [11].

Cholestasis: There is general agreement for a conservative management at 34 and 35 weeks, advising delivery only with the concomitance of higher bile acids and uncontrolled symptoms, at 36weeks. RDS prophylaxis was never advised. Such recommendation is in line with the one considered as EBM for the LP period by Gyamfi-Bannerman et al. [9].

IUGR: The management of IUGR pregnancies is far from being established and still debated [17] However, independently from gestational age, panelists agreed that most important factor indicating delivery is the presence of suspected fetal distress (STV < 3 msec), in line with the criteria adopted in the GRIT study [18,19]. Moreover, the Experts suggest to be conservative at least at the 34th week, in those cases when fetal growth is restricted, even with abnormal Doppler flows. Consensus was not reached how to manage IUGR in case of abnormal umbilical Doppler flow, whether or not fetal growth is restricted. RDS prophylaxis is always recommended at the 34th week. These recommendations are in line with ACOG [13], recommending delivery in the late preterm period only in the case of concurrent conditions (abnormal Doppler studies, oligohydramnios, maternal risk factors, comorbidities). Moreover, Gyamfi-Bannerman et al [9] included "IUGR with abnormal testing or poor interval growth" among the Evidence-based indications for delivery in the LP period, although not specifying the weeks of gestation.

Placenta previa: Apart from recommending a cesarean section after 36 weeks (grade B), available guidelines do not detail management in the LP period. Our panelists agree to be conservative at the first episode of a moderate bleeding. RDS prophylaxis is always recommended at 34 weeks and at 35 weeks for impending delivery, while not recommended at the 36th week. This is in contrast with the importance of such prophylaxis in all women at risk of preterm delivery reported in the NEJM trial [11].

Preeclampsia: Our panelists are in line with most major scientific societies [8,9,13], recommending delivery and RDS prophylaxis in the LP period in case of severe preeclampsia (grade C) while expectant management is recommended in case of mild preeclampsia [20].

However, we have to underline that clinicians believe that antihypertensive treatment is always suggested. This pharmacological approach is not consistent with recommendations of the International Society for the Study of Hypertension in Pregnancy (ISSHP) and allows overtreatment [21]. Similarly, MgSO4 prophylaxis is recommended by this survey also in milder situations when the risk of eclampsia is less likely.

Conclusions

This Delphi exercise, despite requiring a third, open round, was actively participated by more the 80% of invited Experts and

reached agreement for the vast majority of clinical sceneries. The management of IUGR was the only area characterized by lack of consensus. The indications arisen from this study are of particular significance in a field where evidence-based interventions are lacking and Scientific Society guidelines not well detailed.

Although the late preterm period covers only three weeks of gestation, the experts provided different indications according to gestational age. They generally agreed to be more conservative at 34 weeks and being more in favor of delivery at 36 weeks, whatever the clinical scenery was under scrutiny. Accordingly, they also agreed to administer corticosteroids at 34 weeks and found this prophylaxis unnecessary at 36 weeks of pregnancy. This is in line with experts cautioning for potential, not still investigated, long term effects of prenatal corticosteroids administration [22].

Besides providing some guidance on clinical indications for late preterm delivery, these results represent a stimulus for designing future trials investigating this specific area of perinatal medicine.

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