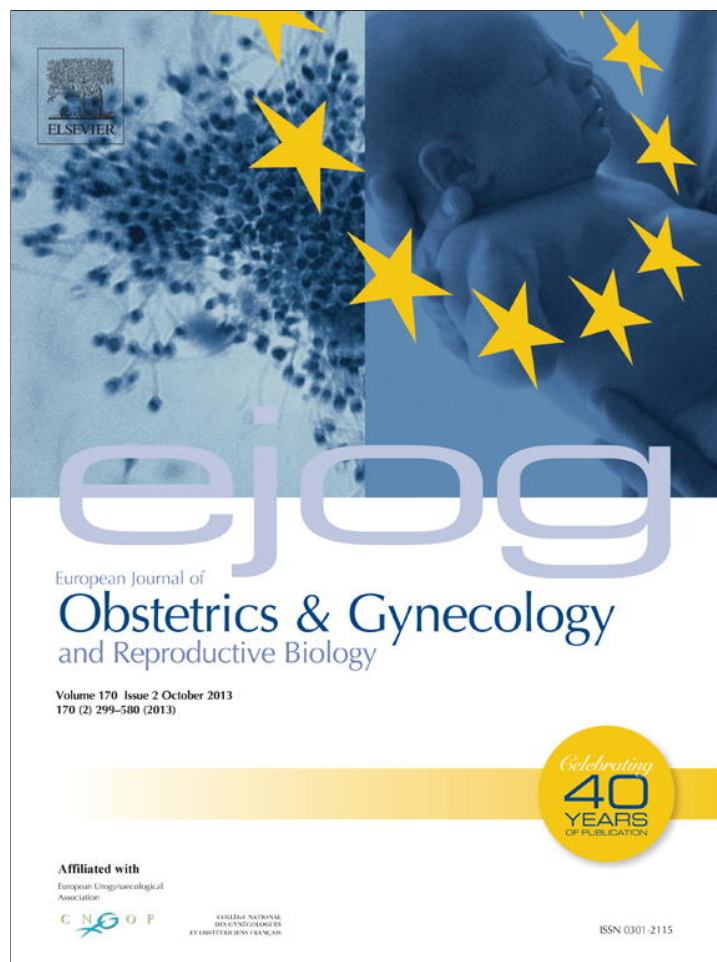


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## The effectiveness of antepartum surveillance in reducing the risk of stillbirth in patients with advanced maternal age



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### ABSTRACT

**Objective:** To estimate the effectiveness of antepartum surveillance and delivery at 41 weeks in reducing the risk of stillbirth in advanced maternal age (AMA) patients.

**Study design:** Retrospective cohort study of all patients managed in one maternal–fetal medicine practice from June 2005 to May 2012. We included all singleton pregnancies delivered at  $\geq 20$  weeks of gestation. All AMA patients (age  $\geq 35$  years at their estimated delivery date) underwent weekly biophysical profile testing beginning at 36 weeks, as well as planned delivery at 41 weeks, or sooner if indicated. We compared the rate of fetal death at  $\geq 20$  weeks and fetal death at  $\geq 36$  weeks in AMA vs. non-AMA patients. Fetal deaths due to lethal and chromosomal abnormalities were excluded.

**Results:** 4469 patients met the inclusion criteria: 1541 (34.5%) were AMA and 2928 (65.5%) were non-AMA. Using our AMA protocol for surveillance and timing of delivery, the incidence of stillbirth was similar to the non-AMA population (stillbirth  $\geq 20$  weeks: 3.9 per 1000 vs. 3.4 per 1000,  $p = 0.799$ ; stillbirth  $\geq 36$  weeks: 1.4 per 1000 vs. 1.1 per 1000,  $p = 0.773$ ). When looking at women age  $< 35$ , age 35–39, and age  $\geq 40$ , the incidence of stillbirth  $\geq 20$  weeks and  $\geq 36$  weeks did not increase across the three groups. Our findings were similar when we excluded all patients with other indications for antepartum surveillance.

**Conclusions:** In AMA patients, antepartum surveillance and delivery at 41 weeks appears to reduce the risk of stillbirth to that of the non-AMA population. Routine antepartum surveillance should be considered in all AMA patients.

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### 1. Introduction

In the United States, the average age of women giving birth is increasing. From 1980 to 2009, the mean maternal age rose from 25.0 to 27.5 years [1]. In 2009, women of advanced maternal age (AMA; 35 years and older) represented 14.2% of all live births in the United States, and women aged 40 years and older represented 2.8% of all live births [1]. It is well known that AMA women are at increased risk of various pregnancy complications, including stillbirth [2–7]. The risk of stillbirth, defined as fetal death at 20 weeks or more, has been quoted as 11–14 per 1000 in women age 35–39 and 11–29 per 1000 in women age 40 and over, compared to 6.4 per 1000 in the general population and 4.0–5.5 per 1000 in low-risk pregnancies [8,9]. Recent data from the United States show an

overall decrease in stillbirth compared to prior data, but a continued increased prevalence among older women, with rates of 6.9 per 1000 in women age 35–39, 9.8 per 1000 in women age 40–44, and 13 per 1000 in women age 45 and older [10]. A recent meta-analysis of 96 population-based studies noted that AMA was a major risk factor for stillbirth, yielding a 7–11% population attributable risk value [11]. The same data indicate that AMA is associated with a 65% increase in the odds of stillbirth and could be responsible for almost 4226 stillbirths in high-income countries each year [11,12].

For women at increased risk of stillbirth due to other causes, such as hypertension and diabetes, antepartum surveillance has been widely integrated into clinical practice, despite a dearth of evidence from randomized controlled trials [13]. The American College of Obstetricians and Gynecologists (ACOG) does not specifically list AMA as an indication for antepartum fetal surveillance. They state, however, that since antepartum fetal surveillance has not been studied rigorously for any indications, all indications for testing should be considered relative, but in general,

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antepartum fetal surveillance has been employed in pregnancies in which the risk of fetal demise is increased [13].

For comparison, the increased risk of stillbirth in AMA patients (OR 1.8–3.3) is similar to patients with chronic hypertension (OR 1.5–2.7), pregnancy-induced hypertension (OR 1.2–4.0), prior stillbirth (OR 1.4–3.2), and multiple gestation (OR 1.0–2.8), all of which are listed by ACOG as indications for antepartum surveillance [13]. Like other established and potential indications for antepartum surveillance, however, it is currently unknown for AMA patients whether antepartum surveillance actually reduces the risk of stillbirth. A recent publication from the Society for Maternal–Fetal Medicine reviews the increased of stillbirth in AMA patients, but also states that “there is insufficient evidence to confirm that antenatal testing for the sole indication of AMA reduces stillbirth or improves perinatal outcomes” [14].

In our practice, we have been routinely performing antepartum fetal surveillance for AMA patients. This involves weekly assessment using the ultrasound portion of the biophysical profile (BPP) [15] testing beginning at 36 weeks of gestation, as well as planned delivery at 41 weeks of gestation, or earlier if indicated. The objective of this study was to estimate the effectiveness of this surveillance strategy in reducing the risk of stillbirth in AMA patients.

## 2. Materials and methods

After Biomedical Research Alliance of New York Institutional Review Boards approval was obtained, we queried the computer delivery database of our maternal–fetal medicine practice for all deliveries of singleton pregnancies  $\geq 20$  weeks over a 7-year period from June 2005 to May 2012. During the study period, our protocol for all patients aged  $\geq 35$  at their estimated date of delivery was to initiate weekly BPP testing at 36 weeks of gestation and planned delivery (induction of labor or cesarean delivery, as indicated) at 41 weeks of gestation, or earlier, as indicated. BPP testing did not include a non-stress test (i.e. the highest score was 8/8) [15]. All BPP testing was done at our affiliate imaging center, Carnegie Imaging for Women, PLLC, by RDMS-certified sonographers under the supervision of maternal–fetal medicine specialists. Abnormal testing was managed by either non-stress testing, prolonged fetal heart rate monitoring, repeat BPP testing, or delivery, as clinical circumstances dictated. Patients with oligohydramnios (amniotic fluid index  $< 5$  cm) were recommended delivery.

From the computerized database we extracted pregnancy and delivery outcomes for all patients, including maternal age, estimated delivery date (EDD), induction of labor, gestational age at delivery, stillbirth, parity, pre-gestational and gestational diabetes, chronic or gestational hypertension, systemic lupus

erythematosus (SLE), and prior stillbirth  $\geq 20$  weeks. Data on stillbirth outcomes for patients who leave our practice after 20 weeks are maintained in our database and were included in this analysis. For women who left our practice and did not have a stillbirth, we did not have access to additional details regarding their pregnancies. All cases of stillbirth  $\geq 20$  weeks were reviewed. Any stillbirths due to known lethal fetal anomalies or chromosomal abnormalities were excluded. The maternal age was defined as the age at the estimated delivery date. Gestational age was determined by last menstrual period and confirmed by ultrasound in all patients. The expected date of delivery was revised if the discrepancy was  $> 5$  days between the calculation from the last menstrual period and ultrasound up to 13 6/7 weeks of gestation,  $> 7$  days if the dating ultrasound was performed between 14 and 20 weeks of gestation, or  $> 14$  days after 20 weeks (all patients had first or second trimester ultrasounds). If the pregnancy was the result of in vitro fertilization (IVF), gestational age was determined from the date of embryo transfer.

We compared stillbirth rates between AMA and non-AMA patients, as well as across three groups: women aged  $< 35$ , 35–39, and  $\geq 40$ . We used two definitions for stillbirth:  $\geq 20$  weeks, which is the standard definition [3], and stillbirth  $\geq 36$  weeks, which is when we initiate antepartum surveillance in AMA patients. For stillbirth  $\geq 36$  weeks, the denominator used was total deliveries after 36 weeks (i.e. excluding all deliveries prior to 36 weeks). We repeated our analysis excluding patients with any other indications for antepartum surveillance.

Chi square testing and Student's *t*-test were used for analysis using SPSS for Windows 16.0 (Chicago 2007). A *p*-value of  $\leq 0.05$  was considered significant. Since we did not have a group of untested AMA patients, we chose non-AMA patients as the control group. Our reasoning was that the increased risk of stillbirth in AMA patients has been established; therefore, if we were able to demonstrate with adequate power no difference in stillbirth rates between our AMA and non-AMA patients, who are all managed similarly in our practice aside from routine antepartum surveillance, it would suggest that our surveillance protocol ameliorates the increased risk of stillbirth in AMA patients. We did not perform a power analysis before the study as we planned to review all charts in our database, which was created in 2005. A power analysis was performed post hoc, however, in order to determine power for our results.

## 3. Results

Over the study period, we cared for 4469 patients with singleton pregnancies  $\geq 20$  weeks. 1541 (34.5%) were AMA and

**Table 1**  
Description of the patients with stillbirths over the course of the study period.

Patient number	Maternal age	Gestational age	Details
1	38.2	39 1/7	Nuchal cord x3
2	41.7	38 4/7	Six days after successful external cephalic version. Elevated KB suggestive of fetomaternal hemorrhage
3	21.8	37 1/7	Nuchal cord x1, cord around body x2
4	30.1	36 5/7	Rh sensitized, but normal testing throughout pregnancy. Nuchal cord x1. No evidence of fetal anemia
5	34.7	36 3/7	X-linked ichthyosis
6	32.9	34 5/7	Knot in cord and nuchal cord x1
7	27.3	34 3/7	Mild ventriculomegaly, normal karyotype
8	41.1	34 3/7	Unexplained. Normal karyotype
9	23.3	34 1/7	Unexplained
10	35.9	29 2/7	Unilateral clubbed foot, normal karyotype
11	35.8	28 6/7	Unexplained. Delivered at outside hospital
12	37.4	27 0/7	Nuchal cord x4
13	25.5	25 3/7	Originally a triplet pregnancy with spontaneous 3–1 reduction at 10 weeks. Normal karyotype
14	24.5	22 4/7	Suspected CMV from placental pathology
15	30.6	21 4/7	Unexplained
16	20.7	21 2/7	Suspected listeria from placental culture

**Table 2**  
Baseline characteristics in AMA and non-AMA patients.

	AMA (n = 1541) (%)	Non-AMA (n = 2928) (%)	P
Multiparous	69.8	67.2	0.083
Pregestational diabetes	1.9	1.1	0.020
Gestational diabetes	6.0	1.7	<0.001
Chronic hypertension	2.7	0.8	<0.001
Systemic lupus erythematosus	0.6	0.4	0.321
Prior stillbirth ≥20 w	4.1	3.2	0.147
Any indication for antepartum surveillance (aside from AMA)	14.1	6.7	<0.001

AMA, advanced maternal age (35 or older).

2928 (65.5%) were non-AMA. Among the AMA patients, 1040 (23.3% of all patients) were aged 35–39 and 501 (11.2% of all patients) were 40 or older. Overall, there were 16 stillbirths ≥20 weeks (0.4%, or 3.6 per 1000) and 5 stillbirths ≥36 weeks (0.1% of the 3804 births >36 weeks, or 1.3 per 1000). The details of the 16 stillbirths are described in Table 1.

Baseline characteristics for AMA and non-AMA patients are described in Table 2. As expected, AMA patients were more likely to have diabetes and hypertension, and were more likely to have any indication for antepartum surveillance (aside from AMA). In Table 3 the risk of the primary outcome, stillbirth, is described. AMA patients were more likely to undergo induction of labor and the mean gestational age at delivery was slightly earlier in the AMA group. There was no difference in the incidence of stillbirth ≥20 weeks or stillbirth ≥36 weeks between the AMA and non-AMA patients. We repeated this analysis excluding all patients

**Table 3**  
Pregnancy outcomes and incidence of stillbirth, based on maternal age.

	AMA (n = 1541)	Non-AMA (n = 2928)	P
Induction of labor	18.5%	15.8%	0.025
Gestational age at delivery	38.41 ± 2.61	38.89 ± 2.24	<0.001
Stillbirth ≥20 w	6/1541 (0.4%) (3.9 per 1000)	10/2928 (0.3%) (3.42 per 1000)	0.799
Stillbirth ≥36 w	2/1414 (0.1%) (1.41 per 1000)	3/2759 (0.1%) (1.09 per 1000)	0.773

AMA, advanced maternal age (35 or older).

**Table 4**  
Pregnancy outcomes and incidence of stillbirth, based on maternal age, excluding patients with any other indication for antepartum surveillance.

	AMA (n = 1324)	Non-AMA (n = 2731)	P
Induction of labor	17.3%	14.5%	0.020
Gestational age at delivery	38.51 ± 2.60	38.96 ± 2.23	<0.001
Stillbirth ≥20 w	5/1324 (0.4%) (3.78 per 1000)	10/2731 (0.4%) (3.66 per 1000)	0.955
Stillbirth ≥36 w	2/1225 (0.2%) (1.63 per 1000)	3/2579(0.1%) (1.16 per 1000)	0.709

AMA, advanced maternal age (35 or older).

**Table 5**  
Incidence of stillbirth, based on maternal age category.

	Age <35 (n = 2928)	Age 35–39 (n = 1040)	Age ≥40 (n = 501)	P (trend across three groups)	P (age ≥40 compared to <35)
Stillbirth ≥20 w	10/2928 (0.3%) (3.42 per 1000)	4/1040 (0.4%) (3.85 per 1000)	2/501 (0.4%) (3.99 per 1000)	0.967	0.840
Stillbirth ≥36 w	3/2759 (0.1%) (1.09 per 1000)	1/964 (0.1%) (1.04 per 1000)	1/450 (0.2%) (2.22 per 1000)	0.801	0.527

with any other indication for antepartum surveillance (diabetes, hypertension, prior stillbirth, SLE) and the results did not differ (Table 4). In Table 5, the incidence of stillbirth across three maternal age categories (<35, 35–39, and ≥40) is described. There was no increased risk of stillbirth ≥20 weeks or stillbirth ≥36 weeks seen across the three groups, nor when we compared women ≥40 to women <35.

Post hoc power analysis was performed. Based on our sample size, we had 80% power to detect with an alpha error of 5% a difference in stillbirth ≥20 weeks from 3 per 1000 in the non-AMA group to 9 per 1000 in the AMA group.

#### 4. Comments

In this study, we found that among a population of AMA patients who undergo routine antepartum surveillance and scheduled delivery at 41 weeks, the incidence of stillbirth ≥20 weeks and stillbirth ≥36 weeks are low and do not differ from non-AMA patients. This is important considering that in the general population AMA is common [1] and a well-known risk factor for stillbirth [2–12]. The published risk of stillbirth in AMA patients is 1.1–2.9%, yet in our population of AMA patients it was 0.4% overall and only 0.1% after 36 weeks. Our study suggests that it is possible to eliminate this increased risk of stillbirth through a protocol of routine antepartum surveillance and planned delivery in all AMA patients. Due to our large sample size we had enough power to demonstrate even a small increase in stillbirth ≥20 weeks (from 3 per 1000 to 9 per 1000) in AMA patients. Based on our data, a routine policy of antepartum surveillance and delivery by 41 weeks appears appropriate for AMA patients.

In this study we also did not see an increased risk of stillbirth in women ≥40 compared to women <35, nor did we find a trend toward higher stillbirth rates across increasing age categories. This suggests that the benefits of antepartum surveillance in AMA women are present even among the oldest pregnant women, who also represent the group at highest risk of stillbirth.

With regard to the risk of antepartum surveillance and delivery by 41 weeks, we did note a small increase in the rate of labor induction in the AMA group compared to the non-AMA group, but the absolute difference was not large (18.5% vs. 15.8%). Therefore, AMA patients can be reassured that antepartum surveillance and delivery by 41 weeks do not markedly increase their risk of labor induction compared to non-AMA patients. Additionally, induction of labor after 41 weeks is not associated with an increased risk of cesarean delivery compared to expectant management [16].

Our data are consistent with a decision analysis model published by Fretts et al., [17] in which weekly testing beginning at 37 weeks appeared to be the most likely successful strategy for preventing stillbirth in AMA patients. Prior to our study, however, direct patient data suggesting a decreased risk of stillbirth in AMA patients with antenatal surveillance was limited. Therefore, our study using direct patient data is novel and adds information to this important and clinically relevant topic. Ideally, the hypothesis that antepartum surveillance reduces the risk of stillbirth in AMA patient should be tested prospectively by randomizing AMA patients to routine antepartum surveillance or standard care. This would not only better define the exact benefits of routine

antepartum surveillance, but also address the potential risks (induction of labor, cesarean delivery). A retrospective study such as ours is limited to properly address this. Due to the rare occurrence of stillbirth, however, a prospective trial would either need to be multicentered, which would be limited by differing management styles and practice patterns across institutions, or in one center over the course of many years, which would be difficult practically. Due to these difficulties in testing antepartum surveillance prospectively, it is not surprising that there are few prospective studies on antepartum testing for any specific indication, and current recommendations are either based on level II evidence, or expert opinion [13]. Therefore, our study, although limited by its retrospective design, is in line with the current level of evidence supporting antepartum testing in other high-risk populations.

Due to the retrospective nature of the study, our power is limited by the number of patients in our practice. We were underpowered to show a difference in stillbirth  $\geq 20$  weeks smaller than our calculated power (from 3 per 1000 to 9 per 1000). Also, we were underpowered to show a difference in stillbirth  $\geq 36$  weeks, specifically. The goal of surveillance, however, is to reduce the risk of stillbirth overall, and not just  $\geq 36$  weeks. Although we begin testing at 36 weeks, it is important to examine stillbirth  $\geq 20$  weeks as the primary outcome, as it could be possible to reduce stillbirths  $\geq 36$  weeks with testing, but if the majority of stillbirths occur  $< 36$  weeks, the testing strategy would not be effective. It is possible that inclusion of other patient data, such as maternal weight and smoking would yield interesting results. Also, it is possible that our patient population is not reflective of the general population and further studies in other populations are warranted to confirm our findings.

One could argue that a more appropriate retrospective control group would be non-tested AMA patients (such as from another institution). We believe, however, that this type of control group would introduce more bias considering that the population characteristics and pregnancy management between the groups are certain to differ, and a regression analysis would not be appropriate given the uncommon outcome of stillbirth. For this reason, we chose non-AMA patients in our own practice as controls as we know that the patient population and pregnancy management are the same, thus isolating AMA and our testing protocol as the only differing variables between the groups. Again, a randomized trial would be ideal, but due to the reasons stated above, very unlikely to be undertaken.

With regard to our specific protocol for AMA patients, it is unknown whether other protocols could achieve the same results. It is possible that the ideal time for the initiation of antepartum surveillance and the ideal frequency of testing are different from 36 weeks and weekly, respectively. Also, although we chose the ultrasound portion of the BPP as our testing modality, it is unknown if other tests, such as the non-stress test, would produce similar results. Finally, the ideal time for delivery in AMA patients is unknown. It is unknown if our policy of delivery by 41 weeks had additional benefit considering that all AMA patients were also undergoing antepartum surveillance. We chose 41 weeks because the risk of stillbirth in the general population increases at this gestational age [18]. In fact, an argument can be made that delivery at 41 weeks is appropriate for all patients, regardless of age [16,19,20]. Routine induction of labor at 41 weeks has been associated with a decreased incidence of stillbirth in the general population overall, although 410 women would need to be induced to prevent one stillbirth [21]. In our population of AMA patients, there were no stillbirths after 40 weeks and only one after 39 weeks (at 39 1/7), so it is unlikely that routine delivery earlier than 41 weeks would have been beneficial in our AMA population undergoing fetal surveillance. Finally, we cannot be certain if our

low rate of stillbirth in AMA patients was due to the antepartum surveillance, delivery at 41 weeks, both, or even some unmeasured factor, such as a heightened awareness to the higher-risk nature of AMA pregnancies in general.

In conclusion, our data suggest that routine antepartum surveillance of weekly BPP testing beginning at 36 weeks along with routine delivery by 41 weeks reduces the risk of stillbirth in AMA patients to that of non-AMA patients. Given the known risk of stillbirth in AMA patients, routine antepartum surveillance should be considered in all AMA patients.

### Conflict of interest

The authors report no conflict of interest.

### Acknowledgement

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