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Single deepest vertical pocket or amniotic fluid index as evaluation test for predicting adverse pregnancy outcome (SAFE trial): a multicenter, open-label, randomized controlled trial

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KEYWORDS: AFI; amniotic fluid index; amniotic fluid volume; labor induction; oligohydramnios; perinatal outcome; SDP; single deepest pocket

ABSTRACT

Objective *To determine whether the amniotic fluid index (AFI) or the single deepest vertical pocket (SDP) technique for estimating amniotic fluid volume is superior for predicting adverse pregnancy outcome.*

Methods *This was a multicenter randomized controlled trial including 1052 pregnant women with a term singleton pregnancy across four hospitals in Germany. Women were assigned randomly, according to a computer-generated allocation sequence, to AFI or SDP measurement for estimation of amniotic fluid volume. Oligohydramnios was defined as AFI ≤ 5 cm or the absence of a pocket measuring at least 2×1 cm. The diagnosis of oligohydramnios was followed by labor induction. The primary outcome measure was postpartum admission to a neonatal intensive care unit. Further outcome parameters were the rates of diagnosis of oligohydramnios and induction of labor (for oligohydramnios or without specific indication), and mode of delivery.*

Results *Postpartum admission to a neonatal intensive care unit was similar between groups (4.2% (n = 21)* vs *5.0% (n = 25); relative risk (RR), 0.85 (95% CI, 0.48–1.50);* P = *0.57). In the AFI group, there were more cases of oligohydramnios (9.8% (n = 49)* vs *2.2% (n = 11); RR, 4.51 (95% CI, 2.2–8.57);* P < *0.01) and more cases of labor induction for oligohydramnios (12.7% (n = 33)* vs *3.6% (n = 10); RR, 3.50 (95% CI, 1.76–6.96);* P < *0.01) than in the SDP group. Moreover, an abnormal cardiotocography was seen more often in the AFI group than in the SDP group (32.3% (n = 161)* vs *26.2% (n = 132); RR, 1.23 (95% CI, 1.02–1.50);* P = *0.03). The other outcome measures were not significantly different between the two groups.*

Conclusions *Use of the AFI method increased the rate of diagnosis of oligohydramnios and labor induction for oligohydramnios without improving perinatal outcome. The SDP method is therefore the favorable method to estimate amniotic fluid volume, especially in a population with many low-risk pregnancies. Copyright © 2016 ISUOG. Published by John Wiley & Sons Ltd.*

INTRODUCTION

Amniotic fluid volume is an integral part of the assessment of fetal wellbeing. Oligohydramnios occurs in many high-risk conditions and is associated with adverse perinatal outcome. The limitations of direct invasive measurement of amniotic fluid volume led to the use of ultrasound for amniotic fluid volume estimation, most often carried out by assessment of the amniotic fluid index (AFI)[1] or the single deepest vertical pocket (SDP)[2] technique[3]. These ultrasound measurements are used in the biophysical profile (BPP), consisting of SDP, fetal movement, fetal tone, fetal breathing and nonstress test[4], and in the modified BPP, consisting of nonstress test and AFI only[5], to evaluate fetal wellbeing. Often, delivery by induction of labor or Cesarean section is scheduled after diagnosing decreased amniotic fluid volume at term.

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However, there is no clear consensus on the best method to assess amniotic fluid adequacy[6,7].

Both techniques are similarly poor predictors, with AFI overestimating and SDP underestimating actual low amniotic fluid volumes[8]. A Cochrane review concluded that the use of AFI increases the rate of diagnosis of oligohydramnios and the rate of induction of labor without improving peripartum outcome[3]. Randomized controlled trials evaluated the different techniques in post-term pregnancies[9], in high-risk pregnancies[8,10] and intrapartum[11]. There is less knowledge in low-risk and term pregnancies. The choice between these two methods is relevant to pregnancies in which the risk of adverse perinatal outcome is also low. The possibility that, in these conditions, ultrasound tests may cause, rather than prevent, morbidity needs to be borne in mind.

The aim of this investigation was therefore to determine, not only in high-risk but also in low-risk pregnancies, which technique for estimating amniotic fluid volume (AFI or SDP) is the best test to predict adverse pregnancy outcome.

SUBJECTS AND METHODS

The SAFE trial (single deepest vertical pocket or amniotic fluid index as evaluation test for predicting adverse pregnancy outcome), an open-label, randomized controlled trial, was undertaken in Germany, with four university hospitals participating. Pregnant women with a singleton pregnancy and a fetus in cephalic presentation at term ($\geq$ 259 days of gestation) were recruited when presenting for delivery or prelabor examination. Women were excluded if they had a primary Cesarean section. Other exclusion criteria were premature rupture of the membranes and no ultrasound examination in the last 7 days, structural or chromosomal fetal malformation, intrauterine fetal death, placenta previa or any other contraindication to vaginal delivery.

Gestational age was assessed from the menstrual history and confirmed by measurement of fetal crown–rump length at a first-trimester ultrasound examination, which was carried out routinely in all participating women in accordance with German maternity guidelines.

The study was approved by the Ethics Committee II at Heidelberg University, Heidelberg, Germany, and had additional local approval from the boards of the other participating hospitals if necessary (reference number 2012-273 N-MA). All participants provided written informed consent before randomization. The study was registered with ANZCTR.org.au, no. ACTRN12612000586819, http://www.ANZCTR.org.au/ACTRN12612000586819.aspx.

The physicians in the labor ward were in charge of enrolment and assignment of the women to one of the two techniques. Participants were allocated randomly to either AFI or SDP measurement. The randomization sequence was created using a computer-generated randomization scheme with a 1:1 allocation for each arm of the study. Consecutively numbered, sealed opaque envelopes were prepared to conceal the random allocation from those responsible for recruiting participants into the study.

In the group assigned to AFI measurement, the physician in the labor ward calculated the AFI by dividing the uterine cavity into four quadrants. The largest vertical diameter of a fluid pocket (not containing small fetal parts or loops of umbilical cord) was measured in each quadrant. The four measurements were added together to provide a single value for AFI. In the group assigned to SDP measurement, the physician in charge measured only the largest vertical diameter of a fluid pocket. This was done if the horizontal measurement of the pocket was at least 1 cm. An AFI $\leq$ 5.0 cm or the absence of a pocket measuring at least 2 $\times$ 1 cm was defined as oligohydramnios[1,2,8].

If amniotic fluid volume was normal and labor had not commenced, the woman left the hospital and measurement of the amniotic fluid was undertaken in the next admission, if the last assessment by AFI or SDP was not made in the last 7 days. If oligohydramnios was diagnosed labor was induced, including in women with one previous Cesarean section.

Pregnancies were regarded as high risk in the presence of gestational diabetes, hypertensive disorder, fetal growth restriction, suspected placental insufficiency or intrahepatic cholestasis of pregnancy.

The primary outcome measure was postpartum admission to a neonatal intensive care unit (NICU). Other outcome parameters were perinatal death, oligohydramnios, induction of labor (without specified indication), induction of labor for oligohydramnios, umbilical artery pH < 7.10, 5-min Apgar score < 7, meconium-stained amniotic fluid, abnormal cardiotocography (CTG, visually interpreted), need for fetal scalp blood sampling, assisted vaginal delivery (without specified indication), assisted vaginal delivery for fetal distress, Cesarean section and Cesarean section for fetal distress. These outcome measures were chosen according to the criteria of the Cochrane review[3].

The data were obtained concurrently with patient care and were recorded by the research team. All statistical calculations were performed using SAS software, release 9.3 (SAS Institute Inc., Cary, NC, USA). Published data have indicated a rate of postpartum admission to NICU of approximately 5% of cases when assessed using the AFI method[11]. It was assumed that the SDP technique might result in a decrease in admissions of at least 2.5%. Under this assumption we needed a sample size of 804 for both groups (assuming $\alpha = 0.05$, power = 0.80 and equal group sizes). Thus we intended to enrol about 500 patients in each arm as we expected that a certain amount of women would have to be excluded from data analysis. The sample size was calculated with the SAS procedure PROC POWER.

Qualitative parameters are presented by absolute and relative frequencies. Furthermore, relative risks (RRs) together with 95% CIs were assessed. For quantitative, approximately normally distributed variables, mean values and SD were calculated. For ordinal-scaled or

quantitative discrete parameters, median values and ranges are given.

Student's *t*-test was used to compare two groups of continuous normally distributed variables. For quantitative discrete or ordinal-scaled variables, the Mann–Whitney *U*-test was performed. The chi-square test or Fisher's exact test was used to analyze proportions, as appropriate. Each of these tests was performed two-sided. Furthermore, multiple tests were done in order to analyze simultaneously the influence of the randomized group and the risk level. A logistic regression analysis or a two-way ANOVA was used for qualitative or quantitative outcome parameters, respectively. In general, a P-value < 0.05 indicated statistical significance.

RESULTS

The SAFE trial was carried out from July 2012 to September 2013. During this study period, 6930 women delivered at the participating institutions. In all, 3625 patients met the inclusion criteria, 1052 of whom provided informed consent for randomization. The trial profile is shown in Figure 1. A total of 525 patients were assigned randomly to AFI measurement. Twenty-seven cases were excluded from the analysis because there was no measurement within 7 days before delivery ($n = 16$), there was a deviation from the study protocol ($n = 5$) or the woman did not deliver in the same hospital as the assessment ($n = 6$). The median gestational age at randomization was 280 (range, 259–293) days with a median randomization-to-delivery interval of 2 (range, 0–7) days.

The number of women randomized to the SDP group was 527, of whom 23 were excluded from the analysis; an actual assessment of amniotic fluid volume was lacking in 16 cases, there was a deviation from the study protocol in six cases and one woman delivered in another hospital. The median gestational age at randomization was 280 (range, 259–296) days with a median randomization-to-delivery interval of 2 (range, 0–7) days. As the reasons for withdrawal were not associated with the technique of estimating amniotic fluid volume, in our opinion the scope of randomization (negligible differences among groups) was not violated and statistical results were not biased.

The demographic and baseline characteristics of the 1002 women analyzed were similar in the two groups (Table 1). There were fewer women with gestational diabetes ($P = 0.02$) and a previous Cesarean section ($P = 0.01$) in the AFI group.

The pregnancies were categorized into low risk and high risk. Pregnancy was defined as high risk in the presence of gestational diabetes, hypertensive disorder, fetal growth restriction, suspected placental insufficiency or intrahepatic cholestasis of pregnancy. In total, there were 828 women with a low-risk and 174 with a high-risk pregnancy (Table S1). Women with a high-risk pregnancy were older ($P = 0.03$), shorter ($P = 0.02$) and more overweight ($P < 0.01$) than were women with a low-risk pregnancy.

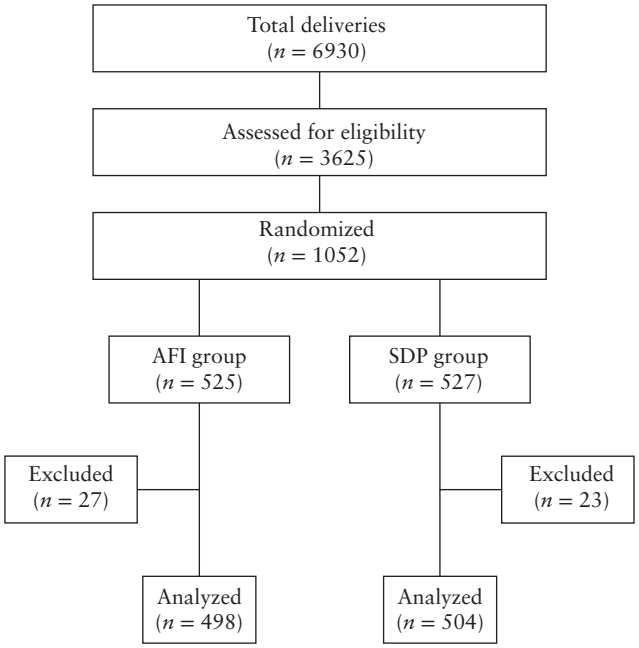

Figure 1 Flowchart of study population of pregnant women, randomized to undergo amniotic fluid volume measurement by either amniotic fluid index (AFI) or single deepest vertical pocket (SDP) technique, to determine which is superior for predicting adverse pregnancy outcome.

Table 1 Baseline demographics and pregnancy characteristics of 1002 pregnant women assigned randomly to undergo measurement of amniotic fluid volume by either amniotic fluid index (AFI) or single deepest vertical pocket (SDP) method

Characteristic	*AFI* (n = *498*)	*SDP* (n = *504*)
Maternal age (years)	30.8 ± 5.3	30.4 ± 5.4
Maternal weight (kg)	76.0 ± 16.4	77.0 ± 16.1
Maternal height (cm)	167.1 ± 6.5	166.6 ± 6.4
Body mass index at delivery (kg/m^2)	27.0 ± 5.6	27.5 ± 5.7
Gravidity	2 (1–10)	2 (1–14)
Parity	0 (0–6)	0 (0–9)
Gestational age at measurement (days)	280.8 ± 7.4	280.5 ± 7.4
Measurement-to-delivery interval (days)	2 (0–7)	1 (0–7)
Measurement-to-delivery interval in cases of induction of labor (days)	2 (0–7)	2 (0–7)
Birth weight (g)	3476.4 ± 455.0	3477.8 ± 435.7
Fetal sex		
Female	248 (49.9)	254 (50.4)
Male	250 (50.1)	250 (49.6)
Hypertensive disorder	14 (2.8)	17 (3.4)
Gestational diabetes	44 (8.8)	68 (13.5)
Smoker	47 (9.4)	56 (11.1)
Fetal growth restriction	15 (3.0)	13 (2.6)
Previous Cesarean section	33 (6.6)	56 (11.1)
High-risk pregnancy	75 (15.1)	99 (19.6)

Data are given as mean ± SD, median (range) or *n* (%).

The outcome parameters of all women are shown in Table 2. The rate of postpartum admission to NICU was similar between the two groups (4.2% ($n = 21$) *vs* 5.0% ($n = 25$); RR, 0.85 (95% CI, 0.48–1.50); $P = 0.57$). There was no difference regarding the

Table 2 Outcomes of 1002 pregnant women assigned randomly to undergo measurement of amniotic fluid volume by either amniotic fluid index (AFI) or single deepest vertical pocket (SDP) method

Outcome	*AFI (n = 498)*	*SDP (n = 504)*	*RR (95% CI)*	P
Postpartum admission to NICU	21 (4.2)	25 (5.0)	0.85 (0.48–1.50)	0.57
Amniotic fluid volume (cm)	10.0 (0–29)	4.4 (0–14.9)		
Oligohydramnios	49 (9.8)	11 (2.2)	4.51 (2.37–8.57)	< 0.01
Induction of labor	260 (52.2)	276 (54.8)	0.95 (0.85–1.07)	0.42
Induction of labor for oligohydramnios	33 (12.7)	10 (3.6)	3.50 (1.76–6.96)	< 0.01
Mode of delivery				0.87
Normal vaginal	355 (71.3)	352 (69.8)		
Assisted vaginal	55 (11.0)	57 (11.3)		
Cesarean section	88 (17.7)	95 (18.9)		
Abnormal CTG	40 (45.5)	35 (36.8)	1.26 (0.88–1.79)	0.20
Arrest in labor	39 (44.3)	50 (52.6)	0.83 (0.62–1.13)	0.23
Placental abruption	0 (0)	1 (1.1)	—	1.00
On request	9 (10.2)	9 (9.5)	1.07 (0.44–2.57)	0.88
Arterial pH	7.25 ± 0.07	7.26 ± 0.08		0.25
Arterial pH < 7.10	8 (1.6)	15 (3.0)	0.54 (0.23–1.26)	0.15
Arterial base excess	−4.4 ± 2.9	−4.3 ± 3.2		0.45
Arterial base excess < −12	5 (1.0)	7 (1.4)	0.71 (0.23–2.22)	0.55
5-min Apgar score	10 (1–10)	10 (4–10)		0.39
5-min Apgar score < 7	3 (0.6)	6 (1.2)	0.51 (0.13–2.01)	0.51
Abnormal CTG	161 (32.3)	132 (26.2)	1.23 (1.02–1.50)	0.03
Fetal blood analysis	73 (14.7)	64 (12.7)	1.16 (0.85–1.58)	0.36
Meconium-stained amniotic fluid	72 (14.5)	80 (15.9)	0.91 (0.68–1.22)	0.53

Data are given as mean ± SD, median (range) or *n* (%). $P < 0.05$ was considered statistically significant. CTG, cardiotocography; NICU, neonatal intensive care unit; RR, relative risk.

Table 3 Two-factor analysis to assess influence of method of measuring amniotic fluid volume (by amniotic fluid index (AFI) or single deepest vertical pocket (SDP)) and level of risk (high or low) on adverse pregnancy outcome

Outcome	*Method (AFI or SDP)* (P)	*Level of risk (low or high)* (P)	*Interaction* (P)
Postpartum admission to NICU	0.86	0.23	0.65
Oligohydramnios	< 0.01	0.65	0.53
Induction of labor	0.84	< 0.01	0.48
Induction of labor for oligohydramnios	< 0.01	0.40	0.94
Mode of delivery	0.47	0.89	0.55
Arterial pH	0.02	0.55	0.02
Arterial pH < 7.10	0.81	1.00	0.05
Arterial base excess	0.49	0.22	0.80
Arterial base excess < −12	0.53	0.42	—
5-min Apgar score	0.49	0.21	0.99
5-min Apgar score < 7	0.34	0.75	—
Abnormal CTG	0.06	0.84	0.63
Abnormal fetal blood analysis	0.17	0.24	0.28
Meconium-stained amniotic fluid	0.42	0.27	0.65

$P < 0.05$ was considered statistically significant. CTG, cardiotocography; NICU, neonatal intensive care unit.

rate of arterial pH < 7.10 (1.6% ($n = 8$) *vs* 3.0% ($n = 15$); RR, 0.54 (95% CI, 0.23–1.26); $P = 0.15$). There were more cases diagnosed with oligohydramnios (9.8% ($n = 49$) *vs* 2.2% ($n = 11$); RR, 4.51 (95% CI, 2.37–8.57); $P < 0.01$) and more labor inductions for oligohydramnios (12.7% ($n = 33$) *vs* 3.6% ($n = 10$); RR, 3.50 (95% CI, 1.76–6.96); $P < 0.01$) in the AFI group than in the SDP group. Moreover, an abnormal CTG was seen more often in the AFI group than in the SDP group (32.3% ($n = 161$) *vs* 26.2% ($n = 132$) (RR, 1.23 (95% CI, 1.02–1.50); $P = 0.03$).

Table S2 presents the outcome parameters of low-risk pregnancies and Table S3 of high-risk pregnancies. There were more cases of oligohydramnios (9.9% ($n = 42$) *vs* 2.0% ($n = 8$); RR, 5.03 (95% CI, 2.39–10.58); $P < 0.01$) and more labor inductions for oligohydramnios (15.3% ($n = 31$) *vs* 3.9% ($n = 8$); RR, 3.89 (95% CI, 1.84–8.27); $P = 0.01$) in low-risk pregnancies measured by the AFI than by the SDP technique. An arterial pH < 7.10 was seen more often in the SDP than in the AFI group (3.5% ($n = 14$) *vs* 1.2% ($n = 5$); RR, 0.34 (95% CI, 0.12–0.94); $P = 0.03$). In high-risk pregnancies (Table S3), the only significant difference was a lower arterial pH in the AFI group compared with the SDP group (7.25 ± 0.08 *vs* 7.28 ± 0.07; $P = 0.01$).

Two-factor logistic regression analysis or ANOVA was used to assess the influences of the randomization arm (AFI or SDP) and the level of risk of the pregnancy (low or high, Table 3), simultaneously, as well as interactions between these two factors. The primary outcome measure, postpartum admission to NICU, was not different between AFI and SDP groups ($P = 0.86$). The majority of the outcome parameters were independent of these two factors. Some, however, were influenced by the measurement technique: oligohydramnios ($P < 0.01$) and induction of labor for oligohydramnios ($P < 0.01$) were more common in the AFI group. Labor induction was conducted more often in high-risk than low-risk pregnancies ($P < 0.01$). In high-risk pregnancies, arterial pH was

Table 4 Indication for induction of labor in pregnant women randomized to amniotic fluid volume measurement by either amniotic fluid index (AFI) or single deepest vertical pocket (SDP) method

Indication for labor induction	*AFI (n = 260)*	*SDP (n = 276)*	P
GA ≥ 41 weeks	110 (42.3)	125 (45.3)	0.49
Oligohydramnios	33 (12.7)	10 (3.6)	< 0.01
Gestational diabetes	27 (10.4)	40 (14.5)	0.15
Hypertensive disorder	8 (3.1)	13 (4.7)	0.33
Intrahepatic cholestasis	2 (0.8)	2 (0.7)	1.00
Fetal growth restriction	9 (3.5)	10 (3.6)	0.92
Suspected macrosomia	5 (1.9)	5 (1.8)	1.00
PROM	25 (9.6)	19 (6.9)	0.25
On request	19 (7.3)	32 (11.6)	0.09
Reduced fetal movements	4 (1.5)	3 (1.1)	0.78
Abnormal CTG	4 (1.5)	3 (1.1)	0.72
Other	14 (5.4)	14 (5.1)	0.87
High risk	57 (21.9)	72 (26.1)	0.26

Data are given as *n* (%). $P < 0.05$ was considered statistically significant. CTG, cardiotocography; GA, gestational age; PROM, premature rupture of membranes.

lower in the AFI group ($P = 0.02$). We found a significant interaction regarding arterial pH ($P = 0.02$), indicating that the difference between the randomized groups depends on the level of risk. For high-risk pregnancies, the mean value was higher in the SDP arm (7.28 ± 0.07 *vs* 7.25 ± 0.08; $P = 0.01$) whereas no difference could be detected in low-risk patients ($P = 0.97$).

The indications for labor induction are shown in Table 4. The only significant difference between groups was a greater number of inductions for oligohydramnios in the AFI group ($P < 0.01$).

DISCUSSION

Amniotic fluid volume assessment is an essential part of the assessment of fetal wellbeing, not only in high-risk pregnancies but also in low-risk conditions. The choice between the two techniques (AFI or SDP) is of clinical importance as it is possible that ultrasound tests may cause morbidity.

The SAFE trial demonstrated that neither of the tests was superior in predicting adverse pregnancy outcome. However, when using the AFI method, it was more likely that oligohydramnios would be diagnosed. As a result of this, there were more inductions of labor for oligohydramnios without improving pregnancy outcome. There was more often an abnormal CTG in the AFI group, especially in low-risk pregnancies.

There was no difference between the two groups for the rate of admission to NICU ($P = 0.86$). This finding is in line with that of the Cochrane review (RR, 1.04 (95% CI, 0.85–1.26); five trials including 3226 newborns)[3]. Neither in this trial nor in other investigations did perinatal death occur[9,10].

The rate of diagnosis of oligohydramnios was higher when AFI was used. This finding has been demonstrated in many investigations previously[3,9–16]. In most of these trials, high-risk pregnancies were evaluated[10,12], whereas most pregnancies in our trial were low risk. The rate of oligohydramnios was higher in the low-risk pregnancies with AFI compared with SDP measurement (9.9% ($n = 42$) *vs* 2.0% ($n = 8$); RR, 5.03; $P < 0.01$) but this was not significantly higher in high-risk pregnancies ($P = 0.10$). The lack of significance may be due to the small sample size and the rather low prevalence.

The rate of labor induction for oligohydramnios was higher in the AFI group, which has also been observed by other authors[3,9–15]. Cochrane analysis stated that the AFI method for fetal surveillance almost doubles the risk for induction of labor (RR, 1.92 (95% CI, 1.50–2.46); four trials including 2138 pregnancies)[3,9–15].

Some trials have demonstrated that Cesarean section for fetal distress is higher when the AFI technique is used[3,11–16]. This finding could not be confirmed in this trial or in others[9,10]. However, we detected more cases with abnormal CTG in low-risk pregnancies without increasing the rate of operative delivery. This may be a result of more inductions of labor with prostaglandin in this group. There were more women with gestational diabetes and previous Cesarean section in the SDP group. These conditions increase the risk for Cesarean section. It can be speculated whether the rate of Cesarean section may be higher in the AFI group when there are more cases with both these risk factors.

In low-risk pregnancies, an umbilical arterial pH < 7.10 was found more often when the SDP technique was used. Since the rate of arterial base excess < −12.0 and 5-min Apgar score < 7 were not different between groups, this finding was considered not clinically relevant. There was also no difference found in other investigations[3,9–15].

The other outcome measures were not significantly different between groups. This correlates with the existing medical literature, demonstrating that the technique has no influence on the presence of meconium, mode of delivery (assisted vaginal delivery, assisted vaginal delivery for fetal distress, Cesarean section) and non-reassuring fetal heart rate tracing[3,9–15].

The SAFE trial has underlined that using the AFI method in routine obstetric assessment, characterized by a large low-risk population, results in more women being diagnosed with oligohydramnios and being induced for an abnormally reduced fluid volume, without improving the outcome. Pregnant women become anxious when diagnosed with oligohydramnios, which is associated with 'something being wrong'. Use of the AFI technique should be considered with caution, since a higher rate of obstetric intervention for oligohydramnios can only be justified if there is a demonstrable decrease in the rate of poor pregnancy outcomes. However, neither of the two techniques was able to show their superiority in the prevention of such poor results. Both methods have a low sensitivity in detecting abnormal amniotic fluid volume and it is questionable whether these measurements are necessary at all in low-risk pregnancies.

If amniotic fluid volume is assessed, the method with the lowest risk for morbidity should be chosen. This

implies that the SDP technique is the favorable method to estimate amniotic fluid volume in clinical routine care. The Royal College of Obstetricians and Gynaecologists recommend the use of SDP in the management of small-for-gestational-age fetuses[17]. However, especially in pregnancies in which the risk of adverse perinatal outcome is low, the choice of method for amniotic fluid volume assessment is relevant and the SDP method should be chosen.

The strengths of our study are its design as a randomized controlled multicenter trial, the sample size and the inclusion of low-risk and high-risk pregnancies. A limitation may be the fact that the sample size of high-risk pregnancies was not very large. There are some trials that have investigated the influence of these two techniques in high-risk pregnancy[10,12]. In these trials, high risk was defined as a complicated pregnancy in need of a weekly BPP. In our study, we defined pregnancy as high risk in the presence of gestational diabetes, hypertensive disorder, fetal growth restriction, suspected placental insufficiency or intrahepatic cholestasis of pregnancy. These previous trials stated that the AFI method increased the risk of intervention without improving the outcome in high-risk pregnancies[10,12].

In conclusion, use of the AFI method in routine obstetric assessment resulted in more women being diagnosed with oligohydramnios and being induced for an abnormal amniotic fluid volume without improving the perinatal outcome. The SDP method is therefore the favorable method to estimate amniotic fluid volume, especially in a population with many low-risk pregnancies.

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SUPPORTING INFORMATION ON THE INTERNET

The following supporting information may be found in the online version of this article:

Table S1 Baseline demographic characteristics of low- and high-risk pregnancies assigned randomly to measurement of amniotic fluid volume by amniotic fluid index or single deepest vertical pocket technique

Table S2 Outcome of 828 low-risk pregnancies assigned randomly to undergo measurement of amniotic fluid volume by amniotic fluid index (AFI) method or single deepest vertical pocket (SDP) method

Table S3 Outcome of 174 high-risk pregnancies assigned randomly to undergo measurement of amniotic fluid volume by amniotic fluid index (AFI) method or single deepest vertical pocket (SDP) method

This article has been selected for Journal Club.

A slide presentation, prepared by Dr Shireen Meher, one of UOG's Editors for Trainees, is available online.

Chinese translation by Dr Yang Fang.

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RESUMEN

Objetivo Determinar cuál es la mejor técnica de estimación del volumen de líquido amniótico con la que predecir los resultados adversos del embarazo: el índice de líquido amniótico (ILA) o la técnica de medición de la columna máxima vertical de líquido amniótico (CMV).

Métodos Se realizó un ensayo controlado aleatorio multicéntrico con 1052 embarazadas con gestaciones únicas a término en cuatro hospitales de Alemania. Las mujeres se asignaron aleatoriamente, mediante una secuencia generada por computadora, a la medición del ILA o la CMV para estimar el volumen de líquido amniótico. El oligohidramnios se definió como un ILA ≤ 5 cm o la ausencia de una columna con un tamaño de al menos 2 x 1 cm. El diagnóstico de oligohidramnios condujo a la inducción el parto. La medida del resultado principal fue el ingreso neonatal después del parto en la unidad de cuidados intensivos. Otros parámetros del resultado fueron las tasas de diagnóstico de oligohidramnios y la inducción del parto (por oligohidramnios o sin indicación específica), y el tipo de parto.

Resultados El ingreso neonatal después del parto en la unidad de cuidados fue similar entre ambos grupos (4,2% (n = 21) frente a 5,0% (n = 25); riesgo relativo (RR), 0,85 (IC 95%, 0,48–1,50), p = 0,57). En el grupo de ILA hubo más casos de oligohidramnios (9,8% (n = 49) frente al 2,2% (n = 11); RR, 4,51 (IC 95%, 2,2–8,57); p <0,01) y más casos de inducción del parto por oligohidramnios (12,7% (n = 33) frente a 3,6% (n = 10); RR, 3,50 (IC 95%, 1,76–6,96); p <0,01) que en el grupo de CMV. Además, se observó con más frecuencia una cardiotocografía anormal en el grupo de ILA que en el grupo CMV (32,3% (n = 161) frente a 26,2% (n = 132); RR, 1,23 (IC 95%, 1,02–1,50), p = 0,03). Las otras medidas del resultado no fueron significativamente diferentes entre ambos grupos.

Conclusiones El uso del método ILA aumentó la tasa de diagnóstico de oligohidramnios y la inducción del parto por oligohidramnios sin una mejora del resultado perinatal. Por lo tanto, el método de CMV es el método más favorable para estimar el volumen de líquido amniótico, especialmente en poblaciones con abundancia de embarazos de bajo riesgo.

目的：研究用于评估羊水量的羊水指数 (amniotic fluid index，AFI) 或单个最大羊水池垂直深度 (single deepest vertical pocket，SDP) 技术是否更适用于预测不良妊娠结局。

方法：本研究为一项多中心随机对照研究，纳入德国 4 所医院的 1052 例足月单胎孕妇。根据计算机生成的分配顺序将孕妇随机分配，分别检测 AFI 或 SDP 来评估羊水量。AFI≤5 cm 或 SDP <2 ×1cm 定义为羊水过少。随后在引产时对羊水过少进行诊断。主要结局检测为产后进入新生儿重症监护病房率。进一步的结局参数为羊水过少诊断率和引产率（由于羊水过少或无特异适应证）以及分娩方式。

结果：2 组相比产后进入新生重症监护病房率相似，分别为 4.2%（n = 21）和 5.0%（n = 25）[相对危险度（relative risk，RR）, 0.85（95%CI，0.48~1.50）；P=0.57]。AFI 组与 SDP 组相比，羊水过少发生率[9.8%（n = 49）和 2.2%（n = 11）；RR，4.51（95% CI，2.2~8.57）；P<0.01]以及由于羊水过少引产率[12.7%（n=33）和 3.6%（n = 10）；RR，3.50（95% CI，1.76~6.96）；P<0.01]较高。而且 AFI 组胎心监护异常率高于 SDP 组[32.3%（n = 161）和 26.2%（n = 132）；RR，1.23（95% CI，1.02~1.50）；P=0.03]。2 组比较其他结局检测未见统计学差异。

结论：采用 AFI 方法能够提高羊水过少以及由于羊水过少引产的诊断率，但不改善围产期结局。因此，SDP 方法更适用于评估羊水量，特别是在包括许多低危妊娠的人群中。