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Systematic review of accuracy of ultrasound in the diagnosis of vasa previa

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KEYWORDS: diagnostic accuracy; ultrasound; vasa previa

ABSTRACT

Objective *Vasa previa is an obstetric complication in which the fetal blood vessels lie outside the chorionic plate in close proximity to the internal cervical os. In women with vasa previa, the risk of rupture of these vessels is increased, thus potentially causing fetal death or serious morbidity. Our objective was to assess the accuracy of ultrasound in the prenatal diagnosis of vasa previa.*

Methods *We searched MEDLINE, EMBASE, the Cochrane Library and PubMed for studies on vasa previa. Two reviewers independently selected studies on the accuracy of ultrasound in the diagnosis of vasa previa. The studies were scored on methodological quality using the Quality Assessment of Diagnostic Accuracy Studies tool (QUADAS-2). Data on sensitivity and specificity were subsequently extracted.*

Results *The literature search revealed 583 articles, of which two prospective and six retrospective cohort studies were eligible for inclusion in the qualitative analysis. All studies documented methods suitable for the prenatal diagnosis of vasa previa. Four out of the eight studies used transvaginal ultrasound (TVS) for primary evaluation, while the remaining four studies used transabdominal ultrasound and performed a subsequent TVS when vasa previa was suspected. The QUADAS-2 tool reflected poor methodology in six of the eight included studies, and prenatal detection rates varied from 53% (10/19) to 100% (total of 442 633 patients, including 138 cases of vasa previa). In the two prospective studies (*n = *33 795, including 11 cases of vasa previa), transvaginal color Doppler performed during the second trimester detected all cases of vasa previa (sensitivity, 100%) with a specificity of 99.0–99.8%.*

Conclusion *The accuracy of ultrasound in the diagnosis of vasa previa is high when performed transvaginally in combination with color Doppler.* Copyright © 2014 ISUOG. Published by John Wiley & Sons Ltd.

INTRODUCTION

Vasa previa is a complication of pregnancy in which fetal blood vessels lie outside the chorionic plate, in close proximity to the internal cervical os. The estimated incidence of vasa previa has been put at between 1:1200 and 1:5000, but recent research indicates that it might not be as rare as once thought[1–3]. Vasa previa can be divided into two subtypes; Type I is the occurrence of a single-lobed placenta with a velamentous cord insertion and Type II is a multilobed placenta with connecting vessels running over the internal cervical os[4]. Normally, the umbilical cord is protected by placental tissue or Wharton's jelly, a specialized tissue that acts as a supportive and protective structure substituting for the adventitia of the umbilical vessels[5]. In vasa previa, this protection is absent and compression of the vessels by the presenting part may lead to fetal heart decelerations and bradycardia on cardiotocography[6–8]. In cases of ruptured membranes, vasa previa fetal vessels can rupture simultaneously, thus potentially causing fetal blood loss and serious neonatal morbidity and mortality[9].

It has been hypothesized that prenatal recognition of vasa previa by ultrasound screening enables elective delivery of the fetus by Cesarean section, thus avoiding potential fetal demise or neonatal morbidity[10]. Nowadays, the majority of pregnant women in the developed world undergo several scans during pregnancy. Locating and documenting the umbilical cord insertion site can be done, but is not routinely carried out. It has been proposed recently that a standard evaluation of the umbilical cord

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insertion site be included in the second-trimester ultrasound examination to detect vasa previa prenatally[9,11,12]. The diagnostic performance of ultrasound in the prenatal detection of vasa previa, however, is unknown, and this information is needed before one can decide whether or not to include screening for vasa previa in standardized prenatal care. The aim of our study was, therefore, to investigate the accuracy of ultrasound in the diagnosis of vasa previa.

METHODS

A medical librarian (J.L.) performed a comprehensive search of MEDLINE (OVID, from 1948), EMBASE (OVID, from 1947), The Cochrane Library, including the Cochrane Central Register of Controlled Trials (CENTRAL, from inception), PubMed (the publisher[sb]-fraction which contains publications ahead of print, not yet included in OVID MEDLINE) and ongoing Trial registers (http://clinicaltrials.gov/) until February 2014. Language restrictions were not applied and animal studies were excluded. The search strategy consisted of subject headings (MeSH, SH) and words in title and abstract for vasa previa or its synonyms (vasa previa Type I). In addition, we searched broadly for diagnostic imaging and screening of abnormal umbilical cord location (vasa previa Types II and III); see Appendix S1 for entire MEDLINE search.

The search included an iterative process for each database, to refine the search strategy through incorporation of new search terms as new relevant citations were identified, i.e. by checking reference lists and citing articles using ISI Web of Science. The bibliographic records retrieved were downloaded and imported into Reference Manager® software version 12.0 (Carlsbad, CA, USA) to exclude duplicates, and the search results stored and analyzed.

Studies were selected in a two-stage process. First, two reviewers (L.R., N.K.) scrutinized titles and abstracts of all studies. Studies were considered eligible if they described ultrasound and its accuracy in the prenatal diagnosis of vasa previa, which was defined as fetal vessels in close proximity of the internal cervical os. Decisions on final inclusions and exclusions were made after the full-text articles identified on first selection had been read independently (L.R., N.K.) and examined in more detail. Disagreements about eligibility were resolved by discussion.

We included prospective and retrospective cohort studies and case–control studies. The index test consisted of an ultrasound evaluation performed during pregnancy with the specific aim of detecting vasa previa. All studies included in the analysis performed at least one second-trimester scan. The reference standard for confirmation of vasa previa after delivery was macroscopic observation of the placenta and umbilical cord insertion site by the caregiver.

Two reviewers (L.R., N.K.) scored all included studies independently on methodological quality with use of the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2)[13]. This tool is recommended for assessment of the risk of bias and the applicability of primary diagnostic accuracy studies in systematic reviews. QUADAS-2 consists of four key domains: 'patient selection', 'index test', 'reference standard' and 'flow and timing'. All four domains are rated in terms of risk of bias, and the last three are also rated in terms of applicability to the review question[13]. The quality items assessed were study design and the conduct and analysis of all included studies. Elements considered to be associated with a risk of bias were the use of retrospective data, non-consecutive patient enrollment, lack of blinding for the outcome of the reference standard at the time of the index test and a discrepancy in the number of patients who received the index test and the reference standard.

Subsequently, both reviewers (L.R., N.K.) extracted clinical study characteristics independently using a predesigned data extraction form, including: country of investigation, period of data collection, number of cases of vasa previa, study population, method of ultrasound, gestational age at diagnosis, index test and reference standard. In addition, data on prenatal detection rates, with sensitivity and specificity, were extracted.

Statistical analysis

We constructed two-by-two tables, cross-classifying the outcome of the index test against the outcome of the reference standard. Sensitivity and specificity were calculated, as well as positive and negative predictive values. Authors were contacted for additional data if it was not possible to create two-by-two tables. A random-effects model was used for statistical pooling of the data and to present pooled data with 95% CIs. Further, an I^2 test was applied to assess heterogeneity among the included studies and to calculate the area under the summary receiver–operating characteristics curve to measure the accuracy of ultrasound.

RESULTS

The initial search resulted in 583 unique articles, of which 563 were excluded after reading the title and abstract (Figure 1). The full text of the remaining 20 articles was examined in more detail and 12 articles were excluded; five did not document prenatal detection of vasa previa, but recorded outcome[2,14,15], management[15], cost effectiveness of screening[16] and the clinical significance of velamentous cord insertion[17], one article was excluded as it reported placental location in the first trimester[12], one article reported on the same cohort as that in another article[3], two articles were reviews[20,21] and three articles were conference abstracts of studies not yet published[22–24]. One article reported on additional cases of a cohort described previously by Lee *et al.* but both articles were included in the analysis after exclusion of the double cases[18,19]. The authors were contacted but no additional data were obtained. Ultimately, we included eight articles in the qualitative analysis.

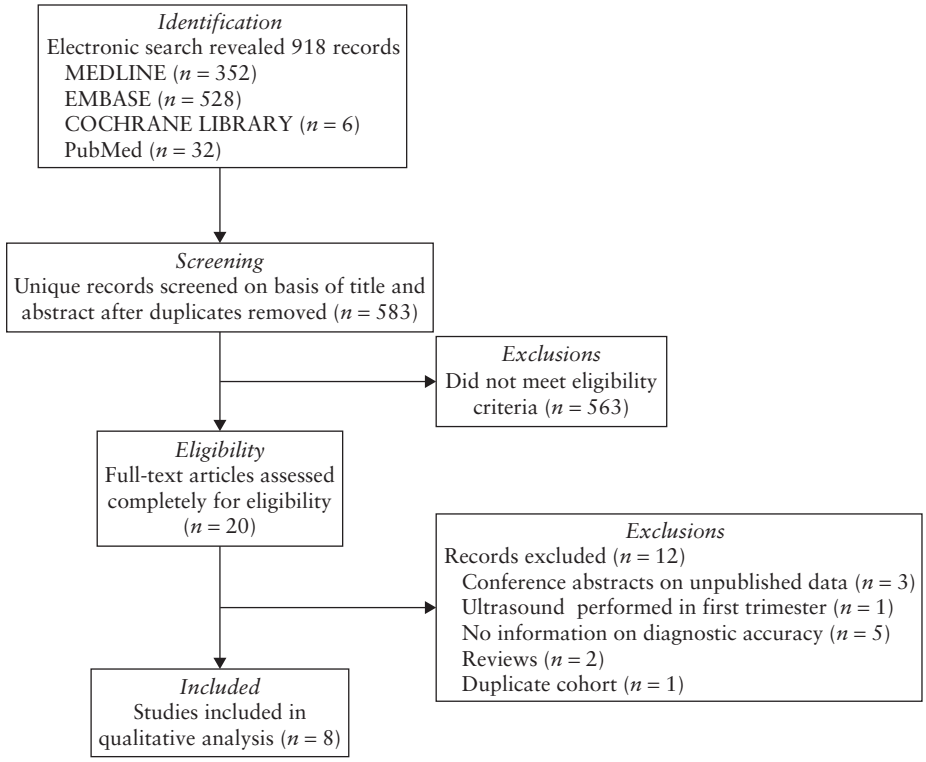

Figure 1 Flowchart summarizing study selection of papers on ultrasound detection of vasa previa.

Table 1 provides an overview of the included studies and their characteristics. A total of 442 633 women were included of which there were 138 cases of vasa previa. The number of vasa previa cases per study varied from 1[25] to 60[19], and all eight of the included studies were cohort studies.

Results of quality assessment of the included studies is summarized in Figure 2. Data collection was prospective in two (25%) studies and sampling of patients was consecutive in five (63%) studies. Patients included in all eight studies were likely to match our target population. In all studies, the outcome of the reference standard was unknown at the time of the index test[26] and all studies documented the methods applied for prenatal diagnosis of vasa previa.

Five studies documented the umbilical cord insertion site in all pregnancies and one study merely recorded this in twin pregnancies[19]. Two studies systematically reported placental location in all investigated pregnancies, while five studies systematically visualized and documented the lower uterine region or internal cervical os[4,11,18,19,27].

Transvaginal ultrasound (TVS) was the primary method used to diagnose vasa previa in four studies and was performed after a transabdominal scan (TAS) in three studies. One study investigated umbilical cord insertion site by TAS in the mid-trimester and patients with an inconclusive diagnosis were scheduled for TVS evaluation between 30 and 36 weeks' gestation[25]. All studies reported the use of color or pulsed Doppler for the diagnosis of vasa previa.

In five of the eight studies[11,18,25,27,28], gestational age at the time of diagnosis at ultrasound was reported, ranging from 18 + 0 to 26 + 6 weeks. Three studies documented early third-trimester ultrasound scans to ascertain the diagnosis of (suspected) vasa previa[4,11,25].

Statistical pooling of the data on predictive parameters for diagnostic accuracy could not be performed because of insufficient data owing to heterogeneity.

In two prospective cohort studies[4,25] detection of velamentous cord insertion and vasa previa were the primary objectives. Nomiyama *et al.*[25] reported that the umbilical cord insertion site was successfully visualized in 99.8% (586/587) of the fetuses and identification of a velamentous cord insertion site by ultrasound evaluation had a sensitivity of 100% (5/5), a specificity of 99.8% (580/581), a positive predictive value of 83% (5/6) and a negative predictive value of 100% (580/580). Catanzarite *et al.*[4] diagnosed 11 (0.03%) cases of vasa previa by ultrasound among 33 208 women. Ten cases were confirmed at delivery while the eleventh case was a false-positive diagnosis that appeared to be a placenta previa at delivery. No standard outcome of all scanned pregnancies was available thus only specificity (100%) could be calculated in this study.

In the remaining retrospective cohort studies, all reported on the number of prenatally diagnosed cases of vasa previa. The prenatal detection rate varied from 53% to 100%, as shown in Table 2, with four studies diagnosing all cases of vasa previa prenatally[4,11,25,29]. In contrast, Smorgick *et al.*[28] diagnosed only 53% (10/19) of cases with vasa previa prenatally. In the nine cases that remained undetected, the umbilical cord insertion site had not been evaluated and only TAS had been performed.

Table 1 Characteristics of included studies on detection of vasa previa (VP) by transvaginal (TVS) and transabdominal (TAS) ultrasound

Study	*Type and setting*	*Inclusion criteria*	*Population (n)*	*Cases of VP (n)*	*Maternal age (years)*	*Index test*	*Reference standard*
Baulies *et al.*[11] 2007	Retrospective cohort, single center, Spain	All deliveries between 2000 and 2005	12 063	9	34 (28–40)	TVS on empty bladder at 20–22 weeks; color Doppler for confirmation of diagnosis	Pathological examination of placenta and membranes in four cases; placental morphologic examination after delivery
Bronsteen *et al.*[19] 2013	Retrospective cohort, single center, USA	All deliveries of confirmed VP between 1990 and 2010 Excluded: patients with VP with prenatal care and delivery in another center	182 554	60	Unknown	TAS on full bladder; TVS with color Doppler when needed; gestational age at diagnosis unknown	Delivery information, medical record or discharge record
Catanzarite *et al.*[4] 2001	Prospective cohort, single center, USA	Patients diagnosed with VP by ultrasound	33 208	10	31	TAS with color Doppler on full bladder after 26 weeks; TVS when cervix could not be seen by TAS; from 1998: routine color sweep over lower uterine segment	Clinical or pathological examination of placenta and membranes
Hasegawa *et al.*[29] 2010	Retrospective cohort, single center, Japan	All deliveries between 2006 and 2009	4532	10	34 ± 4.0	Second-trimester TVS with color Doppler	Not reported
Kanda *et al.*[27] 2011	Retrospective cohort, single center, Japan	Patients with VP in medical records between 2002 and 2007	5131	10	31.5 ± 8.4	Observation of internal cervical os by TVS with color Doppler between 20 and 25 weeks	Clinical examination of placenta and membranes
Lee *et al.*[18] 2000	Retrospective cohort, single center, USA	Patients with suspected VP in a computerized database between 1991 and 1998	93 874	18	Unknown	TAS in early third trimester; evaluation by TVS with color Doppler when suspicion of VP	Clinical or pathological examination of placenta and membranes
Nomiyama *et al.*[25] 1998	Prospective cohort, single center, Japan	Fetuses scanned at 18 and 20 weeks between 1993 and 1996	587	1	Unknown	TAS with color Doppler in second and third trimesters; TVS if cord insertion not seen in third trimester	Pathological examination of placenta and membranes
Smorgick *et al.*[28] 2010	Retrospective cohort, single center, Israel	Patients with VP in medical records between 1988 and 2007 Excluded: cases of velamentous cord insertion without VP	110 684	19	33 (22–46)	TVS with color Doppler between 15 and 33 weeks	Clinical examination of placenta and membranes

Maternal age data provided as median (range) or mean ± SD.

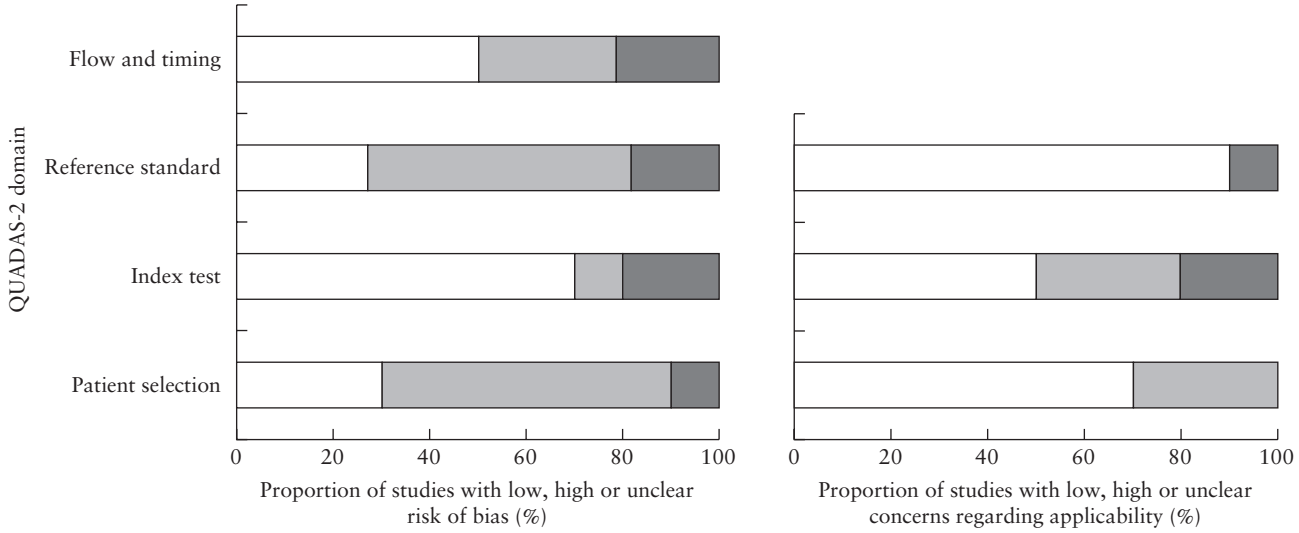

Figure 2 Results of Quality Assessment for Diagnostic Accuracy Studies (QUADAS-2). □, low; ▒, high; ■, unclear.

Table 2 Prenatal detection rates of vasa previa by ultrasound

Study	*Cases of vasa previa*	*Prenatal diagnosis*	*Diagnosed after delivery*
Baulies *et al.*[11]	9	9 (100)	—
Bronsteen *et al.*[19]	60	56 (93)	4 (7)
Catanzarite *et al.*[4]	10	10 (100)	—
Hasegawa *et al.*[29]	10	10 (100)	—
Kanda *et al.*[27]	10	9 (90)	1 (10)
Nomiyama *et al.*[25]	1	1 (100)	—
Smorgick *et al.*[28]	19	10 (53)	9 (47)

Data given as *n* or *n* (%). The study of Lee *et al.*[18] was not included in this table as information regarding prenatal diagnosis of vasa previa was presented in the study of Bronsteen *et al.*[19].

Two studies were able to review images of missed cases; Catanzarite *et al.*[4] re-evaluated the stored images of these cases, and structures suggestive of vasa previa were discovered; Bronsteen *et al.*[19] reviewed retrospectively the digital clips and videos of the first ultrasound in which they missed 13/60 cases initially. Four of those cases had recordings of the lower uterine segment suggestive of vasa previa, six cases had no suspicious areas despite adequate visualization and three had no suspicious areas but also had inadequate visualization for an appropriate evaluation.

Little can be said about the false-positive rates of ultrasound in the diagnosis of vasa previa, owing to a lack of information. Bronsteen *et al.*[19] reported five false-positive cases, but did not elaborate on these further, Nomiyama *et al.*[25] reported one false-positive case and Catanzarite *et al.*[4] reported one false-positive case within their cohort.

DISCUSSION

In this systematic review we found that the accuracy of ultrasound in the prenatal detection of vasa previa is high when performed transvaginally and combined with color Doppler. The median prenatal detection rate was 93%, and specificity was between 99% and 100% in the present studies; however, the quality of the available studies is relatively poor. Prenatal diagnosis of vasa previa was made most frequently at 18–26 weeks' gestation. It is useful to evaluate the placental cord insertion by TAS in the second trimester. An increase in missed cases of vasa previa is seen when ultrasound evaluation does not involve color Doppler, is transabdominal and/or is performed only in the third trimester.

The optimal timing for the detection of vasa previa has been the subject of discussion, and evidence on detection earlier than the second trimester is available. Hasegawa *et al.*[30] visualized the placental cord insertion site in 93.5% of their patients at the time of the nuchal translucency scan. In another study[31], the group found an association between vasa previa and placental cord insertion in the lower third of the uterus in the first trimester. Ultrasound evaluation of the cervical region in the third trimester may be limited owing to the presence of the fetal presenting part or a scar from a previous Cesarean section[27]. Nomiyama *et al.*[25] and Sepulveda *et al.*[32] reported an average of 20–30 additional seconds needed to evaluate the placental cord insertion and, in 95% of cases, the insertion site was seen within 1 min. The occurrence of linear or tubular structures near the internal cervical os should arouse suspicion and mandate referral to a prenatal diagnostic center for further evaluation, given the unfavorable natural course of suspected vasa previa[2].

Awareness of the subject of vasa previa seems to increase prenatal detection rate when we compare the prospective study of Nomiyama *et al.*[25] included in our review with that of Eddleman *et al.*[17], in which a cohort of cases with velamentous cord insertion was reviewed retrospectively and the authors reported that none of the cases was diagnosed prenatally and, moreover, three cases of vasa previa had been missed. This is further supported by the study of Smorgick *et al.*[28] included in our review,

in which, despite the small number of cases ($n = 19$), an increase in prenatal detection rate of vasa previa over two consecutive decades, from 25% in 1988–1997 to 60% in 1998–2007, was documented.

Several potential limitations of our study should be pointed out. Despite our broad literature search, we found only two prospective studies. This may reflect the fact that vasa previa is a rare complication that may result in a lack of attention to the subject. Otherwise, it might reflect the difficulty of performing prospective cohort studies evaluating relatively rare events. Because of heterogeneity between the studies, it was not possible to perform a meta-analysis on sensitivity and specificity of ultrasound as a diagnostic tool for vasa previa. Consequently, most knowledge comes from retrospective studies carrying a substantial risk of selection bias. Verification bias is another concern, whereby performance of the reference test depends on the result of the index test[33], which may introduce a sensitivity estimate that is too high. Moreover, pathological examination cannot provide precise information on the exact position of the fetal vessels with respect to the internal os at the time of delivery. It is important to bear in mind that every false-positive case means a potential unnecessary Cesarean section, with all its consequences.

Many studies reported only postnatally confirmed cases of vasa previa and therefore no sensitivity and specificity could be determined[11,18,19]. Although it seems that the majority of cases of vasa previa have an unfavorable outcome, some remain uncomplicated. Most probably, some undetected cases of vasa previa remain uncomplicated and will not be registered as a false negative. Since there is no place for the documented universal macroscopic evaluation of all placentae, this will remain a limitation of future studies[34].

Lack of documentation on evaluation of overall perinatal death is another limitation that could result in underestimation of perinatal mortality due to vasa previa and, at the same time, an overestimation of the predictive capability of TVS in the diagnosis of vasa previa[11,25,29]. In The Netherlands, Huidekoper[35] found ruptured vasa previa as the cause of bleeding during labor in 16 (0.05%) pregnancies when systematically investigating 30 000 placentae in 1972. Unfortunately, the outcomes of the children involved in these pregnancies were not reported. To assess how many perinatal deaths are attributable to vasa previa, it would be necessary to investigate all cases of perinatal death due to exsanguination over a certain period. As mentioned above, there is no evidence that every case of vasa previa results in fetal demise when it remains undiagnosed.

A final issue to consider is the effectiveness of Cesarean section to prevent hemorrhage of the fetal vessels once vasa previa has been diagnosed. It is difficult to see how randomized clinical trials on the subject could be carried out, therefore it is important to collect data on the outcome of vasa previa in cases of vaginal delivery. Also, we should realize that other studies involving interventions in vaginal delivery, such as artificial rupture of membranes or induction of labor, are usually underpowered to address complications such as bleeding from vasa previa[36,37]. Indeed, historical cohort studies conducted before the era of ultrasound may help us to assess the true importance of undiagnosed vasa previa in perinatal outcomes.

In conclusion, as a first step in the evaluation of potential screening for vasa previa, we conclude that it is possible to diagnose vasa previa by TVS combined with color Doppler in the second trimester of pregnancy. Future studies are needed to review the evidence on incidence and potential risk factors associated with vasa previa, as well as the potential protective effect of a Cesarean section. This will be the most accurate way of making an informed decision on the effectiveness of routine or targeted prenatal screening for vasa previa.

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SUPPORTING INFORMATION ON THE INTERNET

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

Appendix S1 Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed and Ovid MEDLINE(R) 1946 to Present Search Strategy: 2014–02–10

This article has been selected for Journal Club.

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

Chinese translation by Dr Yang Fang. Spanish translation by Dr Masami Yamamoto.

