论著·临床医学

三维超声测量宫颈容积可有效预测自发性早产:一项巢式病例-对照研究

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[**摘要**] **目的** 早产是导致新生儿发病和死亡的主要原因,传统二维超声测量宫颈长度(cervical length,CL)在预测自发性早产(spontaneous preterm birth,SPTB)效能上存在局限性,难以早期准确识别部分早产高危孕妇,通过探讨三维超声测量宫颈容积(cervical volume,CV)对SPTB预测的价值,为预测SPTB提供新方向。**方法** 本研究采用巢式病例-对照研究设计,纳入于2024年1月至2025年11月在陆军军医大学第一附属医院妇产科进行产前检查的孕产妇,分别于妊娠12~24周、妊娠28~32周经阴道二维超声测量CL和三维超声测量CV,通过纳入和排除标准的筛选,将最终完成随访且病历资料完整的237例孕妇纳入研究。根据分娩孕周,将研究对象分为2组:将分娩孕周28~<37周的孕妇设为SPTB组(n=36),分娩孕周≥37周的设为足月分娩(full-term delivery,FTD)组(n=201)。对2组间的各项指标进行单因素分析;为避免模型不稳定,对年龄、孕期增长体质量、孕次、产次、早产史、宫颈锥切手术史、足月分娩史、胎膜早破进行1∶1倾向得分匹配(propensity score matching,PSM),采用单因素及多因素条件Logistic回归分析对PSM后的SPTB组(n=27)和FTD组(n=27)进行分析,评估CL、CV对SPTB的独立预测价值,并采用ROC曲线分析CL与CV对SPTB的预测效能,计算AUC及最佳截断值、敏感度、特异度,采用Pearson相关性分析CL和CV关联强度。**结果** ①组间分析显示,SPTB组与FTD组在年龄、孕期增长体质量、孕次、产次、宫颈锥切手术史、足月分娩史、胎膜早破等因素中差异均有统计学意义(P<0.05);②组间分析显示PSM后的SPTB组与FTD组在年龄、孕期增长体质量、孕次、产次、早产史、宫颈锥切手术史、足月分娩史、胎膜早破等因素中差异无统计学意义;③匹配后妊娠12~24周SPTB组CL略低于FTD组,但差异无统计学意义[(31.90±5.96) mm *vs* (33.70±6.97) mm,P=0.314],SPTB组较FTD组CV小[(28.45±5.67) cm^3 *vs* (32.72±6.23) cm^3,P=0.011];妊娠28~32周SPTB组较FTD组CL更短[(23.69±9.47) mm *vs* (30.58±8.48) mm,P=0.007],CV更小[(22.70±7.64) cm^3 *vs* (28.91±8.09) cm^3,P=0.005];④妊娠12~24周单因素模型中,CV与早产风险显著相关(OR=0.768,95%CI:0.612~0.964,P=0.023),将CL、CV二者同时纳入多因素模型时,CV差异具有统计学意义(OR=0.769,95%CI:0.611~0.967,P=0.025),CV越小,早产风险越大;CV的AUC为0.680(95%CI:0.537~0.824,P=0.023),最佳截断值为32.47 cm^3,敏感度81.5%,特异度51.9%;妊娠28~32周单因素模型中,CL(OR=0.864,95%CI:0.771~0.968,P=0.011)和CV(OR=0.827,95%CI:0.688~0.994,P=0.043)均与早产风险显著相关,将CL、CV二者同时纳入多因素模型时,二者均差异无统计学意义(P>0.05),Pearson相关性分析显示CL和CV有较强的正相关关系(r=0.689,P<0.001);CL的AUC为0.717(95%CI:0.580~0.855,P=0.006),以31.5 mm为截断值,敏感度81.5%,特异度63%。CV的AUC为0.706(95%CI:0.567~0.846,P=0.009),以26.7 cm^3为截断值,敏感度77.8%,特异度63%。⑤CL在妊娠28~32周比妊娠12~24周缩短[(27.13±9.56) mm *vs* (32.80±6.49) mm,P<0.001];CV缩小[(25.80±8.40) cm^3 *vs* (30.58±6.28) cm^3,P<0.001]。**结论** 妊娠12~24周三维超声测量CV可能具有早期识别早产高危孕妇价值。

[**关键词**] 宫颈容积;早产;预测;超声

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Three-dimensional ultrasound measurement of cervical volume effectively predicts spontaneous preterm birth: a nested case-control cohort study

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[**Abstract**] **Objective** Preterm birth is the leading cause of neonatal morbidity and mortality. Conventional two-dimensional (2D) ultrasound measurement of cervical length (CL) has limitations in predicting spontaneous preterm birth (SPTB), making it difficult to accurately identify some high-risk pregnant women at early stages. This study aims to investigate the value of three-dimensional (3D) ultrasound measurement of cervical volume (CV) in predicting SPTB, providing a new direction for SPTB prediction. **Methods** A nested case-control trial was conducted on the pregnant women undergoing prenatal examinations in our department from January 2024 to November 2025. Transvaginal 2D ultrasound measurement of CL and 3D ultrasound measurement of CV were performed at 12 to 24 weeks and 28 to 32 weeks of gestation, respectively. After applying our inclusion and exclusion criteria, 237 cases with complete follow-up and medical records were included as study subjects. According to gestational age at delivery, the participants were divided into an SPTB group (n=36) for deliveries at 28 to <37 weeks, and a full-term delivery (FTD) group (n=201) for deliveries at ≥37 weeks. Univariate analysis was initially performed to compare various indicators between the 2 groups. To ensure model stability, 1∶1 propensity score matching (PSM) was employed for age, gestational weight gain, gravidity, parity, history of preterm birth, history of cervical conization, history of full-term delivery, and premature rupture of membranes. Univariate and multivariate conditional logistic regression analyses were applied to the PSM-matched SPTB (n=27) and FTD (n=27) groups to assess the independent predictive value of CL and CV for SPTB. ROC curves were plotted to evaluate the predictive efficacy of CL and CV for SPTB, calculating AUC values, optimal cutoff values, sensitivities, and specificities. Pearson correlation analysis was conducted to assess the association between CL and CV. **Results** ① Intergroup analysis showed statistically significant differences between the SPTB and FTD groups in terms of age, gestational weight gain, gravidity, parity, history of cervical conization, history of full-term delivery, and premature rupture of membranes (P<0.05). ② After PSM, no significant differences were found between the SPTB and FTD groups in these above factors. ③ At 12 to 24 weeks of gestation after matching, CL was slightly lower in the SPTB group than in the FTD group, but the difference was not statistically significant (31.90±5.96 mm *vs* 33.70±6.97 mm, P=0.314); the CV in the SPTB group was significantly smaller than that in the FTD group (28.45±5.67 cm^3 *vs* 32.72±6.23 cm^3, P=0.011). At 28 to 32 weeks of gestation, the SPTB group exhibited both a significantly shorter CL (23.69±9.47 mm *vs* 30.58±8.48 mm, P=0.007) and a significantly smaller CV (22.70±7.64 cm^3 *vs* 28.91±8.09 cm^3, P=0.005) compared to the FTD group. ④ In the univariate model at 12 to 24 weeks of gestation, CV was significantly associated with the risk of preterm birth (OR=0.768, 95%CI: 0.612 to 0.964, P=0.023). When both CL and CV were included in the multivariate model, CV remained statistically significant (OR=0.769, 95%CI: 0.611 to 0.967, P=0.025), with smaller CV indicating greater preterm birth risk. The AUC value of CV was 0.680 (95%CI: 0.537 to 0.824, P=0.023), with an optimal cutoff value of 32.47 cm^3, a sensitivity of 81.5% and a specificity of 51.9%. In the univariate model at 28 to 32 weeks of gestation, both CL (OR=0.864, 95%CI: 0.771 to 0.968, P=0.011) and CV (OR=0.827, 95%CI: 0.688 to 0.994, P=0.043) were significantly associated with the risk of preterm birth. When both were included in the multivariate model, neither showed statistical significance (P>0.05). Pearson correlation analysis revealed a strong positive correlation between CL and CV (r=0.689, P<0.001). The AUC value of CL was 0.717 (95%CI: 0.580 to 0.855, P=0.006), with

an optimal cutoff value of 31.5 mm, a sensitivity of 81.5% and a specificity of 63%. The AUC value for CV was 0.706 (95%*CI*: 0.567 to 0.846, *P*=0.009), with an optimal cutoff value of 26.7 cm^3, a sensitivity of 77.8% and a specificity of 63%. ⑤ CL was significantly shorter at 28 to 32 weeks of gestation compared to that at 12 to 24 weeks (27.13±9.56 *vs* 32.80±6.49 mm, *P*<0.001), and CV was obviously smaller (25.80±8.40 *vs* 30.58±6.28 cm^3, *P*<0.001). **Conclusion** 3D ultrasound measurement of CV at 12 to 24 weeks of gestation may have value in early identification of high-risk pregnant women for preterm birth.

[**Key words**] cervical volume; preterm birth; prediction; ultrasonography

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早产是围产儿死亡的主要原因,早产儿出生后常伴有呼吸窘迫综合征、坏死性小肠结肠炎、脑瘫等近远期严重并发症,增加家庭及社会的经济负担。据统计,在全球范围内,2010年出生的早产儿估计1 380万,占总活产数的9.8%;2020年出生的早产儿估计1 340万,占总活产数的9.9%[1],早产中近足月儿(胎龄34~36^{+6}周)占70%~80%[2]。近年来,虽然我国早产防治水平逐步提高,但早产率并未下降,早产率从2012年的6.4%上升到2018年的8.8%[3]。早产分为自发性早产(spontaneous preterm birth,SPTB)和治疗性早产,SPTB指妊娠不足37周出现早产临产或胎膜早破,继而发生早产分娩;治疗性早产是由于母体或胎儿因素不允许继续妊娠,在不足37周时终止妊娠,其中早产孕妇中70%为SPTB[4]。因此,早期、准确地识别早产高危孕妇,并实施有效的干预措施,是目前产科面临的核心挑战之一。

无论早产还是足月分娩(full-term delivery,FTD),宫颈均会经历软化、成熟、扩张和产后恢复4个阶段的重塑过程[5],对此过程的早期识别是预测早产的重要手段。目前,预测早产有多种方式,包括母体特征、母体血清标志物、羊水或宫颈分泌物中的生物学指标、超声指标等[6],但尚无同时具备高敏感度和高特异度的预测手段。临床上多以宫颈长度(cervical length,CL)作为预测和监测的指标[7],其优点有操作简单、测量方法标准化、可重复性高,但也具有局限性:当CL尚未明显缩短时,其软化、成熟等早期微观改变已发生,而CL无法识别这些变化[8]。宫颈软化、成熟过程中会出现基质增大、宫颈组织容积增加等改变[9]。若宫颈过早地重塑则可能导致早产,继而衍生出多种新型超声测量指标,如子宫颈角、宫颈弹性波成像、宫颈容积(cervical volume,CV)等来预测早产[10-12]。

随着三维超声技术的不断发展,三维超声及其容积分析软件能够获取宫颈完整容积数据。有研究显示,三维超声比二维超声测量CV更为可靠[13]。国外有少数研究探究用三维超声测量CV来预测早产,研究人群与测量技术不同,研究结论也不尽相同。HOESLI等[14]于1999年首次对低风险人群与高风险人群使用三维超声测量CV,其差异无统计学意义,与CL相比,在预测SPTB方面也并无显著优势,原因可能是高风险组平均分娩孕周为37.8周,可能存在选择偏倚,且高估了早产在人群中的发病率。ROZENBERG等[15]对28例早产高风险人群研究显示三维超声测量CV比二维超声测量CL的阳性预测值更高(80% *vs* 70%)。PARK等[16]对391例无症状低风险人群进行研究发现:CV对妊娠36周前SPTB有预测价值,CV也是早产的独立危险因素,CV越小,早产风险越大,提示了在早产低风险人群中CV预测早产的可行性。在国内这方面研究报道较少,国内将三维超声成像技术常应用于乳腺、宫腔粘连、胎儿畸形筛查等[17-19]。本研究采用巢式病例-对照研究设计,纳入常规产检的孕妇群体(无论有无早产史、有无宫颈手术史等早产高危因素),避免选择的偏倚,且保证测量数据不受主观因素的干扰,于妊娠12~24周、妊娠28~32周进行二维超声测量CL和三维超声测量CV,探究CV是否有预测SPTB的价值,是否可以同时提高敏感度和特异度,为预测早产提供新的理论参考。

1 资料与方法

1.1 研究设计

本研究采用巢式病例-对照研究设计,该研究经过陆军军医大学第一附属医院伦理委员会批准[(A)KY2023181-延1],并在国家医学研究登记备案系统备案(MR-50-24-001326)后实施,所有孕妇在检查前签署知情同意书。

1.2 研究对象

纳入研究对象为2024年1月至2025年11月在陆军军医大学第一附属医院妇产科孕期产检的孕妇,为期23个月,于妊娠12~24周、妊娠28~32周经阴道二维

超声测量CL、三维超声测量CV。纳入标准:①单胎妊娠妇女;②年龄≥18岁;③具有自主行为能力。排除标准:①未有效控制的高血压、糖尿病、风湿免疫病等;②有巨大子宫肌瘤、子宫腺肌症及子宫畸形;③不愿意于本院规范产检。退出标准:①因高血压、糖尿病、胎儿窘迫、胎盘早剥、前置胎盘、感染等妊娠合并症或并发症需要在妊娠37周前终止的孕妇;②胎儿畸形或染色体异常引产的孕妇;③不愿意继续参加的孕妇;④失访者。最初纳入孕妇312例,肾病综合征1例,胎儿畸形或染色体异常引产5例,产前出血流产2例,不愿意继续参加20例,前置血管及中央性前置胎盘提前终止妊娠各1例,失访45例,最终纳入病例资料完整的孕妇237例,追踪其分娩结局,其中SPTB组36例,FTD组201例。孕妇纳入流程图见图1。

1.3 研究方法

1.3.1 测量仪器、指标及方法 所有超声检查采用美国GE-Voluson E系列超声诊断仪,探头频率5.0~7.5 MHz,测量指标包括CL、CV。为尽量减少观察者间的变异性,所有超声检查均由1名具备21年临床超声工作经验的医师完成,该医师在研究开展前已接受标准化测量方法的系统培训。为评估观察者内部一致性,每个CL、CV指标均由检查者计算3次。

二维超声测量CL采用标准化的方法[20]:每个受检者检查前需排空膀胱,取膀胱截石位,超声检查操作时避免对子宫颈施加不适当压力,造成人为的宫颈延长。阴道超声探头消毒后,套避孕套,将探头置于阴道前穹窿,于宫颈外口处清楚显示宫颈正中矢状切面,同时可清楚显示宫颈内口和宫颈外口、宫颈管和黏膜层,宫颈内口以强回声的宫颈内膜为指示点,以免与子宫下段混淆,使用游标尺测量宫颈外口(三角形的强回声区)至内口("V"形切迹)的直线距离,如果宫颈管弯曲,可以使用两种或多种线性测量值并相加,每次扫描持续2~3 min,测量3次,取最小测量值作为CL测量值。

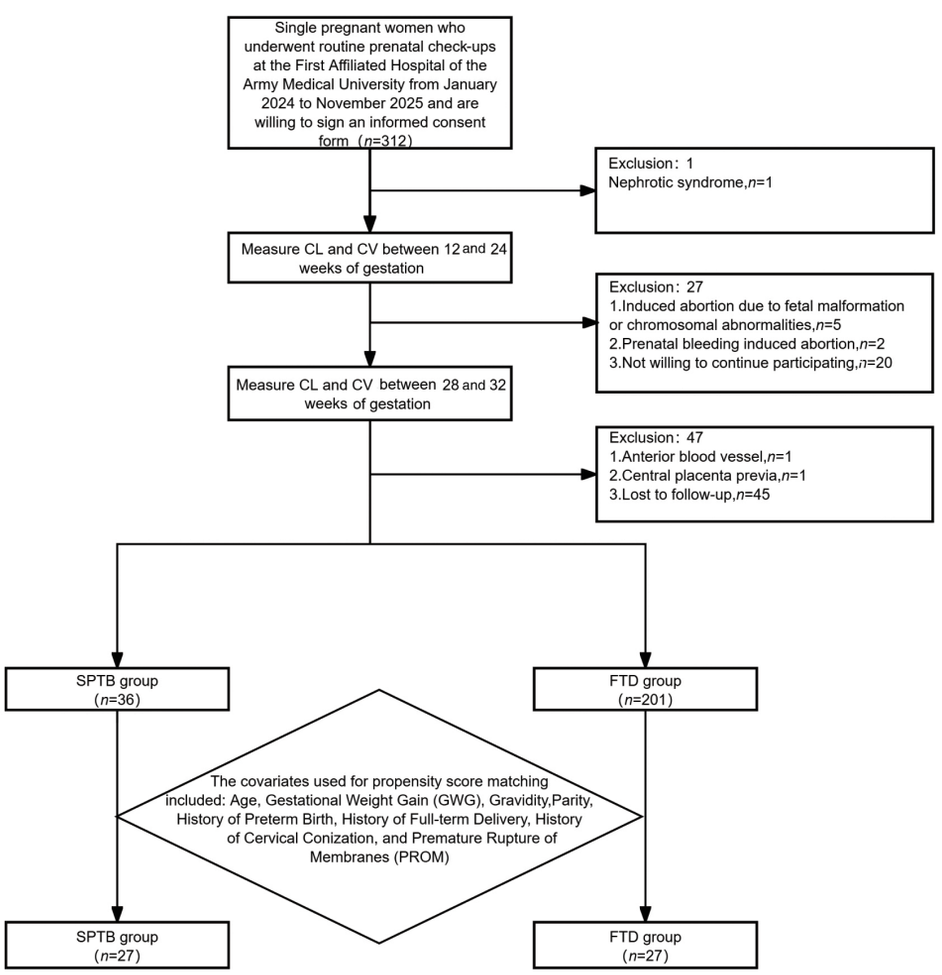


图1 三维超声测量CV的孕妇纳入流程图

Figure 1 Flowchart for pregnant women inclusion in 3D ultrasound measurement of cervical volume

三维超声测量CV的方法参照既往研究[21]:将系统切换到三维模式,不需要更换探头,仍然将阴道超声探头置于阴道前穹窿,于宫颈外口处清楚显示正中宫颈矢状切面,同时可清楚显示宫颈内口和宫颈外口,将宫颈集中于超声屏幕取样框中,开始进行3D图像采集,采集3次,采集后储存数据用于后续分析。利用超声仪虚拟器官计算机辅助分析(virtual organ computer-aided analysis,VOCAL)软件对3次3D图像进行CV计算,以矢状面为参考平面,同时显示出冠状面、轴面,以每30°为一个面进行宫颈面积测量,测量6次,软件自动提供最后的CV,取最小测量值作为CV测量值(图2)。

1.3.2 孕妇资料收集及随访过程 将孕妇的基本信息录入建档系统,包括年龄、身高、孕前体质量、受孕方式、孕次、产次、流产史、早产史、既往手术史、既往分娩情况等。超声系统记录每次孕妇超声检查时CL、CV信息。病历系统记录妊娠期并发症、分娩时间等,对在外院分娩的孕妇,自预产期起每3天进行1次电话随访,随访其妊娠结局,包括分娩孕周、分娩方式、妊娠期并发症、新生儿情况等,3次电话随访无法接通为失访。

1.3.3 结局指标 本研究以分娩孕周为主要结局指标。所有孕妇的孕周根据末次月经并结合妊娠11~13^{+6}周超声测量头臀长校正孕周,若末次月经与彩超测量孕周5 d,以彩超结果为准。将分娩孕周28~<37周的孕妇纳入自发性早产组,分娩孕周≥37周的孕妇纳入足月分娩组。

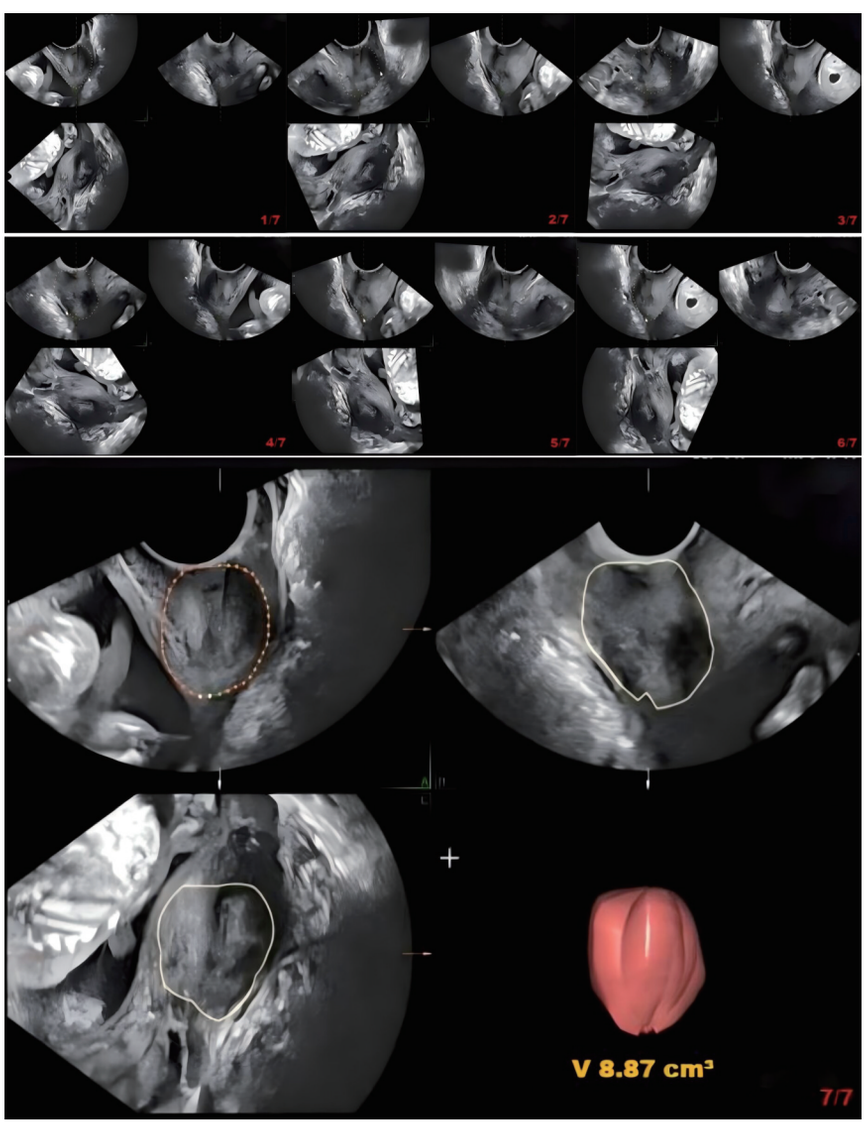


图2 经阴道三维超声测量通过VOCAL软件计算得出的最终CV

Figure 2 Final cervical volume measured by transvaginal 3D ultrasound and calculated using VOCAL software

1.4 统计学分析

使用SPSS 27.0软件进行统计学分析。满足正态分布的计量资料以$\bar{x}\pm s$表示,组间比较采用独立样本t检验,非正态分布计量资料以$M(P_{25},P_{75})$表示,组间比较采用Mann-whitney U检验。计数资料以频数(%)表示,组间比较采用χ^2检验或Fisher精确检验。考虑到目前自发性早产组样本量较少,直接进行多因素Logistic回归分析可能导致模型不稳定,为控制除CL、CV对自发性早产的因素影响,对年龄、孕期增长体质量、孕次、产次、早产史、宫颈锥切手术史、足月分娩史、胎膜早破等协变量进行1∶1倾向得分匹配(propensity score matching,PSM),匹配容差为0.02。采用单因素条件Logistic回归分析对匹配后的2组资料进行分析,并评估CL、CV与自发性早产的关联强度,计算比值比(odds ratio,OR)及其95%*CI*,并将CL、CV同时纳入多因素条件Logistic回归模型,估计校正后的*OR*值及95%*CI*。采用ROC曲线评估CL、CV预测自发性早产的效能,计算AUC及95%*CI*,根据约登指数确定CL与CV的最佳截断值,并计算出最佳截断值时的敏感度及特异度。CL和CV相关性采用Pearson相关性分析,计算相关系数(r)及95%*CI*,以$|r|<0.3$为弱相关,$0.3\leq|r|<0.6$为中等相关,$|r|\geq0.6$为强相关。观察CL、CV随孕周变化的关系采用配对t检验。以$P<0.05$为差异有统计学意义,所有检验为双侧检验。采用R语言4.4.3软件对各条件Logistic回归模型回归系数进行事后统计效能(post-hoc power)分析。

2 结果

2.1 组间分析显示SPTB组、FTD组在多项基线指标上存在显著差异

共纳入237例孕妇,其中SPTB 36例(15.2%),FTD 201例(84.8%)。2组在年龄、孕期增长体质量、孕次、产次、足月分娩史、宫颈锥切手术史、胎膜早破等方面差异有统计学意义($P<0.05$,表1)。

2.2 PSM后SPTB组、FTD组在基线指标上无显著差异

本研究中,早产史在2组中差异无统计学意义,但文献支持早产史是早产的高危因素,仍将其纳入PSM。PSM后在年龄、孕前体质量、孕期体质量、孕期增长体质量、BMI、孕次、产次、早期流产史、晚期流产史、早产史、足月分娩史、宫颈锥切手术史、宫腔手术史、受孕方式、妊娠期糖尿病、甲状腺功能减退症、胎膜早破差异均无统计学意义(表2)。

2.3 PSM后组间分析显示SPTB组CL、CV均小于FTD组

妊娠12~24周SPTB组的CL略低于FTD组,但差异无统计学意义[(31.90±5.96) mm *vs* (33.70±6.97)mm],

表1 SPTB组、FTD组人口统计学特征比较[例(%),$\bar{x}\pm s$,$M(P_{25},P_{75})$]

Table 1 Comparison of demographic characteristics between SPTB group and FTD group [n(%),$\bar{x}\pm s$,$M(P_{25},P_{75})$]

Items	SPTB group(n=36)	FTD group(n=201)	$\chi^2/t/Z$	P
Age/years	32.17±4.37	30.74±3.85	−2.005	0.046
Pre-pregnancy weight/kg	56.78±10.05	55.88±8.41	−0.577	0.565
Weight at delivery/kg	66.38±8.54	67.27±8.80	0.564	0.573
GWG/kg	9.59±4.15	11.41±4.42	2.291	0.023
BMI/(kg/m^2)	22.81±3.92	21.82±3.05	−1.700	0.090
Gravidity	2.50(1.25,4.00)	2.00(1.00,3.00)	2.058	0.040[a]
Parity	0(0,1.00)	0(0,0)	3.144	0.002[a]
Early miscarriage	0.50(0,2.00)	0(0,2.00)	0.562	0.574[a]
Late stage miscarriage	7(19.4)	21(10.4)		0.157[c]
History of preterm birth	4(11.1)	7(3.4)		0.068[c]
History of full-term delivery	13(36.1)	30(14.9)	9.227	0.002[b]
History of cervical conization	6(16.6)	13(6.4)		0.049[c]
History of hysteroscopic surgery	6(16.6)	28(13.9)	0.186	0.666[b]
ART	7(19.4)	37(18.4)	0.022	0.883[b]
GDM	9(25.0)	48(23.8)	0.021	0.885[b]
Hypothyroidism	3(8.3)	28(13.9)		0.435[c]
PROM	18(50.0)	23(11.4)	31.726	<0.001[b]

a: Mann-whitney U test; b: χ^2 test; c: Fisher's exact test. SPTB: spontaneous preterm birth; FTD: full-term delivery; GWG: gestational weight gain; ART: assisted reproductive technology; GDM: gestational diabetes mellitus; PROM: premature rupture of membranes

SPTB组的CV小于FTD组,差异有统计学意义[(28.45±5.67) cm^3 *vs* (32.72±6.23) cm^3, *P*=0.011]。妊娠28~32周SPTB组的CL、CV均小于FTD组,差异有统计学意义(*P*<0.05,表3)。

2.4 CL、CV对自发性早产有预测价值

妊娠12~24周测量CV对妊娠37周前SPTB有预测价值。单因素模型中,CV与早产风险显著相关(*OR*=0.768,95%*CI*:0.612~0.964,*P*=0.023),CL与早产风险无显著相关(*P*=0.346),将CL、CV二者同时纳入多因素模型时,CV仍与早产风险显著相关(*OR*=0.769,95%*CI*:0.611~0.967,*P*=0.025),见表4、5;CV的AUC为0.680(95%*CI*:0.537~0.824,*P*=0.023),最佳截断值为32.47 cm^3,其敏感度81.5%,特异度51.9%,见图3、表6。

妊娠28~32周单因素模型中,CL(*OR*=0.864,*P*=0.011)和CV(*OR*=0.827,*P*=0.043)均与早产风险显著相关,见表4;将二者同时纳入多因素模型时,差异无统计学意义,见表5;CL的AUC为0.717(95%*CI*:0.580~0.855,*P*=0.006),以31.5 mm为截断值,敏感度81.5%,特异度63%;CV的AUC为0.706(95%*CI*:0.567~0.846,*P*=0.009),以26.7 cm^3为截断值,敏感度为77.8%,特异度为63%(图3、表6)。两种预测方式之间差异无统计学意义。CL和CV有较强的正相关关系(*r*=0.689,*P*<0.001,图4)。

2.5 CL、CV随孕周增加而减小

妊娠28~32周比妊娠12~24周测量的CL及CV均有减小。妊娠12~24周、妊娠28~32周SPTB组CL分别为(31.90±5.96) mm、(23.69±9.47) mm,FTD组CL分别为(33.70±6.97) mm、(30.58±8.48) mm,这2组差异均有统计学意义(*P*<0.001)。SPTB组CV分别为(28.45±5.67) cm^3、(22.70±7.64) cm^3,FTD组CV分别为(32.72±6.23) cm^3、(28.91±8.09) cm^3,这2组差异均有统计学意义(*P*<0.001),见表7。

表2 PSM后SPTB组、FTD组人口统计学特征[例(%),$\bar{x}\pm s$,$M(P_{25},P_{75})$]

Table 2 Demographic characteristics of SPTB group and FTD group after PSM [*n*(%),$\bar{x}\pm s$,$M(P_{25},P_{75})$]

Items	SPTB group(*n*=27)	FTD group(*n*=27)	$\chi^2/t/Z$	*P*
Age/years	31.41±4.43	31.07±4.46	−0.275	0.784
Pre-pregnancy weight/kg	55.78±9.88	55.04±7.17	−0.317	0.753
Weight at delivery/kg	65.73±8.91	64.65±8.42	−0.455	0.651
GWG/kg	9.94±4.07	9.59±4.15	−0.311	0.757
BMI/(kg/m^2)	22.37±3.83	21.89±3.12	−0.501	0.618
Gravidity	2.00(1.00,4.00)	3.00(1.00,4.00)	−0.222	0.824[a]
Parity	0(0,1.00)	0(0,1.00)	−0.096	0.923[a]
Early miscarriage	1.00(0,2.00)	0(0,2.00)	0	1.000[a]
Late stage miscarriage	5(18.5)	6(22.2)	0.114	0.735[b]
History of preterm birth	2(7.4)	0		0.491[c]
History of full-term delivery	7(25.9)	9(33.3)	0.355	0.551[b]
History of cervical conization	1(3.7)	3(11.1)		0.610[c]
History of hysteroscopic surgery	5(18.5)	0		0.051[c]
ART	7(25.9)	4(14.8)	1.027	0.311[b]
GDM	7(25.9)	9(33.3)	0.355	0.551[b]
Hypothyroidism	3(11.1)	3(11.1)		1.000[c]
PROM	9(33.3)	8(29.6)	0.086	0.770[b]

a:Mann-whitney *U* test;b:χ^2 test;c:Fisher's exact test

表3 2组孕妇不同孕周的CL、CV比较($\bar{x}\pm s$)

Table 3 Comparison of cervical length and cervical volume between 2 groups at different gestational weeks($\bar{x}\pm s$)

Items	SPTB group(*n*=27)	FTD group(*n*=27)	*t*	*P*
12 to 24 weeks of gestation				
CL/mm	31.90±5.96	33.70±6.97	1.018	0.314
CV/cm^3	28.45±5.67	32.72±6.23	2.630	0.011
28 to 32 weeks of gestation				
CL/mm	23.69±9.47	30.58±8.48	2.817	0.007
CV/cm^3	22.70±7.64	28.91±8.09	2.901	0.005

表4 妊娠12~24周、妊娠28~32周CL与CV的单因素条件Logistic回归分析

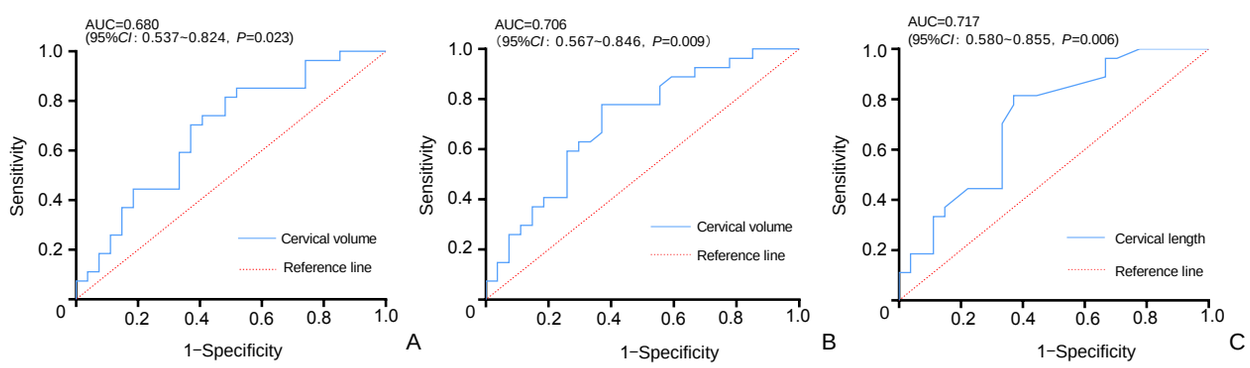
Table 4 Univariable conditional logistic regression analysis of CL and CV at 12 to 24 and 28 to 32 weeks of gestation

Items	Gestational week	β	*SE*	*Wald*	*df*	*OR*	95%*CI*	*P*
CL	12 to 24	−0.039	0.042	0.889	1	0.962	0.886—1.043	0.346
	28 to 32	−0.147	0.058	6.397	1	0.864	0.771—0.968	0.011
CV	12 to 24	−0.264	0.116	5.158	1	0.768	0.612—0.964	0.023
	28 to 32	−0.190	0.094	4.107	1	0.827	0.688—0.994	0.043

表5 妊娠12~24周、妊娠28~32周CL、CV的多因素条件Logistic回归分析

Table 5 Multivariable conditional logistic regression analysis of CL and CV at 12 to 24 and 28 to 32 weeks of gestation

Items	Gestational week	β	*SE*	*Wald*	*df*	*OR*	95%*CI*	*P*
CL	12 to 24	−0.011	0.058	0.035	1	0.989	0.884—1.107	0.851
	28 to 32	−0.092	0.071	1.675	1	0.912	0.794—1.048	0.196
CV	12 to 24	−0.263	0.117	5.043	1	0.769	0.611—0.967	0.025
	28 to 32	−0.108	0.106	1.033	1	0.898	0.729—1.105	0.309



A:CV at 12 to 24 weeks of gestation;B:CV at 28 to 32 weeks of gestation;C:CL at 28 to 32 weeks of gestation

图3 CV、CL预测自发性早产的ROC曲线

Figure 3 ROC curve of predicting spontaneous preterm birth using CL and CV

表6 妊娠12~24周CV、妊娠28~32周CL与CV对自发性早产风险预测效能分析

Table 6 Analysis on the predictive efficacy of CV at 12 to 24 weeks gestation and CL、CV at 28 to 32 weeks of gestation for the risk of spontaneous preterm birth

Gestational week	Diagnostic methods	AUC	Cutoff	Yoden Index	Sensitivity/%	Specificity/%	95%*CI*	*P*
12 to 24	CV	0.680	32.47/cm^3	0.334	81.5	51.9	0.611—0.967	0.023
28 to 32	CL	0.717	31.5/mm	0.445	81.5	63	0.580—0.855	0.006
	CV	0.706	26.7/cm^3	0.408	77.8	63	0.567—0.846	0.009

表7 CL、CV随孕周变化的关系($\bar{x}\pm s$)

Table 7 Changes in CL and CV with gestational week ($\bar{x}\pm s$)

Group	Items	12 to 24 weeks of gestation	28 to 32 weeks of gestation	Difference (95%*CI*)	*t*	*P*
All	CL/mm	32.80±6.49	27.13±9.56	5.67(3.43—7.91)	5.08	<0.001
	CV/cm^3	30.58±6.28	25.80±8.40	4.78(3.10—6.46)	5.71	<0.001
SPTB Group	CL/mm	31.90±5.96	23.69±9.47	8.21(4.01—12.41)	4.01	<0.001
	CV/cm^3	28.45±5.67	22.70±7.64	5.75(2.98—8.51)	4.27	<0.001
FTD Group	CL/mm	33.70±6.97	30.58±8.48	3.12(1.81—4.42)	4.91	<0.001
	CV/cm^3	32.72±6.23	28.91±8.09	3.81(1.78—5.83)	3.86	<0.001

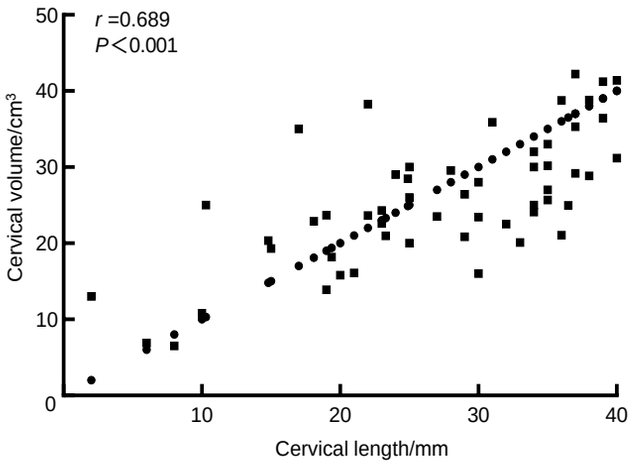


图4 CL和CV的相关性分析

Figure 4 Correlation analysis between CL and CV

2.6 对条件Logistic回归模型回归系数进行事后统计效能(post-hoc power)评估

在单因素模型中,CV在妊娠12~24周、妊娠28~32周的检验效能分别为0.624、0.524,CL在妊娠28~32周的检验效能为0.717,在多因素模型中,CV在妊娠12~24周的检验效能为0.613,在当前样本量下,CV对自发性早产有一定的预测价值。

3 讨论

早产是导致新生儿和5岁以下儿童死亡的首要原因[22]。近年来,随着我国传统生活方式改变、生育政策调整后高龄孕妇增加、妊娠合并内外科疾病发生率增高等原因[3],我国早产发生率呈上升趋势,早产问题仍很严峻。本研究通过对现有数据的分析探讨了CV对自发性早产的预测价值。

3.1 妊娠12~24周测量CV可早期识别早产高危孕妇

本研究结果显示妊娠12~24周SPTB组CV明显小于FTD组[(28.45±5.67) cm^3 *vs* (32.72±6.23) cm^3, *P*=0.011],单因素模型中CV与早产风险显著相关(*OR*=0.768,*P*=0.023),在调整了CL因素后,多因素模型中CV仍与早产风险显著相关(*OR*=0.769,*P*=0.025),CV每增加1 cm^3,早产风险降低约23.1%,而CL未显示出明显差异,这些变化可能源于宫颈早期的微观变化。这与师朝岭等[23]、DE DIEGO等[24]研究发现一致,在CL相似的情况下,先兆早产的孕妇比无症状孕妇的CV更小,提示在宫颈成熟过程中CV比CL更早受到影响。妊娠期宫颈经历4个阶段重塑,妊娠早期开始软化,表现为基质成分更新增加、宫颈组织容积增加等,之后宫颈成熟,表现为宫颈组织顺应性和完整性丧失[25],最后出现宫颈机械性缩短。早产的关键病理环节可能在于过早的软化及成熟,最终表现为容积的病理性缩小。由此可见,是宫颈组织成分的改变继而引起解剖结构变化[26]。本研究在约登指数最大值时CV为32.47 cm^3,可识别81.5%的早产高危孕妇,因此推测CV可能是一个识别早产高危孕妇信号的敏感指标,可能比CL更早识别早产风险,但这需要后期增加样本量、多个时间点纵向研究比较二者在个体水平变化上加以验证。

3.2 妊娠28~32周测量CV与CL对自发性早产的预测价值相似

本研究显示孕晚期(妊娠28~32周)单因素模型中,CL(*OR*=0.864,*P*=0.011)和CV(*OR*=0.827,*P*=0.043)均与早产风险显著相关,单独CL(AUC=0.717)与CV(AUC=0.706)都对自发性早产有一定的预测能力。CL以31.5 mm为截断值时,其敏感度81.5%,特异度63%;CV以26.7 cm^3为截断值时,其敏感度77.8%,特异度63%。目前暂未发现有孕晚期CL与CV对预测早产相比较的研究,多数研究针对孕中期,认为CV不能代替CL,但对联合使用存在看法不一。有研究显示二者联用可以将早产预测准确性提高10倍[27]。BARBER等[28]研究显示二者具有强正相关性(*r*=0.690,*P*<0.001),联用并未提供额外的预测价值,与本研究结论一致(*r*=0.689,*P*<0.001),将二者同时纳入多因素模型中,均未显示出差异统计学意义。这一现象可能源于二者均反映宫颈重塑过程,在孕晚期宫颈已发生显著形态改变(CL缩短),而二者预测能力高度同质,故其单独预测效能相当且联合使用未显示预测效能提高,还可能因样本量、研究人群、测量方法的差异,导致结论不同。

3.3 CV随孕周增加而减小

本研究还观察到SPTB组与FTD组的CV(22.70 cm^3 *vs* 28.45 cm^3、28.91 cm^3 *vs* 32.72 cm^3)、CL(23.69 mm *vs* 31.90 mm、30.58 mm *vs* 33.70 mm)在孕晚期均较孕中期减小,在正常状态下,CL在妊娠14~28周之间相对比较稳定,妊娠28周后将有逐渐变短的趋势[29],理论上这种CV及CL的变化与宫颈为分娩做准备的生理性重塑方向一致。DA FONSECA BORGHI等[21]研究显示宫颈环扎术后CL孕晚期短于孕中期[(28.0±9.2) mm *vs* (31.5±5.1) mm],CV孕晚期大于孕中期[(36.2±17.6) cm^3 *vs* (29.9±16.5) cm^3],可能是干预后宫颈机械性支持作出的反应。YILMAZ等[30]研究显示低风险人群CV随孕周增加而增大(妊娠11~14周平均CV为30.1 cm^3、妊娠24~28周为31.3 cm^3、妊娠32~34周为34.6 cm^3),产后缩小(产后6周为15.3 cm^3)。然

而,也有不同意见,ROVAS等[31]研究显示足月分娩中妊娠17~40周期间CV随孕周无统计学显著变化,导致这种结果原因不明,可能是宫颈重塑过程中,峡部消失,宫颈边界划分不一致。目前关于CV与孕周变化的研究较少,而且纳入人群差异性大,在未来研究可以建立CV的正常动态参数范围,以区分生理性与病理性。但如果CV发生变化较早、较大,考虑是病理性重塑的表现,需引起重视及严密监测[32]。

3.4 CV在不同人群中预测的可行性

目前已有较多研究支持CV对自发性早产有预测价值[15-16],与本研究结论一致。但各研究的纳入人群不同,ROZENBERG等[15]研究纳入早产高风险人群(有早产症状),PARK等[16]研究纳入无症状低风险人群(排除子宫颈畸形、早产史、晚期流产史、宫颈锥切术史、早产症状)。是否在整个人群中均有意义有待考证。故本研究纳入孕妇包括低风险人群和高风险人群,同时为避免其他早产高危因素对预测效能的影响,对年龄、孕次、产次、早产史、宫颈锥切手术史等混杂因素进行倾向得分匹配,结果也显示有预测意义,提示CV在整个人群中预测早产的可行性。

本研究仍存在若干局限性:①未对不同人群(如年龄、既往早产史等)进行亚组分析及交互作用的探讨,无法确定CV的预测效能是否在不同临床特征人群中存在差异,未来可进一步探索;②目前CV的测量方法国际上没有统一的标准,CV的测量高度依赖于操作者的经验和技术水平,对结果的准确性有着重要影响。

综上所述,三维超声测量CV是一种无创、可重复性的方法。三维超声测量CV对妊娠37周前自发性早产有预测意义,妊娠12~24周在CL正常的情况下,测量CV可能更早识别早产高危孕妇。但进入孕晚期,测量CV并不能提供更好的预测能力,而选择简便、经济的CL更具有实用性。随着三维超声技术的不断发展,CV可为预测早产提供新的方法,在未来的开展中,可以寻找更为简单的CV测量方法,多个时间点纵向研究CV随孕周变化的关系,同时可增加评估宫颈成熟度的超声指标,如宫颈弹性波成像,多维度综合评估宫颈状态及机能,构建自发性早产的预测模型,以提高预测早产的能力。另外,再次妊娠时,结合既往早产史、宫颈锥切手术史等高危因素,可在孕12周开始进行CV、CL检查,并监测动态变化,若CL正常,CV进行性缩小,就需引起临床医生的重视,个体化决定是否进行干预。

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