·临床研究·

老年糖尿病合并子宫内膜癌患者根治术后下肢淋巴水肿的影响因素

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【摘 要】 **目的** 探讨老年2型糖尿病(T2DM)合并子宫内膜癌(EC)患者根治术后下肢淋巴水肿(LLL)的现状及其影响因素,构建术后LLL的预警模型。**方法** 选择河北北方学院附属第一医院2022年1月至2023年12月收治的200例老年T2DM合并EC患者为研究对象,按照7∶3比例将患者分为训练集(n=140)与验证集(n=60)。患者均进行EC根治术,术后随访6个月,统计LLL发生率。根据是否发生LLL,将训练集患者分为LLL组(29例)和非LLL(non-NLLL, NLLL)组(111例)。采用SPSS 26.0统计软件进行数据处理,根据数据类型分别采用t检验或χ^2检验进行组间比较。采用多因素logistic回归分析构建老年T2DM合并EC患者术后LLL的预测模型,使用Hosmer-Lemeshow验证该模型的拟合度。绘制受试者工作特征(ROC)曲线,经曲线下面积(AUC)评价该模型的预测能力,以灵敏度与特异度评价该模型的实际应用效能。**结果** 200例患者EC根治术后6个月内LLL发生率为19.50%(39/200),训练集为20.71%(29/140),验证集为16.67%)(10/60),两组患者LLL发生率比较,差异无统计学意义(χ^2=0.438,P=0.508)。多因素logisitc回归分析提示,国际妇产科联盟(FIGO)分期Ⅲ期(*OR*=4.473,95%*CI* 1.617~12.370)、肿瘤组织低分化(*OR*=2.998,95%*CI* 1.805~4.981)、淋巴结转移(*OR*=2.408,95%*CI* 1.676~3.461)、开腹手术(*OR*=2.192,95%*CI* 1.574~3.053)及淋巴结清扫数目>20个(*OR*=5.663,95%*CI* 2.303~13.924)是老年T2DM合并EC患者术后并发LLL的独立危险因素。行前哨淋巴结活检(*OR*=0.476,95%*CI* 0.257~0.882)及保留旋髂淋巴结(*OR*=0.626,95%*CI* 0.499~0.784)是其保护因素。根据回归方程中各变量的回归系数(β)进行赋值,风险预测模型为:Y=1.498×FIGO分期Ⅲ期+1.098×低分化+0.879×淋巴结转移+0.785×开腹手术-0.743×前哨淋巴结活检-0.469×旋髂淋巴结保留+1.734×淋巴结清扫数目(>20个)-4.491。绘制训练集的ROC曲线,结果显示其AUC为0.803(95%*CI* 0.723~0.883),模型的灵敏度及特异度分别为0.862,0.676。绘制验证集的ROC曲线,其AUC为0.760(95%*CI* 0.586~0.934),模型的灵敏度及特异度分别为0.700,0.800。采用Hosmer-Lemeshow拟合优度检验对训练集进行评价,结果显示,χ^2=1.897,P=0.771;对验证集进行评价,结果显示,χ^2=2.741,P=0.469。**结论** 老年T2DM合并EC患者术后6个月内LLL发生率较高,基于多因素logistic回归分析结果可知,LLL预测模型具有良好的应用价值,可为临床医师进行高危LLL人群筛查提供依据。

【关键词】 老年人;子宫内膜癌;糖尿病;术后下肢淋巴结水肿;预测模型
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Influencing factors of lower limb lymphedema after radical resection in elderly diabetic patients with endometrial cancer

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【**Abstract**】 **Objective** To explore the status quo and influencing factors of postoperative lower limb lymphedema (LLL) in elderly patients with type 2 diabetes mellitus (T2DM) complicated with endometrial cancer (EC), and to construct an early warning model of postoperative LLL. **Methods** A total of 200 elderly T2DM patients with EC admitted in our hospital from January 2022 to December 2023 were enrolled and divided into a training set (n=140) and a validation set (n=60) in a 7∶3 ratio. All patients received radical resection of EC. During six months of follow-up after surgery, the incidence of LLL was observed. And then the patients in the training set were assigned into a LLL subgroup (29 cases) and a non-LLL (NLLL) group (111 cases). SPSS 26.0 was used for data processing, and t test or *Chi*-square test was performed for between-group comparison depending on data type. Multivariate logistic regression analysis was used to construct a prediction model of postoperative LLL in elderly T2DM patients with EC. Hosmer-Lemeshow test was used to verify the fitting of the model. Receiver operating characteristic (ROC) curve was drawn and the area under the curve (AUC) was utilized to evaluate the predictive ability of the model. The sensitivity and specificity were used to evaluate the practical application

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efficiency of the model. **Results** Among the 200 eligible patients, 19.50% (39/200) experienced LLL within six months after surgery. The incidence of LLL was 20.71% (29/140) in the training set and 16.67% (10/60) in the validation set, but no statistical difference was seen between them ($\chi^2 = 0.438$, $P = 0.508$). Multivariate logistic regression analysis suggested that International Federation of Gynecology and Obstetrics (FIGO) stage Ⅲ (*OR*=4.473, 95%*CI* 1.617-12.370), poorly differentiated tumor tissue (*OR*=2.998, 95%*CI* 1.805-4.981), lymph node metastasis (*OR*=2.408, 95%*CI* 1.676-3.461), laparotomy (*OR*=2.192, 95%*CI* 1.574-3.053) and dissected lymph nodes >20 (*OR*=5.663, 95%*CI* 2.303-13.924) were independent risk factors, and sentinel lymph node biopsy (*OR*=0.476, 95%*CI* 0.257-0.882) and retention of circumflex iliac lymph nodes (*OR*=0.626, 95%*CI* 0.499-0.784) were protective factors for postoperative LLL in elderly T2DM patients with EC. According to the regression coefficient (β) of each variable in the regression equation, the risk prediction model was shown as Y=1.498×FIGO stage Ⅲ+1.098×low differentiation+0.879×lymph node metastasis+0.785×laparotomy-0.743×sentinel lymph node biopsy-0.469 × retention of circumflex iliac lymph node + 1.734 × number of lymph node dissection (>20) -4.491. ROC curve analysis revealed that the model had an AUC value of 0.803 (95%*CI* 0.723-0.883), a sensitivity of 0.862 and a specificity of 0.676 in the training set, and an AUC value of 0.760 (95%*CI* 0.586-0.934), a sensitivity of 0.700 and a specificity of 0.800 in the validation set. Hosmer-Lemeshow goodness of fit test revealed that the training set showed $\chi^2 = 1.897$ and $P = 0.771$, and the validation set $\chi^2 = 2.741$ and $P = 0.469$. **Conclusion** The incidence of LLL in elderly T2DM patients with EC is quite high within six months after surgery. Multivariate logistic regression analysis indicates that our prediction model for LLL occurrence has good application value, and can provide a basis for clinicians to screen high-risk LLL population.

【Key words】 aged; endometrial cancer; diabetes mellitus; postoperative lower limb lymphedema; prediction model

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子宫内膜癌(endometrial cancer,EC)患者经系统治疗后预后一般较好,但术后继发下肢淋巴结水肿(lower limb lymphedema,LLL)将严重降低幸存者生存质量[1]。并发 LLL 者临床有下肢局部肿胀、疼痛表现,严重者可能导致永久性肢体残疾,而 LLL 一旦形成将会长期存在且难以治愈,因此目前 LLL 的干预以预防为主[2,3],而构建 LLL 风险预测模型,准确识别高危 LLL 人群在指导临床工作中具有重要意义。有研究显示,2 型糖尿病(type 2 diabetes mellitus,T2DM)是 EC 发病的独立危险因素[4]。与无 T2DM 患者相比,合并 T2DM 的 EC 患者具有肿瘤分期靠后、组织学分级高、肌层浸润深、淋巴结转移率高等特点[5],因此有必要将合并 T2DM 的 EC 患者作为单独研究对象。本研究以老年 T2DM 合并 EC 患者为研究对象,对其 LLL 发生率及影响因素进行分析并构建风险预测模型,为临床降低术后继发 LLL 风险提供参考。

1 对象与方法

1.1 研究对象

选择河北北方学院附属第一医院 2022 年 1 月至 2023 年 12 月收治的 200 例老年 T2DM 合并 EC 患者为研究对象,按照 7∶3的比例将患者分为训练集(n=140)与验证集(n=60)。纳入标准:年龄≥60 岁;在本院进行 EC 根治术;经术后病理组织检查证实为 EC;T2DM 诊断参照世界卫生组织(World Health Organization,WHO)相关标准;参与研究时 T2DM 病史≥1 年,单纯控制饮食或服用二甲双胍治疗。排除标准:术前已存在下肢肿胀或下肢活动异常;既往重大下肢外伤或手术史;既往原发性下肢淋巴水肿史;营养不良、肾源性或心源性静脉血栓等其他原因引起下肢水肿;合并其他恶性肿瘤;合并神经系统疾病;随访过程中已出现肿瘤复发、远处转移或确诊时已出现远处转移。

1.2 方法

1.2.1 资料收集 基于文献学习法,经医院妇科肿瘤专家讨论后,本研究决定纳入以下可能与 EC 根治术后下肢淋巴结水肿相关的指标:年龄、体质量指数(body mass index,BMI)、糖化血红蛋白(glycated hemoglobin,HbA1c)、空腹血糖(fasting blood glucose,FBG)、餐后 2 h 血糖(2-hour postprandial blood glucose,2hPG;HbA1c>7.5%即可判断为血糖控制不良)、是否合并高血压或贫血、国际妇产科联盟(International Federation of Gynecology and Obstetrics,FIGO)分期、组织分化程度、有无淋巴结转移、肌层浸润深度、手术方式等。

1.2.2 下肢淋巴水肿诊断 采用妇科癌症淋巴结水肿问卷(gynecologic cancer lymphedema questionnaire,GCLQ)[6]调查患者下肢状况。GCLQ 问卷总得分 0~20 分,总得分≥4 分即可判断为存在下肢淋巴水肿。

所有患者手术前后均由同一名护士采用无弹性的卷尺测量小腿周径,从脚踝开始每隔 10 cm 测量一次,直至 60 cm 处,每相邻两个周径取平均值,计算每段圆柱的体积。与术前相比,6 个圆柱体积相加得的下肢体积增加 10%即为下肢淋巴水肿。

若患者GCLQ量表得分<4分,但周径测量结果阳性也将其判定为发生下肢淋巴水肿。

1.2.3 随访 术后随访6个月,通过电话、微信及患者回院复诊等方式询问患者是否出现下肢肿胀、疼痛或其他症状及体征,指导患者填写相关调查问卷,统计下肢淋巴结水肿发生情况。

1.3 统计学处理

采用SPSS 26.0统计软件进行数据分析。计量资料以均数±标准差($\bar{x}\pm s$)表示,组间比较采用t检验。计数资料以例数(百分率)表示,组间比较采用χ^2检验。将单因素分析中有统计学意义的变量进行多重共线性分析,剔除方差膨胀因子(variance inflation factor,VIF)>10的变量,将不存在共线性的变量纳入多因素logistic回归模型,确定独立危险因素。采用多因素logistic回归分析构建风险预测模型,使用Hosmer-Lemeshow验证该模型的拟合度,绘制受试者工作特征(receiver operating characteristic,ROC)曲线,经曲线下面积(area under the curve,AUC)评价该模型的预测能力,以灵敏度、特异度验证该模型的实际应用效能。$P<0.05$为差异有统计学意义。

2 结 果

2.1 训练集及验证集患者基线资料

两组基线资料比较,差异无统计学意义($P>0.05$;表1)。

2.2 老年T2DM合并EC患者术后LLL发生情况

200例患者EC根治术后6个月内有39例并发LLL(19.50%),其中训练集有29例患者发生LLL(20.71%),验证集有10例发生LLL(16.67%),两组LLL发生率比较,差异无统计学意义($\chi^2=0.438$,$P=0.508$)。

2.3 训练集LLL组与NLLL组患者临床资料

训练集患者中发生LLL者设为LLL组(29例),未发生LLL者设为non-NLLL(NLLL)组(111例)。LLL组HbA1c>7.5%、FIGO分期Ⅲ期、肿瘤组织低分化、淋巴结转移、开腹手术、淋巴结清扫个数>20个患者术后LLL发生率高于NLLL组;行前哨淋巴结活检术及保留旋髂淋巴结者术后LLL发生率低于NLLL组,差异均有统计学意义($P<0.05$;表2)。

2.4 影响患者术后LLL发生的多因素logistic回归分析

对单因素分析中有统计学意义的指标进行共线性诊断,结果显示,所有指标的VIF均>10,不存在多重共线性问题。以老年T2DM合并EC患者术后是否并发LLL作为因变量,将单因素分析中有统计学意义且不存在多重共线性问题的指标作为自变量,行多因素logisitc回归分析,结果提示FIGO分期Ⅲ期、肿瘤组织低分化、淋巴结转移、开腹手术及淋巴结清扫数目>20个是患者术后并发LLL的独立危险因素;行前哨淋巴结活检及保留旋髂淋巴结是其保护因素(表3)。

表1 训练集及验证集患者基线资料比较

Table 1 Comparison of baseline data between training set and validation set

Item	Training set($n=140$)	Validation set($n=60$)	χ^2	P value
Age(years, $\bar{x}\pm s$)	73.49±6.43	74.09±7.06	0.587	0.558
BMI(kg/m^2, $\bar{x}\pm s$)	21.46±2.13	21.87±2.19	1.237	0.218
Education level[n(%)]			1.822	0.402
Primary school or below	14(10.00)	9(15.00)		
Middle school	80(57.14)	36(60.00)		
Junior college or above	46(32.86)	15(25.00)		
T2DM course(years, $\bar{x}\pm s$)	6.48±1.89	6.71±1.77	0.804	0.423
Surgical time(h, $\bar{x}\pm s$)	3.71±0.63	3.78±0.69	0.700	0.485
Postoperative hospital stay(d, $\bar{x}\pm s$)	16.89±2.79	17.46±3.01	1.293	0.198
Pelvic lymph node dissection[n(%)]	110(78.57)	50(83.33)	0.595	0.440
Para-aortic lymph node dissection[n(%)]	16(11.43)	5(8.33)	0.428	0.513
Number of intraoperative lymph node dissection($\bar{x}\pm s$)	11.79±2.15	12.34±2.27	1.630	0.105
Postoperative radiotherapy[n(%)]	123(87.86)	55(91.67)	0.623	0.430
Postoperative chemotherapy[n(%)]	21(15.00)	10(16.67)	0.089	0.765
Lymph node metastasis[n(%)]	14(10.00)	5(8.33)	0.136	0.713
FIGO staging[n(%)]			0.595	0.440
Ⅰ-Ⅱ	110(78.57)	50(83.33)		
Ⅲ	30(21.43)	10(16.67)		
Surgical method[n(%)]			0.792	0.373
Laparoscopy	84(60.00)	40(66.67)		
Laparotomy	56(40.00)	20(33.33)		
Lymphocyst[n(%)]	16(11.43)	8(13.33)	0.144	0.704

BMI: body mass index; T2DM: type 2 diabetes mellitus; FIGO: International Federation of Gynecology and Obstetrics.

表 2 训练集 LLL 组与 NLLL 组患者临床资料比较

Table 2 Comparison of clinical data between LLL group and NLLL group of training set [n(%)]

Item	LLL group(n=29)	NLLL group(n=111)	χ^2	P value
Age			0.946	0.331
60-80 years	13(44.83)	61(54.95)		
≥80 years	16(55.17)	50(45.05)		
BMI			0.868	0.648
<18.5 kg/m^2	5(17.24)	23(20.72)		
18.5-23.9 kg/m^2	10(34.48)	45(40.54)		
≥23.9 kg/m^2	14(48.28)	43(38.74)		
Hypertension	9(31.03)	30(27.03)	0.184	0.668
Anemia	5(17.24)	20(18.02)	0.010	0.923
HbA1c			5.284	0.022
>7.5%	8(27.59)	12(10.81)		
≤7.5%	21(72.41)	99(89.19)		
FBG(mmol/L)	7.61±1.56	7.46±1.67	0.436	0.663
2hPG(mmol/L)	9.23±1.38	9.09±1.53	0.447	0.655
FIGO staging			8.647	0.003
Ⅰ-Ⅱ	17(58.62)	93(83.78)		
Ⅲ	12(41.38)	18(16.22)		
Differentiation degree			12.549	<0.001
Middle-to-high differentiation	12(41.38)	84(75.68)		
Low differentiation	17(58.62)	27(24.32)		
Lymph node metastasis	7(24.14)	7(6.31)	8.123	0.004
Myometrial invasion depth			1.510	0.219
<1/2	6(20.69)	36(32.43)		
≥1/2	23(79.31)	75(67.57)		
Surgical method			9.614	0.002
Laparoscopy	12(41.38)	80(72.07)		
Laparotomy	17(58.62)	31(27.93)		
Sentinel lymph node biopsy	2(6.90)	30(27.03)	5.284	0.022
Pelvic lymph node dissection	26(89.66)	84(75.68)	2.669	0.102
Para-aortic lymph node dissection	4(13.79)	12(10.81)	0.202	0.653
Circumflex iliac lymph node dissection	26(89.66)	71(63.96)	7.132	0.008
Number of lymph node dissection			8.130	0.017
<10	7(24.14)	50(45.05)		
10-20	12(41.38)	46(41.44)		
≥20	10(34.48)	15(13.51)		
Postoperative drainage time			0.542	0.462
<7 d	20(68.97)	84(75.68)		
≥7 d	9(31.03)	27(24.32)		
Postoperative radiotherapy	27(93.10)	96(86.49)	0.944	0.331
Postoperative chemotherapy	4(13.79)	17(15.32)	0.042	0.838
Lymphocyst	3(10.34)	13(11.71)	0.042	0.837

LLL: lower limb lymphedema; NLLL: non-lower limb lymphedema; BMI: body mass index; HbA1c: glycated hemoglobin; FBG: fasting blood glucose; 2hPG: 2-hour postprandial blood glucose; FIGO: International Federation of Gynecology and Obstetrics.

表 3 影响老年 T2DM 合并 EC 患者术后 LLL 发生的多因素 logisitc 回归分析

Table 3 Multivariate logistic regression analysis of postoperative LLL in elderly patients with T2DM complicated with EC

Factor	β	SE	$Wald\ \chi^2$	OR	95%CI	P value
HbA1c>7.5%	0.596	0.311	3.673	1.815	0.987-3.339	0.056
FIGO stage Ⅲ	1.498	0.519	8.331	4.473	1.617-12.370	0.004
Low differentiation	1.098	0.259	17.972	2.998	1.805-4.981	<0.001
Lymph node metastasis	0.879	0.185	22.575	2.408	1.676-3.461	<0.001
Laparotomy	0.785	0.169	21.576	2.192	1.574-3.053	<0.001
Sentinel lymph node biopsy	-0.743	0.315	5.564	0.476	0.257-0.882	<0.001
Retention of circumflex iliac lymph node	-0.469	0.115	16.632	0.626	0.499-0.784	<0.001
Number of lymph node dissection						
<10	-	-	-	1.000	-	-
10-20	1.680	0.897	3.508	5.366	0.925-31.128	0.062
≥20	1.734	0.459	14.272	5.663	2.303-13.924	<0.001

T2DM: type 2 diabetes mellitus; EC: endometrial cancer; LLL: lower limb lymphedema; HbA1c: glycated hemoglobin; FIGO: International Federation of Gynecology and Obstetrics. -: no datum.

2.5 老年 T2DM 合并 EC 患者术后 LLL 预测模型的构建及评价

对多因素 logistic 回归方程中老年 T2DM 合并 EC 患者 LLL 的各危险因素的回归系数(β)进行赋值,风险预测模型为:Y = 1.498×FIGO 分期Ⅲ期+1.098×低分化+0.879×淋巴结转移+0.785×开腹手术−0.743×前哨淋巴结活检−0.469×旋髂淋巴结保留+1.734×淋巴结清扫数目(>20 个)−4.491。

绘制训练集 ROC 曲线,结果显示其 AUC 为 0.803(95%*CI* 0.723~0.883),Youden 指数为 0.538,预测模型的灵敏度及特异度分别为 0.862,0.676(图 1)。绘制验证集 ROC 曲线,其 AUC 为 0.760(95%*CI* 0.586~0.934),Youden 指数为 0.500,预测模型的灵敏度及特异度分别为 0.700,0.800(图 2)。

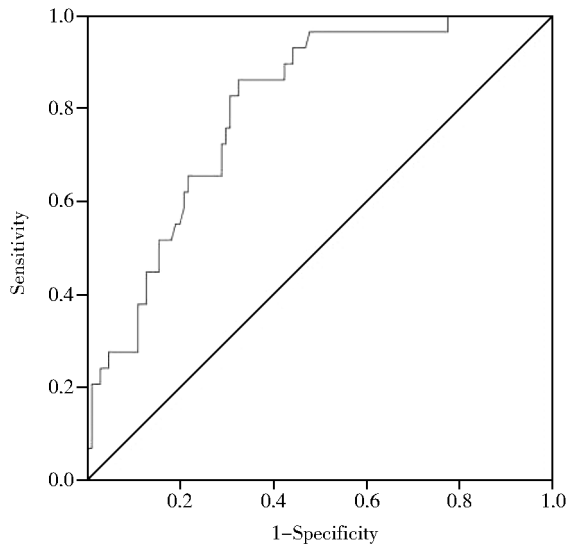


图 1 训练集 ROC 曲线

Figure 1 ROC curve of training set

ROC: receiver operating characteristic.

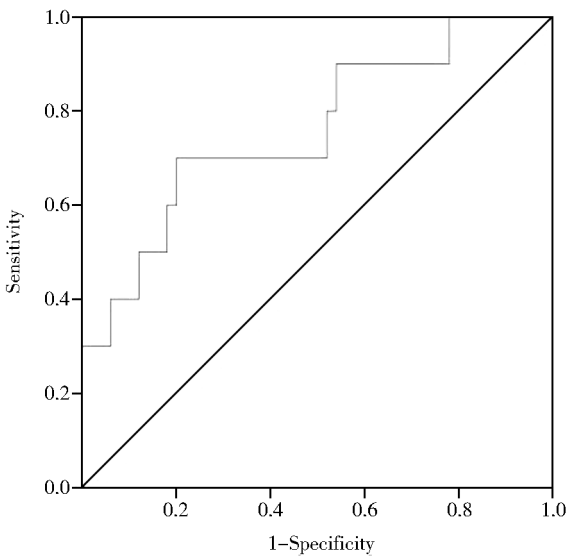


图 2 验证集 ROC 曲线

Figure 2 ROC curve of validation set

ROC: receiver operating characteristic.

采用 Hosmer-Lemeshow 拟合优度检验对训练集进行评价,结果显示χ^2 = 1.897,P = 0.771;对验证集进行评价,结果显示χ^2 = 2.741,P = 0.469,提示模型可靠度较好。

3 讨 论

既往研究报道 EC 术后 LLL 发生率在 1.2%~37.8%[7,8],这可能与各研究所设置的随访时间、LLL 评估工具不同相关。本研究仅对老年 T2DM 合并 EC 患者术后 6 个月内 LLL 发生率进行统计,结果显示,合并 T2DM 的老年 EC 患者术后 6 个月内 LLL 发生率为 19.50%,与吕永利等[9]调查结果相似。

有研究指出,对于合并 T2DM 的 EC 患者来说,积极控制血糖水平在延长患者生存期中具有重要意义[10]。本研究中,HbA1c>7.5%不是影响老年 EC 患者术后并发 LLL 的独立危险因素。这可能与本研究患者的 T2DM 病程在 6 年以上,已养成良好的降糖药物服用依从性,血糖控制稳定有关。

FIGO 分期靠后、肿瘤组织低分化、发生淋巴结转移的 EC 患者均需要相对更大范围的淋巴清扫,患者术后淋巴系统受损程度更高,故其术后 LLL 发生风险更高[11]。进行开腹手术及淋巴结清除数量多一方面提示患者手术范围大、损伤多,对淋巴系统的结构及功能破坏性更高,另一方面也反映了患者病情较为严重,故患者术后 LLL 发生风险更高[12]。淋巴结清扫个数越多,就有越多的盆腔内淋巴血管被切断,进而导致下肢淋巴回流受阻与淋巴循环障碍,增加 LLL 发生风险。提示医护人员应严格按照治疗标准规范操作,降低术中及术后操作对淋巴的损伤,以降低 LLL 发生率。近年来有学者指出,通过前哨淋巴结活检确定后续淋巴结清除范围及个数,能避免不必要的淋巴结切除[13]。本研究结果显示,前哨淋巴结活检术可有效降低老年 T2DM 合并 EC 患者术后 LLL 发生率,是 LLL 的保护因素。旋髂淋巴结有很多分支与腹股沟深淋巴结相连,是下肢淋巴结液进入盆腔的首站,也是当手术切断其他部位的淋巴管后,形成侧支循环引流下肢淋巴液的重要结构[14],因此保留旋髂淋巴结是术后 LLL 的保护因素,建议临床仔细评估患者病情,警示保留旋髂淋巴结在预防 LLL 中的重要性。

以多因素 logistic 回归分析结果所构建的老年 T2DM 合并 EC 患者术后 LLL 预测模型在训练集及验证集中均显示出良好的应用效能。医护人员可利用该模型计算出各 T2DM 合并 EC 患者发生 LLL 的概率,进而筛查出 LLL 高危风险者,便

于临床根据患者 LLL 发生风险制定针对性分层干预措施。

综上所述,老年 T2DM 合并 EC 患者术后 6 个月内 LLL 发生率较高,基于多因素 logistic 回归分析结果所得的 LLL 预测模型具有良好应用价值。但本研究所纳入的病例均来自于同一所医院,且样本量不大,其代表性有限。下一步可开展多中心、大样本量研究,以增强研究结论的可靠性。

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