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A Novel Integrated Machine Learning Model for Preoperative Evaluation and Postoperative Prognosis-prediction in Cervical Cancer Based on Clinical-pathological Parameters and MR Radiomics

Shuqi Li, Chenyan Guo, Yufei Fang, Junjun Qiu, He Zhang, Lei Ling, Jie Xu, Xinwei Peng, Chuchu Jiang, Jue Wang, Keqin Hua

Submitted to: JMIR Cancer
on: November 22, 2024

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Abstract

Background: Machine learning (ML) has been gradually applied to cervical cancer research, but rarely combines both clinical parameters and image data. Meanwhile, more robust and accurate preoperative assessment of parametrial invasion and lymph node metastasis, as well as postoperative prognosis prediction are also in urgent need.

Objective: We aimed to develop an integrated ML model that integrates clinicopathological parameters as well as MR images and includes both pre- and post-operation evaluation in cervical cancer (CC) patients.

Methods: Data of CC patients from 2014 to 2022 in two tertiary hospitals were retrospectively collected and an exempt was granted by the Ethics Committee for this purpose. Variables were analyzed for their predictive value of parametrial invasion, lymph node metastasis, survival and recurrence using 7 ML models. The predictive performance of all 7 ML models was compared and an AI-assisted contouring and prognosis prediction system is developed based on optimal machine learning algorithms.

Results: This study included 250 women for analysis (11 deaths, 24 recurrences): (1) In terms of evaluation of both parametrial invasions and lymph node metastasis, integrated ML models with weighted KNN outperformed other ML models, especially in the case of sensitivity. (2) An integrated model using weighted KNN achieved optimal performance in predicting recurrence and survival times for postoperative CC patients, showing high accuracy and balanced sensitivity. (3) an AI-assisted contouring and prognosis prediction system was developed that assists in lesion identification, preoperative evaluation and postoperative prognosis prediction.

Conclusions: The integration of clinical data and MR image through ML models offers superior preoperative diagnostic and postoperative prognostic prediction capabilities, potentially reducing clinical errors and enabling tailored, precise treatment strategies.

(JMIR Preprints 22/11/2024:69057)
DOI: https://doi.org/10.2196/preprints.69057

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Keqin Hua: Resources, Supervision.
Junjun Qiu: Project administration, Funding acquisition, Writing-Reviewing and editing.

Conflict of Interests

The authors declare no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data Availability Statement

Data can be made available upon reasonable request.

Funding

This study received aid from the Shanghai Shenkang Hospital Development Center Funding (No.

SHDC2020CR4087; to Jun-jun Qiu).

Ethics Statement

This retrospective multicenter cohort study was approved by the Institutional Ethics Committee of Fudan University Obstetrics and Gynecology Hospital (2019-87) and was registered in the Chinese Clinical Trial Registry (ChiCTR1900028702). An exempt was granted by the Ethics Committee for this purpose.

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Abbreviations:
AI, artificial intelligence
AUC, area under curve
CC, cervical cancer
C-index, concordance index
CT, computed tomography
CV, cross-validation
DL, deep learning
DSI, depth of stromal invasion
DT, decision tree
FIGO, International Federation of Gynecology and Obstetrics
HD, Hausdorff distance
HPV, human papillomavirus
ICC, correlation coefficients
IQRs, interquartile ranges
KNN, K-nearest neighbor
LCT, liquid-based cytology
LEEP, loop electrosurgical excision procedure
LVSI, lymph-vascular space invasion
MAE, mean absolute error
MCC, Matthews correlation coefficient
mIoU, mean intersection over union
ML, machine learning
MR, magnetic resonance
NCCN, National Comprehensive Cancer Network
OS, overall survival
PA, pixel accuracy
PET, positron emission tomography
PPV, positive predictive value
RF, random forest
RFS, recurrence-free survival
ROI, region of interest
SCCA, squamous cell antigen carcinoma
SDs, Standard deviations
SVM, support vector machine
T2WI, T2 weighted imaging

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Abstract

Background: Machine learning (ML) has been gradually applied to cervical cancer research, but rarely combines both clinical parameters and image data. Meanwhile, more robust and accurate preoperative assessment of parametrial invasion and lymph node metastasis, as well as postoperative prognosis prediction are also in urgent need. Therefore, we aimed to develop an integrated ML model that integrates clinicopathological parameters as well as MR images and includes both pre- and post-operation evaluation in cervical cancer (CC) patients.

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Keywords: Cervical cancer, Integrated prediction model, Machine learning

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1. INTRODUCTION

As the fourth leading cause of cancer death in women, cervical cancer (CC) accounts for about 661,000 new cases and 341,800 deaths in 2022 worldwide[1]. Despite advances in clinical management, up to 30% of patients still succumb to the disease, resulting in a disproportionately high burden worldwide[2]. However, current methods for preoperative evaluation and postoperative prognosis prediction of CC patients were not comprehensive enough. Preoperative evaluation relies heavily on pelvic magnetic resonance (MR) images to identify primary lesions[3] whereas the recognition rate of parametrial and lymphatic metastases is quite unstable[4]. Besides, for postoperative prognosis prediction, International Federation of Gynecology and Obstetrics (FIGO) staging is currently accepted as the standard staging system in clinical practice, however, it fails to take the heterogeneity of patients into full consideration, such as age, general health condition, and tumor markers, etc. Therefore, a personalized estimation system is desperately needed. For prognosis prediction, to overcome such defects, researchers have tried multiple statistical methods, like logistic and Cox proportional hazards models to estimate individual survival and recurrence outcomes[5, 6]. However, traditional statistical models may have limited effectiveness in handling large and complex datasets and making accurate predictions in dynamically changing environments. To this end, a more accurate and personalized prediction model, which includes both pre- and post-operation evaluation, is in urgent need to optimize treatment decisions and follow-up strategies for CC patients.

In recent years, machine learning (ML) algorithm, which develops dynamic algorithms capable of data-driven decisions, has emerged as a novel medical data processing method and widely applied to a variety of diseases[7]. In the field of CC, our previous multi-center study developed a web-based calculator to predict prognosis in 5112 CC patients using various ML models, which exhibited better prediction accuracy than traditional models[8]. Yet, only clinicopathology information has been concluded in this ML Model building, like other studies[9-11]. Noteworthy, with the progress of technology, medical images can provide more information that cannot be identified by the naked eye, even skillful doctors, hence, a growing number of studies have applied deep learning (DL) algorithms to MR images for diagnosis[12, 13] and classification[14] of CC. However, regrettably, most studies focused on the lesion identification[15, 16] and radiotherapy response prediction[17, 18] in CC, and there is currently lacking ML model that integrates both clinical and imaged data to predict prognosis for CC patients. Therefore, we wonder if we can build an integrated ML model using clinical and imaging data, and whether such a model could achieve a better performance both in preoperative evaluation and prognosis prediction.

Thus, our study aims to build an ML model that integrates clinical-pathological parameters and MR image data, and capable of predicting both pre- and post-operative risk for CC patients. (1) autonomically delineate CC lesion on pelvic MR and precisely evaluate parametrial involvement and lymph node metastasis before surgery to better guide surgical plan; (2) predict individualized post-operative recurrence and survival for precise personalized adjuvant treatment and better guide follow-up strategy.

2. MATERIALS AND METHODS

This retrospective multicenter cohort study was approved by the Institutional Ethics Committee of Fudan University Obstetrics and Gynecology Hospital (2019-87) and was registered in the Chinese Clinical Trial Registry (ChiCTR1900028702).

2.1 Patients

A total of 1076 patients with CC who underwent surgical resection from January 2014 to December 2022 were identified as the study population in two tertiary hospitals in China, Obstetrics and

Gynecology Hospital affiliated to Fudan University and Shanghai First Maternity and Infant Hospital. The inclusion criteria were as follows: (1) patients with pathologically confirmed FIGO stage IA1 and positive lymph-vascular space invasion (LVSI) to IIB cervical cancer; (2) underwent radical hysterectomy based on different stages by the National Comprehensive Cancer Network (NCCN) guidelines at the time[19]; (3) patients with preoperative high-quality pelvic contrast MR images, including coronary T2 weighted imaging (T2WI) fat-suppressed sequence; (4) at least 3-year follow-up data were acquired. The exclusion criteria include: (1) patients who underwent chemotherapy or radiotherapy before surgery (n=23), (2) patients with incomplete medical records (n=61), (3) patients who did not undergo MRI before surgery or who had MRI performed at another institution (n=536), and (4) patients with unsatisfied MR Images (n=98), (5) patient lost to follow-up (n=108). The final study population consisted of 250 patients (Figure 1).

2.2 Clinical Information

For qualified patients, patient demographics, laboratory test results, therapeutic data, and tumor characteristics were collected from medical records. All records were simultaneously reviewed by three experts and independently checked for accuracy by two experts. After diagnosis, demographic variables including age and comorbidity (with hypertension or diabetes) as well as laboratory tests including squamous cell antigen carcinoma (SCCA) and human papillomavirus (HPV) infection status were collected. Before surgery, the history of loop electrosurgical excision procedure (LEEP) was also noted.

During the study period, all surgical procedures were performed by faculty who completed fellowship training in gynecologic oncology. Then, surgical data comprising surgical approach, operative time, blood loss, and blood transfusion. Tumor characteristics, consisting of FIGO stage, tumor size, histology, depth of stromal invasion (DSI), LVSI, surgical margin involvement, parametrial involvement, lymph node metastasis, keratinization, differentiation, and P53, P16, and Ki67 expression. According to NCCN guideline[3], all patients received adjuvant therapy after surgery when they met either of the following criteria: (1) patients with any of high-risk factors including positive surgical margin, parametrial involvement, or lymph node metastasis and (2) patients who met any of Sedlis criteria[20] for intermediate risk factors including tumor size, LVSI, and DSI.

Subsequently, patients received regular follow-ups by 2022 NCCN guidelines[3] after discharge and completion of initial treatment. HPV, liquid-based cytology (LCT), tumor markers, and ultrasonography were conducted every three months for the first two years, semiannually for the next two years, and then annually. Chest computed tomography (CT) scans, contrast upper abdominal CT scans, and pelvic MR were performed annually. Telephone follow-ups were also performed and patients suspected of recurrence by symptoms or abnormal examination findings were suggested to undergo the above tests. For suspected organ or lymph node metastasis, a needle aspiration biopsy was conducted when necessary.

2.3 Region of Interest Delineation and Lesion Recognition on MR Images

The coronary preoperative T2WI fat-suppressed sequence pelvic contrast MR images were gathered for all 250 patients, including both MR sequence source images and lesion segmentation images annotated by radiologists. MR source images were first normalized before further processing. To standardization the two types of MR sequence source images (256 × 256 pixels and 320 × 320 pixels), frames of 320 × 320 pixels were converted to 256 × 256 pixels size by cropping from the center. Meanwhile, the pixel value of the source image from 0 to over 1000 was redefined as [0,1].

After the obtainment of unified MR source images, they were handed over to radiologists for lesion annotation. The region of interest (ROI) for cervical cancer was manually delineated on T2WI

images using ITK-SNAP (version 3.8.0) by two senior radiologists with over 20 years of experience. Each radiologist was responsible for delineating half of the cases and reviewing the segmentation results of the other half. If the two radiologists had a dispute over delineation, negotiations and seeking third-party judgment were adopted to resolve the solution. During the segmentation, radiologists were blinded to the clinical information of the patients.

Subsequently, cervical lesion identification was modeled based on the MR images annotated by the radiologists, adopting an optimized algorithm based on 3D-Unet structure[21] and embedded with SELayer[22] to delineate pixels. Following various steps (supplementary), the input data (C×W×H×D) was compressed, normalized through the Sigmoid activation function[23], and then reshaped back to the original data size. The grayscale image was then segmented through Sigmoid function calculation of the probability that each pixel was classified as a positive sample. An improved FocalLoss function[24] was also introduced due to the imbalance of samples where frames with lesion markers in an MR image sequence were significantly more than those without. The weight factor α was used to balance the positive samples with negative samples, where the loss of easy samples was reduced by a power function. The optimal parameters $\alpha = 0.25$ and $\gamma = 2$ were adopted in this study.

2.4 Outcome

Parametrial invasion and lymphatic metastasis were two key indicators derived from the pathological report of surgically excised cervical carcinoma specimens. Parametrial invasion denotes the infiltration of neoplastic cells beyond the cervix into the adjacent connective tissue (parametrium) whereas lymphatic metastasis refers to the dissemination of malignant cells to regional lymph nodes.

For survival data, recurrence-free survival (RFS) was calculated from the initial cervical cancer diagnosis to the first finding of any recurrence or last follow-up, while overall survival (OS) was calculated from the initial diagnosis to cervical cancer-related death or last follow-up. For recurrence, local recurrences were defined as pathologically confirmed first reappearance of cancer in the cervix or vagina after complete treatment, limited in the pelvis, while distant recurrences were circumscribed as pathologically confirmed first relapse outside of the pelvis ranging from peritoneal spread to involvement of other organs.

2.5 Dataset Processing

After screening out the MR source images corresponding to the segmentation files marked by lesion identification, we processed the filtered original image (256 × 256 pixels) directly pulled into a 65536-dimensional vector. As for clinical data, there were a total of 22 different variables (Table S1), both continuous and categorical. Categorical variables were translated into one-hot codes and then concatenated with continuous variables to obtain preoperative 5-dimensional and postoperative 57-dimensional vectors. For the integrated models, the clinical vectors obtained after processing were stitched into the image vectors to obtain fused data vectors of 65593 dimensions.

2.6 Establishment of Integrated Models

The preoperative recognition model is a model that integrates preoperative clinical parameters and MR images, and outputs binary classification results for parameterized invasion and lymph node metastasis discrimination. The postoperative prognostic prediction model combines postoperative clinical parameters and MR images to predict the possibility of recurrence and death. Moreover, individual-specific RFS and OS time were also predicted.

A total of 7 different ML algorithms were used for model construction, including classical ML algorithms such as K-nearest neighbor (KNN), support vector machine (SVM), decision tree (DT), and random forest (RF), together with weighted KNN, balanced RF, and weighted DT of imbalanced ML algorithms. During the whole modeling process, negative samples were drawn at an approximately 1:1 ratio compared to positive samples to minimize the influence of sample imbalance

on the output of the models.

2.7 Validation, Evaluation, and Implementation

The entire process of the study was constituted of four steps: patient data input, data processing, model development, and model evaluation (Figure 1). Stratified random sampling was used to randomly divide the whole dataset gathered from the two hospitals into training and test sets at a ratio of 8:2. Model development was performed in the training set, while the constructed models were validated in the test set. To avoid overfitting and minimize bias, the constructed models were validated using fivefold cross-validation (CV).

Sensitivity, specificity, accuracy, precision, F1-Score, weighted accuracy, and area under curve (AUC) were used to evaluate the performance of classification models. Mean absolute error (MAE) and concordance index (C-index) were used to evaluate the performance of individual-specific RFS and OS time prediction.

To enhance the application of the prediction model in real-world clinical scenarios and simplify doctors' access, utilization, and management, a web-based predictive-aided diagnostic software was developed using Python.

2.8 Statistical analysis

Continuous variables were reported as mean with Standard deviations (SDs) if normally distributed and medians with interquartile ranges (IQRs) if nonnormally distributed, while categorical variables were reported as numbers and percentages. There was no significant interaction between all variables through correlation matrices assessment. The concordance of continuous variables was analyzed using intraclass for pathology and imaging reports consistency analysis, while categorical variables were analyzed using chi-squared test and Kappa coefficient. Statistical analysis was performed in R statistical software (version 4.1.1) and Python programming software (version 3.10.4). All tests were two-sided, and P value less than 0.05 was considered statistically significant unless otherwise stated.

3. RESULTS

3.1 Baseline characteristics of 884 early-stage CC patients

A total of 250 patients with FIGO Stage IA1(LVSI+)-IIB CC who underwent radical hysterectomy during 2014-2022 were included in the study population (Table 1). The median age was 48.8 years, most patients were stage I (72.8%) with squamous histologic type (80.0%) and more than half of patients (191,76.4%) underwent adjuvant therapy. There were 24 (9.6%) women who experienced recurrence and 11 (4.4) who died in duration. Among the recurrence cases, there were 9 (37.5%) patients with initial recurrence in the local region, and 15 (62.5%) with distant recurrence, including 4 (16.7%) in the thoracic region, 5 (20.8%) in the abdominal region, 6 (25%) in the bone, respectively. The medium RFS was 33.8 (24.9-42.4) months and the medium OS was 34.6 (26.0-42.8) months. 1-year RFS and OS rate were 94.4% and 99.2%, while 3-year RFS and OS rate was 90.1% and 95.4% respectively (Figure S1).

Table 1
Baseline Characteristics of Stage IA1 (LVSI +) to IIB Cervical Cancer Patients.

Characteristics	Overall (N=250)	Train (N=200)	Test (N=50)	p-Value
Clinical Variables				
Age at diagnosis (years), mean ± SD	48.8±9.6	48.3±9.7	50.9±9.1	0.0870
FIGO Stage, n (%)				0.4025
IA1	2 (0.8)	1 (0.5)	1 (2.0)	
IA2	0 (0.0)	0 (0.0)	0 (0.0)	
IB1	148 (59.2)	123 (61.5)	25 (50.0)	
IB2	32 (12.8)	26 (13.0)	6 (12.0)	
IIA1	52 (20.8)	37 (18.5)	15 (30.0)	
IIA2	14 (5.6)	11 (5.5)	3 (6.0)	
IIB	2 (0.8)	2 (1.0)	0 (0.0)	
Comorbidity, n (%)				0.7326
Yes	41 (16.4)	32 (16.0)	9 (18.0)	
No	209 (83.6)	168 (84.0)	41 (82.0)	
HPV infection, n (%)				0.3434
Yes	117 (46.8)	91 (45.5)	26 (52.0)	
HPV 16/18	74 (29.6)	60 (30.0)	14 (28.0)	
Other HPV Type	43 (17.2)	31 (15.5)	12 (24.0)	
No	6 (2.4)	6 (3.0)	0 (0.0)	
Unknown	127 (50.8)	103 (51.5)	24 (48.0)	
SCCA (ng/ml), median (IQR)	2.1 (1.0–4.9)	2.1 (1.0–5.0)	1.5 (0.8–4.5)	0.9325
Post-surgery adjuvant therapy, n (%)				0.9406
Yes	191 (76.4)	153 (76.5)	38 (76.0)	
No	59 (23.6)	47 (23.5)	12 (24.0)	
Surgery Related Variables				
Surgery approach, n (%)				
MH	246 (98.4)	197 (98.5)	49 (98.0)	0.5615
LH	221 (88.4)	175 (87.5)	46 (92.0)	
Robotic	25 (10.0)	22 (11.0)	3 (6.0)	
OH	4 (1.6)	3 (1.5)	1 (2.0)	
Operative time (min), median (IQR)	180.0 (159.0–225.0)	180.0 (157.0–222.5)	180.0 (160.0–230.0)	0.7951
Blood loss (ml), median (IQR)	200.0 (100.0–300.0)	200.0 (100.0–200.0)	200.0 (100.0–300.0)	0.1237
Transfusion, n (%)				0.2587
Yes	5 (2.0)	3 (1.5)	2 (4.0)	
No	245 (98.0)	197 (98.5)	48 (96.0)	
Pathologic Variables				
Tumor size (cm) , n (%)				0.1136
[0, 0.5)	8 (3.2)	6 (3.0)	2 (4.0)	

Characteristics	Overall (N=250)	Train (N=200)	Test (N=50)	p-Value
[0.5, 1)	0 (0.0)	0 (0.0)	0 (0.0)	
[1, 1.5)	13 (5.2)	6 (3.0)	7 (14.0)	
[1.5, 2)	13 (5.2)	12 (6.0)	1 (2.0)	
[2, 2.5)	33 (13.2)	26 (13.0)	7 (14.0)	
[2.5, 3)	29 (11.6)	26 (13.0)	3 (6.0)	
[3, 3.5)	38 (15.2)	31 (15.5)	7 (14.0)	
[3.5, 4)	39 (15.6)	31 (15.5)	8 (16.0)	
[4, 4.5)	23 (9.2)	20 (10.0)	3 (6.0)	
[4.5, 5)	23 (9.2)	16 (8.0)	7 (14.0)	
≥ 5	28 (11.2)	23 (11.5)	5 (10.0)	
Histology, n (%)				0.2037
SCC	200 (80.0)	161 (80.5)	39 (78.0)	
AC	29 (11.6)	25 (12.5)	4 (8.0)	
AS	19 (7.6)	12 (6.0)	7 (14.0)	
Rare Type	2 (0.8)	2 (1.0)	0 (0.0)	
DSI, n (%)				0.5070
Negative	24 (9.6)	21 (10.5)	3 (6.0)	
Inner 1/3	30 (12.0)	26 (13.0)	4 (8.0)	
Middle 1/3	28 (11.2)	21 (10.5)	7 (14.0)	
Outer 1/3	168 (67.2)	132 (66.0)	36 (72.0)	
LVSI, n (%)				0.2000
Yes	145 (58.0)	120 (60.0)	25 (50.0)	
No	105 (42.0)	80 (40.0)	25 (50.0)	
Surgical margin involvement, n (%)				0.7764
Yes	32 (12.8)	25 (12.5)	7 (14.0)	
No	218 (87.2)	175 (87.5)	43 (86.0)	
Parametrial involvement, n (%)				0.6053
Yes	16 (6.4)	12 (6.0)	4 (8.0)	
No	234 (93.6)	188 (94.0)	46 (92.0)	
Lymph node metastasis, n (%)				0.3486
Yes	64 (25.6)	51 (25.5)	13 (26.0)	
Pelvic lymph nodes	54 (21.6)	45 (22.5)	9 (18.0)	
Common iliac lymph nodes	6 (2.4)	4 (2.0)	2 (4.0)	
Para-aortic lymph nodes	4 (1.6)	2 (1.0)	2 (4.0)	
No	186 (74.4)	149 (74.5)	37 (74.0)	
Keratinization, n (%)				0.9596
Yes	87 (34.8)	71 (35.5)	16 (32.0)	
No	92 (36.8)	73 (36.5)	19 (38.0)	
Non-SCC	50 (20.0)	39 (19.5)	11 (22.0)	
Unknown	21 (8.4)	17 (8.5)	4 (8.0)	
Differentiation, n (%)				0.0388
Low	1 (0.4)	1 (0.5)	0 (0.0)	

Characteristics	Overall (N=250)	Train (N=200)	Test (N=50)	p-Value
Intermediate	4 (1.6)	3 (1.5)	1 (2.0)	
High	2 (0.8)	0 (0.0)	2 (4.0)	
Unknown	243 (97.2)	196 (98.0)	47 (94.0)	
P53, n (%)				0.4766
-	73 (29.2)	60 (30.0)	13 (26.0)	
+	172 (68.8)	137 (68.5)	35 (70.0)	
++	0 (0.0)	0 (0.0)	0 (0.0)	
+++	0 (0.0)	0 (0.0)	0 (0.0)	
++++	0 (0.0)	0 (0.0)	0 (0.0)	
Unknown	5 (2.0)	3 (1.5)	2 (4.0)	
P16, n (%)				0.2720
Negative	5 (2.0)	3 (1.5)	2 (4.0)	
Positive	240 (96.0)	194 (97.0)	46 (92.0)	
Unknown	5 (2.0)	3 (1.5)	2 (4.0)	
Ki67, n (%)				0.8576
-	0 (0.0)	0 (0.0)	0 (0.0)	
0-20%	16 (6.4)	13 (6.5)	3 (6.0)	
20-40%	48 (19.2)	37 (18.5)	11 (22.0)	
40–60%	77 (30.8)	61 (30.5)	16 (32.0)	
60–80%	71 (28.4)	60 (30.0)	11 (22.0)	
80–100%	32 (12.8)	25 (12.5)	7 (14.0)	
Unknown	6 (2.4)	4 (2.0)	2 (4.0)	
Survival Outcomes				
Recurrence, n (%)				
Yes	24 (9.6)	18 (9.0)	6 (12.0)	
Local Region	9 (3.6)	7 (3.5)	2 (4.0)	
Thoracic Region	4 (1.6)	2 (1.0)	2 (4.0)	
Abdominal Region	5 (2.0)	3 (1.5)	2 (4.0)	
Bone	6 (2.4)	6 (3.0)	0 (0.0)	
Other Regions	0 (0.0)	0 (0.0)	0 (0.0)	
No	226 (90.4)	182 (91.0)	44 (88.0)	
RFS (month), median (IQR)	33.8 (24.9–42.4)	33.2 (24.5–42.6)	35.0 (26.8–41.4)	0.4880
Death, n (%)				0.5374
Yes	11 (4.4)	8 (4.0)	3 (6.0)	
No	239 (95.6)	192 (96.0)	47 (94.0)	
OS (month), median (IQR)	34.6 (26.0–42.8)	34.2 (25.3–43.0)	35.0 (27.9–41.4)	0.4733

Note: Data are reported as number of patient and percentage of total in parentheses, unless otherwise noted. Abbreviations: SD = standard deviation; FIGO = International Federation of Gynecology and Obstetrics; HPV = human papillomavirus; SCCA = squamous cell carcinoma antigen; IQR = interquartile range; LEEP = loop electrosurgical excision procedure; MH = minimal invasive hysterectomy; LH = laparoscopic hysterectomy; OH = open hysterectomy; SCC = squamous cell

carcinoma; AC = adenocarcinoma; AS =adenosquamous carcinoma; DSI = depth of stromal invasion; LVSI = lymphovascular space invasion; RFS = recurrence-free survival; OS = overall survival .

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3.2 Preoperative Prediction Performance

We constructed 7 integrated ML models using MR images and 5 clinical parameters, including age, comorbidity, HPV infection, SCCA, and LEEP history (Table 2). Given the imbalance of data with negative cases of parametrial invasions and lymphatic metastasis outcompete positive cases, we adopted weighted KNN, an algorithm optimized for unbalanced data to further explore the evaluation performance of different types of models. The weighted-KNN model has the highest sensitivity in predicting parametrial invasion and the highest sensitivity and F1 score in predicting lymph node metastasis. Therefore, an integrated model using two-dimensional data has great advantages in the early identification of parametrial invasion and lymphatic metastasis of cervical cancer patients. These results shed light on the enormous potential of integrated ML models in preoperative decisions as a non-invasive and cost-effective risk stratification tool.

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Table 2
The Result of Pre-surgery Diagnosis Prediction Using Various Kinds of Integrated ML Models for Stage IA1 (LVSI +) to IIB Cervical Cancer Patients.

Models	Sensitivity	Specificity	Accuracy	Precision	F1-Score
Parametrial Invasions Prediction					
Classical ML					
KNN	0.00	0.99	0.83	0.00	0.00
SVM	0.57	0.56	0.56	0.21	0.31
DT	0.50	0.59	0.57	0.20	0.29
RF	0.00	0.99	0.83	0.00	0.00
Unbalanced ML					
Balanced RF	0.81	0.85	0.85	0.53	0.64
Weighted KNN	0.98	0.25	0.37	0.21	0.35
Weighted DT	0.29	0.93	0.82	0.46	0.35
Lymph Node Metastasis Prediction					
Classical ML					
KNN	0.31	0.77	0.60	0.46	0.37
SVM	0.66	0.52	0.57	0.46	0.54
DT	0.53	0.60	0.58	0.45	0.49
RF	0.33	0.87	0.66	0.60	0.42
Unbalanced ML					
Balanced RF	0.45	0.87	0.71	0.68	0.54
Weighted KNN	0.67	0.61	0.63	0.52	0.58
Weighted DT	0.38	0.74	0.60	0.47	0.42

Note: All remain models were constructed using both MRI and clinical data.

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3.3 Postoperative Prediction Performance

To test whether such integrated models could also achieve great performance in postoperative prognosis prediction, we constructed 8 integrated ML models using pure MR images and 21 clinical parameters (Table S1) to predict the likelihood of individual recurrence and death in CC patients (Table 3). Among 7 ML methods, the best results were still achieved by weighted KNN (AUC 0.861) (Figure 2C).

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Table 3
The Result of Post-surgery Prognosis Prediction Using Various Kinds of Integrated ML Models for Stage IA1 (LVSI +) to IIB Cervical Cancer Patients.

Models	Sensitivity	Specificity	Accuracy	Precision	F1-Score
Recurrence Prediction					
Classical ML					
KNN	0.00	0.89	0.89	0.00	0.00
SVM	0.00	0.89	0.89	0.00	0.00
DT	0.00	0.89	0.87	0.00	0.00
RF	0.00	0.89	0.89	0.00	0.00
Unbalanced ML					
Balanced RF	0.80	0.37	0.41	0.12	0.21
Weighted KNN	0.80	0.96	0.94	0.67	0.73
Weighted DT	0.00	0.96	0.86	0.00	0.00
Death Prediction					
Classical ML					
KNN	0.00	0.92	0.92	0.00	0.00
SVM	0.00	0.92	0.92	0.00	0.00
DT	0.00	0.92	0.92	0.00	0.00
RF	0.00	0.92	0.92	0.00	0.00
Unbalanced ML					
Balanced RF	0.33	0.71	0.69	0.07	0.11
Weighted KNN	0.33	0.99	0.97	0.99	0.50
Weighted DT	0.00	0.96	0.86	0.00	0.00

Note: All remain models were constructed using both MRI and clinical data.

Considering the importance of sensitivity for prognosis prediction in guiding post-operative treatment and follow-up, a weighted accuracy was introduced as the evaluation indicator to the models, and a variety of weights were applied for the testing (Table S2).

In searching for better guidance on individual follow-up plans, we also explored the specific time prediction of RFS and OS for stage IA1 (LVSI +) to IIB CC patients. We adopted 4 ML methods (weighted KNN, SVM, RF, and DT) to predict the time of recurrence and death of CC patients (Table 4). For integrated models, weighted KNN and RT have the best performance for recurrence (with an MAE of 8.53 months and a C-index of 0.83) and death (with an MAE of 4.36 months and a C-index of 0.99) time prediction respectively. In general, the prediction performance of integrated models with the weighted KNN algorithm exhibits a more balanced and good prediction capability on postoperative prognosis both in recurrence and death. This inspiring result motivates both personalized prognosis evaluation and future follow-up plan-making in clinical practice.

Table 4
The Mean Absolute Error and C-index of Postoperative Recurrence and Death Time Prediction Using Integrated Models Using MR and Clinical Parameters for Stage IA1 (LVSI +) to IIB Cervical Cancer Patients.

Models	Mean Absolute Error (month)	C-index
RFS Prediction		
weighted KNN	8.53	0.83
SVM	9.13	0.33
RF	8.83	0.5
DT	10.74	0.17
OS Prediction		
weighted KNN	4.69	0.67
SVM	5.31	0
RF	19.81	1
DT	4.36	1

Note: IM was achieved by the MR and clinical integrated models using weighted KNN algorithm in recurrence and death prediction.

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3.4 AI-assisted contouring and prognosis prediction system

To enhance the application of the prediction model in real-world clinical scenario and simplify doctors' access, utilization, and management, above optimal AI prediction models are integrated into a web-based software that aids in contouring lesions on MR and predicting prognosis outcomes (Figure 3). By inputting important preoperative clinical parameters of individual patients, as well as uploading the DCM files of the preoperative MR image, the AI system can automatically identify lesions on the MR image and provide predictions regarding the patient's risk of parametrial invasion and lymphatic metastasis. Similarly, by inputting important postoperative clinical, surgical, and pathological parameters, along with uploading the MR images, the system can predict the patient's risk of recurrence, and death, as well as the specific duration of RFS and OS. This AI-assisted system assists doctors in accurately contouring patients' lesions as well as evaluating parametrial invasion and lymphatic metastasis status before surgery, thus optimizing the treatment decision-making for CC patients. Additionally, the system aids in formulating postoperative follow-up plans and guiding further adjuvant treatment strategies for CC patients (more details are available at https://aigja.fckyy.org.cn/zcpt/login).

4. DISCUSSION

In this study, a retrospective analysis was conducted on 884 patients diagnosed with FIGO stage IA1 (LVSI+) to IIB cervical cancer, who underwent surgical treatment at two tertiary institutional hospitals. Utilizing a multidimensional approach that incorporated clinicopathologic characteristics and MR images, our research team successfully developed predictive models for parametrial invasions, lymph node metastasis, recurrence, and mortality. The integrated models combined both clinical and MR imaging data based on the weighted KNN algorithm and showed the best performance in both preoperative evaluation and postoperative prognosis prediction. These findings suggest that a multi-dimensional approach that incorporates both clinical parameters and imaging data can improve the accuracy of cervical cancer evaluation and prognosis prediction.

Two primary obstacles persist in the current clinical management of cervical cancer. Firstly, preoperative assessment predominantly relies on pelvic contrast MR imaging due to its cost-effectiveness and accessibility. However, the interpretation of MR images is heavily contingent upon the expertise of radiologists, leading to substantial shortcomings in detecting parametrial invasion and lymphatic metastasis, particularly in primary care settings. Secondly, there is a dearth of personalized and precise prediction models for evaluating postoperative prognosis, as most extant models are grounded in traditional linear assumptions ill-suited for clinical application. Consequently, an increasing number of studies are incorporating ML models into prognosis and survival prediction[8, 10, 11, 17, 18, 25-30]. Nevertheless, these studies seldom integrate clinical images with other parameters. In light of the aforementioned challenges, we delved into ML approaches with the aim of devising an optimal model that amalgamates clinicopathologic parameters and clinical images to accurately identify preoperative parametrial invasions and lymph node metastasis, as well as forecast postoperative recurrence, and survival prognosis in cervical cancer patients. To the best of our knowledge, our models represent the first ML models developed for cervical cancer patients based on the most comprehensive MR and clinical data available, offering an intuitive comparison with models constructed using purely clinical or radiological information.

For preoperative assessment, we first analyzed the validity and reliability of the radiological diagnosis by comparing the MR reports interpreted by radiologists based on MR images with the gold standard of pathological diagnosis of IA1 (LVSI +) to IIB cervical cancer patients (Table 2). Regardless of parametrial invasion or lymphatic metastasis, the F1 score and precision of radiological diagnosis were low, and their consistency with pathological diagnosis remained poor. This indicates the significant challenges radiologists faced when identifying parametrial invasion and

lymphatic metastasis based solely on MR images. Besides, both identifications demonstrated low sensitivity and high specificity, possibly due to radiologists' conservative approach to diagnosing MR images, providing positive diagnoses only when they have a high degree of certainty and classifying difficult images as negative. Then, we further explore the capability of integrated models, skipping pure clinical models given the limited number of preoperative clinical parameters. Our unprecedented models integrating clinical and MR data showed significant improvements in the detection of both lymphatic metastasis and parametrial invasion, indicating that models integrating radiological and clinical information are better than those based on limited information. Our integrated models achieved even better prediction accuracy than a previous pure clinical model combing postoperative findings of metastasis to the pelvis, uterus, and vagina[9]. This could imply that complete MR images contain much more potential information than simple pathological confirmation of local metastases. Although some studies achieved better predictive performance than ours for lymphatic metastasis[15], such discrepancy may be due to the different orientations of MR images, as the axial images used in their study may provide more information than coronal images in terms of lymphatic metastases. Overall, our integrated model far surpassed the evaluations of our radiologists, indicating that appropriate use of MR images and clinical information may lead to a new non-invasive approach for evaluating parametrial invasion and lymphatic metastasis, aiding in more accurate preoperative staging and more precise surgical planning in clinical practice[31].

For postoperative prognosis prediction, we constructed integrated models based on weighted KNN for both recurrence or death likelihood classification (Table 3) and specific OS or RFS time prediction (Table 4). Considering that for prognosis prediction, detection of all potential recurrence or death patients was preferred, and the harm of missed diagnosis is relatively higher than that of misdiagnosis, a weighted accuracy was introduced as an evaluation indicator to the models, and a variety of weights of sensitivity and specificity were applied for the testing. Upon analysis of the results, we found that as the weight of sensitivity increases, the accuracy of detecting potential recurrence and death patients by integrated model also increases, and the superior performance of the integrated model becomes more apparent (Table S2), which was consistent with previous studies' results[8, 29]. This suggests that clinical features can serve as a complementary tool to the over-complicated image information in enhancing predictive performance. The integration of clinical and imaging information can thus be deemed an effective approach to improving the predictive ability of prognostic models. A similar conclusion was also reached in a previous study considering [18F] FDG positron emission tomography (PET) radiomics[25]. Overall, these results once again demonstrate the superiority of integrated models over ordinary models that are limited in their information.

Despite the favorable performance of the integrated ML models, there are several limitations in this study. First, given the retrospective nature and relatively small sample size, future prospective studies and big data validation are still necessary and more positive samples were needed to achieve further analysis. Second, due to the relatively short follow-up period (<5 years), the estimation of long-term prognostic outcomes still require longer follow-up periods. Third, it is widely believed that DL models outperform classic ML models when the amount of data is large. In this study, the performance of the DL models is not ideal due to parameter constraints. We are looking forward to building more comprehensive models in the future to further explore the advancement of DL techniques.

5. CONCLUSIONS

In conclusion, this study used ML technology to develop diagnostic and prognostic models based on clinical and MR image data to precisely detect pre-operative parametrial involvement and lymph node metastasis and estimate postoperative survival and recurrence in stage IA1 (LVSI +) to IIB cervical cancer patients. We trained and externally validated the models based on the data of 250

patients from two tertiary hospitals. In both preoperative diagnosis and postoperative prediction models, ML models integrating clinical and MR information showed good diagnosis performance. The findings suggest that combining ML with clinical and MR images may serve as a better tool to diagnose and predict the prognosis of cervical cancer and can help to reduce clinical misdiagnosis caused by human factors and provide personalized and precise treatment for patients.

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Supplementary Files

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Figures

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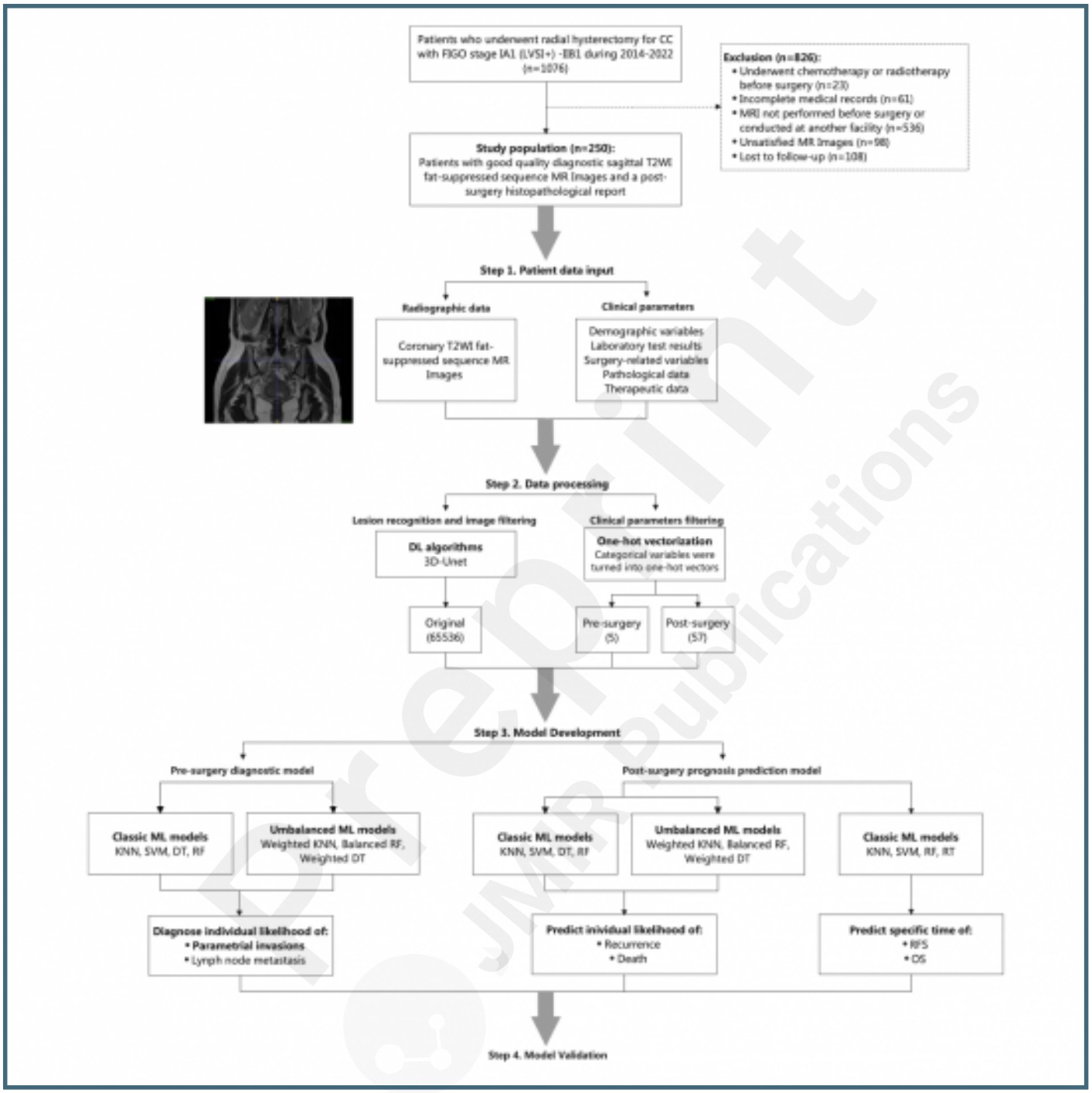
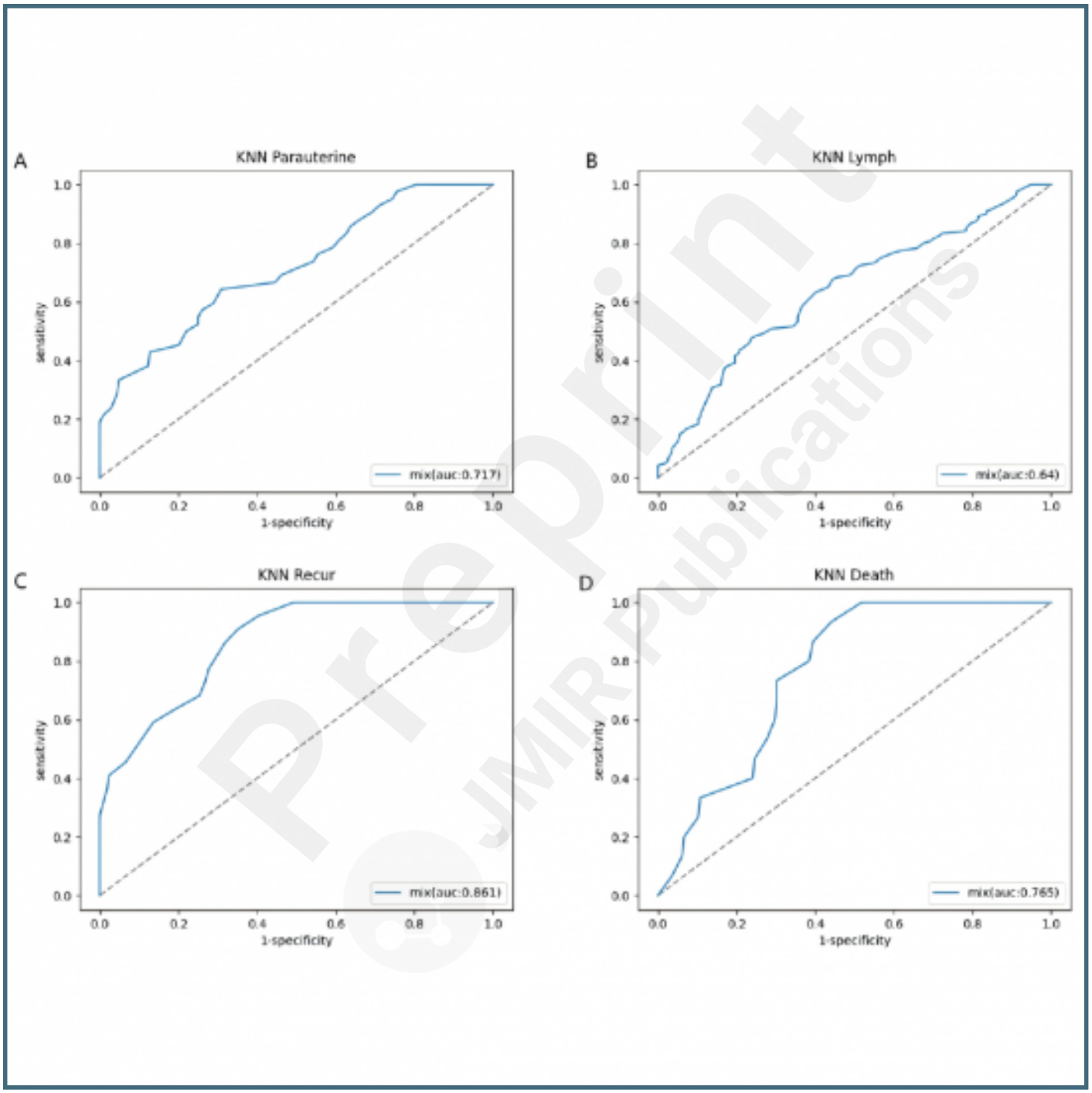
Flow diagrams of the selection of study population and the consecutive process of model construction.



ROC curves of postoperative recurrence and death prediction for stage IA1 (LVSI +) to IIB cervical cancer patients using various kinds of integrated weighted KNN models. The horizontal coordinate is 1-specificity while the vertical coordinate is sensitivity. (A-B) Integrated model constructed by both clinical parameters and imaging data were constructed to evaluate parametrial invasion (A) and lymphatic metastasis (B). (C-D) Integrated model constructed by both clinical parameters and imaging data were constructed to predict recurrence (C) and death (D).



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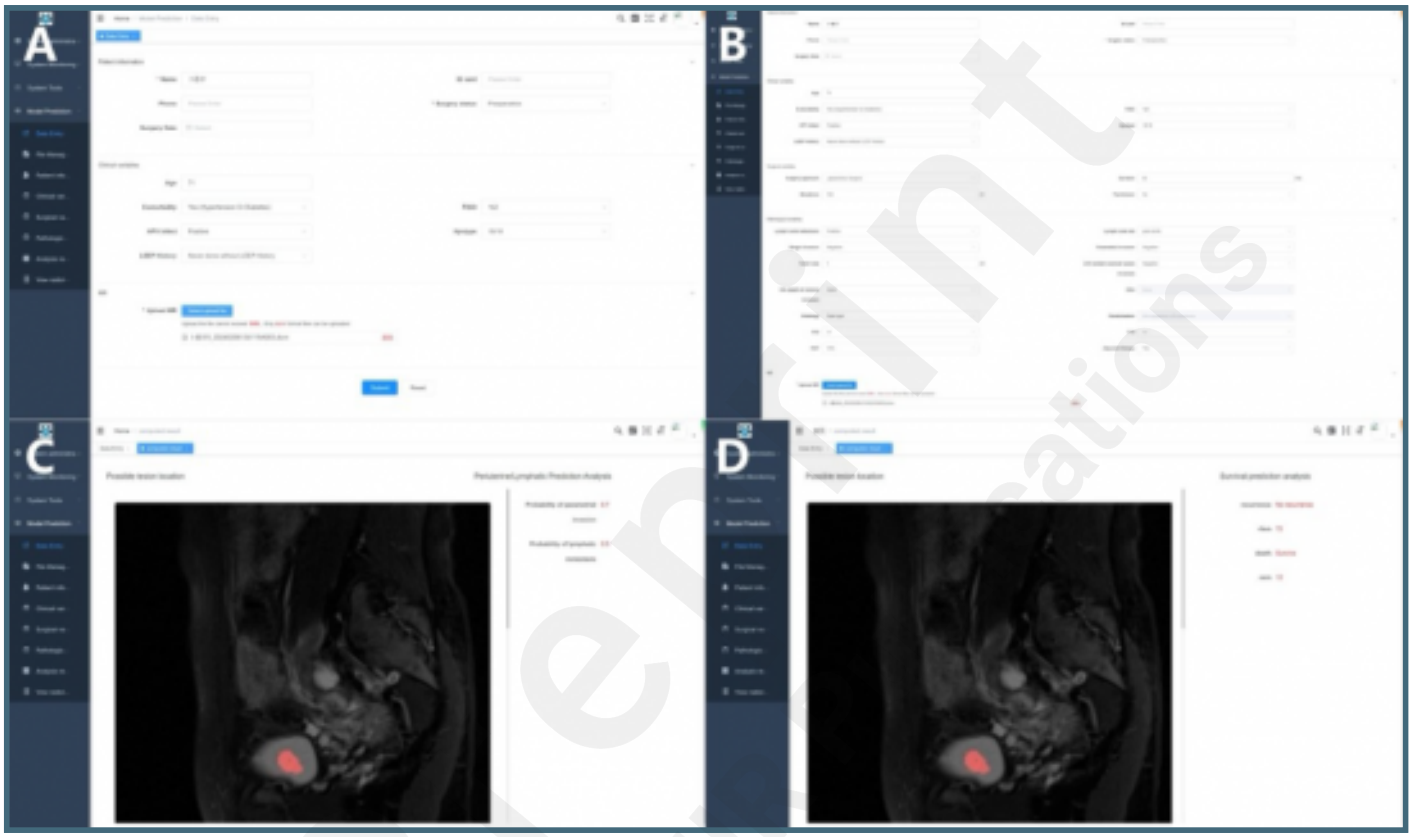
Screenshots for the web-based aided diagnostic software designed to assist with the pre-surgical determination of patient-specific lesion characteristics, parametrial invasion, and lymph node metastasis, as well as to forecast post-surgical recurrence and mortality probabilities, along with RFS and OS projections. (A-B) To utilize this diagnostic aid, which is accessible at https://aigja.fckyy.org.cn/zcpt/login, one must input the requisite details for each parameter, upload the MR images in dcm format, and then initiate the analysis by clicking the "Submit" button. (C-D) After submission of important parameters and uploading of MR images, the specific lesion of the patient is outlined, parametrial invasions and lymph node metastasis (C) as well as recurrence and mortality probabilities (D) are calculated.



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