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be rapidly and fully apply to cervical cancer patients in China,  
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**Concordance Study Between IBM Watson for Oncology and real clinical practice for Cervical cancer patients in China : a Retrospective analysis.**

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**Running title:** Watson for Oncology for Chinese Cervical Cancer Patients.

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**KEYWORDS:** Artificial intelligence, Watson for Oncology, Cervical cancer, concordance.

## **Introduction**

### **Watson for Oncology and Its application in China**

Artificial intelligence (AI) is the frontier and dominating terrain of Information Technology which able to simulate human mental status and cognitive function<sup>[1]</sup>. With the development of artificial intelligence and medical diagnosis technology, clinical decision-support systems (CDSS) with intelligent diagnostic function has become one of the important issues of science for medical information<sup>[2]</sup>. It is bringing a paradigm shift to healthcare, powered by increasing availability of healthcare data and rapid progress of analytics techniques. Watson for Oncology<sup>[3]</sup> (WFO, IBM Corporation, United States) is a representative AI clinical decision-support systems that trained by Memorial Sloan Kettering Cancer Center (MSKCC). Its helps physicians quickly identify key information in a patient's medical record, surface relevant evidence and explore treatment options. WFO first officially landed in China in 2016, until now, more than 80 hospitals across China to adopt Watson for Oncology to help physicians personalize cancer care, and WFO can provide counseling services for patients with lung cancer, breast cancer, rectal cancer, colon cancer, gastric cancer, cervical cancer, thyroid cancer, liver cancer, ovarian cancer, prostate cancer, bladder cancer and endometrial cancer. But limited reports on whether WFO is suitable for Chinese patients, especially patients with cervical cancer, exist.

### **Current status of cervical cancer in China**

Cervical cancer is common in the female genital tract malignant tumors, and the incidence of which is second only to that of breast cancer among women worldwide, making it the second-most serious cancer threatening the health and lives of women<sup>[4]</sup>. Compared to breast cancer, cervical cancer are more common in developing countries due to the poor health status, and it is the most common in China. According to statistics: In China, there are more than 150 thousand new cases of cervical cancer every year, accounting for almost 28 percent of that in the world<sup>[5]</sup>. And rural and remote areas are also prevalent region for cervical cancer in China. But the current

problem of the medical service is that the main hospitals hold too many premium resources, but at the mean time the primary health agencies are excessively lack of resources<sup>[6]</sup>. Cervical cancer patients in rural and remote areas can not reach the effective treatment recommendation, especially at centers where cancer expert resources are limited. So, WFO is of great significance for Chinese patients with cervical cancer, especially patients in rural and remote areas with limited medical resources.

Therefore, we conducted a retrospective and observational study on cervical cancer at the Second Xiangya Hospital Cancer Center to investigate the concordance of treatment recommendations between WFO and real clinical practice for Cervical cancer patients supported by an expert panel of cancer specialists in Second Xiangya Hospital Cancer Center. Indeed, to our best knowledge, this study provides the first evidence that whether WFO is suitable for Chinese patients with cervical cancer.

## **Methods**

### **Study population**

This retrospective study was reviewed and approved by the medical ethics committee of the Second Xiangya Hospital of Central south university (approval number was GBIRB2017-329). We retrospectively and randomly selected 300 cases of cervical cancer patients who were hospitalized in the Second Xiangya Hospital Cancer Center from May 2017 to August 2018. Patients with cervical cancer confirmed by pathology at the Second Xiangya Hospital Cancer Center and received antitumor treatment for the first time were included in our study. Patients who received only examinations and did not receive any antitumor treatment were excluded from our study. A total of 16 cases were excluded from our study. For some clinical settings, including treatment options for recurrent tumors and those with rare histology that not yet trained to offer treatment options by WFO system were also excluded from our study. A total of 12.7% (38/284) cases were not supported by WFO. And according to the statistics, the

remaining 246 patients were included and a total of 54 patients were excluded in our concordance study. The detailed patient selection process is shown in **Figure 1**.

### **Watson for Oncology**

WFO (IBM Corporation, United States, version 18.1R) used in our study were provided by Baheal Intelligent Technology Co., Ltd (<https://www.bsmartd.com>). IBM WFO initially be available in the English language only, Baheal Intelligent Technology provide some translation support to ensure Watson's treatment insights, such as drug labels and treatment guidelines are available to customers in appropriate Chinese dialects. The clinicopathologic datas of supported cases were extracted and entered into the WFO system. Treatment options recommended by WFO were presented in three categories: **Blue** represents “Recommended” with a strong evidence supported, **Orange** represents “For consideration” with a potentially suitable evidence-based alternative considered by oncologists based on their clinical judgment, and **Red** represents that are “Not recommended” that a treatment with contraindications or strong evidence against its use.

### **Data acquisition and concordance judgment**

The available clinicopathologic datas of 246 patients included registered residence, age, performance status, pathological type, differentiation degree, FIGO stage, lymphatic and distant metastasis, HPV status, and detailed clinical treatment plan were collected from Second Xiangya Hospital Cancer Center clinical lectronic medical records and entered manually into WFO system by two trained oncologists. Treatment options generated by WFO and recorded through two trained oncologists. It should be noted that in the data analysis process, real clinical practice were defined as concordant if treatment options were designated “recommended” or “for consideration” by WFO. if the real clinical practice was not recommended by WFO or if WFO did not provide the same treatment options, the recommendations were considered as discordant. The discordant cases were reevaluated by two senior oncologists provided their reasons for choosing the real treatment options. The

specific study design and procedures and are shown in **Figure 2**. Concordance of treatment option between WFO and real clinical practice was analysed statistically.

### **Statistical Analysis**

SPSS20.0 statistics software ((SPSS, USA)) and Microsoft Excel (2012) were employed to undergo statistical analysis. Descriptive statistics of 246 patients were calculated and presented as means  $\pm$  standard ( $\bar{x} \pm s$ ) or median. Differences between the clinicopathological characteristics of the groups were analyzed by Pearson's  $\chi^2$  test. Correlation between real clinical practice and WFO recommendations were assessed by the chi-square test. A logistic regression model was estimated with odds ratios (OR) and 95% confidence intervals (CIs).  $P < 0.05$  was considered to indicate a statistically significant difference. The values were designated as  $*P < 0.05$ .

### **Results**

#### **Clinicopathological characteristics of supported cases**

Of the 300 accrued cervical cancer patients, 246 patients were eligible for WFO analysis. Overall, 82% (246/300) of our enrolled cases were supported by WFO. Clinicopathological characteristics of 246 supported cases are detailed in **Table 1**. Among the 246 supported cases in our study, median age was 53 years (range, 35-78 years), and rural registration patients, stage II/II disease, squamous cell carcinoma, middle/poorly differentiated accounted for 66.2% (165/246), 77.7% (101+90/246), 89.0% (219/246), and 80.6% (90+108/246), respectively. These proportions were largely consistent with clinicopathological distribution of cervical cancer in China.

#### **Concordance between WFO and real clinical practice**

After reevaluated by two senior oncologists of discordant cases, there was no change to the primary concordance. Overall treatment concordance between WFO and real clinical practice occurred in 72.8% (179/246) of cervical cancer cases, among the concordant cases, treatment options that designated "Recommended" or "For



consideration” by WFO accounted for 41.5% (102/246) and 31.3% (77/246), respectively. Also, there were 27.2% (67/246) of case cannot consistent with real clinical practice, among the discordant cases, treatment options that not recommended by WFO or did not provided by WFO accounted for 4.8% (12/246) and 22.4% (55/246), respectively. Dates shown in **Table 2**.

### **Subgroup analyses**

Subgroup analyses of treatment concordance with clinicopathological characteristics were also carried out. The result showed that urban registration patients [96.3% (78/84)], low age group ( $\leq 45$ y and 45-65y gruops) [86.2% (25/29), 81.2% (134/165) respectively], good ECOG performance status (0-1 and 2 points gruops) [77.9% (145/186), 66.1% (31/47), respectively], and stage II/III disease [80.2% (87/101), 86.7% (78/90) respectively] exhibiting higher concordance than rural registration patients [61.2% (101/165)], advanced age gruop ( $\geq 60$ y) [38.5% (20/52)], poor ECOG performance status ( $\geq 3$  points) [23.1% (3/13)], and stage I/IV disease[41.4% (12/29), 7.96% (2/26) respectively]. While, there were no obvious difference among lymphatic and distant metastasis disease, pathological types, differentiation degrees. Dates shown in **Table 1** and **Figure 3,4,5**.

### **Logistic regression analysis**

The logistic regression analysis showed that, compared with patients  $\leq 45$  years of age, concordance declined significantly in patients  $\geq 65$  years of age and older[0.08 (0.03-0.28),  $P=0.032$ ].And Concordance was particularly low for patients with rural registration[0.64 (0.427-0.946),  $P=0.025$ ],compare with urban patients. Poor ECOG performance status ( $\geq 3$  points) patients exhibiting lower concordance than good ECOG performance status patients[0.29 (0.083-1.058),  $P=0.048$ ].Odds ratios of concordance varied by stage, showed that compared with stage I disease, stages II-III disease were significantly more likely to be concordant ([2.08 (1.002-4.325),  $P=0.046$ ],[2.09(1.001-4.381),  $P=0.047$ ],respectively), whereas, concordance declined remarkably in stages IV disease [0.19 (0.038-0.91),  $P=0.025$ ]. While, lymphatic and

distant metastasis disease, pathological types, differentiation degrees were not found to affect concordance. Dates shown in **Table 3**.

### **Analysis of Reasons for discordant cases**

There were four critical factors attributed to 27.2% (67/246) of the discordant cases. Firstly, Cisplatin is the main chemotherapy drug recommended by WFO, but in our study, of 46.4% (31/67) cases select nedaplatin due to cannot tolerate gastrointestinal reactions of cisplatin. Next, bevacizumab as a routine options recommended by WFO for stage IV stage, but bevacizumab is not in medical reimbursement plan for cervical cancer in China, of 26.9% (18/67) patients reject bevacizumab therapy for financial burden. Thirdly, for satge Ib2 and IIb disease, only concomitant radiochemotherapy was recommended by WFO, in our study, of 19.4% (13/67) patients prefer surgical therapy instead of concomitant radiochemotherapy. Moreover, neoadjuvant/adjuvant chemotherapy and programmed death-1 and ligand antibodies (PD-1/PD-L1 antibodies) drugs recommendations are not included in the WFO system, in our study, there were 9.1% (6/67), 2.8% (2/67) patients chose neoadjuvant/adjuvant chemotherapy and pembrolizumab therapy. Dates shown in **Table 4**.

## **Discussion**

### **Concordance studies of Watson for Oncology**

AI techniques have sent vast waves across healthcare, even fuelling an active discussion of whether AI doctors will eventually replace human physicians in the future<sup>[7]</sup>. IBM Watson for Oncology is one of the leading AI cognitive technologies combines leading oncologists' deep expertise in cancer care with the speed of IBM Watson to help clinicians as they consider individualized cancer treatments for their patients. From 2013, concordance studies between WFO and physicians have been performed in various countries and cancer types. A retrospective study from India showed that 93% concordance rate for 638 breast cancer patients<sup>[8]</sup>. Other study from India for 1000 consecutive cases showed 80% concordance between Multidisciplinary

Team (MDT)<sup>[9]</sup>. A observational study from Korea showed a 73% concordance rate for coloncancer and a 49% concordance rate for gastric cancer<sup>[10]</sup>. A retrospective study<sup>[11]</sup> of 211 cases from Thailand indicated that the overall concordance rate was 83%; 89% for colorectal, 91% for lung, 76% for breast, and 78% for gastric cancer. Also, a retrospective study reported by our center revealed that treatment concordance between WFO and MDT occurred in 65.8% (98/149) of lung cancer<sup>[12]</sup>. It appears that the concordance results varies by countries and cancer types<sup>[13]</sup>. For China, a huge population and regional differences created a different therapeutic experiences and considerations for cancer patients, as well as large differences with Western countries<sup>[14]</sup>. So, foreign research can be used as a reference, while localization research about concordance data of Chinese cancer patients is even more meaningful.

### Principal Findings of Our Study

This retrospective study provides the first evidence that accelerate localization and improvement were needed for WFO before comprehensively application in cervical cancer patients in China. Although treatment options generated by WFO were mostly concordant with real clinical practice, there are still unresolved issues. **Firstly**, as mentioned in the manual<sup>[15]</sup>, some clinical settings are not yet supported by WFO system. In our study, of 73.7% (28/38) unsupport cases were recurrent tumors patients. But compare with our center, grass-roots hospitals have greater proportion of patients with recurrent tumors. So, the cases that cannot supported by WFO system are very large for cervical cancer patients in China. **Secondly**, localization factors such as physical of patients, medical reimbursement plan, economic condition, and patient preferences of China were different from western countries, and they ultimately affect the inconsistency. In our study, of 46.4% (31/67) cases select nedaplatin due to cannot tolerate gastrointestinal reactions of cisplatin, of 26.9% (18/67) patients reject bevacizumab therapy for financial burden. of 19.4% (13/67) patients prefer surgical therapy instead of concomitant radiochemotherapy. **Moreover**, registered residence, age, performance status, FIGO stage have remarkable impact on consistency. Urban registration patients, low age group, good performance status, and stage II/III disease

exhibiting higher concordance than rural registration patients, advanced age group, poor performance status, and stage I/IV disease. These personal factors make WFO unable to achieve individualized treatment and affect the consistency significantly in China. **Finally**, neoadjuvant/adjuvant chemotherapy<sup>[16]</sup>, chemotherapeutic drugs<sup>[17]</sup> such as gemcitabine, docetaxel, mitomycin, irinotecan, pemetrexed, vinorelbine, and PD-1/PD-L1 antibodies<sup>[18]</sup> drugs recommendations that performed in real clinical practice are not included in the WFO system. Therefore, to be rapidly and fully apply to cervical cancer patients in China, accelerate localization and improvement were needed for WFO.

### **Limitations and Strengths of Our Study**

Our study contains some limitations. Firstly, this was a retrospective and observational study with control groups lacked, several unmeasured elements may influence the outcome. Secondly, 246 supported patients were enrolled in our study, sample size is relatively small. Thirdly, the distribution of clinicopathological characteristics among patients is imbalanced, for example, fewer patients were stage I and IV diseases, fewer patients were  $\geq 3$  points of ECOG performance status, a variety of bias exists may lead to different results. Finally, although real clinical practice were supported by an expert panel of cancer specialists in Second Xiangya Hospital Cancer Center, treatment preferences among different experts also affect consistency. However, we believe this was an important and meaningful study, and several strengths contained in our study. Firstly, this was a first study to report concordance between IBM Watson for Oncology and real clinical practice for Cervical cancer patients in China, we provide the first evidence that WFO is not suitable for Chinese patients with cervical cancer currently. Secondly, we not only reported the consistency between WFO and real clinical practice, but also analyzed several influence elements and offered certain advises for the improvement of WFO to better suit Chinese patients.

### **Suggestions for Watson for Oncology**

AI techniques have sent vast waves across healthcare, AI can definitely assist physicians to make better clinical decisions with increasing availability of healthcare data and rapid development of big data analytic methods<sup>[19]</sup>. For WFO, WFO could be an essential tool for clinicians, provides good references and literature for medical students, or even give some treatment advices to nonspecialist<sup>[20]</sup>. However, we believe that human physicians will not be replaced by AI in the foreseeable future, WFO still has a long way to go to replace oncologists. Medicine is not just a science, but also social and psychological subject. Any tool and guidelines can only be used as a doctor's reference, localization factors and individual elements should be considered for different patients, especially for cancer patients with large heterogeneous<sup>[21]</sup>. Therefore, WFO must be significantly improved to adapt the real clinical practice in different countries. Patient's physical and mental state, economic situation, complications, patient's treatment preference and medical reimbursement plan in different countries should be taken into account and not just provide advice based on existing knowledge. For China, a unique medical database with Chinese characteristics should be created by WFO to adapt and serve Chinese cancer patients.

## **Conclusions**

WFO recommendations were in 72.8% of concordance with real clinical practice for cervical cancer patients in China. However, several localization and individual factors limit its wider application. So, WFO cannot replace oncologists for cervical cancer patients in China currently. WFO could be an effective decision-support tool in cancer therapy for Chinese physicians, it also helps to standardize the treatment of cervical cancer. To be rapidly and fully applied to cervical cancer patients in China, acceleration and improvement were needed for WFO.

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### **Disclosure of conflict of interest**

None declared.

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## Tables

**Table 1.** Clinicopathological characteristics of cervical cancer patients(N=246).

Clinicopathological characteristics	Total cases	Concordant cases
<b>Age,years, n (%)</b>		
≤ 45	29(11.8)	25(86.2)
45-65	165(67.1)	134(81.2)
≥ 65	52(21.1)	20(38.5)
Median age (range)	53 (35-78)	
<b>Registered residence, n (%)</b>		
Urban registration	81(33.8)	78(96.3)
Rural registration	165(66.2)	101(61.2)
<b>ECOG<sup>a</sup> performance status, n (%)</b>		
0-1 points	186(75.6)	145(77.9)
2 points	47(19.1)	31(66.1)
≥ 3 points	13(5.3)	3(23.1)
<b>FIGO stage, n (%)</b>		
I	29(11.8)	12(41.4)
II	101(41.1)	87(86.1)
III	90(36.6)	78(86.7)
IV	26(10.5)	2(7.96)
<b>Lymphatic metastasis, n (%)</b>		
Positive	114(46.3)	82(71.9)
Negative	132(53.7)	97(73.5)
<b>Distant metastasis, n (%)</b>		
Positive	19(7.7)	10(52.6)
Negative	227(92.3)	169(74.5)
<b>Pathological types, n (%)</b>		
Squamous cell carcinoma	219(89.0)	159(72.6)
Adenocarcinoma	16(6.5)	125(75)
Adenoscale squamous cell carcinoma	10(4.1)	7(70)
Small cell carcinoma	1(0.4)	1(100)
<b>Differentiation degrees, n (%)</b>		
High differentiation	48(19.5)	35(72.9)
Middle differentiation	90(36.6)	64(71.1)
Poorly differentiation	108(43.9)	80(74.1)

<sup>a</sup>Eastern Cooperative Oncology Group, ECOG

**Table 2.** Concordance between WFO and real clinical practice(N=246).

Supported cases	Recommendations	Availability	Total
Concordant cases, n (%)	102 (41.5)	77 (31.3)	179 (72.8)
Discordant cases, n (%)	12 (4.8)	55 (22.4)	67 (27.2)

<sup>a</sup>Recommended.

<sup>b</sup>For consideration.

<sup>c</sup>Not recommended.

<sup>d</sup>Not available.

**Table 3.** Logistic regression model of concordance between Watson for Oncology and real clinical practice(N=246).

<b>Clinicopathological characteristics</b>	<b>OR<sup>b</sup> (95% CIs<sup>c</sup>)</b>	<b><math>\chi^2</math></b>	<b>P value</b>
Registered residence(Urban and Rural)	0.64 (0.427-0.946)	5.017	0.025 <sup>*</sup>
Lymphatic metastasis(P <sup>d</sup> and N <sup>e</sup> )	1.02 (0.694-1.503)	0.012	0.913
Distant metastasis(P <sup>d</sup> and N <sup>e</sup> )	1.41 (0.641-3.12)	0.744	0.388
<b>Age,years</b>			
≤ 45(Reference)	1.00		
45-65	0.94 (0.527-1.685)	0.041	0.841
≥ 65	0.08 (0.03-0.28)	4.609	0.032 <sup>*</sup>
<b>ECOG<sup>a</sup> performance status</b>			
0-1 points ( <b>Reference</b> )	1.00		
2 points	0.84 (0.512-1.399)	0.425	0.514
≥ 3 points	0.29 (0.083-1.058)	3.917	0.048
<b>FIGO stage</b>			
I ( <b>Reference</b> )	1.00		
II	2.08 (1.002-4.325)	3.968	0.046 <sup>*</sup>
III	2.09 (1.001-4.381)	3.958	0.047 <sup>*</sup>
IV	0.19 (0.038-0.91)	5.036	0.025 <sup>*</sup>
<b>Pathological types</b>			
Squamous cell carcinoma( <b>Reference</b> )	1.00		
Adenocarcinoma	1.03 (0.476-2.244)	0.007	0.935
Adenosquamous carcinoma	0.96 (0.359-2.588)	0.005	0.942
Small cell carcinoma	1.38 (0.086-22.187)	0.051	0.821
<b>Differentiation degrees</b>			
High differentiation( <b>Reference</b> )	1.00		
Middle differentiation	0.97 (0.568-1.675)	0.008	0.928
Poorly differentiation	1.01 (0.602-1.714)	0.003	0.953

<sup>a</sup>Eastern Cooperative Oncology Group, ECOG.

<sup>b</sup>Odds ratio,OR.

<sup>c</sup>Confidence intervals,CIs.

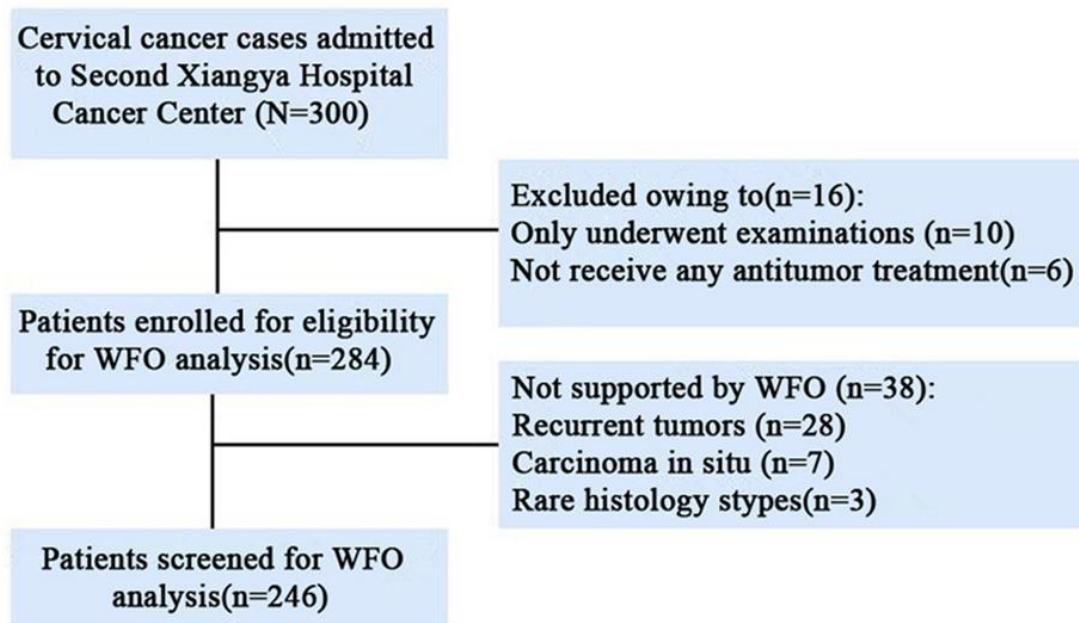
<sup>d</sup>Positive and <sup>e</sup>Negative

<sup>\*</sup>  $P < 0.05$ .

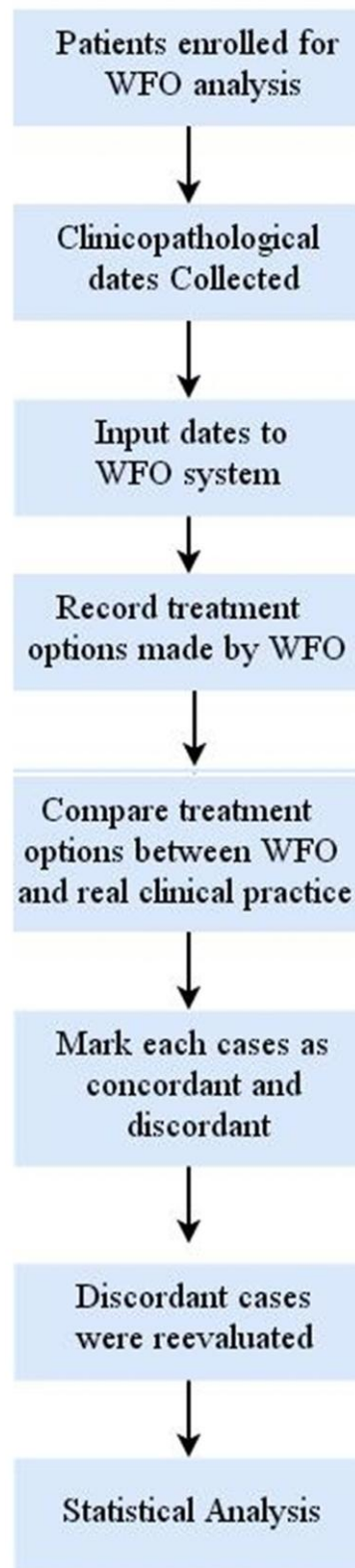
**Table 4.** Analysis of Reasons for discordant cases(n=67).

<b>Reasons for discordant cases</b>	<b>Cases, n (%)</b>
Substitution of nedaplatin for cisplatin	28 (41.8)
Reimbursement plan of bevacizumab	18 (26.9)
Surgical preference	13 (19.4)
Neoadjuvant/adjuvant chemotherapy	6 (9.1)
PD-1/PD-L1 antibodies	2 (2.8)

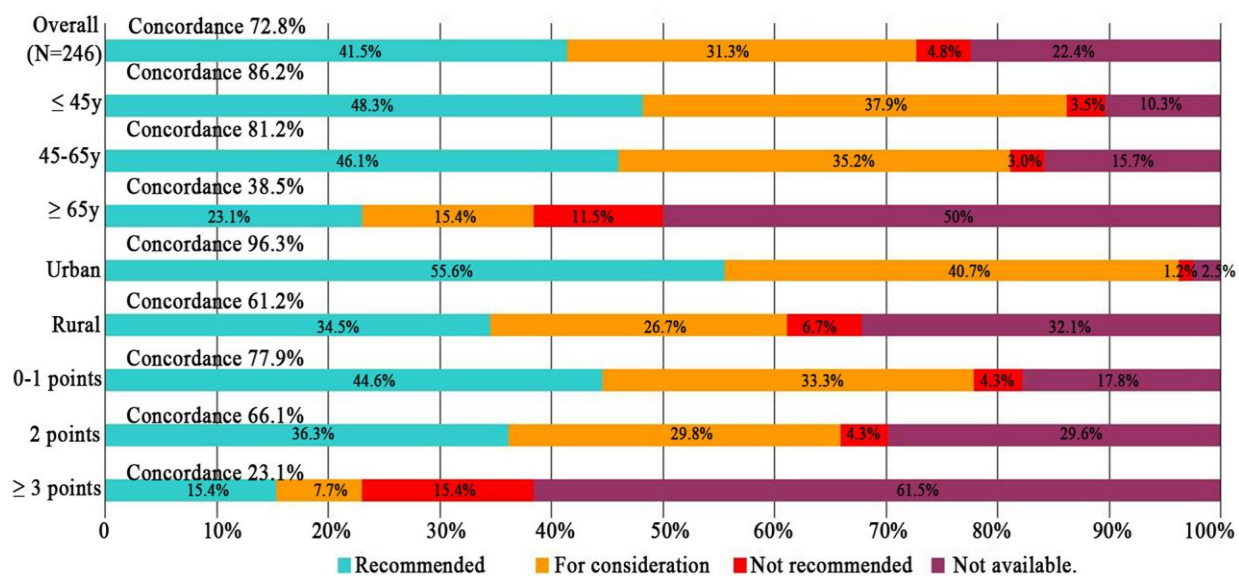
## Figures and figure legends



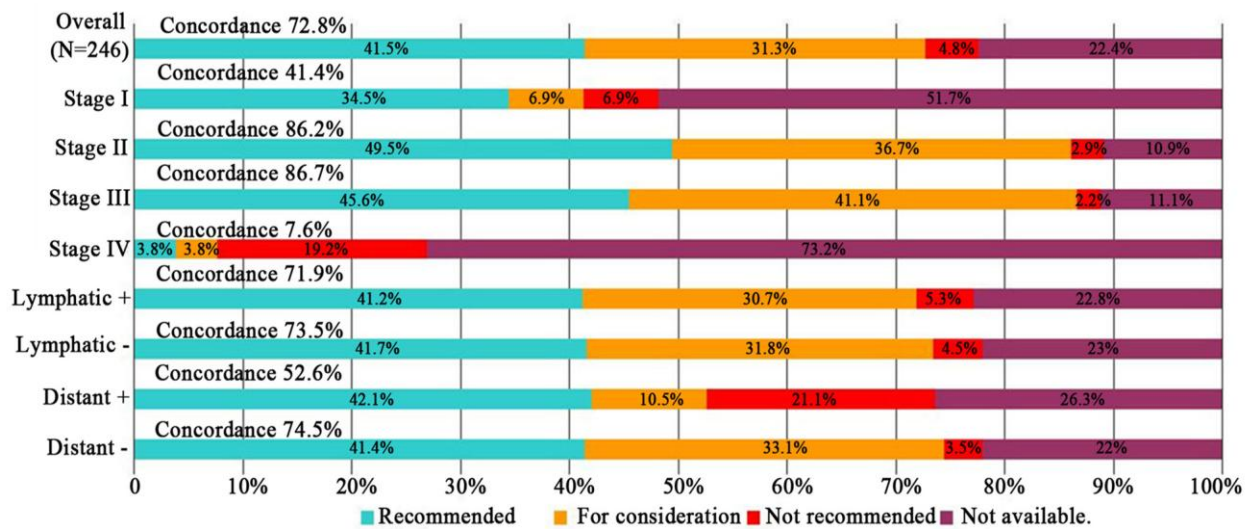
**Figure 1.** CONSORT diagram. WFO, Watson for Oncology.



**Figure 2.** Flow diagram of the study design. WFO, Watson for Oncology.

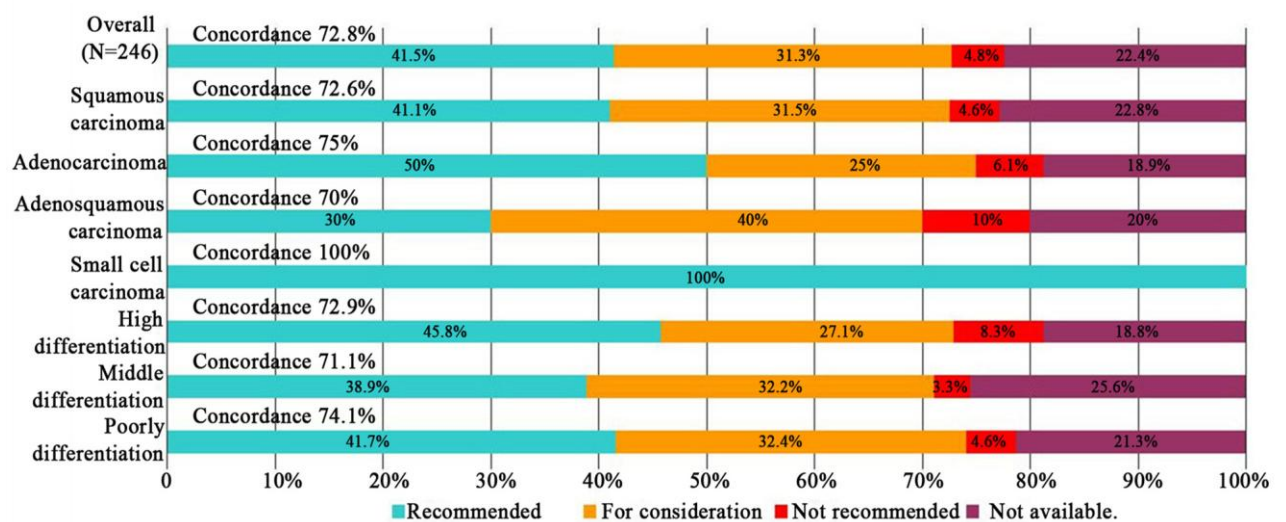


**Figure 3.** Treatment concordance between WFO and real clinical practice, divided by age, registered residence, and ECOG performance status.  
WFO, Watson for Oncology.



**Figure 4.** Treatment concordance between WFO and real clinical practice, divided by FIGO stage, lymphatic and distant metastasis.  
WFO, Watson for Oncology.





**Figure 5.** Treatment concordance between WFO and real clinical practice, divided by pathological types and differentiation degrees.  
WFO, Watson for Oncology.