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Research Article

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A Comparative Study Between the Simplified Reid's Colposcopic Index and the Swede Score in Early Detection of Cervical Intraepithelial Neoplasia

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Abstract

Objective: The comparative study between the simplified reid's colposcopic index (Simplified RCI) and the swede score in early detection of cervical intraepithelial neoplasia and correlation of the findings with the histopathology reports.

Methods: In the present prospective study, 6390 women were screened by pap and VIA. Cytology and/or VIA positive women were taken for colposcopy. Colposcopic findings of 147 women were scored by Simplified RCI and Swede score; and compared. Reports and findings were correlated with histopathology reports. Data was compiled and exported in SPSS V20 for Windows for statistical analysis.

Results: In this study, at cutoff of 3 for Simplified RCI sensitivity 100%, specificity 69.70%, PPV 80.40%, and NPV 100% with accuracy of 86.49% were calculated. At cutoff of 4 for Swede score sensitivity 97.60%, specificity 60.60%, PPV 75.50%, and NPV 95.20% with accuracy of 81.08% were calculated. Simplified RCI and Swede score had good correlation with the correlation coefficient (r) 0.983; P<0.0001. AUC of ROC of both tests showed excellent performance with 0.937 for Simplified RCI and 0.936 for Swede score.

Conclusions: Simplified RCI was easier to document and to recall, which makes follow up easier. Simplified RCI scoring system is based on lesion findings of each quadrant separately, so severity of lesion not affected by size.

Keywords: Cervical screening, Colposcopy, Simplified RCI, Swede score.

Introduction

Cervical cancer is an important public health problem in the world as well as in India. Among the women worldwide, cervical cancer is the fourth most common cancer. In 2018, around 5,70,000 women were diagnosed with cervical cancer worldwide representing 6.6% of all female cancers and approximately 3,11,000 women died from the disease [1]. In India cervical cancer is third most common cancer in women of India. In 2018, around 96,922 women were diagnosed with cervical cancer in India and 60,078 women died because of cervical cancer [2]. Cervical cancer most commonly caused by infection with human papillomavirus (HPV). HPV infection is very common, and many of people who are sexually active will get this infection in their lifetime. HPV infection is usually asymptomatic infection. Many of HPV infections get cured on their own. Persistent high-risk HPV infection for a long time can cause more severe ("high grade") changes in cervical cells. These high-grade changes are more likely to lead to cervical cancer [3].

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During long precancerous stage of cervical cancer, various screening modalities can be used for early diagnosis of high grade changes of cervix. This fact has made cervical cancer screening successful. Because of various screening modalities such as Pap smear, visual inspection with acetic acid, visual inspection with Lugol's iodine, and HPV DNA (deoxyribonucleic acid) testing, cervical cancer can be prevented. Diagnosis of preinvasive cervical lesion confirmed by cervical biopsy. To guide the cervical biopsy colposcopy had been very useful. Colposcopy was invented by Dr. Hans Hinselmann in Altona, Germany, in 1925. The Reid's Colposcopic Index (RCI) was proposed by Reid and Scalzi to make colposcopic diagnosis less subjective, currently RCI is the most accepted scoring system [4, 5]. In Simplified reid‘s colposcopic index (Simplified RCI) interpretation, documentation and follow up becomes easy as it simplifies the colposcopic picture of cervix in a simple equation. In this method, cervix was divided into four quadrants, each quadrant was scored and documented in an equation style; examination was done in a clockwise direction starting from the right upper quadrant [6]. In 2005, by recognizing the correlation of size of the lesion with likelihood of harboring high-grade disease, a new scoring system known as the Swede score has been devised by Strander et al. This scoring system also incorporates lesion size as a variable in addition to the various parameters of RCI [7]. In the present study, comparison between two colposcopy scoring methods, Simplified RCI and Swede score was done for early detection of cervical intraepithelial neoplasia, then the findings and results of both the colposcopic scoring methods correlated with the histopathology reports of cervical biopsy.

Material and Methods

After approval by Institutional ethics committee NSCB medical college, the present prospective study was conducted in Department of obstetrics and gynaecology, NSCB medical College & Hospital, Jabalpur from 1st February 2019 to 31st July 2020 Sample size was estimated using following simple random sampling formula for infinite population

$$n = z^2pq/l^2$$

Where, n=required minimum sample size

z= 1.96 at 95% confidence interval, 5% alpha (type 1 error) and 80% power

p= probability of sensitivity of Simplified RCI which was considered 90% based on literature pertaining with 5% precision (marginal error) i.e., 90 ± 5(85-95%) [6,8,9].

q= 1-p

l= marginal error which was considered 5%.

Therefore, the estimated sample size was 140.

Inclusion Criteria: Age 25-65 years; Pap smear showing ASCUS or worse (cytology positive); VIA or VILI positive; Persistent inflammatory smears; Unhealthy looking cervix; Persistent discharge per vaginum; Postcoital bleeding; Persistent inadequate smear; HPV test positive.

Exclusion Criteria: Obvious growth; Previous procedure on cervix, e.g., excisional biopsy, cryotherapy, and conization; Pregnant women and puerperium; Severe debilitating disease; Inadequate colposcopy; Unmarried women; Bleeding at the time of examination.

Methodology: All women of age 25-65 years visiting gynaecology outpatient department of N.S.C.B. medical college, Jabalpur with inclusion criteria were screened by pap smear and VIA. Written consents were taken after explaining advantages and steps of examination and need for the biopsy and follow up. Women (for pap smear and VIA) were taken for examination. First, a naked eye examination was done, after that examination of cervix and vagina was done. A cusco‘s speculum was applied according to the parity. Pap smear was taken and fixed with 95% ethanol, then slide was sent to pathology department. Then freshly prepared 5% glacial acetic acid solution was applied on the ectocervix for 1 minute.

VIA is interpreted as **POSITIVE-** When there is visualization of the dense aceto-white lesion with sharp margins, located in the transformation zone, close to squamo-columnar junction. **NEGATIVE-** When no aceto-white lesions were observed on the cervix , polyp protruding from cervix , bluish white in color, nabothian cysts which appear as button like areas as whitish area or pimples, areas present in the endocervix which were grape–like columnar epithelium staining with acetic acid, if there were shinny pinkish white , cloudy white or bluish white , faint patchy or doubtful lesions with ill-defined , indefinite margins or irregular , aceto-white lesions resembling geographical lesions away from the squamo-columnar junction. **INCONCLUSIVE-** When no distinct aceto-white lesion or somewhat doubtful lesions or when the cervix could not be adequately assessed [10]. Among these women, those with inclusion criteria were subjected to colposcopic examination (by Karl Kaps Germany Colposcope). Women was taken on colposcopy examination chair, a self-retaining cusco‘s speculum was applied, cervix was cleaned with normal saline swab and examined under magnification and green filter then findings noted. Freshly prepared 5% glacial acetic acid solution was applied on the ectocervix for one minute, findings were noted in proforma, then lugol‘s iodine applied on cervix . As per IFCPC 2011 classification normal and abnormal findings were noted and scoring was done as per Simplified RCI and swede score.

In cases where the Simplified RCI score was 0-2 and swede score was 0-3, initially we had taken biopsy but

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reports were suggestive of chronic cervicitis, subclinical papilloma infection or squamous metaplasia, so biopsy was not done in other cases with RCI <3 and Swede score <4, due to ethical reasons as histopathology reports were showing sub-clinical infection in present study and also in previous research [6]. If the RCI score of quadrants in Simplified RCI was ≥3 and in swede score was ≥4, then colposcopy guided biopsies were taken with "Baby Tischler Forceps". The tissue was immediately transferred to a vial containing 10% formaldehyde and sent for histopathological examination in Department of pathology, NSCB medical college, Jabalpur (M.P.). Pressure applied at the site of biopsy to control the bleeding. Women were counselled for follow-up and genital hygiene. They were reviewed with cytology and histopathology reports (HPR) after 2 weeks. Colposcopy and histopathology reports were compared and further management was done according to guideline for CIN, CIS and stage-1 cervical cancer.

Data collection and statistical analysis plan: All the records were recorded by using case proforma and entered in Microsoft Excel Sheet. After validation, checking for error, coding and decoding, the data was compiled and exported in SPSS V20 for Windows for statistical analysis. Categorical variables were tabulated in frequency and percentage and continuous variables were summarized and presented mean ± SD. Categorical variables were analyzed using chi square and/or Fisher exact test as appropriate. Diagnostic performance of Simplified RCI and Swede's scores was analyzed using sensitivity, specificity, positive and negative predictive values, accuracy analysis methods. ROC analysis was also performed to calculate the area under curve (AUC) and sensitivity and specificity at various cutoff values. Pearson's correlation coefficient was calculated to test the association of Simplified RCI and Swede's score. The critical value for statistical significance (type I error or alpha) was considered at 0.05 or less.

Results and Observations

A total of 147 women referred to colposcopy were recruited in this study. Many women came with multiple complains, 110 women had white discharge, 88 women had pain in lower abdomen, 28 women had irregular menses, 19 women had itching at private part, 10 women had post coital bleeding, 7 women had pruritis and 4 women had swelling at private part. Out of 147 women majority 61.2% (90) had unhealthy cervix, 21.1% (31) had cervical hypertrophy, 11.6% (17) had ectropion and other 11.6% (17) had nabothian cyst.

Women recruited for colposcopy either were cytology positive by pap smear or VIA positive. ASCUS or worst cytology was reported in 120 women, out of which 24 lost for follow up and 96 taken for colposcopy. 98 women were VIA positive, out of which 20 lost for follow up and 78 taken

Table 1: Basic characteristics

Characteristics	Findings (%)	
Age in years		
25-34	26 (17.7)	
35-44	72 (49)	
45-54	35 (23.8)	
≥55	14 (9.5)	
Mean age	41.84	
Type of family		
Nuclear	101 (68.7)	
Joint	46 (31.3)	
Education	**Wife**	**Husband**
Illiterate	59 (40.1)	27 (18.4)
Primary	40 (27.2)	28 (19)
Middle	31 (21.1)	41 (27.9)
Secondary	5 (3.4)	35 (23.8)
Graduate	8 (5.4)	10 (6.8)
Postgraduate	4 (2.7)	6 (4.1)
Occupation		
Daily wage worker	41 (27.9)	60 (40.8)
Farmer	29 (19.7)	48 (32.7)
Service	7 (4.8)	26 (17.7)
Business	---------	12 (8.2)
Housewife	70 (47.6)	---------
Others	----------	1 (0.7)
Marital life in years		
<5	2 (1.4)	
05-Oct	11 (7.5)	
Nov-20	46 (31.3)	
21-30	61 (41.5)	
≥31	27 (18.4)	
Parity		
≤1	12 (8.2)	
2	39 (26.5)	
3	40 (27.2)	
4	34 (23.1)	
≥5	22 (15)	

for colposcopy. Among these, 25 women were positive for cytology as well as for VIA. Total 149 colposcopy were done and 147 were included in study as other 2 were inadequate.

Table 2: Distribution of Women According to Simplified RCI (SRCI) Score

SRCI Score	Frequency (N)	Percentage (%)
0-2	89	60.5
03-Apr	21	14.3
05-Aug	37	25.2
Total	**147**	**100**

Table 3: Distribution of Women According to Swede Score

Swede Score	Frequency (N)	Percentage (%)
0-4	100	68
05-Jun	22	15
07-Oct	25	17
Total	**147**	**100**

Distribution of women according to cervical biopsy report. Cervical biopsy was not taken of 63 (42.9%) women. 33 (22.4%) women had cervicitis, 25 (17%) women had CIN1, and 13 (8.8%) women had CIN2. CIN3, CIS and SCC each was reported in 1 (0.7%) cervical biopsy report. We had no records of biopsy report of 10 (6.8%) women because of loss of follow up (patient didn't submitted cervical biopsy).

Table 4: Biopsy Vs SRCI (Coded in Binary as Negative or Benign and Positive or Preinvasive cervical lesion).

Biopsy	SRCI		Total
	Positive	Negative	
Positive	41	0	41
Negative	10	23	33
Total	51	23	74

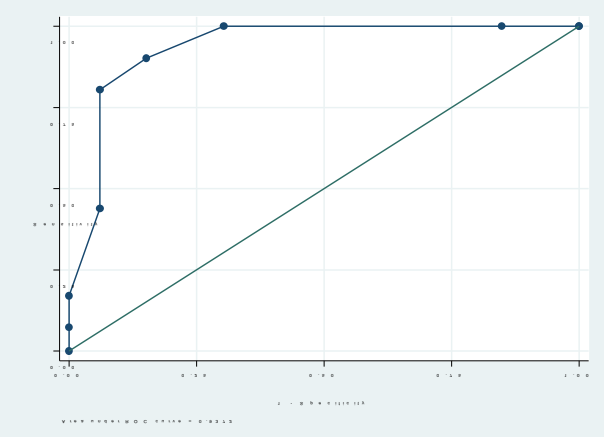
Table No.4 depicts that 41 women had pre-invasive cervical lesion of cervical cancer in cervical biopsy report and all had SRCI score ≥3. 33 women was negative for pre-invasive lesion for cervical cancer in cervical biopsy, out of those 10 was having SRCI score ≥3 and 23 had SRCI score 0-2.

Table no. 5 revealed that Simplified RCI score was highly sensitive (100%) and less specific (69.7%). It had accurately diagnosed the pre-invasive cervical lesions for cervical cancer in 86.49% women. As per ROC analysis Simplified RCI score can predict pre-invasive cervical lesions for cervical cancer at 85% accuracy (AUC= 0.85; 95%CI= 0.77-0.93).

Table no. 7 depicts that 41 women had pre-invasive cervical lesion of cervical cancer in cervical biopsy report, out

Table 5: Diagnostic Performance of Simplified RCI Score (Compared with Cervical Biopsy as Gold Standard)

Diagnostic performance		95% CI	
		Lower	Upper
Sensitivity	100.00%	91.40%	100.00%
Specificity	69.70%	51.30%	84.40%
ROC area under curve	0.85	0.77	0.93
Positive predictive value	80.40%	66.90%	90.20%
Negative predictive value	100.00%	85.20%	100.00%
Accuracy	86.49%	76.55%	93.32%



Graph 1: ROC analysis to predict the malignancy using SRCI score where Biopsy considered as gold standard

Table 6: Sensitivity and Specificity of Simplified RCI Score at Various Cut off Points

Cutpoint	Sensitivity	Specificity	Correctly Classified	LR+	LR-
(>=1)	100.00%	0.00%	55.41%	1	
(>=2)	100.00%	15.15%	62.16%	1.1786	0
(>=3)	100.00%	69.70%	86.49%	3.3	0
(>=4)	90.24%	84.85%	87.84%	5.9561	0.115
(>=5)	80.49%	93.94%	86.49%	13.2805	0.2077
(>=6)	43.90%	93.94%	66.22%	7.2439	0.5972
(>=7)	17.07%	100.00%	54.05%		0.8293
(>=8)	7.32%	100.00%	48.65%		0.9268
(> 8)	0.00%	100.00%	44.59%		1

AUC	SE	95% CI	
		Lower	Upper
0.9372	0.031	0.8765	0.9978

Table 7: Biopsy Vs Swede (Coded in Binary as Negative or Benign and Positive or Preinvasive cervical lesion)

Biopsy	SWEDE		Total
	Positive	Negative	
Positive	40	1	41
Negative	13	20	33
Total	53	21	74

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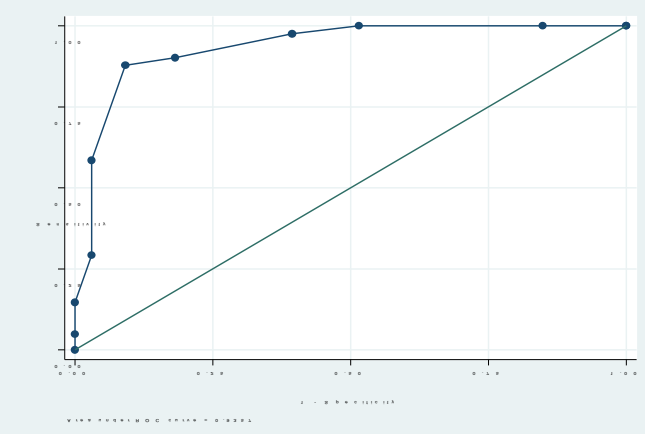
Table 8: Diagnostic Performance of Swede Score (Compared with Cervical Biopsy as Gold Standard)

Diagnostic performance		95% CI	
		Lower	Upper
Sensitivity	97.60%	87.10%	99.90%
Specificity	60.60%	42.10%	77.10%
ROC Area under curve	0.79	0.7	0.88
Positive predictive value	75.50%	61.70%	86.20%
Negative predictive value	95.20%	76.20%	99.90%
Accuracy	81.08%	70.30%	89.25%



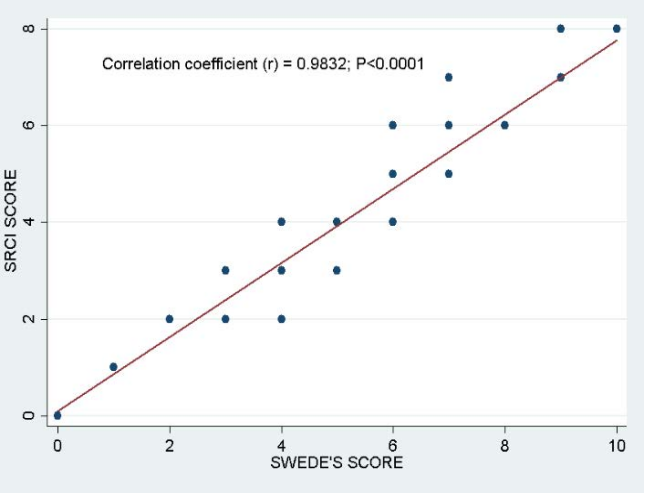
Graph 2: ROC analysis to predict the malignancy using SWEDE score where Biopsy considered as gold standard

Table 9: Sensitivity and Specificity of Swede Score at Various Cut off Points

Cutpoint	Sensitivity	Specificity	Correctly Classified	LR+	LR-
(>=1)	100.00%	0.00%	55.41%	1	
(>=2)	100.00%	15.15%	62.16%	1.1786	0
(>=3)	100.00%	48.48%	77.03%	1.9412	0
(>=4)	97.56%	60.61%	81.08%	2.4765	0.0402
(>=5)	90.24%	81.82%	86.49%	4.9634	0.1192
(>=6)	87.80%	90.91%	89.19%	9.6585	0.1341
(>=7)	58.54%	96.97%	75.68%	19.3171	0.4276
(>=8)	29.27%	96.97%	59.46%	9.6585	0.7294
(>=9)	14.63%	100.00%	52.70%		0.8537
(>=10)	4.88%	100.00%	47.30%		0.9512
(>10)	0.00%	100.00%	44.59%		1

AUC	SE	95% CI	
		Lower	Upper
0.9357	0.0294	0.8781	0.9933

of these 40 had Swede score ≥4, and 1 had Swede score 0-3. 33 women were negative for pre-invasive lesion for cervical cancer in cervical biopsy, out of these 13 were having Swede score ≥4 and 21 had Swede score 0-3.



Graph 3: Scatter plot with linear fit line showing correlation of SRCI score and Swede score (Correlation coefficient (r) = 0.9832; P<0.0001).

Table no. 8 revealed that Swede score was highly sensitive (97.6%) and less specific (60.6%). Swede score had accurately diagnosed the pre-invasive cervical lesions for cervical cancer in 81.08% women. As per ROC analysis Swede score can predict pre-invasive cervical lesions for cervical cancer at 79% accuracy (AUC= 0.79; 95% CI= 0.7-0.88).

Distribution of women according to management of lesions. 97 (66%) women with normal colposcopic findings and normal/cervicitis findings in biopsy, managed conservatively or by medical management. Cryosurgery was done of 13 (8.8%) women, LEEP was done of 3 (2%) women, surgeries like TAH (total abdominal hysterectomy), VH (vaginal hysterectomy) and fothergill was done of 7 (4.8%) women, and 7 (4.8%) women with CIN in biopsy report managed conservatively. 20 (13.6%) women lost for follow up.

Discussion

Age wise

In present study, 49% women were from age group 35-44 years and 23.8% women were from 45-54 years, so in total majority of women i.e., 72.8% from the age group 35-54 years. Mean age in study was 41.84 ± 8.19 years, and range of age was 25-65 years. In study by C. Suwanthananon and P. Inthasorn [11] (2020) mean age was 40.65 years, in other study by S. Kushwah and B. Kushwah [8] (2017) women

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of age group 30-59 with mean age 40.05 ± 7.84 years were included and in study by Renu Ranga et al [9] (2017) 150 women of age group 30-59 years were included.

Presenting complains

In present study, main indication for colposcopy were VIA positive findings and/or Cytology positive report of women. Total 147 colposcopy done, in which 94 (63.95%) women were cytology positive and 78 (53.06%) women were VIA positive. While 25 (17%) women were cytology positive as well as was VIA positive. Among these women, there were women with presenting complain of white discharge (74.8%), pain in lower abdomen (59.9%), burning micturition (31.3%), irregular bleeding (19%), itching (12.9%) at private part, and post coital bleeding (6.8%). In study by S. Kushwah and B. Kushwah [8] (2017) main indication for colposcopy was abnormal pap smear; 65 (81.25%) women had abnormal pap smear reports (≥ASCUS). Persistent discharge, postcoital bleeding, and unhealthy cervix were other indications in 6 (7.5%), 2 (2.5%), and 7 (8.75%) women respectively.

In study by Ranga et al [9] (2017) main indication for colposcopy was abnormal pap smear (ASCUS or worse cytology) in 119 (79.3%) cases. Persistent discharge, postcoital bleeding and unhealthy cervix were other indications in 14 (9.3%), 6 (4%), and 11(7.4%) cases respectively. In study by Pimple et al [13] (2010) used VIA as screening test and referred all VIA positive patients for colposcopy.

Cervical findings on per speculum examination

Out of 147 women included in present study 90 (61.2%) had unhealthy cervix, 57 (38.8%) had normal appearing cervix, 31 (21.1%) had cervical hypertrophy, 17 (11.6%) had ectropion, and 17 (11.6%) had nabothian cyst. In study by Shaki et al [14] (2018) out of 1100 women screened on speculum examination of the cervix, 17.1% women had normal looking cervix, 56% had discharge mostly asymptomatic, 11% had unhealthy looking cervix, 15% had cervical erosion, and 2% had ectropion.

SRCI and Swede score

Evaluating cervical lesions through colposcopy is operator dependent. Thus, colposcopic scoring system helps personnel to be more accurate and less subjective [9]. The RCI score and Swede score both are acceptable for cervical lesions evaluation. Though, the RCI is the more widely acceptable system [9]. The Swede score is scoring system in colposcopy, with the same score values (0,1,2) as the RCI but with the addition of fifth variable lesion size. While in Simplified RCI score had same scoring as per RCI but evaluate whole cervix as four quadrants in clockwise manner starting from RU quadrant and findings also noted down in formula form, this makes documentation and follow up easier. The present study showed that SRCI and Swede score had good correlation with the correlation coefficient (r) 0.983; P<0.0001. Both Simplified RCI and Swede score had good performance. AUC of ROC of both tests showed excellent performance with 0.937 for Simplified RCI and 0.936 for Swede score. We could use both systems to evaluate the cervical lesions.

In the present study, the Simplified RCI performed well in terms of both sensitivity and specificity, though Swede score is also very much comparable and acceptable. At cutoff of 3, sensitivity, specificity, PPV, and NPV of Simplified RCI were 100%, 69.7%, 80.4%, and 100% respectively with accuracy of 86.49%; and at cutoff of 4, sensitivity and specificity were 90.24% and 84.85% respectively with accuracy of 87.84%. At cutoff of 4, sensitivity, specificity, PPV, and NPV of Swede score were 97.6%, 60.6%, 75.5%, and 95.2% respectively with accuracy of 81.08%; and at cutoff of 6, sensitivity and specificity were 87.8% and 90.91% respectively with accuracy of 89.19%. In a study by C. Suwanthananon and P. Inthasorn [11] (2020) correlation coefficient between RCI and Swede score was 0.986; and in present study correlation coefficient between SRCI and Swede score was 0.983. In the similar comparative study between RCI and Swede score by Ranga et al[9] (2017) strength of correlation between RCI and Swede score was 0.937 with correlation coefficient 0.919.

In study by C. Suwanthananon and P. Inthasorn [11] (2020) sensitivity, specificity, PPV, NPV, and accuracy of RCI score were 83.7%, 89.7%, 75%, 93.7% and 88.1% respectively at cutoff 5. In same study sensitivity, specificity, PPV, NPV, and accuracy of Swede score were 88.4%, 87.1%, 71.7%, 95.3% and 87.4% respectively at cutoff 5. According to this study both the RCI and Swede scoring systems performed well and had good correlation, but this study recommends using Swede score instead of RCI due to its simplifier. In study by S. Kushwah and B. Kushwah [12] (2017) sensitivity, specificity, PPV, and NPV of RCI score were 94.44%, 91.48%, 80.95% and 97.73% respectively at cutoff 5. In same study sensitivity, specificity, PPV, and NPV of Swede score were 100%, 91.3%, 82.6% and 100% respectively at cutoff 5. This study concluded that both the scores RCI and Swede score performed well and from study, it is evident that Swede score of 8 or more has 100% specificity and can be used for performing direct excisional procedure as a “see and treat” method at this cutoff.

In the study by Ranga et al [9] (2017) sensitivity, specificity, PPV, and NPV of RCI score were 96.97%, 95.35%, 88.89%, and 98.8% respectively at cutoff 5; comparable to sensitivity (80.49%) and specificity (93.94%) of SRCI at cutoff 5 in present study. In the same study by Ranga et al [9] sensitivity, specificity, PPV, and NPV of Swede score were 100%, 88.37%, 76.74%, and 100% respectively at cutoff 5; comparable to sensitivity (90.24%) and specificity (81.82%) of Swede score at cutoff 5 in present study. According to

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study by Ranga et al [9], RCI is better than Swede though Swede score demonstrated a flexibility of usage that allows for variable usage.

Conclusions

Simplified RCI performed well in terms of both sensitivity (100%) and specificity (70%). In Swede score there is a possibility that lesion size could affect the total score and grade of cervical lesion. In the present study, it was found that Simplified RCI was easier to document and to recall the colposcopic findings of particular case with formula, which makes follow up easier as compared to Swede score. In Swede score the criterion of size of lesion is measured in millimeters, which is difficult in clinical practice and is extrapolated as number of quadrants. In contrast to this Simplified RCI scoring system is based on lesion findings of each quadrant separately, thus making its use more user friendly.

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