International Journal of Community Medicine and Public Health
Katz LMC et al. Int J Community Med Public Health. 2024 Jul;11(7):2895-2900
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20241854

Short Communication

Validation of the colposcopic report for screening intraepithelial lesions and cervical cancer

Leticia M. C. Katz[1]*, Ana L. R. de Vasconcelos[1], Sydia R. de A. Oliveira[1], Júlio C. P. Resende[2], Andre L. Carvalho[3]

[1]Department of Public Health, Aggeu Magalhães Institute/ Fiocruz, Recife, Pernambuco, Brazil
[2]Barretos Cancer Hospital, São Paulo, Brazil
[3]International Agency for Research on Cancer, Lyon, France

Received: 11 May 2024
Revised: 13 June 2024
Accepted: 14 June 2024

***Correspondence:**
Dr. Leticia M. C. Katz,
E-mail: leticiackatz@gmail.com

ABSTRACT

For optimal cervical cancer care pathway, effective communication among colposcopist professionals regarding colposcopic findings, diagnosis, and treatment of intraepithelial lesions is crucial; standardization of the colposcopic report may serve as a beneficial strategy for this purpose. Elaborate and validate the colposcopic report for screening intraepithelial lesions and cervical cancer using a committee of specialists. This validation study used the item-level content validity index (I-CVI) to verify the agreement of judges per item, and the scale-level content validity index (S-CVI) to determine the mean of the proportion of items classified as "no disagreement"; items with an I-CVI≥0.80 and S-CVI≥0.90 were considered approved. The binomial test was used to select the items that should be revised based on the p value of the proportion (rejecting the H0 if p≤0.8); statistical significance was set at p<0.05. Results: Seven judges participated in this study. The 11 items of the Colposcopic Report were validated, but items classified as “disagreement” (1, 2, 5, and 9) or “neither agree nor disagree” (3, 10, and 11) were taken to a consensus meeting. Six of the seven judges of the first stage participated in the consensus meeting. Suggestions for modifying item nine were not accepted, and item 11 underwent a slight modification. The colposcopic report was validated and achieved greater reliability, suggesting its inclusion in the cancer information system.

Keywords: Cervical squamous intraepithelial lesions, Colposcopy, Early cancer detection, Validation study, Uterine cervical neoplasms

INTRODUCTION

Colposcopy is used to screen high-grade intraepithelial lesions and cervical cancer. Reviews and meta-analysis studies compared this method with other technologies, with sensitivity ranging from 58% to 100% and specificity from 29% to 96%.[1-3] The variation observed in these measurement properties may be due to the screening method used (cytology or high-risk human papillomavirus [HPV] test), the age of the patient, and the number of biopsies performed; however, the colposcopy performance is considered high quality.[4]

The first nomenclature to describe colposcopy was proposed by Hinselmann in 1933.[5] Then, several nomenclatures were described, and the most recent was developed in 2011 by the nomenclature committee of the International Federation of Cervical Pathology and Colposcopy (IFCPC). This committee recommends that the colposcopy should be evaluated according to the adequacy of the examination, visibility of the

squamocolumnar junction, and type of transformation zone (TZ). Also, the location of the lesion (inside or outside the TZ), the definition of the lesion size, and the location of cervical lesions should be considered.[6]

Based on a retrospective study, the standardization of the interpretation of the colposcopic findings promoted by the IFCPC improved the accuracy of colposcopic diagnosis.[6] However, some findings need to be discussed to qualify the diagnosis of high-grade intraepithelial lesions, such as the staining presented by Lugol's solution.[7]

In 2021, the World Health Organization published guidelines for the screening and treating intraepithelial lesions and invasive cervical cancer; they recommended the use of the DNA of the HPV as the primary screening test instead of visual inspection with acetic acid or cytopathological examination; however, these recommendations are based on “screening, triage and, treatment” approaches. Among the definitions of good practice for diagnosing and treating cervical lesions, some prefer the "screening followed by treatment", while others prefer the "screening, triage, and treatment". In the latter approach, the decision to treat is based on a positive screening result, followed by a second positive screening test with or without a confirmed histopathological diagnosis; colposcopy stands out as essential in this approach.[8]

In Brazil, the decision to treat is usually based on the "screening, triage, and treatment" approach; however, comprehensive and uniform standardization for the Colposcopic Report is still being determined. Thus, the present study aimed to construct and validate the content of the Colposcopic Report based on the terminology proposed by the IFCPC (2011). This validation seeks to integrate the protocol for the screening of intraepithelial lesions and cervical cancer in the state of Pernambuco.

METHODS

This study was conducted to validate the content of the colposcopic report using a committee of specialists (judges). They were selected based on at least one of the following criteria: (i) having a specialist degree in cervical pathology or colposcopy, (ii) working in this specialty for at least twenty years (or both). These criteria correspond to the first two of the five proposed by Jasper (i) having skill or knowledge acquired through experience; (ii) having skill or knowledge acquired in a specialization course; (iii) approval in a specific test to identify experts; (iv) having a high classification as experts assigned by an authority; and (v) having special skills to participate in this type of study.[9] The invitation letter, informed consent form, questions related to the professional profile (judge selection criteria), and the colposcopic report proposal were sent by e-mail.

Nine specialists were invited, and seven participated in the validation, without needing to replace the loss based on Pasquali’s recommendation, which establishes a number of judges ranging from six to twenty.[10]

The colposcopic report comprises items: the macroscopic examination of the vulva and perianal region; overall assessment of colposcopy (conditions for examination); visibility of the squamocolumnar junction; TZ; abnormal colposcopic findings (location and grade 1 (minor) and grade 2 [major] findings); non-specific findings; Lugol’s solution uptake; suspicion of invasion; and colposcopy referral.[11]

The items were scored using the Likert scale11 for non-disagreement: 2 points (no disagreement or totally agree), 1 point (agree), and 0 (neither agree nor disagree), and disagreement: -1 (disagree) and -2 (strongly disagree). The judges could write down their suggestions when the item was classified as "neither agree nor disagree", "disagree", or "strongly disagree".

The scale-level content validity index (S-CVI) was used to determine the mean of the proportion of items scored as "no disagreement" (S-CVI =sum of S-CVI/AVE points [scale-level content validity index, Average Calculation Method] divided by the total number of judges). An S-CVI≥0.90 was considered approved in the validation.[12]

The item-level content validity index (I-CVI) was used to assess the degree of agreement among judges per item (i.e., the proportion of judges who scored positively or neutrally [no disagreement]). The mean proportion of "no disagreement" was calculated as the sum of "no disagreement" points divided by the total number of judges; the result was divided by the number of items. The item that obtained an I-CVI≥0.80 was considered approved in the validation. The binomial test was used to select the items that should be revised or modified based on the p-value of the proportion (rejecting the H0 if $p \leq 0.8$); statistical significance was set at $p<0.05$.[10]

To review, accept, or reject suggestions for modification on items classified as “disagreement” (1, 2, 5, and 9) or “neither agree nor disagree” (3, 10, and 11) in the first stage of this validation, a consensus meeting was held online on July 5, 2022.

Following Resolution 466/2012 of the National Health Council, this study was submitted to the research ethics committee of Hospital Agamenon Magalhães (CAAE: 63345522.8.0000.5197) and approved on 09/27/2022 (no. 1,814,698).

RESULTS

Four of the seven judges were women and all had worked as colposcopists for over twenty years.

Six of them held the title of qualification in lower genital tract pathology and colposcopy issued by the Associação Brasileira de Patologias do Trato Genital Inferior e

Colposcopia, which has the following prerequisites to take the title exam: present a medical graduation from a higher education institution approved by the Ministry of Education; complete a medical residency in gynecology and obstetrics at an official institution recognized by the Ministry of Education; having proof of an internship in pathology of the lower genital tract and colposcopy totaling 180 hours. The only judge without the qualification title in lower genital tract pathology and colposcopy met the requirements for taking the exam that granted this title, and participated in the study representing the health policy of women of the state of Pernambuco.

The mean of the proportion of items scored "no disagreement" (i.e., the S-CVI) was 0.94, evidencing that the Colposcopy Report was approved (Table 1). Also, the S-CVI/AVE values observed for 'no disagreement' were below ≥0.90 in only two out of the seven judges (judge 2=0.82 and judge 6=0.73). Table 2 shows that the mean proportion of "no disagreement" among the judges per item (I-CVI) was 0.93, which is above the acceptable validity coefficient (I-CVI≥0.80). However, item 1 was not considered approved in the validation by the I-CVI (below 0.80). Nevertheless, the binomial test demonstrated that all 11 items were validated at a significance level of ≤0.05.

Table 1: Proportion of judges not disagreeing with the items on the colposcopic report, and the respective scale content validity indices (S-CVI). Recife, Pernambuco, Brazil, 2022.

Judges	Disagreement		Not disagreement			∑n (%)	S-CVI/AVE (*)
	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Totally agree		
1			5		6	11 (100.0)	1.00
2		2	2	3	4	9 (81.8)	0.82
3			1		10	11 (100.0)	1.00
4			1		10	11 (100.0)	1.00
5				1	10	11 (100.0)	1.00
6		3			8	8 (72.7)	0.73
7				1	10	11 (100.0)	1.00
							6.55
					(**) S-CVI 6,55 ÷ 7 = 0,94		

Source: Authors; S-CVI Validity Coefficient ≥0.90; (*) S-CVI/AVE (Scale-level Contente Validity Index, Average Calculation Method); (**) S-CVI = ∑ of S-CVI/AVE points ÷ No of judges.

Table 2: Validation of the colposcopic report performed by 7 judges, and the respective content validity indices at item level (I-CVI). Recife, Pernambuco, Brazil, 2022.

Items	Not disagreement		I-CVI	P value (*)
	Total	%		
1: Macroscopic examination of the vulva and perianal region	5	71.4	0.714	0.00671 (**)
2: General evaluation of colposcopy	6	85.7	0.857	0.00805 (**)
3: Visibility of the squamocolumnar junction	7	100.0	1.000	0.00939 (**)
4: Transformation zone (TZ)	7	100.0	1.000	0.00939 (**)
5: Abnormal colposcopic findings (localization)	6	85.7	0,857	0.00805 (**)
6: Abnormal colposcopic findings Grade 1 (Minor)	7	100.0	1	0.00939 (**)
7: Abnormal colposcopic findings Grade 2 (Major)	7	100.0	1	0.00939 (**)
8: Non-specific findings	7	100.0	1	0.00939 (**)
9: Lugol's solution uptake	6	85.7	0,857	0.00805 (**)
10: Suspected invasion	7	100.0	1	0.00939 (**)
11: Colposcopy referral	7	100.0	1	0.00939 (**)
	Mean: 0.93			

Source: Authors; Validity coefficient I-CVI≥0.80; (*) Binominal test, using the p value of the proportion, rejecting H0 if p≤0.8; (**) Validated items, at significance level ≤0.05. Mean =∑ points of disagreement (=72) ÷ No of judges (=7) ÷ No of items assessed (=11).

Despite this result, the decision was made to hold a consensus meeting to present the judges with suggestions for modifying items classified as "disagreement" (1, 2, 5 and 9) or "neither agree nor disagree" (3, 10 and 11). The consensus meeting was conducted online, and six out of the seven judges from the first stage participated. Among the four items with "disagreement", only the changes suggested for item 9 were not accepted, and among the three in the neutral position, only item 11 underwent a slight modification (Table 2).

Figure 2 shows the validated Colposcopic Report.

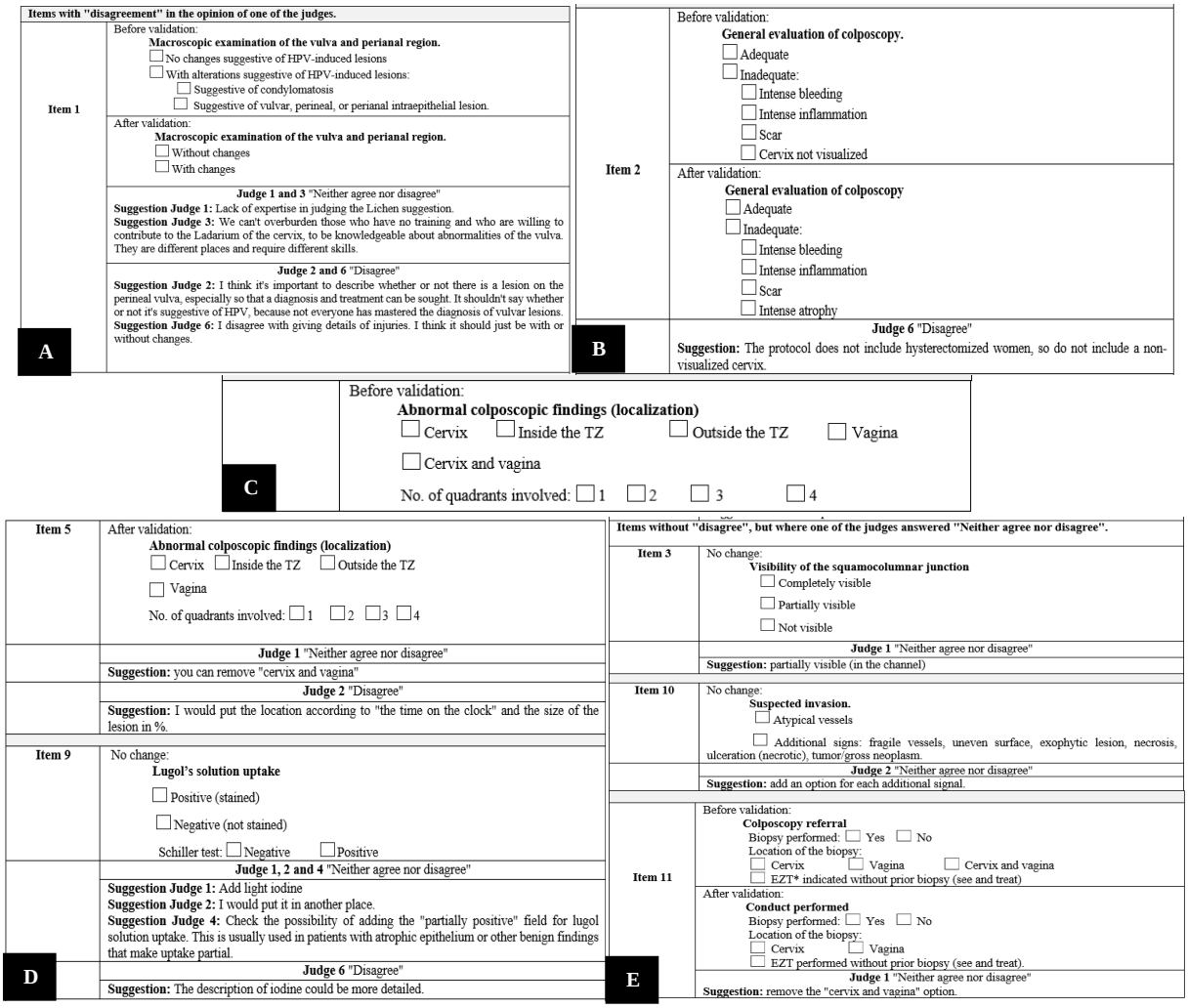

Figure 1 (A-E): Decisions from the consensus meeting (2nd stage of this validation) of the Colposcopic Report whose response from one or more judges was "neither agree nor disagree", "disagree", or "totally disagree". Recife. Pernambuco, 2022.

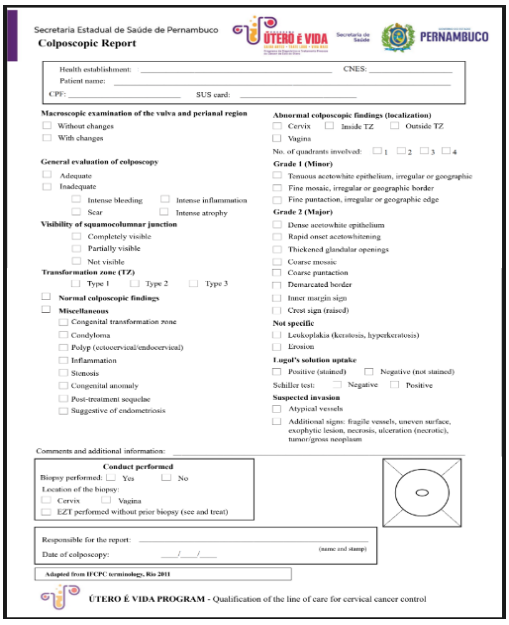

Figure 2: Colposcopic Report validated on 07/05/2022. Recife-Pernambuco-Brazil.

DISCUSSION

The validation of the colposcopic report ensured greater reliability to this tool, which will be integrated into the protocol for screening intraepithelial lesions and cervical cancer; this evaluation will be important to reduce mortality in Pernambuco. Studies have been increasingly using methodologies to develop and validate content in healthcare, either as an educational technology or to promote individualized care. For instance, we developed and validated educational booklets for self-care at home after gynecologic surgeries and for palliative care at home after hospital discharge;[13,14] and instruments for assessing self-perceived health in adults, recognizing clinical deterioration in hospitalized children, and evaluating hospital infection control programs.[15-17]

In 2019, the American Society for Colposcopy and Cervical Pathology (ASCCP) released guidelines based on high-grade lesion risk management, which was different from those previously adopted and was based on algorithms focused on outcomes18. Within this perspective, the colposcopic report evaluates abnormal findings, the type of TZ and visibility of the squamocolumnar junction, and Lugol's solution uptake, potentially providing future insights into high-grade lesion risk management and monitoring the quality of colposcopies performed.

The Brazilian guidelines for cervical cancer screening recommend using the colposcopic terminology of IFCPC (2011).[6,8,19] This recommendation has been incorporated into the colposcopy report, contributing to the standardization of this information tool that will monitor the quality of colposcopy.

Previous studies did not use a colposcopy database registered in the Unified Health System information system, and the data presente are only quantitative.[20] A national study used qualitative colposcopy data based on the terminology proposed by the IFCPC (2011); however, data were collected in a private information system.[21]

In the Cancer Information System (SISCAN), information from a colposcopic report is only described in cases that present colposcopic alterations that trigger a biopsy, as part of the "Histopathological Examination Request - Cervix", aiming to provide clinical support for the histopathological diagnosis. Even in these cases, no Colposcopic Reports were issued, limiting access to the data of these women regarding colposcopy.[17] Therefore, the Colposcopy Report must be incorporated into SISCAN to standardize data, facilitate local and inter-federative studies, provide training for healthcare professionals, and standardize the procedure. Valls et al used a protocol of colposcopy in women who had detectable high-risk HPV; the tool presented a good performance for detecting intraepithelial lesions and cervical cancer.[4]

CONCLUSION

The colposcopic report was validated and achieved greater reliability, suggesting its inclusion in the cancer information system. The standardization of the colposcopy report will allow public managers to adjust their decision-making regarding clinical management based on monitoring the quality of the service provided; the colposcopy will be a diagnostic method. For this purpose, colposcopy needs to be evaluated quantitatively and qualitatively, as do the other procedures that comprise cervical cancer care.

ACKNOWLEDGEMENTS

We are grateful to the judges who have devoted their time, knowledge, and years of extensive experience to contribute to improving communication among professionals in caring for women.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

REFERENCES

1. Mitchell M. Colposcopy for the diagnosis of squamous intraepithelial lesions: A meta-analysis. Obstetrics & Gynecology. 1998;91(4):626–31.
2. Mustafa RA, Santesso N, Khatib R, Mustafa AA, Wiercioch W, Kehar R, et al. Systematic reviews and meta-analyses of the accuracy of HPV tests, visual inspection with acetic acid, cytology, and colposcopy. Int J of Gynaecology and Obstet. 2016;132(3):259–65.
3. Qin D, Bai A, Xue P, Seery S, Wang J, Mendez MJG, et al. Colposcopic accuracy in diagnosing squamous intraepithelial lesions: a systematic review and meta-analysis of the International Federation of Cervical Pathology and Colposcopy 2011 terminology. BMC cancer. 2023;23(1):187.
4. Valls J, Baena A, Venegas G, Celis M, González M, Sosa C, et al. Performance of standardised colposcopy to detect cervical precancer and cancer for triage of women testing positive for human papillomavirus: results from the ESTAMPA multicentric screening study. Lancet Glob Health. 2023;11(3):e350–60.
5. Jordan JA. Colposcopy in the Diagnosis of Cervical Cancer and Precancer. Clin Obstet Gynaecol. 1985.;12(1):67–76.
6. Bornstein J, Bentley J, Bösze P, Girardi F, Haefner H, Menton M, et al. 2011 Colposcopic Terminology of the International Federation for Cervical Pathology and Colposcopy. Obstet & Gynecol. 2012;120(1):166–72.
7. Zhang B, Hong S, Zhang G, Rong F. Clinical application of the 2011 IFCPC colposcope terminology. BMC Women's Health. 2021;21(1).

8. WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, 2021. Available at: https://www.who.int/publications/i/item/9789240030824. Accessed 22 February 2024.
9. Jasper MA. Expert: a discussion of the implications of the concept as used in nursing. J Adv Nurs. 1994;20(4):769–76.
10. Pasquali L. Instrumentação psicológica: Fundamentos e práticas. Porto Alegre, Brasil: Artmed. 2010; 506–520.
11. Likert R. A technique for the measurement of attitudes. Archives of Psychology. 1932;22(140):1-55.
12. Lynn MR. Determination and Quantification Of Content Validity. Nurs Res. 1986;35(6):382–6.
13. Lins MLR, Evangelista CB, Gomes GLL, Macedo JQ. Home self-care after gynecological surgeries: elaboration and validation of educational material. Acta Paul Enferm. 2021;34:eAPE03154.
14. Silva FR, Pereira RA, Souza AC, Gimenes FR, Simino GP, Dessote CA, et al. Construção e validação de cartilha para cuidados paliativos domiciliares após alta hospitalar. Acta Paul Enferm. 2022;35:eAPE028112.
15. Mattos S, Moreira T, Florêncio R, Cestari V. Elaboração e validação de um instrumento para mensurar Autopercepção de Saúde em adultos. Saúde Debate. 2021;45(129):366-77.
16. Oliveira TL, Miranda JOF, Sobrinho VLN, Mendoza RF, Monaghan AP, Alencar AA. Desenvolvimento e validação de conteúdo do Escore Pediátrico de Alerta. Rev Soc Bras Enferm Ped. 2021;21(2):91-101.
17. Alvim ALS, Gazzinelli A, Couto BRGM. Construção e validação de instrumento para avaliação da qualidade dos programas de controle de infecção. Rev Gaúcha Enferm. 2021;42:e20200135.
18. Perkins RB, Guido RS, Castle PE, Chelmow D, Einstein MH, Garcia F, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines Committee. 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. J Low Genit Tract Dis. 2020;24(2):102-31.
19. Instituto Nacional de Câncer José Alencar Gomes da Silva (INCA). Coordenação de Prevenção e Vigilância. Divisão de Detecção Precoce e Apoio à Organização de Rede. Diretrizes brasileiras para o rastreamento do câncer do colo do útero. 2. ed. Rio de Janeiro: INCA; 2016. Available at: https://www.inca.gov.br/publicacoes/livros/diretrizes-brasileiras-para-o-rastreamento-do-cancer-do-colo-do-utero. Accessed 22 August 2022.
20. Instituto Nacional de Câncer José Alencar Gomes da Silva (INCA): DADOS E NÚMEROS SOBRE CÂNCER DO COLO DO ÚTERO Relatório Anual 2022 (setembro 2022). Available at: https://www.inca.gov.br/sites/ufu.sti.inca.local/files/media/document/dados_e_numeros_colo_22setembro2022.pdf. Accessed 24 February 2022.
21. Maffini CF, Collaço LM, Sebastião APM, Zanine RM. Colposcopic Findings and Diagnosis in Low-Income Brazilian Women with ASC-H pap Smear Results. Rev Bras de Ginecol Obstet 2022;44(02):178–86.

Cite this article as: Katz LCM, de Vasconcelos ALR, de A. Oliveira SR, Resende JCP, Carvalho AL. Validation of the colposcopic report for screening intraepithelial lesions and cervical cancer. Int J Community Med Public Health 2024;11:2895-900.