Study on the Protective Effect of Finger Cuff in Vaginal Palpation

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Abstract: This paper aims to study the protective effect of finger cuff in vaginal palpation. First, the introduction section introduces the definition, application of vaginal tactile examination and its problems, including patient discomfort and difficulty for medical staff to obtain sufficient information. Secondly, the risk of vaginal infection and cross-infection is described. In the definition, use and protection of the cuff, the materials, characteristics, use methods and techniques, and the protective effect of the cuff in vaginal inspection are discussed in detail. Next, an experimental study was conducted comparing the risk of infection and patient comfort in cases with and without a finger cuff. The experimental results show that the use of finger sleeves can effectively reduce the risk of infection and improve patient comfort. Finally, the conclusions section summarizes the study findings and suggests widespread application of finger sets to protect patient health and reduce the risk of infection. This study has important guidance for improving the safety and effect of vaginal tactile test.

Keywords: Vaginal Palpation; Finger Cuff; Protective Effect; Cross Infection; Vaginal Infection

1. Foreword

Vaginal palpable inspection is a common diagnostic method in gynecological medicine and is used to assess the health status of the female reproductive system. However, protecting patient safety and health becomes particularly important due to the possibility of cross-infection and other potential risks during vaginal tactile inspection. In recent years, the finger cuff, as a commonly used aid for vaginal palpation, has attracted much attention in [1].

2. Status and problems of vaginal palpation

2.1 Common problems and challenges of vaginal tactile inspection

However, vaginal palpation faces some common problems and challenges in practice. First, for patients, vaginal tactile examination may cause discomfort and pain, leading to unwillingness to accept tests or anxiety.In addition, for medical staff, multiple tactile tests may lead to fatigue and hand discomfort, reducing the accuracy and efficiency of tactile examination [2].

2.2 Risk of vaginal infection and cross-infection

In the vaginal tactile examination, there is a potential risk of vaginal infection and cross-infection. The vagina is a microecosystem in which multiple beneficial bacteria are present. However, foreign bacteria may be introduced during the tactile inspection, destroying the microecological balance of the vagina and leading to the occurrence of infection. In addition, if medical personnel repeat the same finger cuff between multiple patients, it may cause the spread of cross-infection, increasing the risk of infection [3].

3. Definition, use and protection of finger sets

3.1 Materials and characteristics of the finger sleeve

A finger cuff is a protective tool for vaginal tactile testing and is usually made of soft, sterile medical material. Common finger sleeve materials include latex, polyethylene, etc. These materials have good elasticity and moderate softness to ensure patient comfort and safety during touch inspection. In addition, the cuff should be sterile to prevent microbial

cross-infection.

3.2 Protective effect of the finger sleeve

The finger cuff plays an important protective role in the vaginal palpation examination. First, the finger cuff can effectively isolate the fingers of medical workers from the patient's vaginal tissue, reducing direct contact and thus reducing the risk of microbial cross-infection.Secondly, as an auxiliary tool of vaginal tactile test, the finger cuff can reduce the friction and stimulation of vaginal tissue by medical staff, thus reducing the degree of pain and discomfort of patients. In addition, the finger cuff can provide a physical barrier to prevent the pathogenic microorganisms of vaginal infection from entering the patient with [4].

4. Experimental study: the protective effect of the finger cuff in vaginal palpation examination

4.1 Experimental design

4.1.1 Purpose of the experiment:

The purpose of this test is to evaluate the potential of the test sample to elicit vaginal tissue irritation reactions under the test conditions.

4.1.2 Experimental materials

Sample name	Finger cuff
manufacturer	Beijing Sappho Technology Co., LTD
Model or specification	12/box
Batch processing or serial No.	N/A
Sample status	non-sterile
Physical description	solid
Manufacturing date	N/A
Shelf life or expiration date	N/A

Note: Samsample information is provided by the applicant, and detailed in the Sample Test Form

Extraction of the vehicle (control device), polarity (SC)	And 0.9% sodium chloride solution
manufacturer	SJZ No.4 Pharmaceuticals, Ltd.
write instructions or comments on No.	2211103204
Extraction vehicle (control), Nonpolar (CSO)	cso
Manulaktur	Ohno Research Institute, FDSC
write instructions or comments on No.	C-221
reagent	Freund Complete adjuvant (FCA)

4.1.3 Preparation of samples

The extraction of the test samples and the blank control group (the extraction vehicle without the test samples) is shown below. Extraction was performed while stirring. Extraction was performed at agitation (80 r/min)

group	Polar(SC)		Non-polar(CS)	
	Test	Control	Test	Control
extraction ratio	0.2 g/mL	/	0.2 g/mL	/

amount	1 g	/	1 g	/
Extract vehicle	5 mL	20 mL	5 mL	20 mL
Extraction conditions	37℃ 72 h			
Extract Status	Clear	Clear	Clear	Clear
	Particle free	Particle free	Particle free	Particle free

group	Polarity(SC)		Non-polar(CS)	
	Test	Control	Test	Control
extraction ratio	0.2 g/mL	/	0.2 g/mL	/
amount	1.5 g	/	1.5g	/
Extract vehicle	7.5 mL	20 mL	7.5 mL	20 mL
Extraction conditions	37℃ 72 h			
Extract Status	Clear	Clear	Clear	Clear
	Particle free	Particle free	Particle free	Particle free

Rationale: In the current test standards, the rabbit was recommended as a preferred animal for the vaginal irritation test

4.1.4 Feeding conditions and feeding methods

The feeding conditions of Tianjin Customs Industrial Product Safety Technology Center met the requirements of the animal use license with the number of SYXK(Jinbin)2021-0010. Growing feeds were provided to the rabbits daily. The quality of the feeds met the requirements of the animal use license. The drinking water was provided using suitable water containers. Pollution was avoided during the feeding and the water supply process, so that the test results were not affected.

4.1.5 Test personnel

The relevant testing personnel have received the relevant training and passed the assessment.

4.1.6 Animal welfare and ethics

According to the regulatory requirements, proper medical care was given to the animals during the test, and the anesthesia and analgesia of animals were provided under the guidance of veterinaries. According to the current veterinary medical practice, the animals at the humane endpoint were euthanized.

4.2 Experimental Procedures

The vaginal discharge, edema, and/or other infection, irritation and/or injury of the animals should be checked before each test procedure. During the estrus phase of the animals, the vagina should also be checked to avoid false positive reactions due to physiological changes in the vagina.

Test group: One short, flexible tube(6cm) was connected to a syringe(volume:>1mL), and then the syringe and catheter were fully filled to allow the animal to receive 1mL of the test sample. Each animal should be provided with one set of the syringe and connecting tube. The animal was secured in a restrainer to facilitate access to the vagina. Alternatively, it was bound by a restrainer and its hind limbs secured to expose the vagina, which was moistened by the CSO. Then the moistened catheter was gently inserted into the vagina, through which 1 mL of the test sample was injected with a syringe. Then, the catheter was withdrawn and disposed of appropriately. The above steps were continuously repeated for at least 5 day at an interval of 24 h. The discharge, erythema, and edema of the vaginal opening and perineum shouldbe recorded at 24 h after the initial contact and before each test procedure.

Negative control group: The sample procedures for the test group were conducted.

The animal was euthanized at 24 h after the last contact, then its vagina was completely removed and longitudinally dissected to examine the irritation, injury, and necrosis of the epithelial tissue layer. The removed vaginal tissue was placed

in an appropriate fixative for histological evaluation. Both ends and thecentral part of each vaginal tissue should be harvested. The condition of the vaginal tissue of each animalunder macroscopic observation was recorded and described, and attention should be paid to the differencesbetween the test group and the control group.

4.3 Experimental results

4.3.1 Evaluation and Data Analysis

The vaginal tissue irritation reactions were evaluated by the pathologist, and each tissue was scored using thescoring system specified in Table 1. The microscopic evaluation scores of the animals in the test group wereadded up and divided by the total number of observed animals to obtain the mean score for the test groupThe maximum score was 16.

Table 1 Microscopic Scoring System for the Vaginal Tissue Reaction

Reactions		Score
Epithelium	Normal, intact	0
	Cell degeneration or flattening	1
	Tissue deformation	2
	Local erosion	3
	Extensive erosion	4
Leukocytic infiltration	N/A	0
	Minimal(below25)	1
	Mild(26-50)	2
	Moderate(51-100)	3
	Severe(above 100)	4
Vascular congestion	N/A	0
	Minimal	1
	Mild	2
	Moderate	3
	Severe	4
Edema	N/A	0
	Minimal	1
	Mild	2
	Moderate	3
	Severe	4

Table 2 Reaction Type

Mean Score	Reaction type
0	N/A
1-4	Minimal
5-8	Mild
9-11	Moderate
12-16	Severe

4.3.2 Results

During the test, all the animals were normal.

Table 3: Observation Scores

Group	Animal No.	Score				Mean Score
		Epithelium	Leukocyte infiltration	Vascular congestion	Edema	

Test(SC)	004	0	0	0	0	0
	005	0	0	0	0	
	006	0	0	0	0	
Control (SC)	001	0	0	0	0	0
	002	0	0	0	0	
	003	0	0	0	0	
Test(SC)	004	0	0	0	0	0
	005	0	0	0	0	
	006	0	0	0	0	
Control (SC)	001	0	0	0	0	0
	002	0	0	0	0	
	003	0	0	0	0	

Appendix 1: Photos of Pathological Sections, Showing the Score of Each Animal.

4.3.3 Microbiological test report

Name of culture medium	Incubation time（days）													Test result
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	

SCDM（Soy casein digestion and culture）		-	-	-	-	-	-	-	-	-	-	-	-	-	-	Aseptic growth
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
negative control	SCDM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Aseptic growth
		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
positive control	SCDM	+	+	+	Colony count: 69 CFU / mL											Grow well
Remarks."+"express bacterial growth, “-"express aseptic growth. The positive control strain was Staphylococcus aureus ATCC 6538																

4.3.4 Experimental conclusion

The finger cuff will not produce adverse reactions in the vaginal tactile test, which reduces the risk of microbial infection and reduces the discomfort to the experimental subjects.

5. Conclusion

Through this experimental study, we found that the use of finger cuff in vaginal palpation is effective in reducing the risk of infection and improving patient comfort.As an auxiliary tool for the vaginal tactile test, the finger cuff can isolate the direct contact between the fingers of the medical staff and the vaginal tissue, reducing the possibility of cross-infection.In addition, the finger cuff can also reduce the friction and irritation of the vaginal tissue, reducing the pain and discomfort of patients. Therefore, we strongly recommend extensive application of finger cuff during vaginal palpation to protect the patient health and reduce the risk of infection.

References

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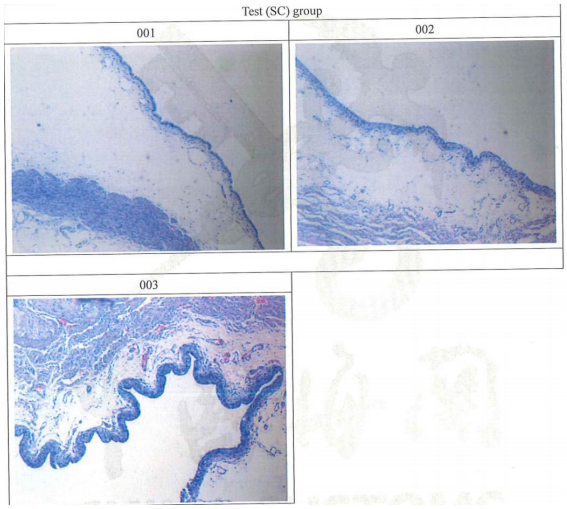
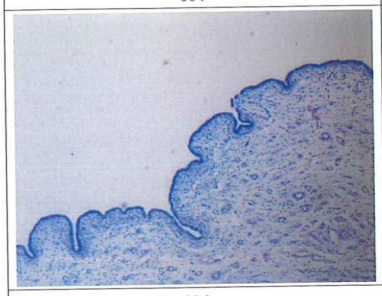
Appendix 1: Photos of Pathological Sections, Showing the Score of Each Animal.



Negative Control (SC) Group

004



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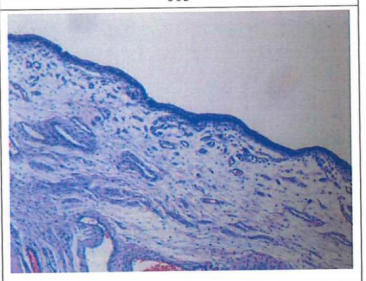

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