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Research Article

**DEVELOPING AND VALIDATING A RISK FACTORS
ASSESSMENT TOOL FOR THE PAP TEST CYTOLOGICAL
CHANGES IN IRAN: A METHODOLOGICAL STUDY****Gita Sangestani¹, Pantaleo Greco², Ali Reza Soltanian³, Mahnaz Khatiban^{4*}**¹ BSc, MSc, PhD, Mother and Child Care Research Centre, Dept. of Midwifery, School of Nursing and Midwifery, Hamadan University of Medical Sciences, Hamadan, Iran.² MD, Obstetrician and Gynecologist, Dept. of Morphology Surgery and Experimental Medicine, University of Ferrara, Ferrara, Italy.³ BSc, MSc, PhD, Dept. of Biostatistics, School of Public Health, Modeling of non-communicable diseases Research Centre, Hamadan University of medical Sciences, Hamadan, Iran.⁴ BSN, MSN, PhD, Mother and Child Care Research Centre, Dept. of Medical Surgical Nursing, School of Nursing and Midwifery, Hamadan University of Medical Sciences, Hamadan, Iran.**Abstract:**

Pap test is a lifesaving tool which can detect atypical cellular changes before the cervical cancer develops. In developing countries just 5% of women are typically screened for cervical cancer by Pap test. So having a risk factor assessment tool for the Pap test cytological changes can be very helpful in order to approach an early diagnosis and treatment by physicians, midwives and the other health care givers in face with their clients. To develop a valid and reliable risk factors assessment tool for the Pap test cytological changes towards cervical cancer. This is a methodological study. In order to identify full content domain, items generation and creation of the initial tool draft, an extensive article study was conducted. Then, the validity and reliability of the research tool were confirmed. Results of this study led to develop a valid and reliable tool entitled: "Risk factors assessment tool for the Pap test cytological changes towards cervical cancer". It has 50 items in three parts including demographic characteristic, health history and clinical manifestations. As the risk factors assessment tool for the Pap test cytological changes towards cervical cancer is valid and reliable, we strongly recommend applying this tool in facing with the patients in all clinics that are open to women about gynecological problems. It can help the professionals to have a suitable and quick action especially in those areas with limited access to the specialists.

Keywords: Risk factor, Pap test, Assessment tool, Cytological changes, Iran.**Corresponding author:****Mahnaz Khatiban,**

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INTRODUCTION:

Invasive cervical cancer is listed as the third most common cancer and the fourth leading cause of cancer death among women worldwide [1-5]. Although cervical cancer is 13%-15% of all the females' cancers globally, it accounts for 20%-30% of that in Asia and it is a major cause of death in women living in developing countries [3, 6, 7]. The disease has a very rough distribution; more than 85% of cases can be found in poor countries including sub-Saharan Africa, Central America, South-Central Asia, and Melanesia [3, 5]. However, cervical cancer remains a leading cause of morbidity and mortality in women worldwide [8, 9]. So the cervical cancer is still a serious disease for women worldwide. Particularly in those countries with rare screening and lack of high-quality treatment or unaffordable treatment, health outcomes for women with cancer are poor [10]. During the past 20 years a decline has been observed in cervical cancer incidence and deaths in the developed world but, unfortunately, there has not been a significant change in the same key indicators in developing countries [11]. In Iran, the incidence and mortality rates of cervical cancer are 2.4% and 1.6% respectively and cervical cancer was diagnosed in 4.1% of women living only in Tehran (2012), the capital city of Iran [12, 13]. Although most of the cervical cancers in the population are diagnosed with an advanced stage of the disease, there is no organized cervical screening program in Iran and some other developing countries. Generally speaking, referring to the Pap smear is not desirable in poor countries. Women undergo the Pap smear screening test by chance for example when they visit a doctor for gynecological symptoms or the other health problems. In Iran, Pap smear screening is not well covered by private or public insurance. As a result, only a small percentage of women with high socioeconomic status undergo regular screening [13-15]. In a few words, in countries with well-established screening programs, the incidence of cervical cancer has been decreased about 70-90%. Inversely, in developing countries because of low access to screening services the incidence of cervical cancer continues to exist at high levels [16]. Now it has been well established that 99.7% of cervical cancer cases are linked to persisting HPV infection, a common virus which is sexually transmitted [16-18]. The two most common high-risk subset of HPV strains are HPV-16 and -18 that are found in 60-78% of cervical squamous cell carcinomas and 72-94% of adenocarcinomas [19]. HPV vaccination against the virus types causing cervical cancer has been officially recommended for girls aged 12-17 since 2007. But it is strongly emphasized that annual screening attendance is necessary despite vaccination

because of the residual risk of becoming infected with other potentially carcinogenic HPV types not covered by the vaccine and because of the possibility of having been infected with the high-risk HPV types prior to vaccination [20-22]. Among several diagnostic methods, despite its low sensitivity, the Pap test which has introduced to the world of medicine in 1941 is one of the most successful cancer screening tests of all time. Pap test has made a dramatic decrease in invasive cervical cancer incidence and mortality rates in countries with high-quality and broad-coverage screening programs [23, 24]. Cervical cancer is less common in the Western world due to fully accessible Pap test. Studies indicate that about 54% of women with invasive cervical cancer have never been screened or have not been screened regularly before diagnosis. [2, 13, 16]. In developed countries, 75% of women are screened for cervical cancer, typically by Pap smears and more recently HPV test, compared with just 5% in developing countries [4]. Therefore we can consider Pap test as a life-saving tool which can detect changes inside the cells of the cervix before cancer develops [25]. As the necessity of conducting the present research it can be mentioned that although cytological screening has started in developing countries, the adoption of pap smear as a screening approach in the developing world has been found to be a low screening and limit progress against the burden of cervical cancer due to the lack of trained cytologists, laboratories and inefficient health systems for evaluation and follow-up of the test results [16, 26]. So in this situation, using a risk factors assessment tool for the Pap test cytological changes will help clinicians identify individuals at higher risk of cervical cancer, allowing for earlier or more frequent screening and counseling of behavioral changes to decrease the risks. It can also be used in gynecological clinics by physicians and health caregivers to face with their clients in order to approach an early diagnosis and treatment. It could also be an effective help for researchers conducting clinical or educational interventions in this area through providing a standard solution to match the case and control groups. To develop a risk factors assessment tool for the cytological changes towards cervical cancer in Pap test.

MATERIALS AND METHODS:

Study design: This is a methodological study. Methodological research is the development and evaluation of data collection instruments, scales or techniques [27].

Scale development: To identify full content domain and items generation, an extensive literature review was conducted. Some keywords including "risk

factors", "Pap smear", "HPV", "facilitators", "inhibitors" and "cervical cancer" were used to obtain the relevant articles in the Google Scholar, Pubmed, Cochrane, Embase, CINAHL, PsycINFO, Iranian biomedical journals (Iranmedex), Iranian Research Institute of Information and Documentation (IranDoc) and Iranian Scientific Information Database (SID) between 1996 and 2016. The tool items and content was developed. The initial draft of the research tool was developed as follows:

Age [28-31], Age of menarche [4], Ever having sex [32], Number of sexual Partners [28, 32, 33], Sex of partners [32], Residency [29, 31, 34], Type of housing [31], Race/ Ethnicity [28, 31], Marital Status [28, 29, 32], Education [28, 29, 31], Class Major [9, 32], Religion [4, 28], Occupational status [29, 31, 35], Income Level per year (Euro) [28, 29], Perceived financial status [29], Health Insurance [28, 29, 36], History of genital warts [28, 37], Age of the first sex [28, 32, 34], Age at the first birth [4], Taking illegal drugs [28], Lifetime history of STDs [28, 32], Smoking status [9, 35], Smoking duration and frequency [28, 34], Status of diet or nutrition [28, 38, 39], Tampon use [28], Oral contraceptives consumption [28, 34], Sexual experience [28], Protection use (condom) [28, 32, 34, 40], Pap test history [22, 26, 28-30, 32, 36, 41-43], History of HPV infection and vaccination [19, 34, 36, 37, 44], Family history of HPV infection [28, 44], Education about cancer of cervix/ Pap Smear [37], Number of deliveries [4, 34, 43], Presence of white discharge [34], Family history of cancer [4, 31, 34], Sanitary napkins/ Cloths use [34], History of abortion [34], Unprotected sex [31], Infection with Chlamydia [31], Having a sexual partner with many previous partner [31], Having a weakened immune system [31], History of Bacterial Vaginosis [33, 45], History of pelvic infection [4], Age at the first sexual intercourse [43], Alcohol drinking status [9, 35], BMI Status [35, 46, 47], Had ever heard of HPV [40], Vaginal bleeding with clots, Bleeding between periods, Bleeding after sex, Bleeding during pregnancy, Any changes in menstrual period, Persistent Vaginal discharge, unexplained weight loss, Foul-smelling vaginal discharge, Post-menopausal Bleeding, Purulent vaginal discharge, Yellowish vaginal discharge [48-50], Painful sex, Abdominal pain, Pelvic pain, Unusual fatigue, Severe headache, Low back pain, Sensation of hardness or enlargement in the uterus, Loss of appetite [2, 48, 50, 51], Contraceptive method including: Hormonal contraceptive, IUD, Condom, Pregnant at first attendance [48], Status of the cervix including: Healthy and unhealthy cervix [52], History of HIV-Positive [46], Knowledge about Pap test [16, 41], Exposure to diethylstilbestrol (DES) in uterus [38],

History of repeated curettages [38], Having partner with penile cancer [38], partner's other wife having cervical cancer [38], Low personal hygiene [38], History of trauma to the cervix [38]. Then, an expert panel including the researcher team and three specialists (Gynecologist and midwives) confirmed the assimilation of the items into usable format [53]. As a result, the items were classified in three parts: demographic characteristics, health history and clinical manifestations. Finally, the developed research tool was assessed for the validity and reliability.

Validity and reliability of the research tool: To assess the Research Tool for the face and content validity, 10 faculty members of various specialties related to the fields of Gynecology and Midwifery were asked to leave their comments about reasonableness, appropriateness, and logical sequence of items. They were also asked to add or remove any item they considered as a necessity. Moreover, the content validity was determined by the content validity rate (CVR) and content validity index (CVI). "The CVR is a statistic item that is usual in the rejection or retention of specific items" [54]. To examine the CVR, the Research Tool was given to 10 experts in the specialties related to the field of Gynecology; the answers were designed based on a three-point Likert scale consisting of: "It is necessary", "It is useful but not necessary", and "It is not necessary". Then the Research Tool's CVR was assessed; according to the Lawshe table if the item score was over 0.62, the item was considered as an appropriate and necessary one [54]. After the items have been identified for inclusion in the final form, the content validity index (CVI) is computed for the whole tool. To distinguish between CVI of the means and Waltz and Bausell's CVI, the views of 10 faculty members of related fields were used. The indexes of "Relevance", "Clarity", and "Fluency" examined the questions of the questionnaire based on four-point scale [55, 56]. The excellent Scale's CVI (S-CVI) is equal or higher than 0.90 [56]. For reliability, the internal consistency of the tool was examined by Cronbach Alpha which should be equal to or greater than 0.8 [57].

Ethics: The present research project was approved in the University of Ferrara and the Ethics Committee of the Hamadan University of Medical Sciences.

Statistics: For estimating the content validity rate (CVR) we used the following formula. $CVR = (N_e - N/2) / (N/2)$. In this formula, the N_e is the number of expert panel signifying "essential" and N is the total number of experts in panel. For item-level content validity index (I-CVI), the number of experts giving a score 3 or 4 to the relevancy of each item divided by the entire number of experts. The scale-level content

validity index (S-CVI) was calculated by the averages of the I-CVIs.

RESULTS:

In the stage of assessing the CVR, 10 items were removed or merged together and 50 items entered the second stage for the measurement of the CVI. The mean of the total CVRs was 94.39. The item-level CVIs (I-CVIs) were calculated for each item. Items with the score of over 0.78 were retained as appropriate ones. The Criteria of CVI were also calculated and the results were as follow, Relevance=94.96, Clarify=96.67 and Fluency=96.39. The Scale's CVI (S-CVI) was 96.01. There was not

any eliminated question in the CVI assessment, and all the questions had a score above 0.78. By the way, no more items were recommended by the experts to be added. The Cronbach's alpha coefficient value for assessment of the research tool's reliability was 0.96 (the total means); for the demographic part was 0.97; for the health history was 0.95; and for clinical manifestations (Sign & Symptom) was 0.97. As the final result, a tool entitled: Risk factors assessment tool for the cytological changes towards cervical cancer in the Pap test was developed (Table 1). It has 50 items in three parts: demographic characteristics, health history and clinical manifestations (signs and symptoms).

Table 1: The Risk Factors Assessment Tool for the Cytological Changes towards Cervical Cancer in Pap test

DEMOGRAPHIC CHARACTERISTICS						
1-	Age (Year):					
2-	Age of menarche (Year):					
3-	Residency:	<input type="checkbox"/> Rural	<input type="checkbox"/> Urban	<input type="checkbox"/> Other		
4-	Type of housing:	<input type="checkbox"/> Tenant	<input type="checkbox"/> Owner	<input type="checkbox"/> Other		
5-	Education:	<input type="checkbox"/> Illiterate	<input type="checkbox"/> Primary school	<input type="checkbox"/> Secondary school		
		<input type="checkbox"/> Undergraduate	<input type="checkbox"/> Postgraduate			
6-	Class Major	<input type="checkbox"/> Health- related	<input type="checkbox"/> Non health-related			
7-	Race	<input type="checkbox"/> White	<input type="checkbox"/> Black	<input type="checkbox"/> Caucasian		
8-	Ethnicity	<input type="checkbox"/> Fars	<input type="checkbox"/> Kord	<input type="checkbox"/> Tork	<input type="checkbox"/> Lor	<input type="checkbox"/> Other Please name: ...
9-	Religion	<input type="checkbox"/> Muslim	<input type="checkbox"/> Christian	<input type="checkbox"/> Catholic	<input type="checkbox"/> Jewish	<input type="checkbox"/> Other
10-	Occupational	<input type="checkbox"/> Employed	<input type="checkbox"/> Unemployed	<input type="checkbox"/> Retired		
11-	Income Level per year (Rials):					
12-	Health Insurance:	<input type="checkbox"/> None	<input type="checkbox"/> Private	<input type="checkbox"/> Publicly funded		
13-	BMI Status:	<input type="checkbox"/> Underweight	<input type="checkbox"/> Normal	<input type="checkbox"/> Overweight	<input type="checkbox"/> Obese	
HEALTH HISTORY						
14-	Smoking status:	<input type="checkbox"/> Smoker	<input type="checkbox"/> Ex-smoker	<input type="checkbox"/> Non smoker	<input type="checkbox"/> Expose to	
	If smoking	How many per day (Number): How long (Year):				
15-	Taking illegal drugs:	<input type="checkbox"/> No	<input type="checkbox"/> Yes			
16-	Alcohol drinking status	<input type="checkbox"/> Non drinker	<input type="checkbox"/> User	<input type="checkbox"/> Alcohol dependent		
17-	Marital Status:	<input type="checkbox"/> Single	<input type="checkbox"/> Married	<input type="checkbox"/> Widowed		
		<input type="checkbox"/> Divorced	<input type="checkbox"/> Dating	<input type="checkbox"/> Living with significant other		
18-	Number of vaginal Delivery:					
19-	Age at the first birth (Year):					
20-	History of abortion:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	If "yes", How many times?		
21-	Using Hormonal contraceptive	<input type="checkbox"/> Never	<input type="checkbox"/> < 5 Years	<input type="checkbox"/> > 5 Years		
22-	History of Using IUD	<input type="checkbox"/> Never	<input type="checkbox"/> < 5 Years	<input type="checkbox"/> > 5 Years		
23-	History of Using condom:	<input type="checkbox"/> Never	<input type="checkbox"/> Rarely	<input type="checkbox"/> Usually	<input type="checkbox"/> Always	
24-	Age of the first sex (Year):					
25-	Using tampons:	<input type="checkbox"/> No	<input type="checkbox"/> Yes			
26-	doing Pap test up to now	<input type="checkbox"/> Never	<input type="checkbox"/> Irregularly	<input type="checkbox"/> Regularly		
Continue.....						

27-	If irregularly or never, Why?	<input type="checkbox"/> Never heard of it	<input type="checkbox"/> It is not important	<input type="checkbox"/> It is expensive	<input type="checkbox"/> It is hard to access
28-	The current Pap test status	<input type="checkbox"/> Benign/Reactive <input type="checkbox"/> HSIL	<input type="checkbox"/> ASCUS <input type="checkbox"/> Squamous Cell Carcinoma	<input type="checkbox"/> LSIL	
29-	Having a sexual partner with many previous partner:	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
30-	Sex of partners:	<input type="checkbox"/> Men	<input type="checkbox"/> Women	<input type="checkbox"/> Both	
31-	Number of sexual Partners:				
32-	Sexual experience:	Currently involved	Not currently involved	Never had sexual intercourse	
33-	History of HPV infection: Did you get any treatment?	<input type="checkbox"/> No <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> Not known If "Yes" how many weeks ago? ...	
34-	History of Bacterial Vaginosis: Did you get any treatment?	<input type="checkbox"/> No <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> Unknown If "Yes" how many weeks ago? ...	
35-	History of Chlamydia Infection Did you get any treatment?	<input type="checkbox"/> No <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> Unknown If "Yes" how many weeks ago? ...	
36-	History of pelvic infection Did you get any treatment?	<input type="checkbox"/> No <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> Unknown If "Yes" how many weeks ago? ...	
37-	History of HPV Vaccination	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Unknown	
38-	Lifetime history of STDs	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Unknown	
39-	Family member with HPV	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Unknown	
40-	Family history of cancer:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	If "Yes" Kind of cancer: Kind of relative:	
41-	Having a weakened immune system (e.g. because of HIV/AIDS, immunosuppressant drugs or having a transplant)			<input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown
42-	Had ever heard of HPV:	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
43-	Reason for the current Pap screening test:	<input type="checkbox"/> Visit a doctor	<input type="checkbox"/> Check up		
44-	Chief complain for visiting a doctor/ midwife	<input type="checkbox"/> Pain (low Abdominal, Low back, Pelvic) Disparonia	<input type="checkbox"/> Vaginal discharge	<input type="checkbox"/> Post coital spotting	<input type="checkbox"/> AUB
45-	History of trauma to cervix (Cotter /Cryo)	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
46-	History of Curettage	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Recurrent	
CLINICAL MANIFESTATIONS					
47-	Status of the Cervix:	<input type="checkbox"/> Healthy Cervix	<input type="checkbox"/> Unhealthy cervix		
48-	If unhealthy Cervix:	<input type="checkbox"/> Chronic cervicitis <input type="checkbox"/> Erosion/ Laceration <input type="checkbox"/> Cervical Polyp <input type="checkbox"/> Hypertrophied	<input type="checkbox"/> Congestion <input type="checkbox"/> Bleeds on touch <input type="checkbox"/> Irregular Contour <input type="checkbox"/> White Plaque on Anterior lip		
49-	Existence of Signs	<input type="checkbox"/> Bleeding after sex <input type="checkbox"/> Any changes in menstrual period <input type="checkbox"/> Persistent vaginal discharge	<input type="checkbox"/> Unexplained weight loss <input type="checkbox"/> Genital warts		
50-	Existence of Symptoms	<input type="checkbox"/> Painful sex <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Pelvic pain <input type="checkbox"/> Sensation of hardness or enlargement in the uterus	<input type="checkbox"/> Unusual fatigue <input type="checkbox"/> Severe headache <input type="checkbox"/> Low back pain		

DISCUSSION:

In this study, a risk factor assessment tool for the cytological changes towards cervical cancer in Pap test was methodologically developed. Based on the studies, there are some scientific tools for cervical cancer assessment and one of them is the Pittsburgh Cervical Cancer Screening Model (PCCSM). According to Austin et al (2010) the “PCCSM is a dynamic Bayesian network consisting of 19 variables available in the laboratory information system, including patient history data, Papanicolaou test results, high-risk HPV results, procedure data, and histopathologic results” [58]. Despite being more detailed and précised, PCCSM is totally different from our tool. It is more useful in societies with well documented medical records and higher health care systems. But in the most of the developing countries, lack of medical documentation for the patients makes it useless. Moreover, vaccination against HPV and HPV test in developing countries like Iran is not pervasive now. The present tool can cover this blank part in developing countries. It also includes the clinical manifestations so it is enough complete to find those women who are at risk of cytological changes towards cervical cancer. There is already an online screening tool for cancers [59] but ours is a special tool just for cytological changes towards cervical cancer with more details. A risk scoring system for the prediction of cervical cancer at the Gynecology Clinics can be used for reducing the cost of universal screening by including only high-risk subjects to laboratory screening procedure (Pap test) in population setting [60]. The recent study confirms that having a risk assessment tool has been in view of the scientists for many years to enhance the ability of prediction for cervical cancer even before doing screening tests. It is necessary to update the risk assessment tools along with the cultural and socioeconomic changes in different communities and also along with the passage of the time. What that we did in our research. Lee and colleagues (2014) also rendered a model of risk factors for cervical cancer in the Eastern Asia, Taiwan. Although being similar to the present study, it is a cohort study focused on HPV infection and cervical cancer and there is not any assessment tool presented as well [61]. It is also emphasized that the better resource allocation and safety will be provided for women through a risk assessment model [62].

CONCLUSION:

The strength of our assessment tool is using of the studies conducted in different populations. This is a comprehensive tool as it considers the demographic characteristics, health history and clinical manifests affect cytological changes towards cervical cancer.

This tool is useable not only by midwives and physicians but also by the healthcare givers. In this tool the clinical manifestations are taken into the consideration along with the risk factors. So the assessment of the women’s health status will be more accurately.

Limitation

In this study, just English language articles have been used which can be considered as a limitation.

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