

CLINICAL TRIAL ON EFFECT OF VAGINAL DOUCHE USING *TRIPHALA HPAN HSEI*: ON PATIENT WITH *SWETA PRADARA* (LEUCORRHOEA)

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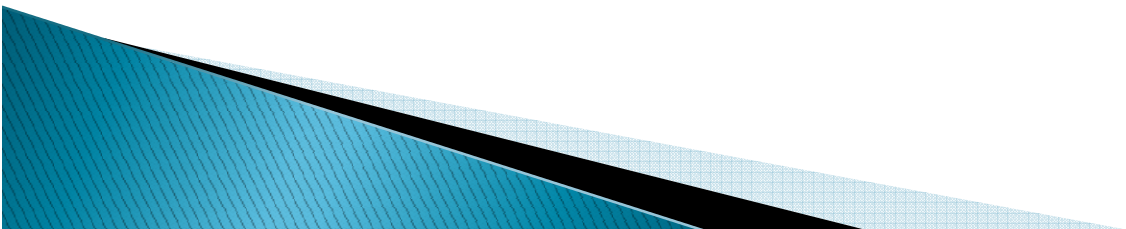
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INTRODUCTION

Sweta pradara is define as white discharge in Ayurvedic Medical Term, (*Sweta* means ‘white’ and *pradara* means ‘discharge’)

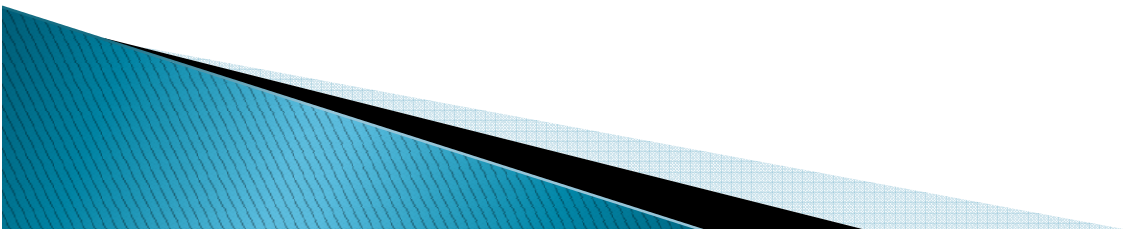
Sweta Pradara can be define as Leucorrhoea in modern medicine.

Leucorrhoea means as 'a running of white substance' and the term should be restricted to mean an excessive amount of the normal discharge, mucopurulent or frankly purulent, yellow or green, offensive

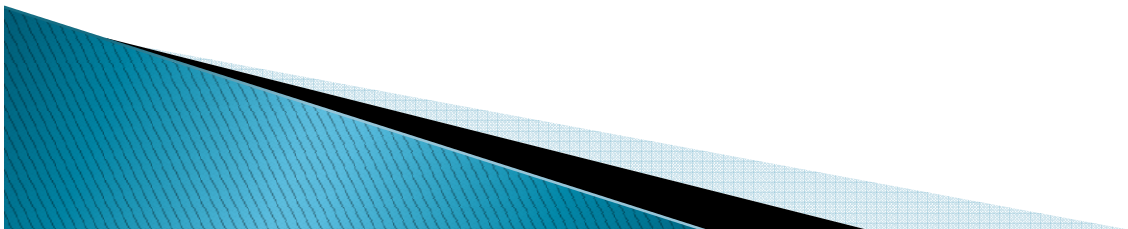


Causes of physiological discharge

- (i) oestrogen related states such as pregnancy, puberty
- (ii) cycle related states such as maximal mid-cycle,
premenstrual
- (iii) sexual excitement
- (iv) intercourse

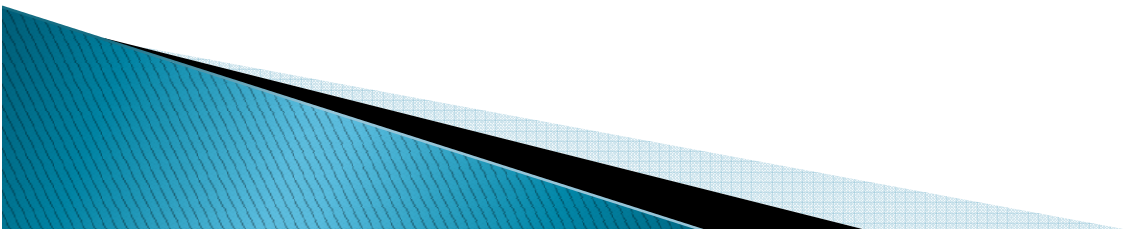


Causes of pathological discharge may be due to infection or non-infection



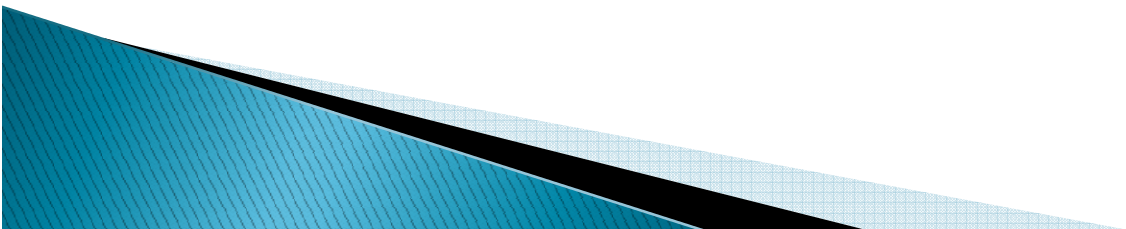
The common infections are

- (i) non-sexually transmitted infections (bacterial vaginosis, *candidiasis*)
- (ii) sexually transmitted infections (*trichomonas vaginalis*, *chlamydia*, *gonorrhoea*)



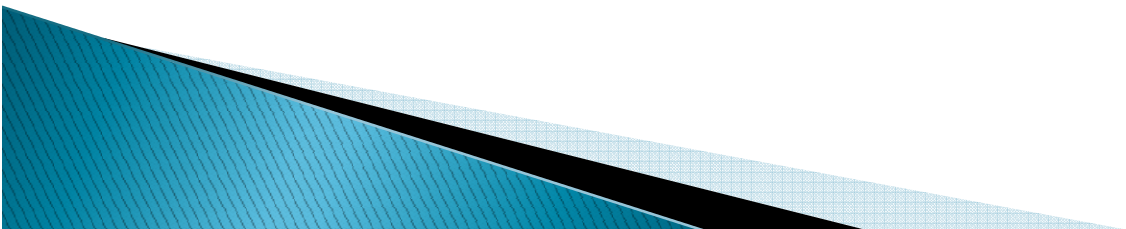
The causes of non-infection are

- (i) foreign body such as retained tampon, condom, post-partum swab
- (ii) malignancy such as any part of the genital tract
- (iii) atrophic vaginitis such as often blood-stained
- (iv) cervical ectropion or endocervical polyp
- (v) allergic reactions

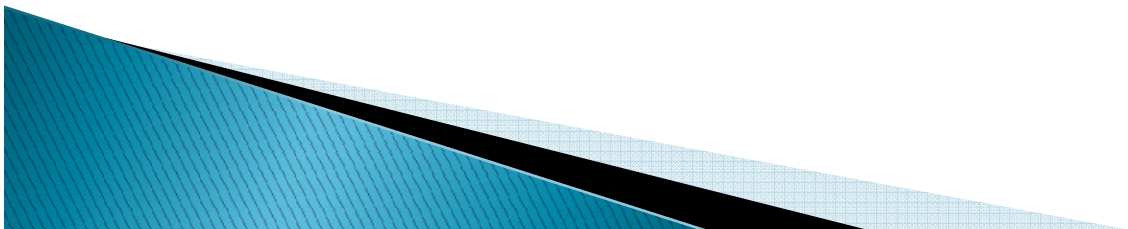


Management of Leucorrhoea (Modern Medicine)

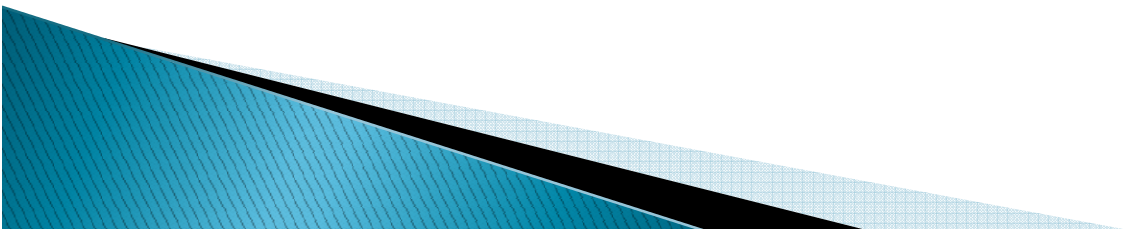
There are many treatment regimens in the management of leucorrhoea such as oral medicines, injection and vaginal suppository



- Most of the patients cannot follow the right regimens so failure rate is high and signs and symptoms were recurred
- In case of treatment with vaginal suppository a well-experienced health provider and detail instruction are needed



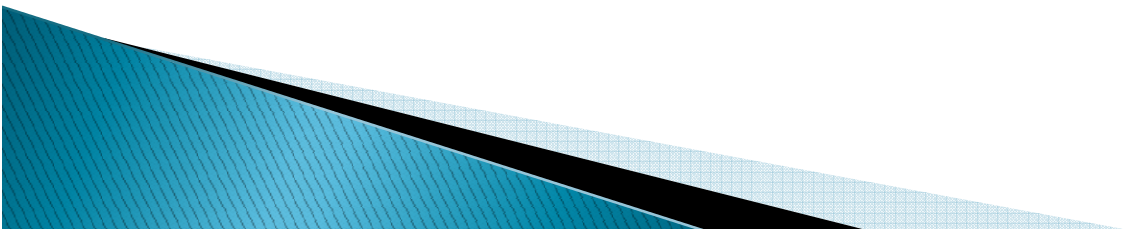
- Most of the western oral medicines are effective but sometimes unwanted effects can occurred
- Some patients who want to avoid these undesirable effects want to use the traditional medicine



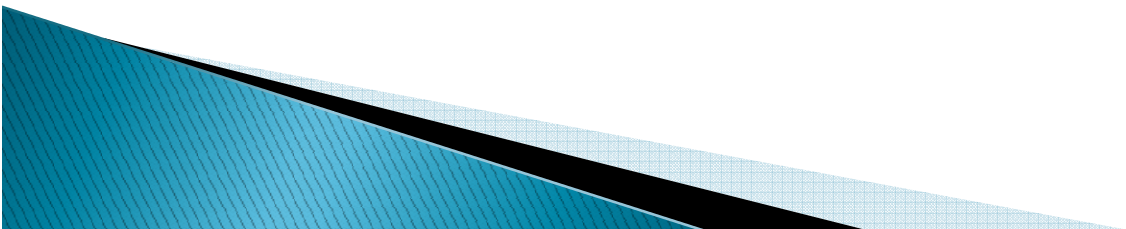
Management of Leucorrhoea in Traditional Medicine

There are many treatment regimens in the management of leucorrhoea such as

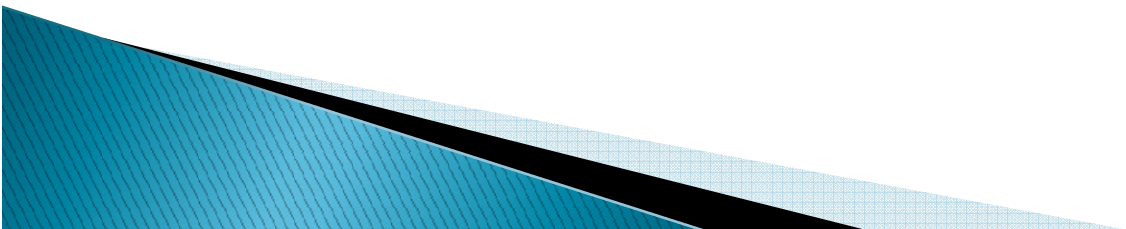
- oral medicines
- vaginal douche



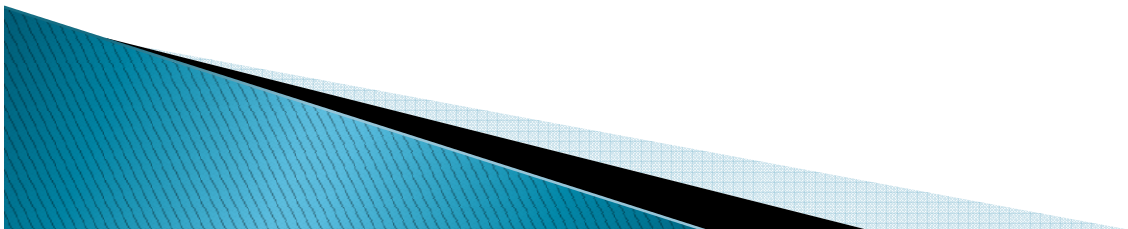
There are many kinds of *Hpan Hsei*: used as vaginal douche, among them *Triphala Hpan Hsei*: has been used on *Sweta pradara* many traditional practitioner



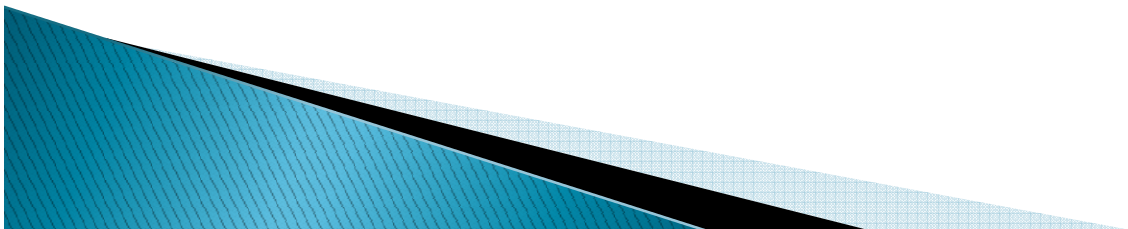
The ingredients of *Triphala Hpan Hsei*: are *Emblica officinalis* Gaertn. (Zi: bju), *Terminalia chebula* Retz. (Hpan ga:), *Terminalia belerica* Roxb. (Thi' hsein.) and *potassium aluminium sulphate* (Kjau' chin)



All ingredients used in this vaginal douche have pharmacological action such as anti-inflammatory, anti-fungal activity, anti-microbial activity and anti-bacterial activities



- These ingredients are effective in treating *Sweta pradara* and easily available drug
- *Triphala Hpan Hsei*: can be easily prepared and good therapeutic outcome

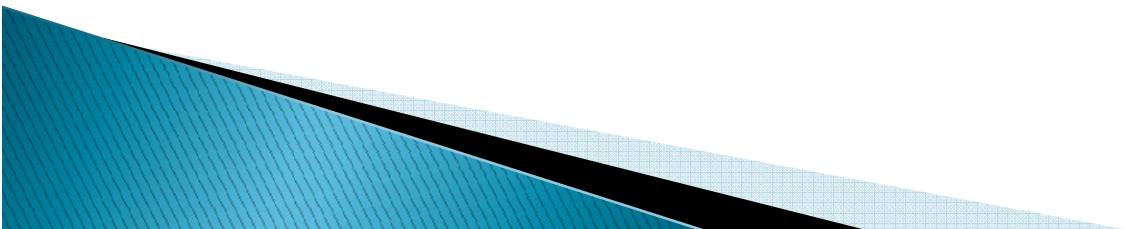


OBJECTIVES

- ▶ To compare the clinical presentations of *Sweta pradara* (Leucorrhoea) before and after treatment
- ▶ To detect the anti-microbial effects of *Triphala Hpan Hsei*: on *Sweta pradara* (Leucorrhoea) before and after treatment

METHODOLOGY

- Hospital based clinical trial design from 1st September 2015 to 31st October 2016 (1 year)
- Total 29 subjects were obtained informed consent from OPD and IPD in 100 bedded TMTH, Mandalay



Inclusion criteria

- (1) Female subjects who are the age group between 20-60 years
- (2) Patients having complaints of *Sweta pradara*
- (3) Married

Exclusion criteria

- (1) Known case of cervical or uterine malignancy
- (2) Pregnant women
- (3) Diabetes mellitus

*Triphala Hpan Hsei: are Zi: bju (Emblica officinalis) 10g,
Hpan ga: (Terminalia chebula) 10g, Thi' hsein
(Terminalia belerica 10g (95%) Kjau' chin (Potassium
aluminium sulphate) 1.5 g (5%)*



***Emblica officinalis* Gaertn. (Zi: bju)**



***Terminalia chebula* Retz. (Hpan ga:)**



***Terminalia belerica* Roxb. (Thi' Hsein.)**



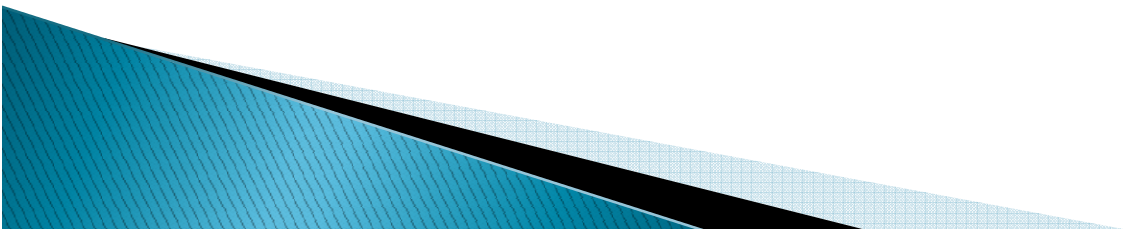
Alum (Kjau' chin)



Triphala Hpan Hsei: powder and solution

Investigations

- ▶ Pap smear
- ▶ Endocervical swab
- ▶ High vaginal swab





Materials or Instruments



Pap smear



Glass slide



Fix with spirit



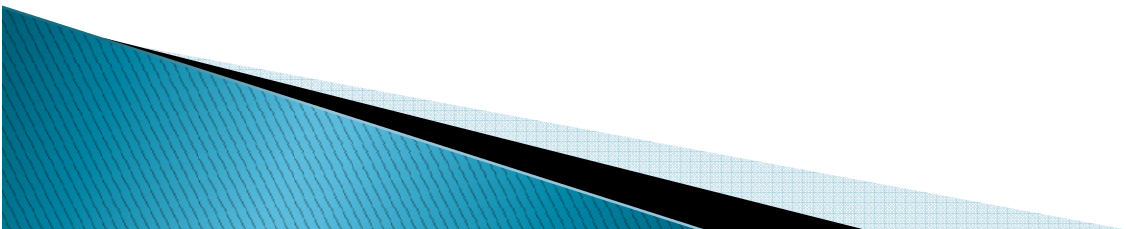
High vaginal swab



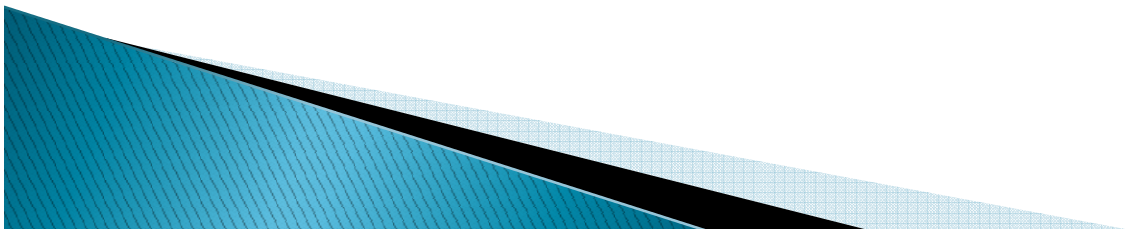
Endocervical swab

Procedure of Vaginal Douching

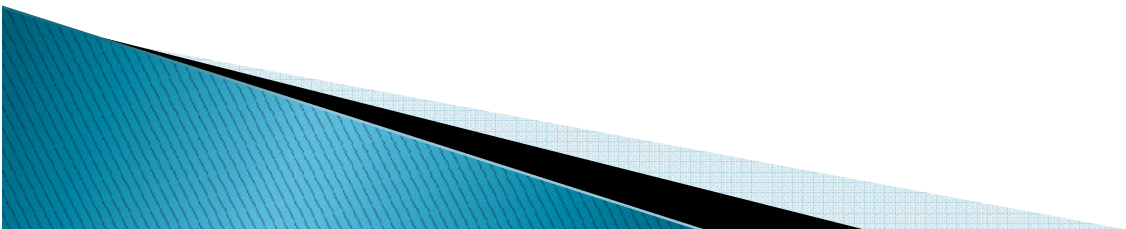
- ▶ Firstly, all the instruments were sterilized for ready to use
- ▶ Twenty grams of *Triphala Hpan Hsei*: powder is dissolved in 1 litre of boiling water
- ▶ This solution was used at 30°C - 40°C
- ▶ And then, this solution was filtered by filter



- ▶ The patient was placed in the lithotomy position on the sterile condition
- ▶ Vaginal speculum was applied with lubricant and gently pushed into the vaginal canal
- ▶ The warm vaginal douche at 30°C - 40°C was passed into the vaginal canal to expose the cervix



- ▶ Vaginal douche was done thoroughly up to all the solution were run out
- ▶ After vaginal douching, the patient needs to take a rest on the bed for 10 minutes
- ▶ This procedure was done for seven consecutive days
- ▶ The assessment of signs and symptoms was done on day 0 and day 7





Enema set

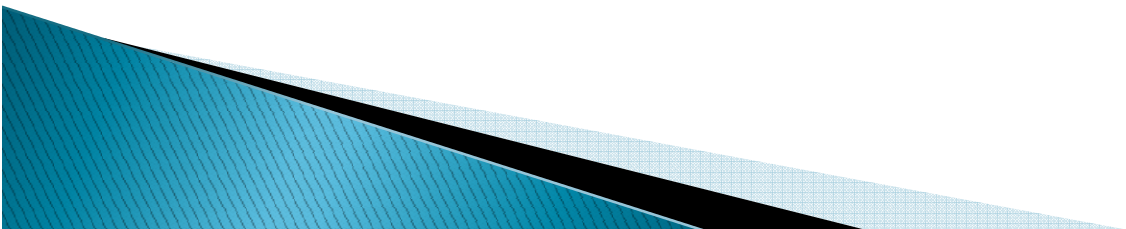


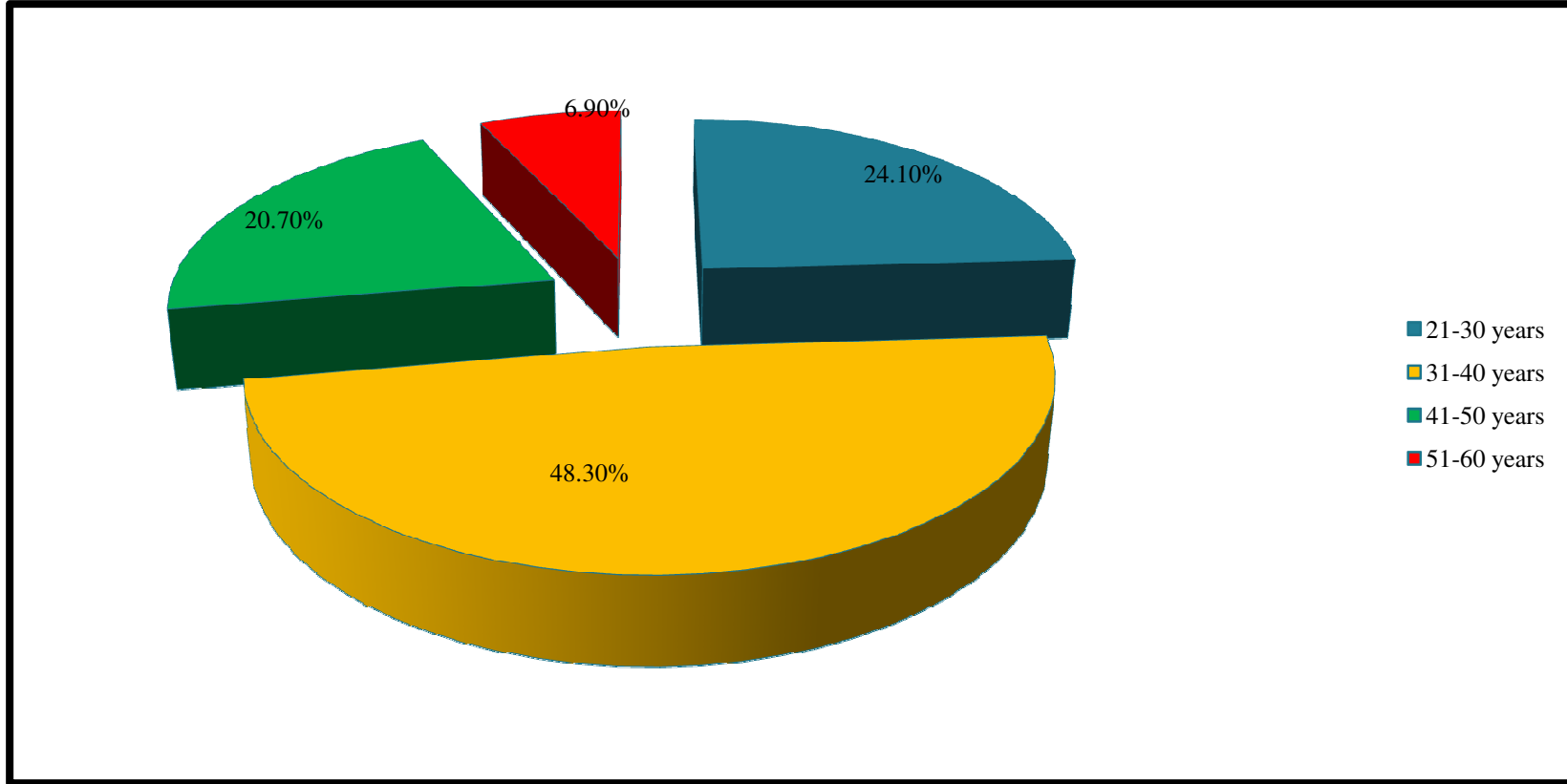
Vaginal douche using *Triphala Hpan Hsei*:

Criteria for assessment

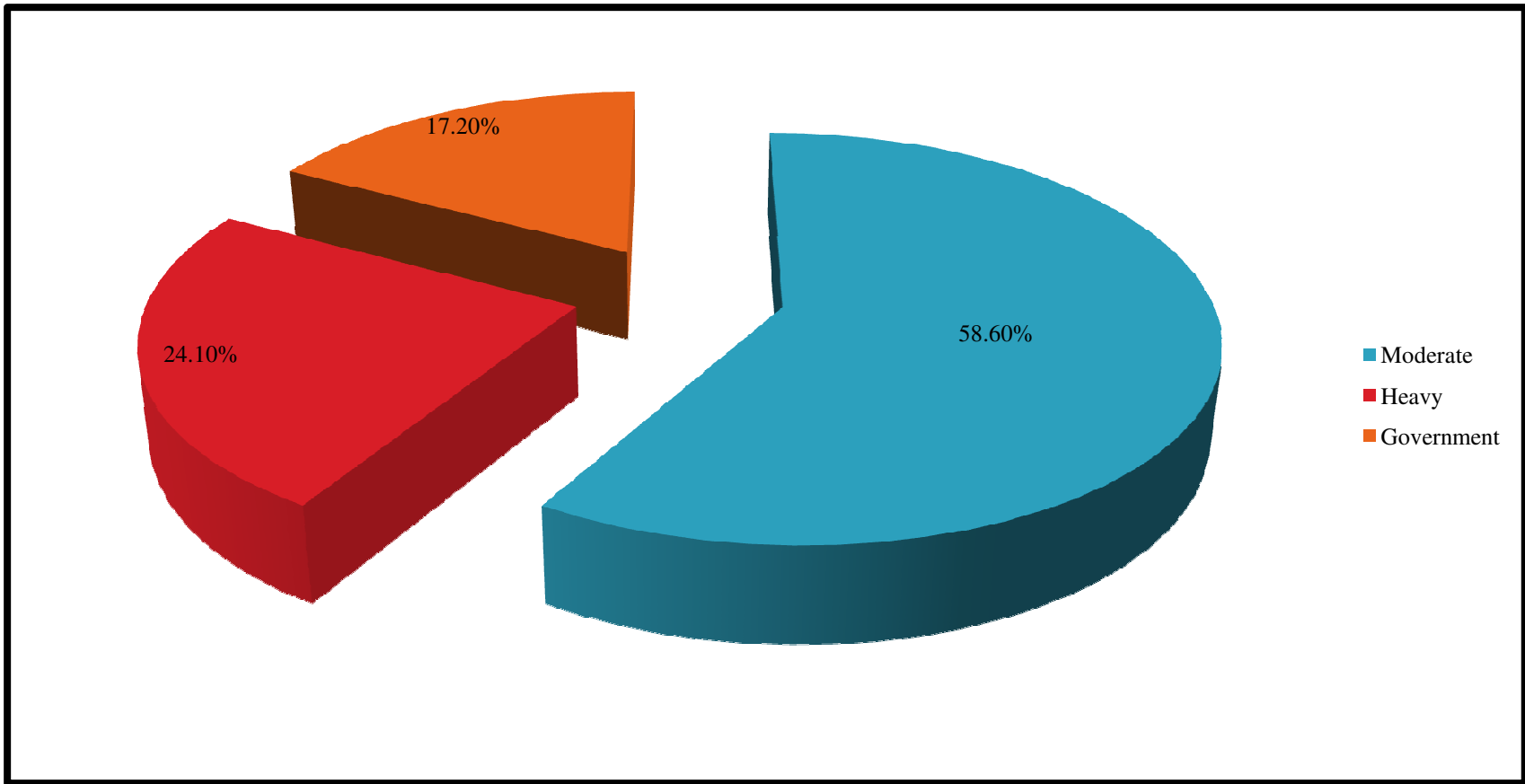
Sr No.	Signs and Symptoms	Score			
		None 1	Mild 2	Moderate 3	Severe 4
1.	Odour	No	Noticed by self but no other	Noticed by other but not offensive	Offensive smell noticed by self and other
2.	Hot discharge	No complain of hot sensation	Negligible of hot sensation	Occasional and tolerable hot sensation	Constant but tolerable burning sensation
3.	Colour	No	Discharge with white	Discharge with whitish yellow	Discharge with yellowish green
4.	Pain in suprapubic area	Pain free	Particular time concerned with menstrual cycle	Pain particular time of day relieves after rest	Severe continuous pain more relief even after rest
5.	Itching	No	Sometimes	Often	Continuous
6.	Burning sensation	No	Sometimes feel	Often feel	Continuous feel
7.	Excessive vaginal discharge	Normal	Persistent moistness of vulva	Need to change the under garments frequently	Need to use an extra cloth or pad

RESULT

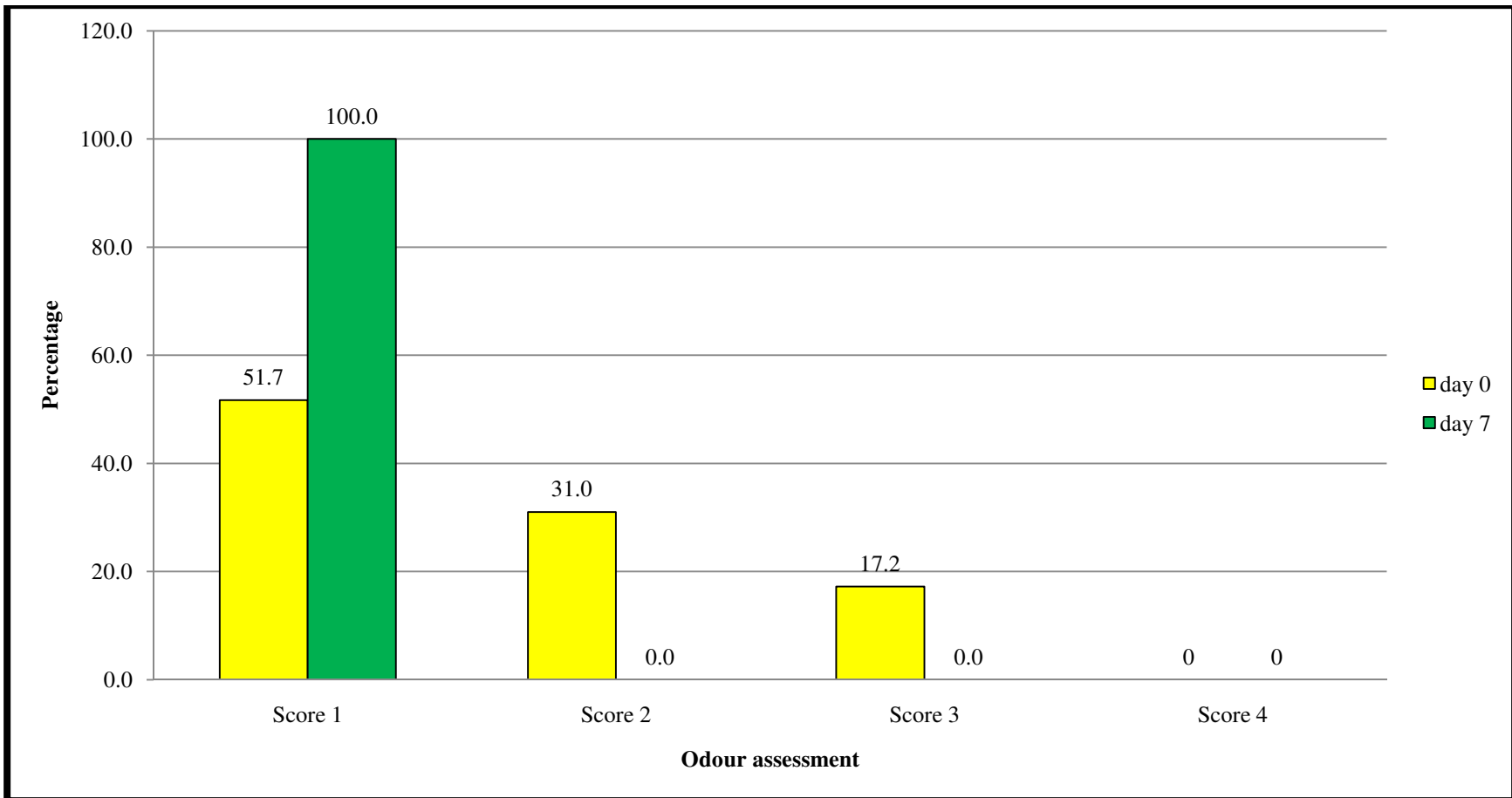




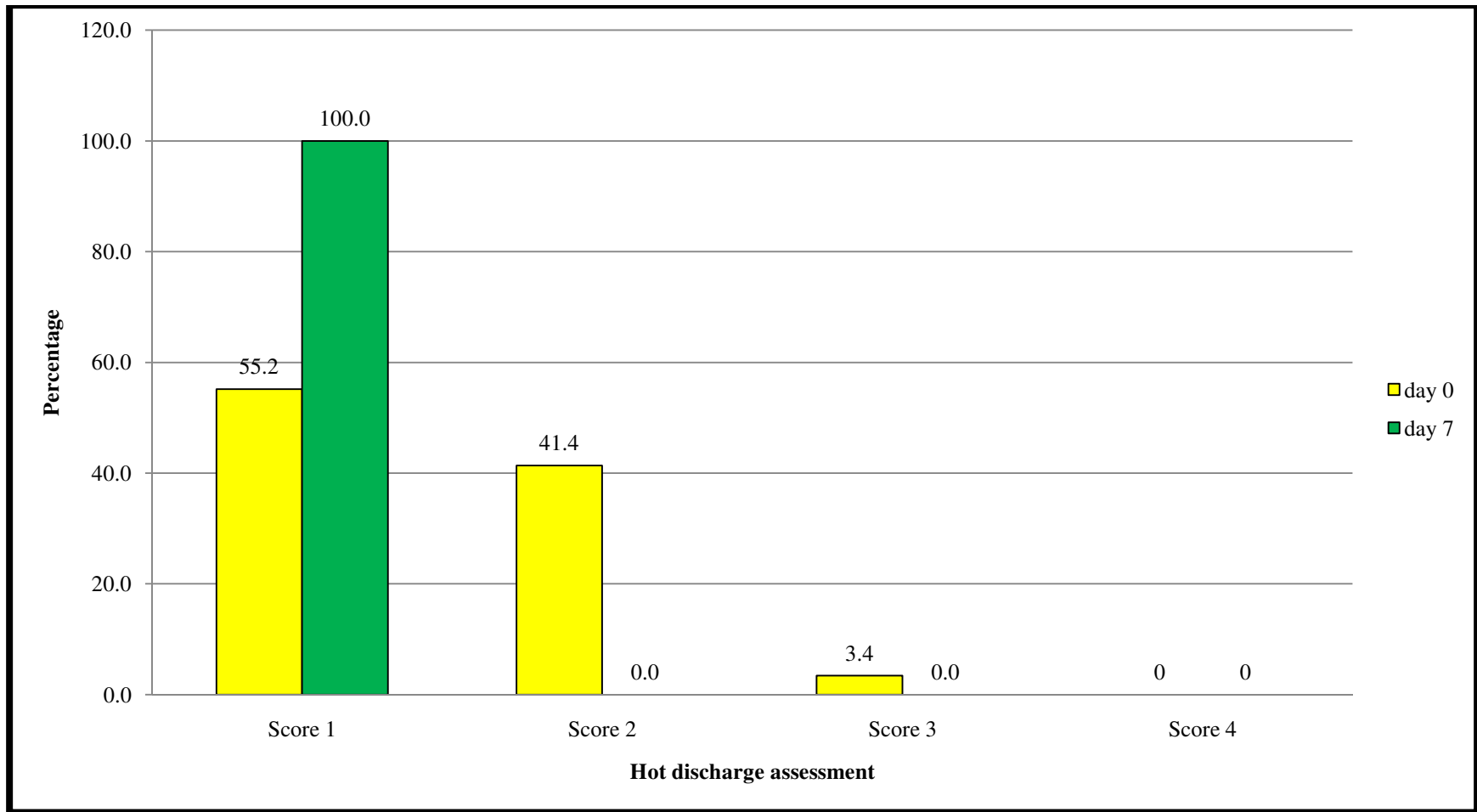
Age distribution of study population



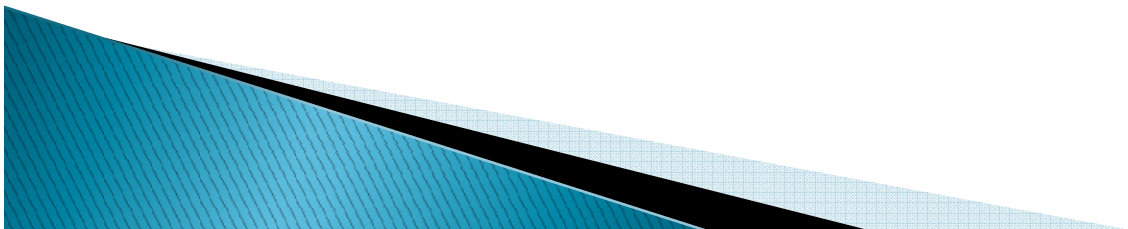
Distribution of occupation

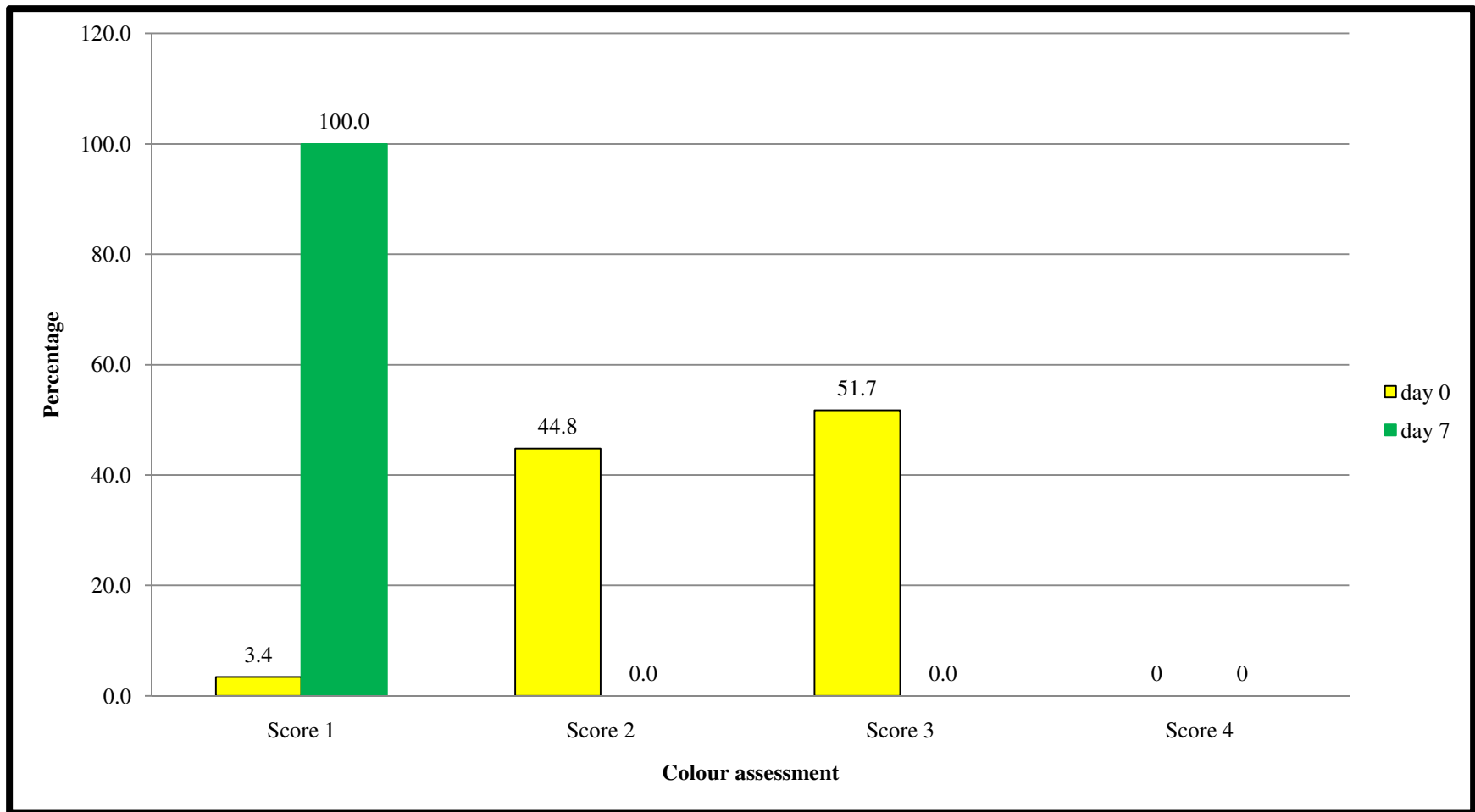


Comparison of odour score

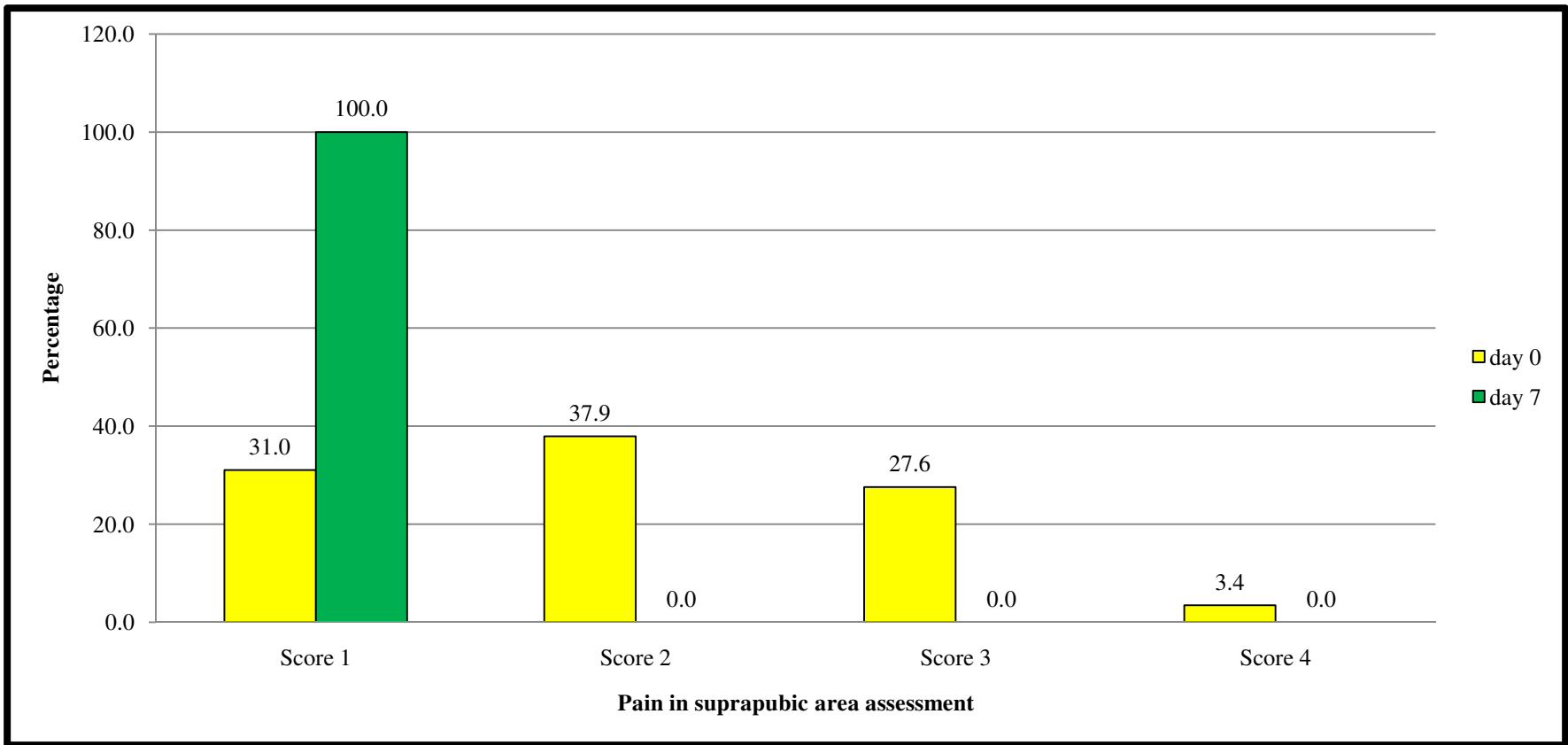


Comparison of hot discharge score

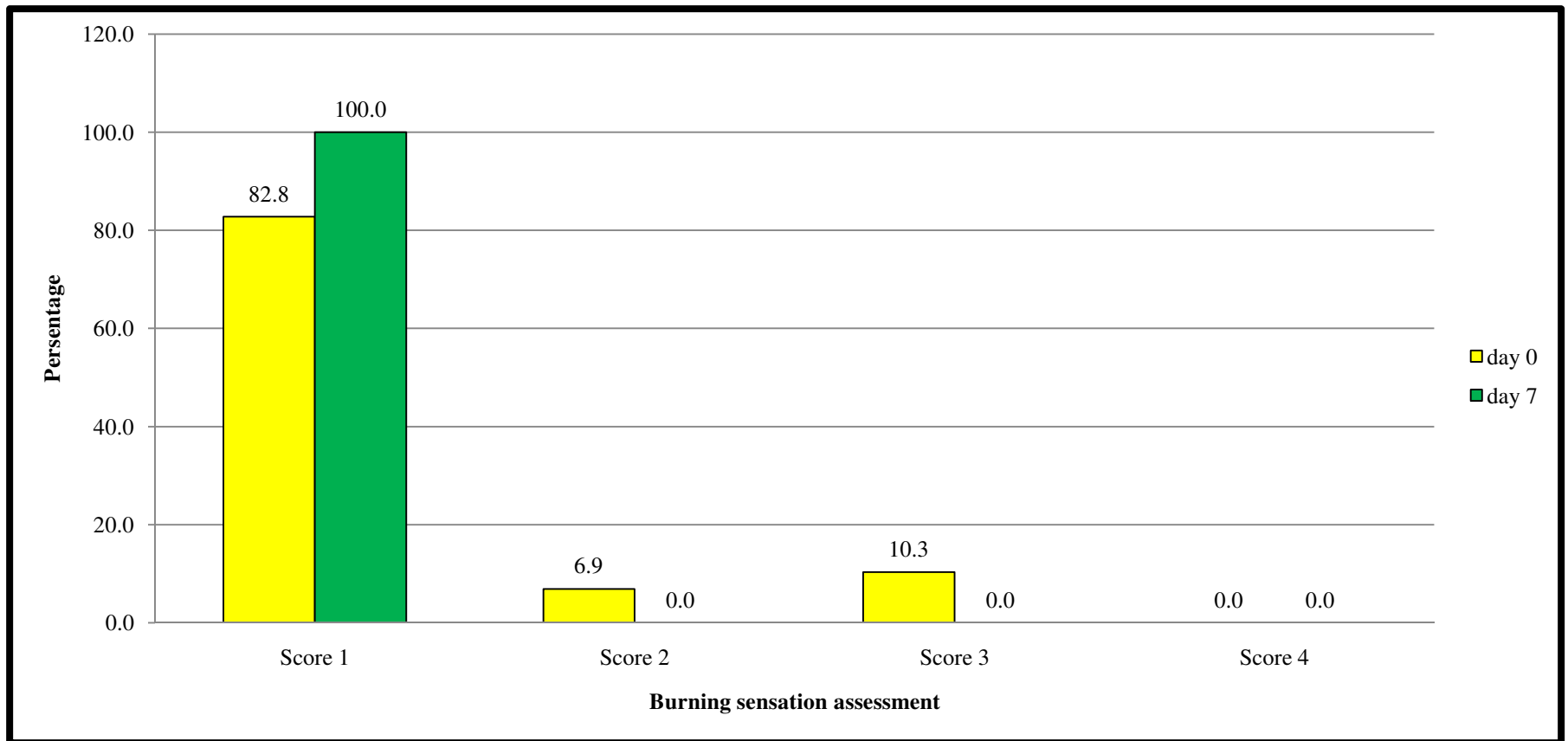




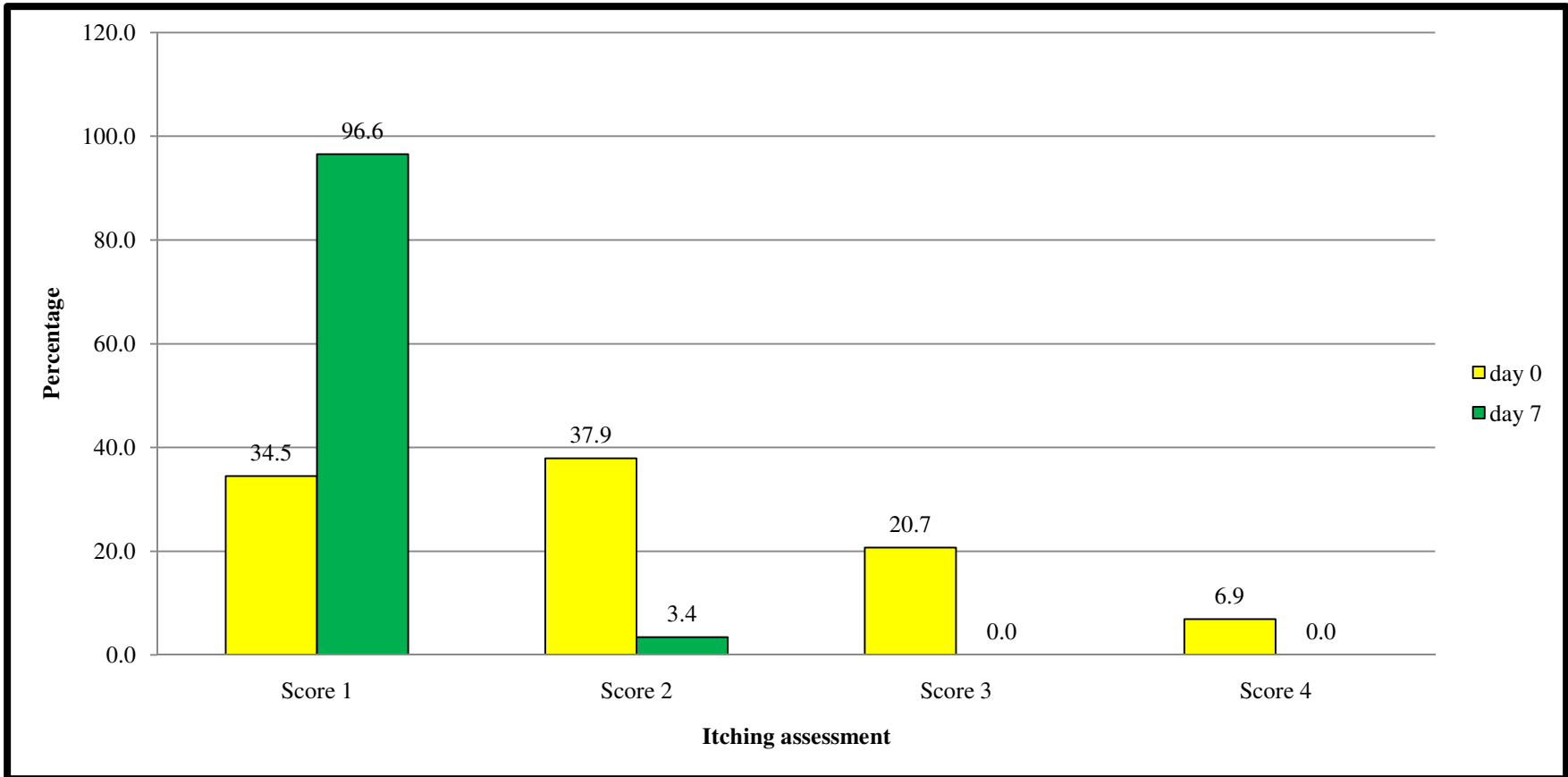
Comparison of colour score



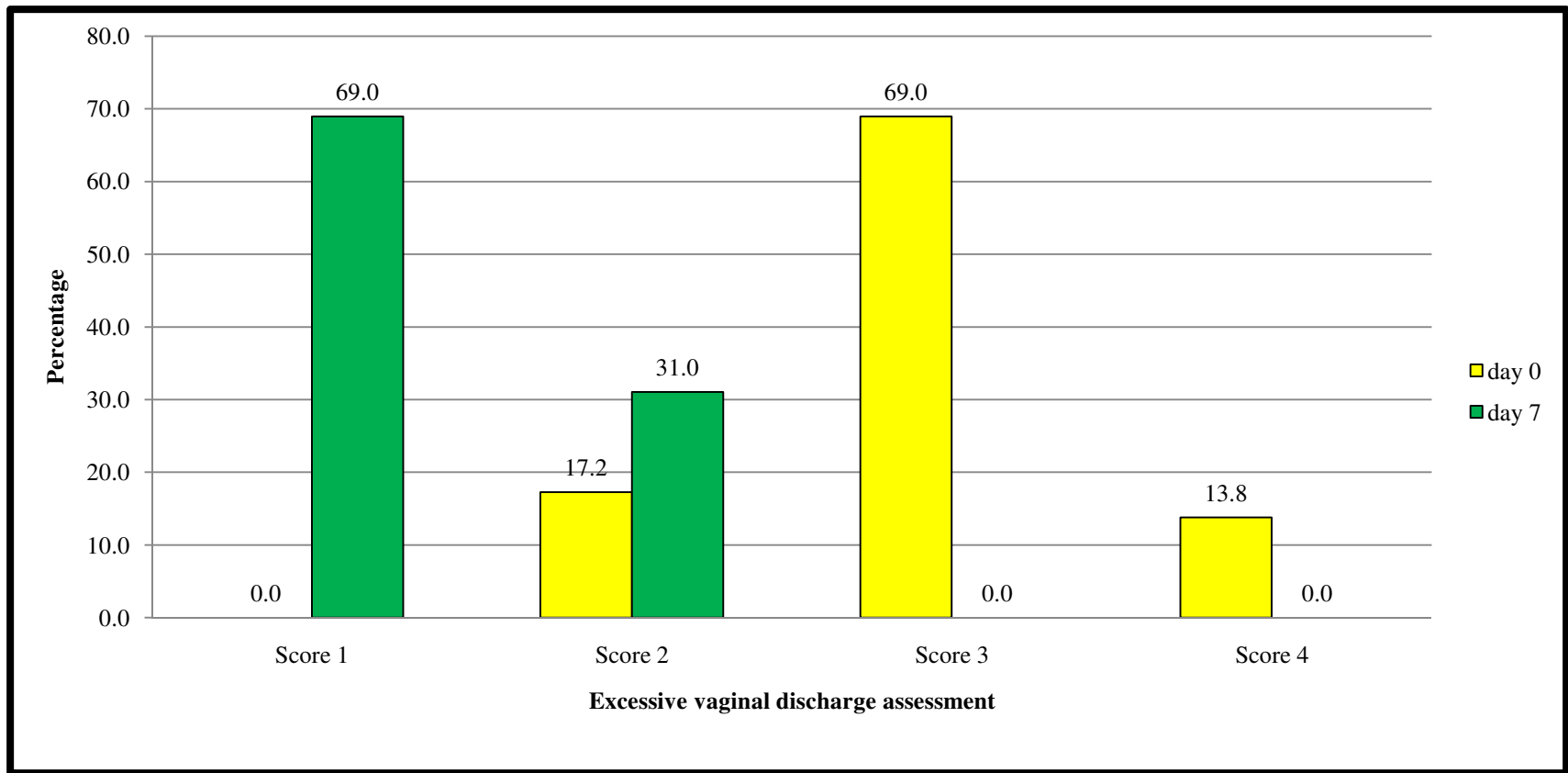
Comparison of pain in suprapubic area score



Comparison of burning sensation score



Comparison of itching score



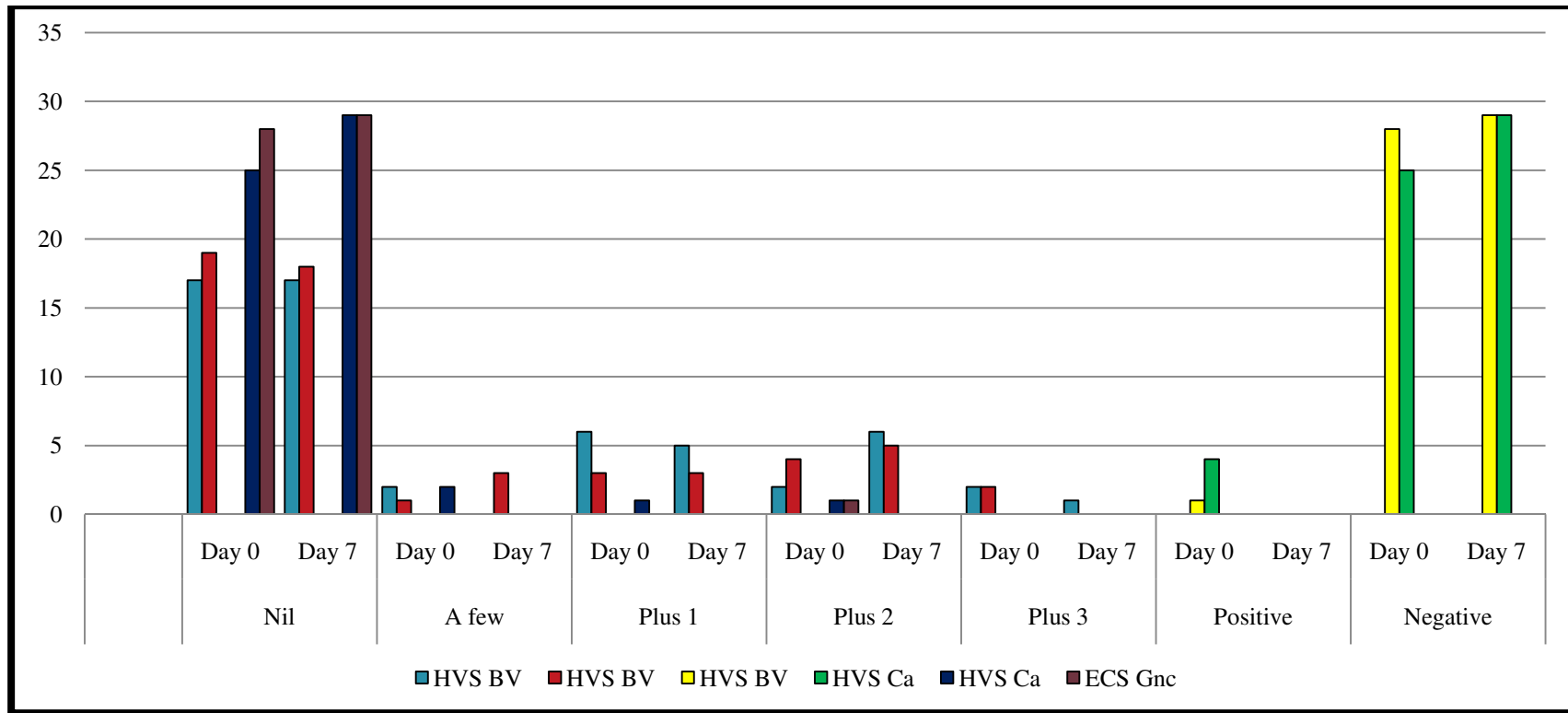
Comparison of excessive vaginal discharge score

Changes in mean score of signs and symptoms

Signs and symptoms	Day 0				Day 7				Percent Relief	P value
	N	MS	SD	SE	N	MS	SD	SE		
Odour	14	1.66	0.769	0.143	29	1.00	0.000	0.000	39.75	0.000
Hot discharge	13	1.48	0.574	0.107	29	1.00	0.000	0.000	32.43	0.000
Colour	28	2.48	0.574	0.107	29	1.00	0.000	0.000	59.67	0.000
Pain in supra-pubic area	20	2.03	0.865	0.161	29	1.00	0.000	0.000	50.73	0.000
Itching	19	2.00	0.926	0.172	28	1.03	0.186	0.034	48.5	0.000
Burning sensation	5	1.28	0.649	0.121	29	1.00	0.000	0.000	49.87	0.030
Excessive vaginal discharge	20	2.97	0.566	0.105	20	1.31	0.471	0.087	55.89	0.000

Percent improvement of mean score on overall signs and symptoms

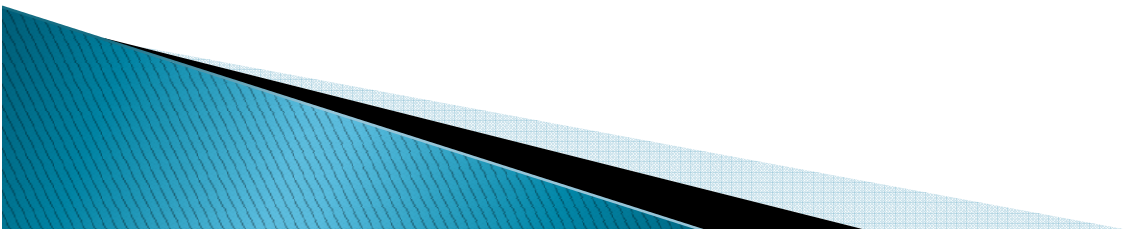
Comparison of mean score on overall signs and symptoms	Day 0 mean score	Day 7 mean score	Mean Difference	Percent relief
Day 0 - Day 7	13.9	7.34	6.56	47.19



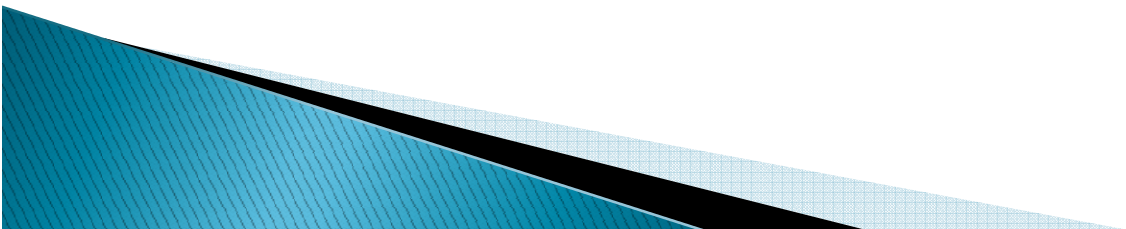
Comparison of High vaginal swab and Endocervical swab result before and after treatment

Above figure described the comparison of High vaginal swab and Endocervical swab result before treatment (day 0) and after treatment (day 7).

- According to the result of High vaginal swab; in bacterial vaginosis, *gram positive bacilli*
- 2 patients had a few state
- 6 patients had plus one (+) state
- 2 patients had plus two (++) state
- 2 patients had plus three (+++) state



- *gram negative bacilli*
- 1 patient had a few state
- 3 patients had plus one (+) state
- 4 patients plus two (++) state
- 2 patients had plus three (+++) state
- *Gardnerella vaginalis* - 1 patient had positive before treatment (day 0)



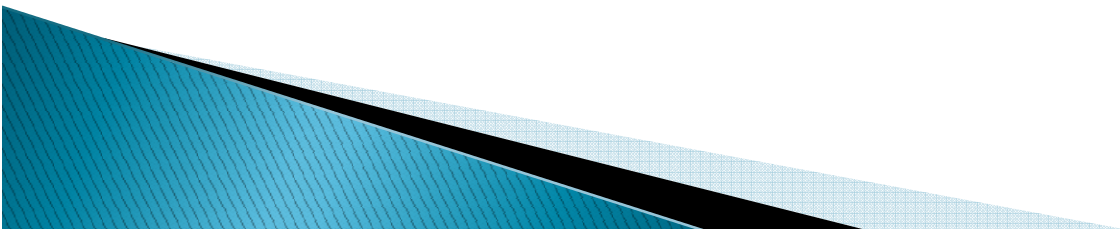
In *Candidiasis*,

- *Candida albican* - 4 patients positive
- *yeast cell*
 - 2 patients had a few
 - 1 patient had plus one (+) state
 - 1 patient plus two (++) state at before treatment (day 0)

After treatment (day 7)

gram positive bacilli,

- there had no a few patient
- 5 patients had plus one (+) state
- 6 patients had plus two (++) state
- 1 patient had plus three (+++) state

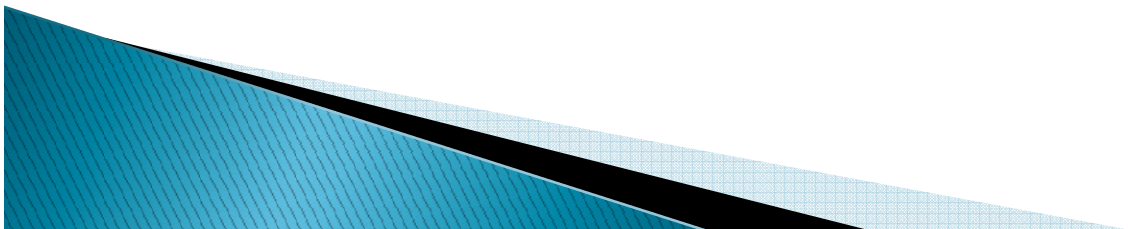


gram negative bacilli

- 3 patients had a few state
- 3 patients had plus one (+) state
- 5 patients plus two (++) state
- there had no plus three (+++) state
- *Gardnerella vaginalis* had negative
- *Candida albican* had negative
- all patients had no *yeast cell*

According to the result of Endocervical swab, at before treatment (day 0),

- 1 patient had plus two (++) growth of *gram negative cocci*
- plus two (++) patient had no growth of *gram negative cocci* at after treatment (day 7)

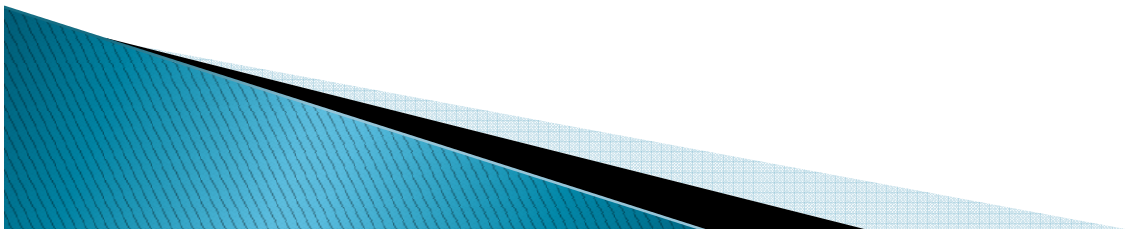


CONCLUSION

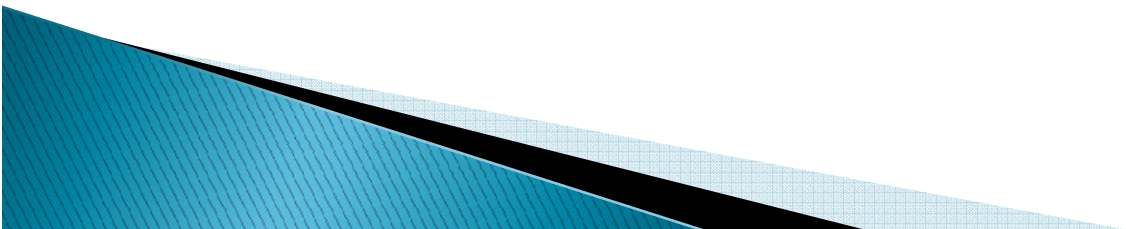
According to the Results, *Triphala Hpan Hsei*: is the effective treatment of all *Sweta pradara* patients

Especially it is more appropriate for *Sweta pradara* patient infected by *Gardnerella vaginalis*, *Candidiasis*, *gram negative cocci*

- According to laboratory results, *Triphala Hpan Hsei*: had no changed significantly on *gram positive bacilli*, *gram negative bacilli* to give a definite conclusion
- The present study was aimed to evaluate clinically the effect of treatment of vaginal douche using *Triphala Hpan Hsei*: for management of *Sweta pradara*



- This finding and result showed that vaginal douche using *Triphala Hpan Hsei*: is rationally appropriate in *Sweta pradara* patients
- To revive the proper and systematic Myanmar Traditional Medicine is highlighted by the effective result of this treatment



SUGGESTIONS

- further study should be carried out with large sample size for adequate time
- *Sweta pradara* patients vaginal douche should be combine with oral medication in all *Sweta Pradara* patients
- effect of *Triphala Hpan Hsei*: is needed to compare with other various vaginal douches in treatment of Leucorrhoea
- this treatment regime should be applied in all Traditional Medicine Hospitals

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- U Maung Maung Oo, Managing Director of Great Wall Traditional Medicine Manufacturing Co., Ltd.

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