

# မင်္ဂလာပါ



# **EFFECT OF KSHARA SUTRA THERAPY USING PAPAYA LATEX IN THE TREATMENT OF BHAGANDARA (FISTULA-IN-ANO)**

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# INTRODUCTION

- *Kshara Sutra* Therapy (KT) - described in all the ancient books of *Ayurveda* as caustic thread
  - in the treatment of Fistula-In-Ano
  - gradual excision of overgrown soft tissues including piles, polyps, warts, papillae and non-healing chronic sinuses and ulcer (Sharma *et al.*, 1995)<sup>1</sup>.




- KT is a technique derived from the ancient text books
- modified on the basic of a number of experimentations and experiences.
- the authors of *Ayurvedic Samhitas* including *Charak*, *Sushruta* and *Vagbhata*, its preparation has hardly been mentioned any one (Sharma *et al.*, 1995)<sup>1</sup>.

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- U Aung Kyaw Min, Professor and Head of Department of Ulcer and Sore Therapy, University of Traditional Medicine (Retired) introduced KT in Myanmar.
  - He attended KT training in *Ayurvedic* University, India from 1999 December 5 to 2000 March 5


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- Introduced in Traditional Medicine Teaching Hospital, Mandalay (TMTHM) for the treatment of FIA.
  - It is effective on patients with FIA by his dissertation of the study on the effectiveness of KT on *Bhagandara* (Fistula-In-Ano) with statistically significance ( $p < 0.001$ ) (Aung Kyaw Min, 2012)<sup>2</sup>.



- Fistul-In-Ano called *Bhagandara*, is one of the commonest diseases occurs in ano-rectal region.
- It is also one of the most painful ano-rectal diseases.
- The word “*Bhagandara*” derived from “*Bhaga*” and “*Dara*”; “*Bhaga*” means both male and female genital organs and anus. “*Dara*” means perforating.

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- Therefore, “*Bhagandara*” is the disease which perforates the anus and genital organs.
  - There are many therapies in the management of *Bhagandara* in Myanmar Traditional Medicine such as clearing the putrid, pacifies *doshas* and *malas*, using *Hpan-hsei*: for cleaning the sore, using *Mann-hsei*: which is antiseptic taken orally or externally or inhalant and contact the ulcer with the medical fume (အုန်းရွှေ ဝဇ္ဇဝံ)<sup>3</sup>.






In India, KT is prepared by repeated coatings of


1. *Euphorbia nerifolia*,
2. *Achyranthus aspera* alkaline salt and
3. *Curcuma longa*.

In Myanmar, KT is prepared by


1. *Euphorbia antiquorum*,
2. *Achyranthes aspera* alkaline salt and
3. *Curcuma longa*.



However *E. nerifolia* and *E. antiquorum* are not available throughout the year as effective latex and they have burning effect due to pH 5.6 (Sharma *et al.*, 1995)<sup>1</sup>.



During and after application of KT some patients complain of burning type of pain (Vikas *et al.*, 2013)<sup>4</sup>. Therefore, it is needed to search another latex to substitute for the latex of *E. nerifolia* and *E. antiquorum*.

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- Papaya latex has to wound healing properties and antibiotic effect
  - Papaya latex is owing to adhesive properties (Gurunga & Basnet, 2009).
  - However there is no scientific study concerned with the effect of KT using Papaya latex on patients with *Bhagandara*.
  - Therefore, KT using with Papaya latex was used on the patients with *Bhagandara* in this study.



## Objectives

1. To prepare *Kshara Sutra* thread by using Papaya latex
2. To describe demographic characteristics of *Bhagandara* (Fistula-In-Ano) patients
3. To evaluate the effect of *Kshara Sutra* Therapy using Papaya latex on *Bhagandara* (Fistula-In-Ano)



## METHODOLOGY

- Study Design- Quasi-experimental Study
- Study Period- 1<sup>st</sup> September 2015 to 31<sup>st</sup> October 2016
- Sample Size- 26 subjects
- Study Area- Ulcer and Sore Therapy Ward in 100 bedded Traditional Medicine Teaching Hospital, Mandalay.



## **Inclusion criteria**

1. Age 15 to 70 years
2. All cases of Fistula-In-Ano attended in Traditional Medicine Teaching Hospital, Mandalay
3. FIA Patients with Diabetes Mellitus (fasting blood sugar  $\leq$  200 mg/dl)



## **Exclusion criteria**

1. Patients with HIV
2. Pregnant women
3. FIA Patients with Diabetes Mellitus (fasting blood sugar  $> 200$  mg/dl).






# Investigation

1. HIV screening test
2. Blood sugar Level



## **Data Collection and Data Analysis**

For comparison of the effect of KT using Papaya latex on Fistula-In-Ano before and after treatment and showing effect of signs and symptoms before and after, chi square test and student t' test was applied.



## Preparation of *Kshara Sutra* Therapy using Papaya latex

To prepare the *Kshara Sutra* Therapy using  
Papaya latex,

1. *Carica papaya* latex,
2. *Achyranthes aspera* alkaline salt and
3. *Curcuma longa* powder
4. Surgical linen thread No.20
5. Hanger



**Figure 1.** Collection of Papaya latex



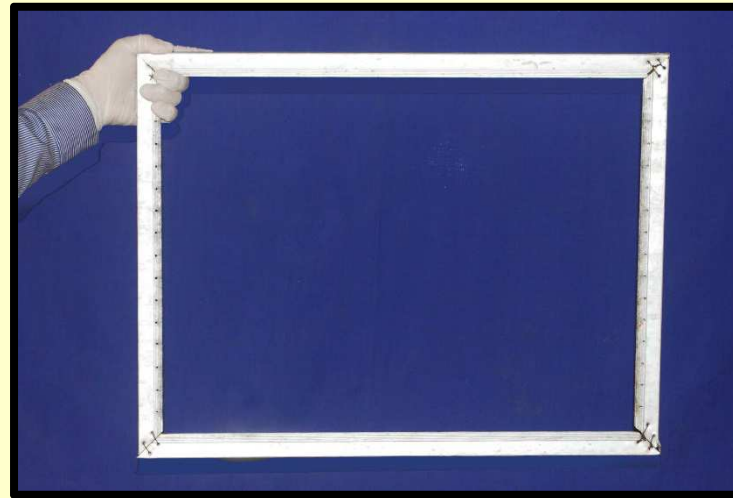
**Figure 2.** *Achyranthes aspera* Linn. alkaline salt




**Figure 3.** Powder of *Curcuma longa* Linn.



**Figure 4.** Surgical linen thread No.20



**Figure 5.** Hanger



***Kshara Sutra* Therapy using Papaya latex was prepared by repeated 21 coatings**

1. 11 coatings of *C. papaya* latex,
2. 7 coatings of *A. aspera* Linn. alkaline salt with *C. papaya* latex
3. 3 coatings of *C. longa* powder with *C. papaya* latex.



**Figure 6.** Tying the surgical linen thread No.20 at the Hanger



**Figure 7.** Coating of the thread with *Carica papaya* latex



**Figure 8.** Coating of the thread with *A. aspera* alkaline salt



**Figure 9.** Coating of the thread with *C. longa*


## **Treatment procedures of *Kshara Sutra* Therapy using Papaya latex**

- The subjects were selected according to inclusion and exclusion criteria
- Fistula-in-Ano, patient's consent was taken by using consent form.
- After that the patient was asked to the lithotomy position on the labour bed.



- The index finger of the same side of the fistula will lubricate with *Hpajaun Hpju* (TMF-49) and introduced it into the patient's anal orifice.
- The site of the opening be kept in mind and the tip of the index finger was placed over it.
- Then next step was to pass a probe through the external opening to explore the entire course of the fistulas tunnel.

- Attempt was made to guide the probe towards the internal opening by the finger in the rectum.
- It was possible negotiate the tip of the probe with the tip of the finger.
- When the eye of the probe protruded out of the anal orifice it was thread with a *Kshara Sutra* Therapy using Papaya latex after stripping off its coatings for about an inch or two.

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- Then the probe gently withdrawn so that the entire tract of the fistula was threaded by *Kshara Sutra* Therapy using Papaya latex thread.
  - The two ends of the thread was snug tied outside ano-rectal canal as just fitting



- The thread was exchanged by rail road method weekly and measures the thread for cutting rate five times in this study.
- In this study, it was assessed by cutting rate, Unit Cutting Time (UCT), pain, burning sensation, itching sensation and discharge.



Figure.10 . Probe

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Figure.11. Alkaline Thread

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Figure.12. *Hpajaun Hpju* (TMF-49)

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**Figure 13.** Patient with Fistula-In-Ano



**Figure 14.** Protruding the probe



**Figure 15.** Protruding the alkaline thread using probe



**Figure 16.** Threading of Fistula-In-Ano



**Figure 17.** Tying the thread



**Figure 18.** Tying the thread



**Figure 19.** Tying the thread

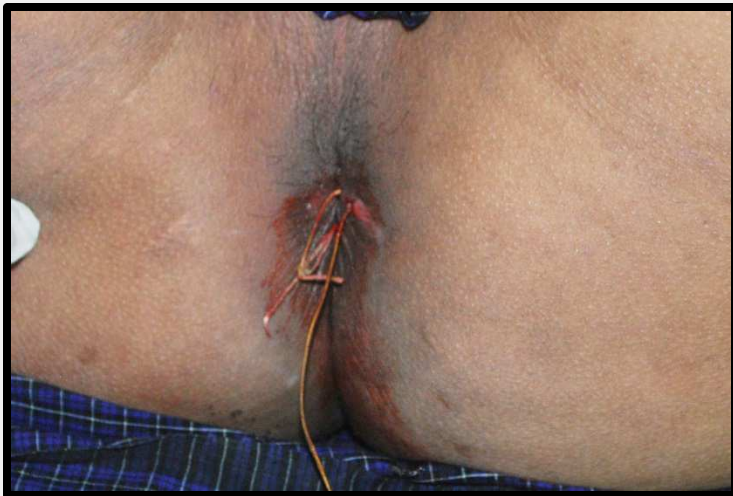
## Changing of The Alkaline Thread



**Figure 120.** Changing the alkaline thread



**Figure 21.** Changing the alkaline thread



**Figure 22.** Changing the alkaline thread

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**Figure 23.** Changing the alkaline thread

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## Outline assessment

On completion of treatment, the outcome was assessed by using the following formula:

$$\text{Unit Cutting Time (UCT)} = \frac{\text{Total numbers of days}}{\text{Initial length of the tract (Thread)}}$$



Figure.24 Measuring of External thread



Figure.25 Measuring of External thread



Figure.26 Measuring of the whole thread

**Table 1. Assessment of Pain**

Pain	VAS Score	Score
No pain	0	1
Mild pain	1 – 3	2
Moderate pain	4 – 6	3
Severe pain	7 – 10	4

**Table 2.** Assessment of Burning Sensation

Condition	Criteria	Score
Nil	No complaint of burning sensation	1
Mild	Negligible of burning sensation	2
Moderate	Occasional and tolerable burning sensation	3
Severe	Constant but tolerable burning sensation	4
Excruciating	Intolerable burning sensation makes the patient uncomfortable and makes the patient to go for help (Siddaram, 2012)	5

**Table 3. Assessment of Itching Sensation**

Condition	Criteria	Score
Nil	No complaint of itching	1
Mild	Negligible itching, occasional in a day	2
Moderate	occasional itching, with 4-6 hours gap	3
Severe	Frequent itching, with 2-3 hours gap	4
Excruciating	Frequent and continuous itching sensation (Siddaram, 2012)	5

**Table 4. Assessment of Discharge**

Condition	Criteria	Score
Nil	No discharge	1
Mild	If wound wets 1×1 cm gauze piece	2
Moderate	If wound wets 2×2 cm gauze piece	3
Severe	If wound wets more than 2 cm gauze piece	4
Excruciating	Continuous and profuse discharge (Lobo, 2015)	5

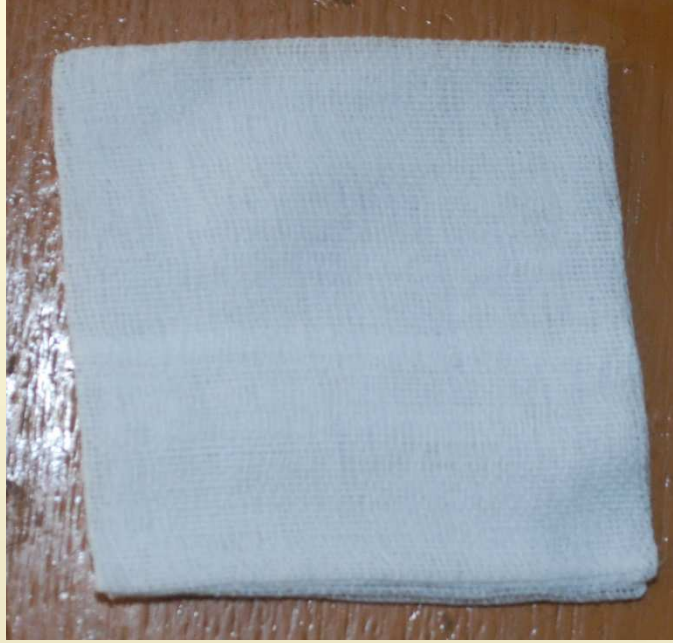



Figure. 27. Gauze Piece

## FINDING AND DISCUSSION

**Table 8. Sex distribution of patients with FIA**

Sex	Frequency	Percent
Male	19	73.1
Female	7	26.9
Total	26	100.0





**Table 9. Occupation distribution of patients with FIA**

Occupation of the patients	Frequency	Percent
Cultivator	8	30.8
Teacher	3	11.5
Members of religious order	2	7.7
House Wife	2	7.7
Tradesman	11	42.3
Total	26	100.0

**Table 10. Site distribution of patients with FIA**

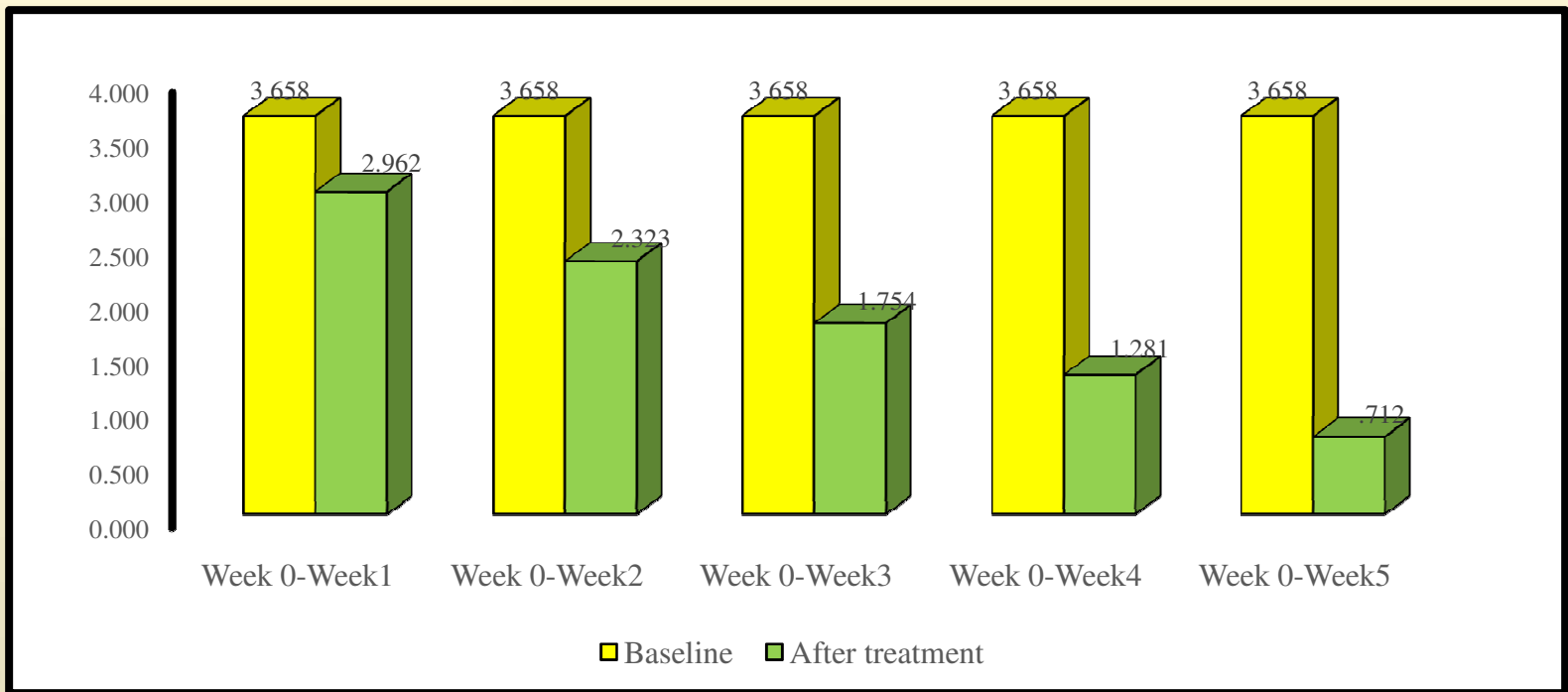
Site of FIA	Frequency	Percent
Posterior Left	10	38.5
Posterior Right	5	19.2
Posterior Middle	6	23.1
Middle	2	7.7
Anterior Right	1	3.8
Anterior Middle	1	3.8
Anterior left	1	3.8
Total	26	100.0



**Table 11. O' clock position distribution of patients with FIA**

Site	Frequency	Percent
1-3 O' Clock	3	11.5
4-6 O' Clock	16	61.5
7-9 O' Clock	5	19.2
10-12 O' Clock	2	7.7
Total	26	100.0

Figure.28 Comparison of Cutting length of KT using Papaya Latex






## Comparison of Cutting length of KT using Papaya Latex

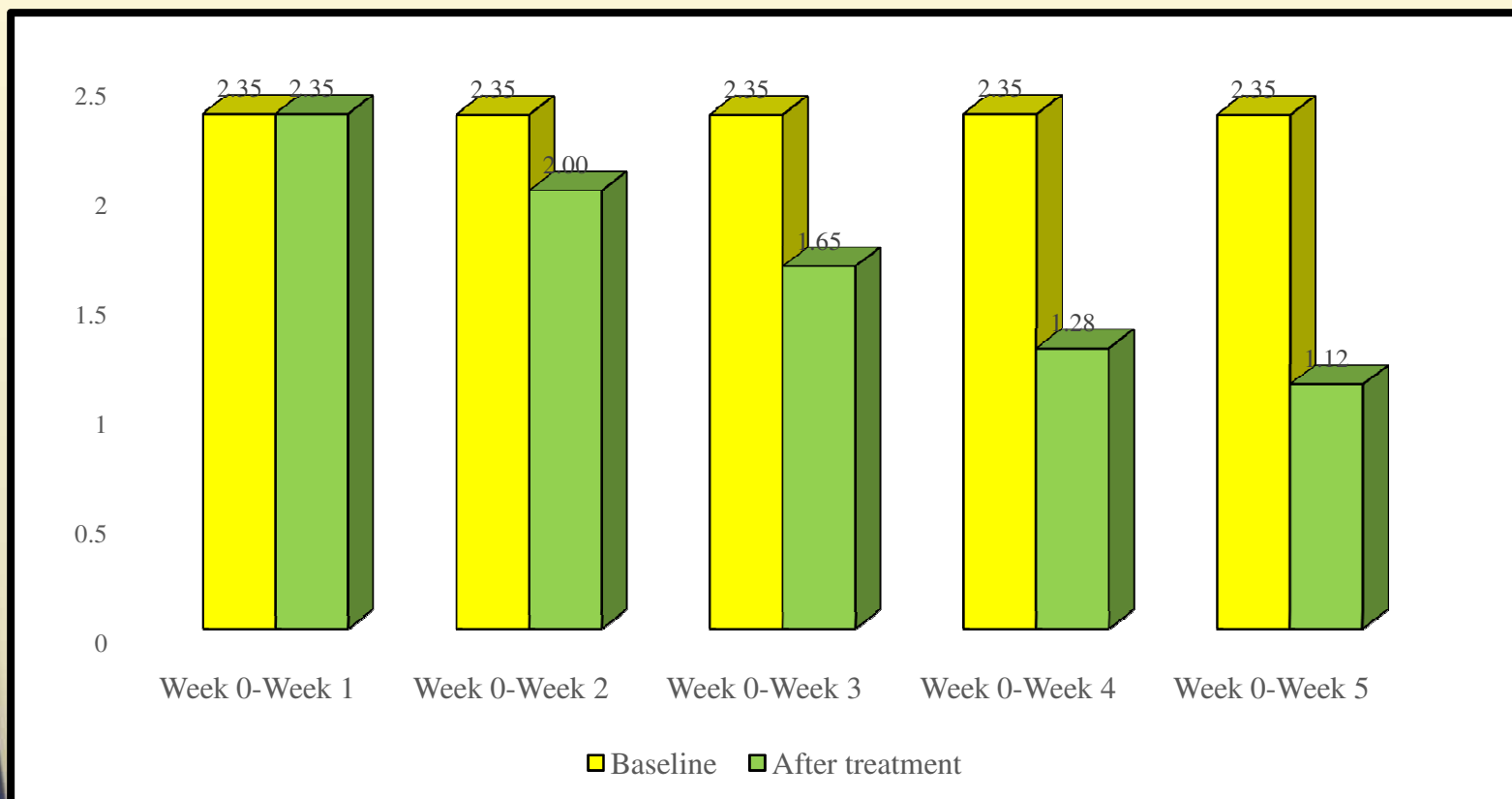
Figure 25 described the comparison of the cutting length before and 1-5 weeks after treatment on FIA. .

Mean difference value between

- week 0 and 1 week after treatment was 0.696 cm, The p value was  $< 0.001$ .
- week 0 and 2 weeks after treatment was 1.335 cm, The p value was  $< 0.001$ .

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- week 0 and 3 weeks after treatment was 1.904 cm, The p value was  $< 0.001$ .
  - week 0 and 4 weeks after treatment was 2.377cm, The p value was  $< 0.001$ .
  - week 0 and 5 weeks after treatment was 2.946cm. The p value was  $< 0.001$ .

# Figure 29. Comparison of pain






## Comparison of pain

This figure. 26 showed that the effect of pain due to KT using Papaya latex in before and 1-5 week after treatment on FIA. Mean difference value between

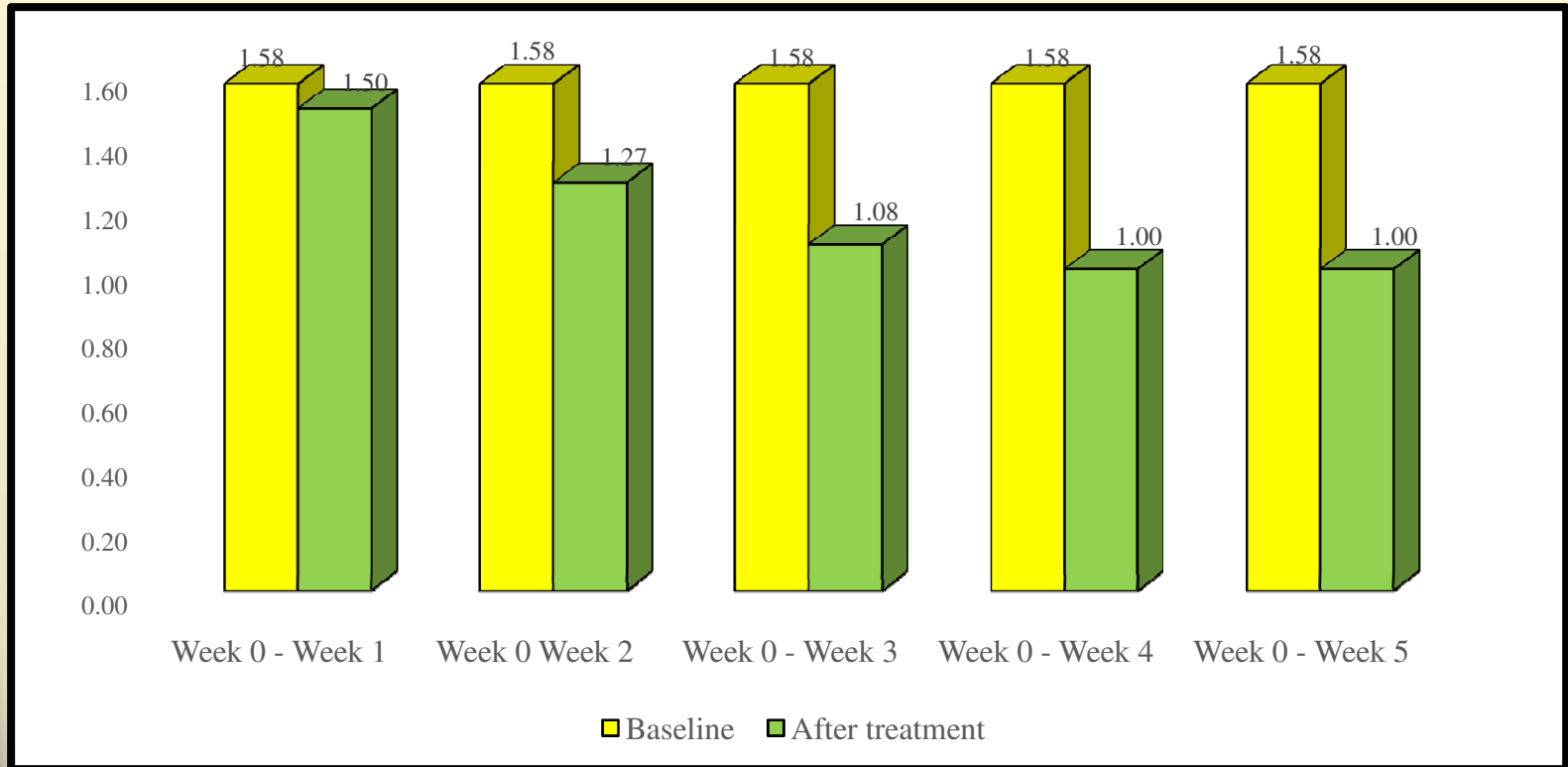
- week 0 and 1 week after treatment was 0. There was statistically not significance before and 1 week after treatment on FIA with KT using Papaya latex.



- week 0 and 2 weeks after treatment was 0.35, The p value was 0.001.
- week 0 and 3 weeks after treatment was 0.7, The p value was 0.000.
- week 0 and 4 weeks after treatment was 1.07. The p value was 0.000.

- 
- week 0 and 5 weeks after treatment was 1.23. The p value was 0.000.
  - Finally, the effect of KT using Papaya latex in pain was improved week by week. 52.3% of pain was achieved.

# Figure 30. Comparison of Itching







## Comparison of Itching

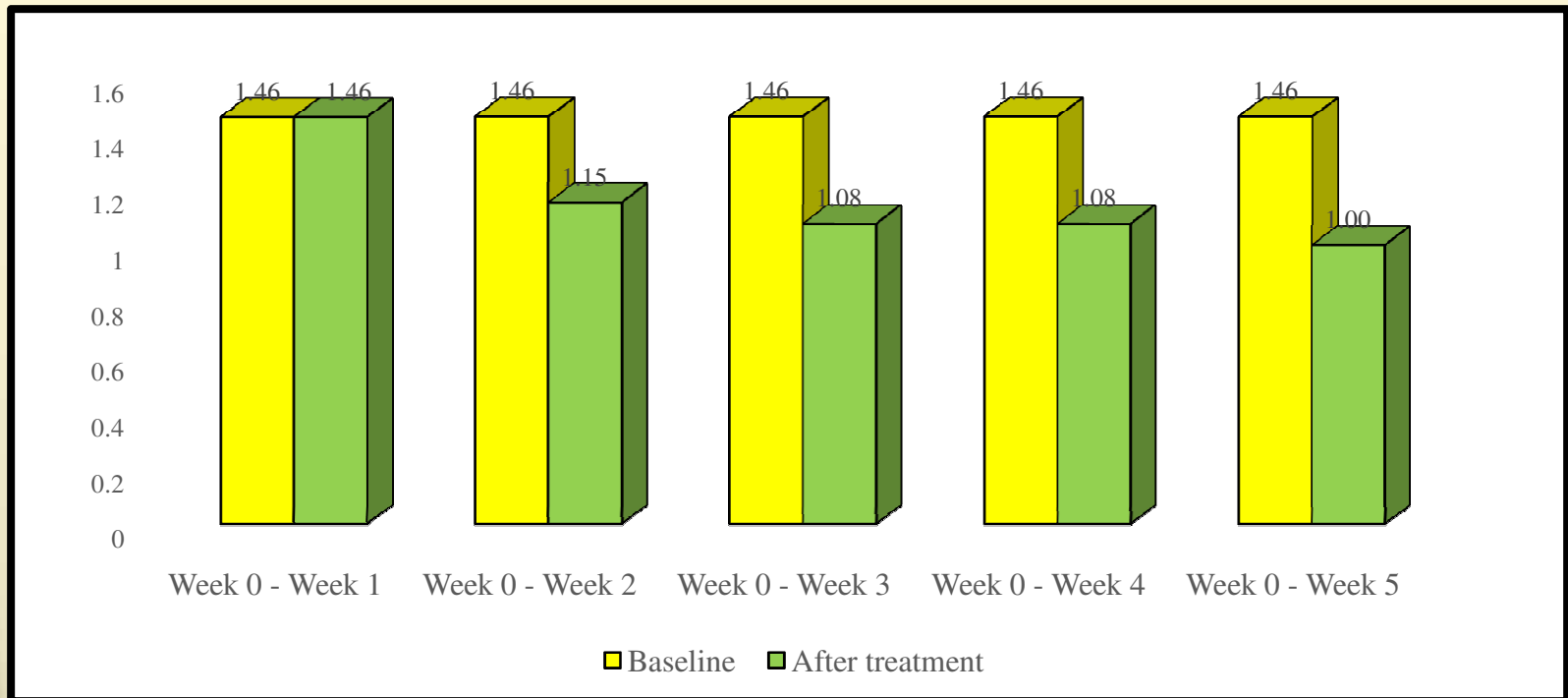
This figure 27 showed that the effect of itching due to KT using Papaya latex in before and 1-5 week after treatment on FIA. Mean difference value between

- week 0 and 1 week after treatment was 0.08. The p value was 0.003.
- week 0 and 2 weeks after was 0.31. The p value was 0.000.

- 
- week 0 and 3 weeks after treatment was 0.5. The p value was 0.000.
  - week 0 and 4 weeks after was 0.58. The p value was 0.000.
  - week 0 and 5 weeks after treatment was 0.58. The p value was 0.000.

- 
- There was statistically significance before and 5 weeks after treatment on FIA with KT using Papaya latex. In 5 weeks after treatment, itching was 36.7 % relieved.

# Figure 31. Comparison of Burning Sensation





## Comparison of Burning Sensation

This figure 28 showed that the burning effect of KT using Papaya latex in before and 1-5 week after treatment on FIA. Mean difference value between


- week 0 and 1 week after treatment was 0.00
- week 0 and 2 weeks after treatment was 0.31.

The p value was 0.008.

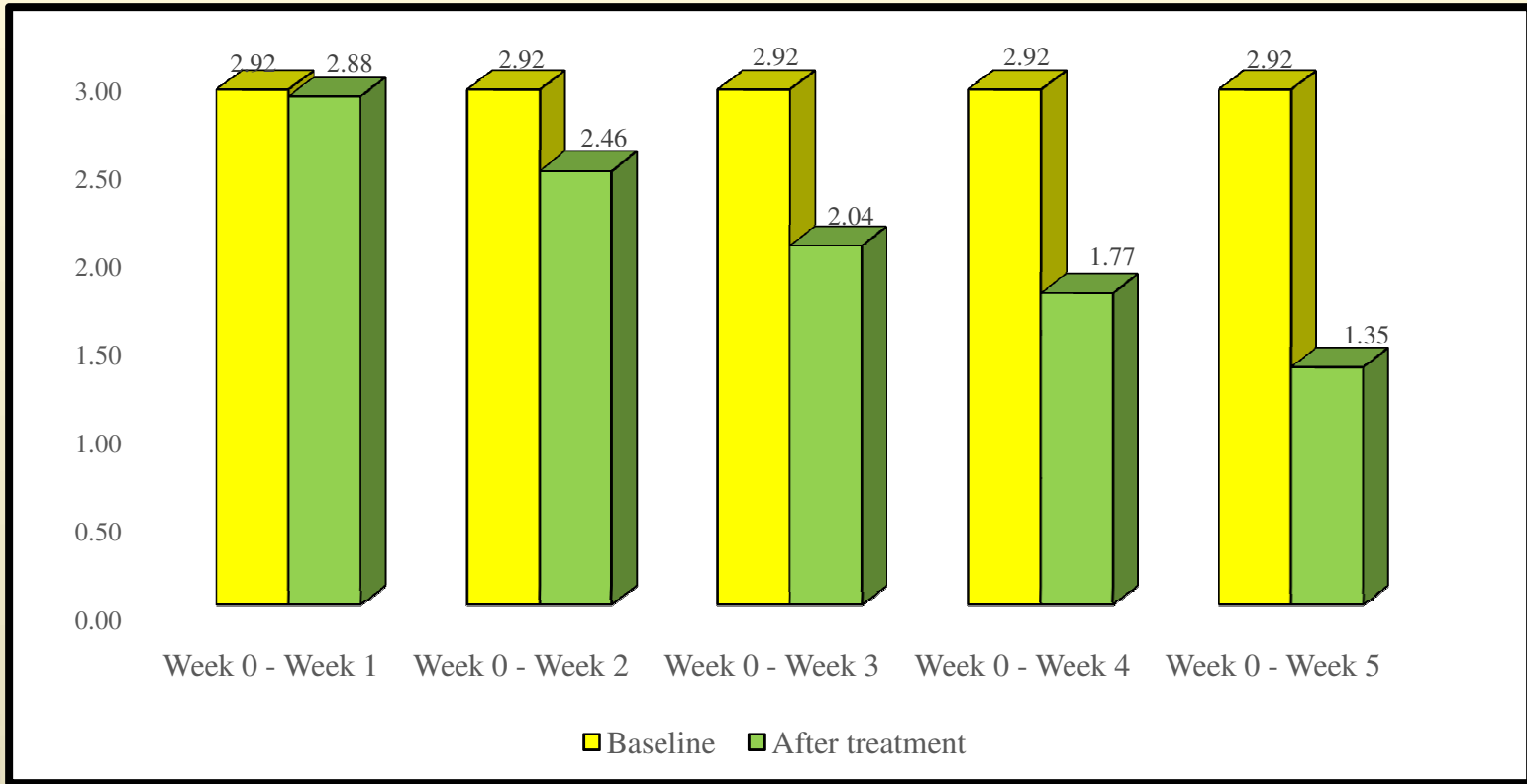
- week 0 and 3 weeks after treatment was 0.38.


The p value was 0.005.



- 
- week 0 and 4 weeks after treatment was 0.38.  
The p value was 0.005.
  - week 0 and 5 weeks after treatment was 0.46.  
The p value was 0.003.
  - The effect of KT using Papaya latex in burning sensation was improved week by week. 31.5% of burning sensation was achieved.

# Figure 32. Comparison of Discharge






## Comparison of Discharge


This figure 29 showed that the effect of discharge due to KT using Papaya latex in before and 1-5 week after treatment on FIA. Mean difference value between

- week 0 and 1 week after treatment was 0.04. The p value was 0.327. Statistically not significance.
- week 0 and 2 weeks after treatment was 0.46. The p value was 0.001.



- week 0 and 3 weeks after treatment was 0.88.  
The p value was 0.000.
- week 0 and 4 weeks after treatment was 1.15.  
The p value was 0.000.
- week 0 and 5 weeks after treatment was 1.57.  
The p value was 0.000.

- 
- Therefore, there was statistically significance before and 5 weeks after treatment on FIA with KT using Papaya latex. In 5 weeks after treatment, discharge was 53.8 % relieved.



## Table 5. Assessment of Unit Cutting Time

<b>One-Sample Statistics</b>				
	<b>N</b>	<b>Mean</b>	<b>Std. Deviation</b>	<b>Std. Error Mean</b>
Average day per cm cutting	26	-12.7570	3.12826	.61350

This table 5 showed that the unit cutting time of KT with Papaya latex was 12.76 day/cm.

**Table 6. Percent improvement of mean score on overall signs and symptoms**

<b>Comparison of mean score on overall signs and symptoms</b>	<b>Week 0 Mean score</b>	<b>Week 5 Mean score</b>	<b>Mean Difference</b>	<b>Percent relief</b>
Week 0 - Week 5	8.31	4.47	3.84	46.20

This table 6 showed that the overall effect of signs and symptoms are 46.20% relieved after five weeks treatment.

## CONCLUSION AND SUGGESTION

- The clinical presentation (cutting length, pain, itching, burning sensation and discharge) of fistula-in-ano patient by comparing before and after statistically significant  $p$  0.00.
- All signs and symptoms were approved clinically and statically. This study included 26 patients with FIA and 80.5 % of the length of the tract was relieved and its unit cutting time was 12.757 day/cm.





- At the end of this study, 52.3% of the pain was relieved, itching was relieved 36.7%, burning sensation was relieved 31.5 % and discharge was relieved 53.8%.
- KT using Papaya latex is effective and recommended in the treatment of patients with Fistula-In-Ano.


- It was suggested that KT using Papaya latex is effective in the management of FIA patients according to this study because it has no side effect and more cost effectiveness and easily available ingredients.

- The present study was conducted not only in limited sample size but also for short-term study. Therefore, further study should be carried out in large sample size for long term study related with the effect of KT using Papaya latex.




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