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# EFFECT OF ACUPUNCTURE IN PRIMARY DYSMENORRHOEA – A PILOT RANDOMIZED CONTROL TRIAL

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## ABSTRACT

**Background:** Primary dysmenorrhea (PD) is one of the common medical problems among the adolescent girls and young women. According to modern medicine, PD is painful menstruation without any underlying pathologies. Whereas in TCM PD refers to menstrual pain that occurs due to blockage or deficiency of chi, heat retention, liver, and kidney imbalance, dampness of wind. Acupuncture has good impact in case of pain and hormonal problems. Hence, acupuncture can be a good choice of intervention for PD.

**Methods:** A total of sixty subjects, mean aged (21.1 ± 1.81) were randomly assigned into two groups after satisfying the inclusion and exclusion criteria. Experimental group (EG, n=28, dropouts 2) and control group (CG, n=26, dropouts 4). Both groups were assessed at baseline and after 6 months with WHOQOL BREF questionnaire. With the help of VAS (Visual Analog Scale) the pain was assessed during the menstrual phase prior to the acupuncture intervention and post intervention periods on the first, second, third and after 6 months. TCM based acupuncture was given to EG and western acupuncture was given to CG. The intervention was during the menstrual phase for 3 consecutive months in both the groups. Follow up was conducted after 6 months. 28 subjects of EG and 26 subjects of CG completed the study successfully.

**Results:** The EG showed significant improvement in the pain and quality of life in all domains as compared to the CG.

**Interpretation and Conclusion:** TCM based acupuncture given for 3 months during the menstrual phase showed pain reduction in the consecutive follow up months and thereby it also showed improvement in the quality of life.

**Key Words:** Primary Dysmenorrhea, Acupuncture, TCM Acupuncture, Western Acupuncture, Pain management, Quality of Life.

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## INTRODUCTION

Dysmenorrhea is one of the common gynecological problem where there will be painful cramps of uterus during menses[1]. There are two categories of dysmenorrhea, primary and secondary. Primary dysmenorrhea (PD) is termed as painful menstruation without any organic pathology. Although the cause of PD is unknown, elevated endometrial prostaglandins and its metabolites are said to be the causative factor. Nearly about 50% of the menstruating women are facing PD around the world. PD is not only a clinical problem, but also a biggest social issue for menstruating women[2]. Till now there is no evident found for the possible mechanism for the etiology of the PD. Current research states that the excess or imbalance of the prostanoids and the eicosanoids which is released from the endometrium during the menstruation is the possible cause of the pain. Evidence from research states that uterine hyper contractility, reduced uterine blood flow, increased peripheral hypersensitivity induces pain[3]. Prostaglandin is found to be involved in the hyperactivity of the myometrium. There are also other possible mechanisms such as cervical factors, ovarian hormones, vasopressin, nerve, and psychological factors also act through prostaglandin release. Sometimes an action directly on the myometrium and blood flow may also occur[4].

Acupuncture is one of the best treatment measure for reducing pain[5]. Acupuncture is held to have originated in China. Acupuncture is the medicine where fine needles will be inserted in the specific points of the meridian corresponding to the ailment. The various strands of TCM acupuncture theories and practice were brought together into a single strand called Traditional Chinese Medicine (TCM). The theoretical basis of TCM comprises of “meridian” and the vital energy “Qi”[6]. TCM views the menstrual cycle as the function of the chongmai, liver and kidney channels. The uninhibited flow of energy in these channels will lead to the proper menstrual cycle[7]. TCM categorizes the dysmenorrhea patients into different categories according to the clinical manifestations. The following are the patterns based on the theories of the TCM[8-13].

i. Qi and blood stagnation
ii. Kidney and liver qi deficiency
iii. Accumulation of dampness
iv. Qi and blood deficiency
v. Cold stagnation

  

## AIM

The aim of this study was to compare the effectiveness of acupuncture points based on a common protocol and individual based selected acupuncture points on pain and quality of life in Primary dysmenorrhea.

## OBJECTIVES OF THE STUDY

- Reducing the pain in primary dysmenorrhea, and
- Improving the quality of life

### Diagnostic Criteria

The diagnostic tool used in this study for confirming primary dysmenorrhea is Menstrual Symptom Questionnaire developed by Margaret A. Chesney and Donald L. Tasto, Department of Physiology, Colorado state university, USA, 197423.

## MATERIALS AND METHODS

### Subjects:

A total of 60 subjects of female gender with age group ranging between 17 to 24 years participated in the study.

### Description of the subjects including the selection of samples:

The study subjects were randomly recruited from the outpatient department of Government Yoga and Naturopathy Medical College and Hospital, Arumbakkam, Chennai, Tamilnadu, India.

### Demographics:

**Table No.1 Describes the demographic details of the subjects**

| | EXPERIMENTAL GROUP | CONTROL GROUP |
|---|---|---|
| **Age[Mean ± SD]** | 21.43 ± 1.66 | 20.77 ± 1.91 |
| **Distribution** | N=30<br>2 dropouts | N=30<br>4 dropouts |
| **Total Participants Completed the Study** | 28 | 26 |
| **Ages Range** | 17 – 24 years | |

  

**Ethical Clearance:**

Ethical clearance was sought from the Institutional Ethics Committee prior to the start of the study and approval for the same was granted.

**Written Informed Consent:**

All the subjects expressed their willingness to participate in the study by giving a signed informed consent.

**Inclusion Criteria:**

The following criterions were used to select the subjects into the study.

- Age group: 14 to 25 years.
- Adolescent girls and Young women with Primary Dysmenorrhea.

**Exclusion Criteria:**

- People with underlying pathological condition along with PD
- Pregnancy
- Use of oral contraceptives
- Intrauterine devices
- Lactating Mothers
- History of abdominal surgery
- Participation in other therapies for pain

**Randomization:**

Randomization was done using the online randomization tool at a website www.sealedenvelope.com Block randomization method was used. 6 Blocks with 10 units in a block was generated and subjects were taken into the study according to that.

**Allocation of Patient into Study and Control Groups:**

The patients were allocated randomly to the experimental or the control group. Neither the investigator nor the patients were blinded to the intervention. The subjects were not informed of the group they were taken in. 69 subjects were initially screened and sixty of them were recruited and randomly assigned to two groups based on the block randomization list

retrieved from the online source as Experimental group (Group A) (n=30) and Control Group (Group B) (n=30).

The trail profile of the study is presented as **Figure 1** which illustrates the study plan, flow of patients across data points and reasons for the drop out.

**Figure 1:**

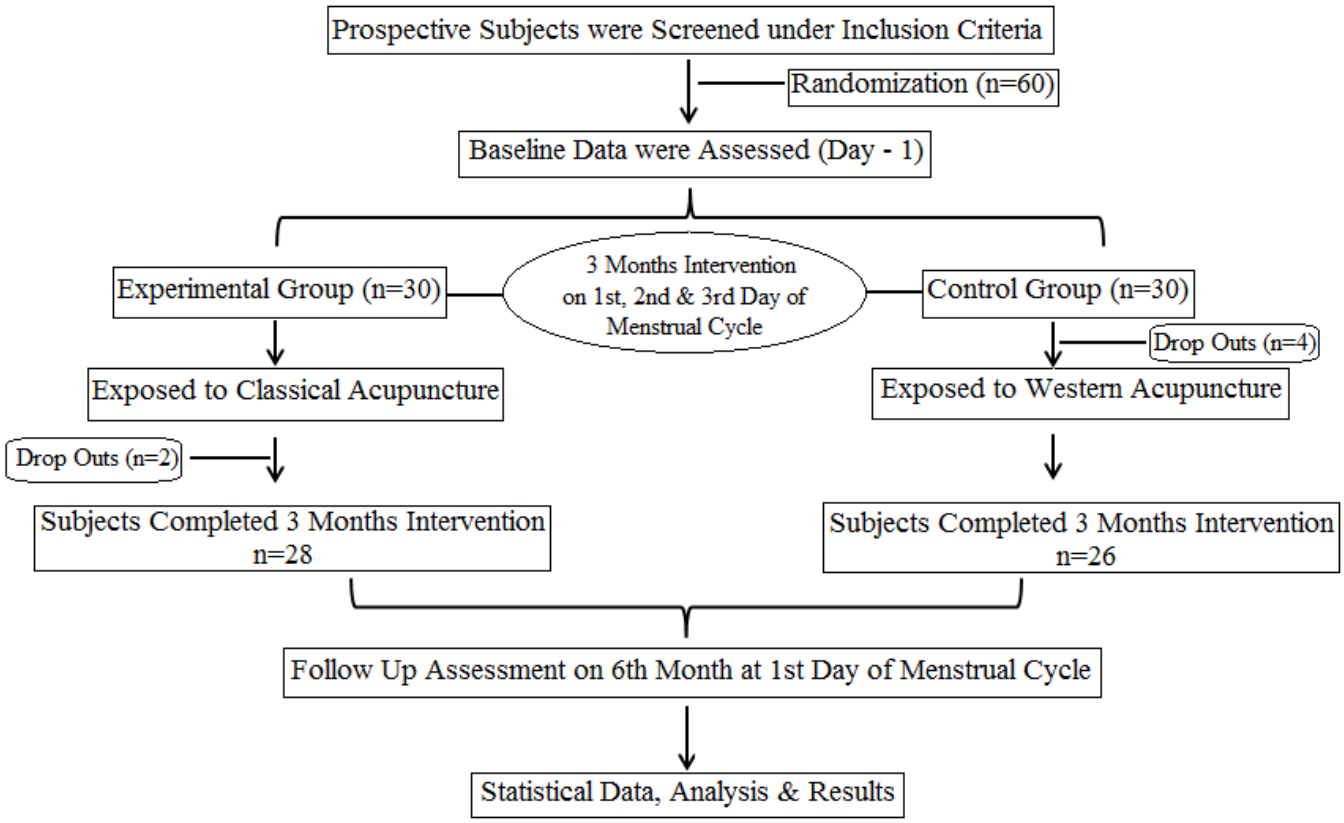


**Table 2: List of Primary and Secondary outcome variables**

| PRIMARY OUTCOME VARIABLES | SECONDARY OUTCOME VARIABLES |
|---|---|
| Visual Analog Scale (VAS) | WHO QOL BREF (Quality of Life Questionnaire) |

**Primary and Secondary Outcome Variables:**

The Visual Analogue Scale (VAS) is a simple and most commonly used tool for the measurement of the pain in the subjects. This is considered the effective tool to assess the

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efficacy of any intervention in clinical practice[14]. WHO-QOL BREF is developed by the WHO-QOL team who has previously developed the WHO-QOL 100. It is developed with fifteen international field centers with an aim to develop the quality of life that can be applied cross-culturally.

**Test Intervention:**

The TCM acupuncture group will be diagnosed according to the diagnostic patterns and points will be prescribed to each subject in the experimental group accordingly. Maximum of seven points was given to each subject. The following **Table 3** explains the diagnostic patterns:

**Table 3: Diagnostic Patterns**

| TCM Patterns | Symptoms or Clinical Features Presented by Patient | Points Prescribed |
|---|---|---|
| Qi and Blood Stagnation | • Abdominal distention<br>• Pain in lower chest region<br>• Breast distension<br>• Dark flow with clots<br>• Depression<br>• Anger<br>• Increased flow | Liv 3, Sp 4, Sp 6, Sp 10, LI 4, Ren 3, Ren 6, UB 32 |
| Kidney and Liver Qi Deficiency | • Pain during the flow<br>• Pressure relieves the pain<br>• Weakness<br>• Muscle pain<br>• Pale tongue with thin coating | St 36, Sp 6, Ren 4, Ren 3, UB 17, UB 18, UB 23, K 3 |
| Qi and Blood Deficiency | • Pain during and after the flow<br>• Palpitation<br>• Insomnia<br>• Dream disturbed sleep<br>• Scanty flow | St 36, Sp 6, Sp 8, Ren 3, Ren 4, UB 17, UB 20, UB 32 |
| Stagnation of Cold | • Warmth relieves the pain<br>• Scanty flow<br>• Aversion to cold<br>• Cold sensation in limbs | UB 23, Ren 3, Ren 4, Ren 6, Lu 7, K 6, Du 4, St 36 |
| Accumulation of Dampness | • Burning sensation<br>• Pain during the flow and duration is prolonged<br>• Fever sometimes<br>• Yellow purulent vaginal discharge | Sp 12, St 32, LI 11, Sp 10, P4 |

  

**Control Intervention:**

In this study, Western Acupuncture (WA) is used in the control group being the Group A and TCM acupuncture is used in the Experimental group being the Group B.
Point pre-selected for the WA group are, Sp-6, LI-4, Ren-2, Ren-3, St-36 and P-6.

**Data Extraction:**

The data was collected using primary outcomes and secondary outcome variables. The assessments were done on the first day, second day and third day of the menstrual phase of first, second and third months (baseline data) and on sixth month, first day of the menstrual phase (post data). The data was organized in Microsoft Excel Sheets (Version 2010).

**Data Analysis:**

Data expressed as Mean and SD. Inter group and intra group comparison of mean difference was done by paired and unpaired t test using R statistical software version 3.1.1.

**RESULTS**

The study was conducted to evaluate the difference in the effect of western and TCM acupuncture on the pain and QOL in subjects with primary dysmenorrhea. Subjective measures were taken for assessment. VAS and QOL was taken from all the participants in the study. VAS was taken before and after the intervention on each day of the bleeding phase of the menstrual cycle for three days. First month the significance in the experimental group was p=0.001, 0.003 and 0.04 on the first three days respectively which is considerably significant ($p<0.05$). Similar data obtained during the second month was p=0.002, 0.03 and 0.04 respectively on first three days of the bleeding phase of the menstrual cycle. The third month the significant was found to be less significant on the second day, p=0.04, 0.002 and 0.1 respectively.
In control group similar data was obtained with the VAS. This was also significant but less as compared to the experimental group. This signifies that TCM acupuncture helped in the pain relief much better than western acupuncture.

The post VAS scores were compared between the experimental and the control groups where the p value was 0.001 through all days of intervention in the first three months.

The result can be explained as that the TCM acupuncture is very significant, where only 0.001 can be of the negative side.

The VAS was also checked on the first day of the sixth month. This was also compared between the two groups and was found the results were significant (p=0.001).

When it comes to the QOL, the significance was good in both the groups for domain 1 and domain 2. But in domain 3 and 4, experimental group had significant result (p=0.01, 0.002), whereas in the control group the significancy was found to be less (p=0.06, 0.08). From this it can be clearly understood that both the types of acupuncture helped to improve the physical and psychological health, but the TCM way of selecting acupuncture points helped in improving the social relationship and the quality of life to the environment they live in. This can help in reducing the absenteeism, irritability etc. in the young adolescent women suffering from the PD.

**Table 4: Comparison of VAS score in Experimental group**

| VAS score | | Pre score | Post score | P value |
|---|---|---|---|---|
| 1st month | 1st day | 9.107±0.21 | 1.64±0.26 | **0.001** |
| | 2nd day | 4.35±0.27 | 0.57±0.11 | **0.003** |
| | 3rd day | 0.64±0.24 | 0.14±0.08 | **0.04** |
| 2nd month | 1st day | 5.5±0.31 | 1.10±0.15 | **0.002** |
| | 2nd day | 0.32±0.11 | 0±0 | **0.03** |
| | 3rd day | 0.14±0.08 | 0±0 | **0.04** |
| 3rd month | 1st day | 2.17±0.33 | 0.10±0.05 | **0.002** |
| | 2nd day | 0.07±0.04 | 0±0 | **0.1** |
| | 3rd day | 0±0 | 0±0 | **0** |

**Table 5: Comparison of VAS score in Control group**

| VAS score | | Pre score | Post score | P value |
|---|---|---|---|---|
| 1st month | 1st day | 8.78±0.49 | 7.10±0.46 | **0.58** |
| | 2nd day | 8.61±0.18 | 6.65±0.19 | **0.38** |
| | 3rd day | 7.84±0.24 | 5.07±0.25 | **0.04** |
| 2nd month | 1st day | 8.65±0.24 | 6.84±0.29 | **0.39** |
| | 2nd day | 8.31±0.23 | 6.65±0.30 | **0.29** |
| | 3rd day | 6.42±0.29 | 2.57±0.39 | **0.48** |
| 3rd month | 1st day | 8.21±0.12 | 6.21±0.16 | **0.07** |

| | | | | |
|---|---|---|---|---|
| | 2nd day | 6.84±0.27 | 3.07±0.36 | **0.01** |
| | 3rd day | 5.61±0.27 | 1.7±0.36 | **0.02** |

**Table 6: Comparison of Post VAS score in between Experimental and Control group**

| VAS score | | Experimental | Control group | P value |
|---|---|---|---|---|
| 1st month | 1st day | 1.64±0.26 | 7.10±0.46 | **0.001** |
| | 2nd day | 0.57±0.11 | 6.65±0.19 | **0.001** |
| | 3rd day | 0.14±0.08 | 5.07±0.25 | **0.001** |
| 2nd month | 1st day | 1.10±0.15 | 6.84±0.29 | **0.001** |
| | 2nd day | 0±0 | 6.65±0.30 | **0.001** |
| | 3rd day | 0±0 | 2.57±0.39 | **0.001** |
| 3rd month | 1st day | 0.10±0.05 | 6.21±0.16 | **0.001** |
| | 2nd day | 0±0 | 3.07±0.36 | **0.001** |
| | 3rd day | 0±0 | 1.7±0.36 | **0.001** |

**Table 7: Comparison of QOL scores before and after the intervention in between Experimental and Control group.**

| QOL | Experimental group | | P value | Control Group | | P value |
|---|---|---|---|---|---|---|
| | **Before** | **After** | | **Before** | **After** | |
| Domain 1 | 40.33±15.82 | 82.92±10.84 | 0.0001 | 26.53±8.97 | 59.08±6.48 | 0.001 |
| Domain 2 | 45.50±13.41 | 64.89±11.84 | 0.0001 | 42.63±9.49 | 52.96±9.55 | 0.001 |
| Domain 3 | 41.83±13.60 | 43.89±14.69 | 0.01 | 31.37±9.74 | 33.23±.08 | 0.06 |
| Domain 4 | 69.53±13.60 | 72.46±13.76 | 0.002 | 61.43±10.37 | 63.19±9.02 | 0.08 |

## DISCUSSION

The result of this trial was expected to produce clinical evidence that TCM acupuncture is the effective way to relieve the pain and improve the QOL in the Primary dysmenorrhea subjects. Acupuncture is well established for its effect in pain relief[15]. As the incidence of PD is increasing, mainly in the young adolescent women, this trial was conducted. For the young women with the PD, severe pain being the most critical symptom became the key reason to disturb their QOL. On a 10-pointed VAS, it was found that on average 8-10 points was given by many young PD suffering women[16]. A pilot study has concluded that the pain experienced by the PD women is similar to the pain of a renal colic. So, the women suffering from the PD

also requires similar attention and care that a renal colic patient gets[17].

The common management which is taken by most of the PD suffering women is the use of NSAIDs. The mechanism behind the use of NSAIDs is by the inhibition of the cyclooxygenase which is an enzyme responsible for the formation of the prostaglandins and other prostanoids. The excess of the prostaglandins and the prostanoids serves to be the major reason for the un-rhythmic contractions in the uterus associated with the reduced local blood flow. It is also noted that in such cases the sensitivity of the peripheral nerves is increased when the prostaglandins are increased[18,19]. A meta-analysis has analyzed about 20 RCTs with 2134 participants and has found that there is a moderate level of evidence that supports the benefits of acupuncture or moxibustion in the PD[20].

A systematic review has reported that, acupuncture is a promising tool for the management of the menstrual pain. It has also stated that there are certain methodological flaws which give limitations for the studies conducted. It was also stated that neither acupuncture nor moxibustion should be interchanged with each other in providing relief to the PD patients[21].

60 subjects were recruited for this study based on the inclusion criteria in both the control and experimental group. The intervention was given for three months during their bleeding phase for the first three days in both the groups. VAS was taken for both the groups before and after the needling procedure. No electrical stimulation was given to any acupuncture points to the subjects of any group. After three months of intervention, the VAS and QOL was taken by the sixth month (means in the follow up period). VAS was taken during the first day of their bleeding phase in the sixth month.

The results from this study revealed that the TCM way of selection of acupuncture points for the primary dysmenorrhea patients is more effective in relieving their pain as compared to the western acupuncture. In addition to the pain relief there was also sufficient improvement in the QOL in the patients.

There is a significant difference ($p<0.05$) in the VAS scores of the PD subjects within the experimental group when compared with the first and third month of the intervention. The QOL scores was compared between the two groups before the start of the intervention and after three months of the intervention period which was found to be significant too ($p<0.05$). Within the control group the significance ($p=0.04 – 0.58$) was slightly less after the first month intervention. The significance found to be better on the second and third months of intervention. The significance ($p=0.02$) was better in the control group by third month of the

intervention. In the experimental group the significance (p=0.001) was far better than the control group.

Pricking an acupuncture point with an acupuncture needle generates a nerve signal in the skin, activates the sensory receptors residing in the subcutaneous tissue and the muscles located under the acupuncture point. There is also evidence to state that the acupuncture point needling stimulates the mechanoreceptors and the pain receptors in the tissues under the acupuncture point[22,23].

The mechanoreceptors in the skin and the tissues underneath include the Meissner's corpuscles, Merkel's corpuscles and the Pacinian corpuscles[24].

Acupuncture needling

↓

Activates the Mechano and the Pain receptors underneath the Needling areas.

↓

Sensory signal is generated

↓

Sensory signals are transmitted to the spinal cord through the receptor called as Aβ axon.

↓

This receptor have low threshold of activation as compared to the C or Aδ axon which have a high threshold of activation that is able to transmit pain, temperature, and crude touch sensation[25].

**Mechanism of the TCM acupuncture:**

The pathogenesis of the TCM is widely grouped into three as, Pathogenesis of Qi, Pathogenesis of Yin-Yang imbalance, and External and Internal Pathogenic Factors. In primary dysmenorrhea the pathogenesis lie in any pathology in Qi or the Pathology with the external or internal pathogenic factors[26, 27].

Any of such above pathologies hamper the function of the internal organs and the normal physiology. When left untreated it may become chronic which is visible as a diseased condition. According to the TCM Qi and Blood is very essential to be in a normal circulation for a harmonious menstrual cycle. Liver energy nourishes the blood and regulates the

menstruation. Kidney stores the essence and governs the reproduction and growth. Accumulation of dampness can lead to the infections and any inflammations further [28-31].

TCM Explanations of the points given to the Experimental group:

Qi and Blood stagnation:

- Liv 3- Moves Qi and Blood and Eases the pain.
- Sp 4- Regulates the menstruation, eliminates the dampness
- Sp 6- Helps to move the blood and ease pain
- Sp 10- Moves blood
- LI 4- Analgesic point
- Ren 3- Regulates the menstruation
- Ren 6- Tonify Qi and Blood
- UB 32- strengthens the Kidney

Kidney and Liver Qi Deficiency:

- St 36- Regulates the Spleen, nourishes the blood and yin
- Sp 6- Nourishes the Yin
- Ren 4- Nourishes the kidney
- Ren 3- Strengthens the kidney
- UB 17- Nourishes the Yin
- UB 18- Spreads the liver Qi, regulates, and nourishes the Liver blood
- UB 23- Strengthens the kidneys, tonifies the kidney Qi and nourishes the kidney yin.
- K 3- Nourishes the kidney yin, tonifies the kidney yang

Qi and blood deficiency:

- St 36 – Tonifies the Qi and Blood; Regulates the Uterus connecting channel.
- Sp 6- Nourishes the Blood, regulates the menstruation.
- Sp 8- Regulates the Uterus and Blood
- Ren 3- Regulates the menstruation
- Ren 4- Tonifies the Qi
- UB 17 – Removes Blood stasis, Nourishes and harmonizes the blood
- UB 20 – Regulates the Qi in the middle and raises the Qi.
- UB 32- Strengthens the genitals

Stagnation of cold:

- UB 23- Eliminates the cold
- Ren 3- Drains the dampness and dispels the stagnation of cold.
- Ren 4- Eliminates the cold and dampness
- Lu 7- opens the directing vessel and regulates the uterus

- K 6- Clears the empty heat and nourishes the kidney
- DU 4- Warms the channel, strengthens the kidney
- St 36- Transforms the dampness and cold, Tonifies the Qi

Accumulation of dampness:

- Sp 12- Clears heat and Drains the Dampness
- St 32- Opens the channel and eliminates the wind and dampness.
- LI 11- Drains the dampness
- Sp 10- Regulates the menstruation, expels the dampness
- P 4- Tonifies the blood and eliminates the dampness

Possible set of interpretations of TCM based Points and their neurobiological and fascia network models[32-34]. It was found that the points selected by the TCM have more sensitivity than the other areas which are also an acupuncture point. Here the difference lies in the intensity of the response rather than the structural components.

## LIMITATIONS

The sample size is relatively smaller. Hence, generalizing the study outcomes to a larger population would not be definitely conclusive. Only subjective measures were used to assess the effect of the interventions like the QOL scale and VAS. More objective measures could validate the study. Double or triple blinding was not possible in this study since the patients come for the acupuncture treatment and no medicines were given. This may affect the credibility of the study. All the participants of this study were college students which limit the generalization of the result to a diverse group of people.

## DIRECTIONS FOR FUTURE RESEARCH

This study should be replicated with a larger sample size. The study should be conducted in a generalized population with a prolonged duration will be better. Objective measures can be assessed to make the study more credible.

## CONCLUSION

The initiation of this study was keeping in mind the discomfort faced by the young adolescent women during their menstrual cycle, which affected their quality of life leading to the absenteeism in their workplace and college. The most common preferred management for the

pain during the primary dysmenorrhea is NSAIDs and OCPs. Regular intake of these drugs does not seem to be safe. Studies have proven adverse effects of these drugs[35]. The study conducted showed that the selection of acupuncture points based on the TCM method have a significant effect in easing the pain and improving the quality of life of young adolescent women. The study limited to the college students, limited the effects among the generalized population. Further research may warrant these limitations. Acupuncture was found to be a safe and effective treatment option for the primary dysmenorrhea in young adolescent women.

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