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Effect of *Sikanjabeen Lemooni* in *Qay'al-Haml:* An Open Observational Study

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Abstract: *Qay'al-Haml (Nausea and vomiting in pregnancy) is defined as the symptom of nausea and/or vomiting during early pregnancy. It occurs in up to 80% of pregnant.The physical problems of coping with qay'al-haml can lead to emotional problems, which can in turn exacerbate the physical problems, having a significant reduction in quality of life. The first line of treatment being doxylamine –pyridoxine combination; although effective has reported side effects. Various unani drugs mentioned for the treatment of qay'al-haml include gulqand, sharbate anar sheerin, sikanjabeen lemooni, jawarishe anarain etc, although studies proving their effectiveness are scarce. The aim of the study is to evaluate the efficacy of sikanjabeen lemooni in qay'al-haml.*

Method: *The trial was designed as open observational study, conducted in Dept. of OBG, NIUM hospital, Bengaluru. 30 patients with qay'al-haml between gestational age 7 to 14 weeks were included in the study. Participants were given sikanjabeen lemooni 25 ml twice daily for 14 days. Nausea and vomiting and improvement in quality of life were assessed by PUQE Index and NVPQOL questionnaire respectively. Patients were followed for two weeks during treatment and one week thereafter. Student t test and paired proportion test were used to find the significance of study parameters.*

Results: *There was a significant decrease in PUQE and NVPQOL scores on day 7, continued through day 14 and after treatment with a P value <0.001. 86.6% patients achieved complete relief from NVP and accomplished much higher than average quality of life at the end of treatment period*

Conclusion: *Sikanjabeen lemooni is effective in management of Qay'al-Haml and is comparable with other existing treatment options. Long term follow-up of the patients until delivery showed no adverse effect of sikanjabeen lemooni on the newborns. However, further randomised controlled trials are needed.*

Keywords: *NVPQOL Score, PUQE Index, qay'al-haml, sikanjabeen lemooni.*

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I. Introduction

Nausea and vomiting in pregnancy is used to describe a wide spectrum of symptoms; at one end of the spectrum is the common, mild to moderate nausea and vomiting that is usually limited to the first trimester & at the other end are the intractable, severe symptoms of hyperemesis gravidarum (HG) that is associated with weight loss, dehydration, electrolyte imbalance and hospitalisation.[1] Whether symptoms are mild, moderate, or severe, they can have a negative effect on the pregnant woman's quality of life.[2] It is the most common complication affecting women in the first trimester,[3] occurring in 44% to 89% of pregnant women.[4]

The Pregnancy –Unique Quantification of Emesis (PUQE) score was to assess the severity of NVP, as well as to follow the response to treatment and improvement over time,[5] QOL was measured with the only existing NVP-specific QOL questionnaire.[2]

Nausea and vomiting often pose a significant problem because they last longer and are more distressing than is generally understood. Uncertainty about how long it will take for symptoms to resolve may lead women to feel disorganized and even to lose control over themselves, their families, and their work.[6] Concern about the harmful effect of medication on the fetus may cause many women not to seek treatment or to try alternative therapies for nausea and vomiting. The only medicine that is FDA-approved for NVP is doxylamine – pyridoxine combination; although effective has reported side effects like somnolence, headache, dizziness, dry mouth, and hypersensitivity.[7]

Various unani drugs are mentioned for the treatment of *qay'al-haml* including *gulqand, sikanjabeen sada, sharbat anar sheerin, sikanjabeen lemooni, jawarish anarain, mastagi, ilaichi* etc[8-11] although studies proving their effectiveness are scarce. Addressing these issues in the primary care management of the pregnant

women with nausea and vomiting is the focus of this paper. *Sikanjabeen lemooni*, a poly herbal unani formulation consisting of *sirka* (acetum vinegar), *aab-e-limu* (citrus limon), *sat limu* (citric acid), *qand safaid* (sugar)[12] possessing properties viz antiemetic, antianemic, appetizer, digestive, exhilarant, anti oxidant properties is selected for the study.[13, 14] The aim is to validate scientifically the efficacy of *sikanjabeen lemooni* in *qay'al-haml*.

II. Materials And Methods

2.1 Study design

Open observational study was carried out from January 2017 to December 2017 in Dept. of OBG National Institute of Unani Medicine hospital, Bengaluru. Ethical clearance was obtained from institutional ethical committee vide no. NIUM/IEC/2015-16/012/ANQ/04.

2.2 Sample size calculation

Sample size was calculated by using formula, $n = 2[(Z_\alpha - Z_\beta) \times \sigma]^2 / (\mu 1 - \mu 2)$[15] around the mean difference of PUQE of two estimates. Mean and SD of PUQE was taken from previous studies.

n = sample size required, $\mu 1$ = mean score before treatment, $\mu 2$ = mean score after treatment, $\mu 1$-$\mu 2$ = clinically significant difference, σ = standard deviation. The sample size calculated was 27.08; considering 10% dropout, a total sample size of 30 was taken.

2.3 Selection criteria

Pregnant woman with c/o nausea and vomiting with singleton intrauterine pregnancy within gestational age 7 to 14 weeks included in the study. Women with hyperemesis gravidarum, treated by other antiemetics, with any medical conditions associated with pregnancy like severe anemia, hypertension and diabetes mellitus and with history of other non-obstetrical causes of vomiting like cholecystitis and appendicitis were excluded from the study by performing Hb%, RBS, CUE, USG-obstetric.

2.4 Participants

Total 68 patients were screened; 3 patients were not eligible due to HG. Out of 65 eligible patients; 22 refused to participate and 13 were excluded; 1 patient aborted before treatment started, 1 had twin pregnancy, in 2 patients each gestational age was >14 weeks and Hb% < 11; 3 had hypothyroidism and 4 patients had UTI. 30 patients were included in the study.

2.5 Intervention

Sikanjabeen lemooni containing –
Aab-e-leemu (citrus. limon),
Sirka desi (acetum vinegar),
Shakar safaid (sugar),
Sat leemu (citric acid).
This syrup was prepared according to the standard methods of preparation.
Dose: *Sikanjabeen Lemooni* 25 ml twice daily for two weeks
The drug was dispense in bottles for 1 week only and the patient was asked to come with bottle in the follow up during treatment to check the compliance. As compliance is an important consideration as most NVP treatment is done on an outpatient basis**.**

2.6 Subjective parameters

Nausea and vomiting in pregnancy.

2.7 Objective parameters

PUQE (Pregnancy Unique Quantification of Emesis)
NVPQOL (Nausea and vomiting in pregnancy-specific Quality of life questionnaire)

2.8 Study procedure

The patients fulfilling the inclusion criteria were enrolled after explaining the study in detail and receiving the written informed consent. Mild and moderate cases assessed by using PUQE Index were enrolled. *Sikanjabeen lemooni* was given 25 ml twice daily orally for two weeks. Assessment of severity of nausea and vomiting was done by PUQE Index and assessment in improvement of quality of life was done by NVPQOL questionnaire before treatment, each follow up during treatment and after treatment. (i.e. D_0, D_7, D_{14}, D_{21}).

2.9 Treatment outcome:
Relieved: No longer having NVP.
Not Relieved: NVP reduced in severity but persist.

3.0 Statistical analysis: Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The Statistical software namely SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data.

III. Results

Table 1: Maternal Characteristics And NVP Status Of The Patients Studied

Age in years	**No. of patients**	**%**
• 18-24	24	80.0
• 25-29	6	20.0
Socio Economic Status		
• Lower	2	6.7
• Lower Middle	11	36.7
• Upper Lower	15	50.0
• Upper Middle	1	3.3
• Upper	1	3.3
NVP (Severity)		
• Mild	9	30
• Moderate	21	70
GAO(In Weeks)		
• 5-8 weeks	24	33.3
• 8-10	6	66.7
H/o Nausea and vomiting in pregnancy		
• Absent	22	73.3
• Present	8	26.7
H/o Motion sickness		
• Absent	24	80.0
• Present	6	20.0
H/o Migraine		
• Absent	30	100.0
Diet		
• Mixed	29	96.7
• Veg	1	3.3
Order of Gestation		
• Primi	17	56.7
• Multi	13	43.3
Nutrition status		
• Average	23	76.7
• Good	7	23.3
BMI		
• <24	23	76.7
• 24-28	4	13.3
• >28	3	10.0
Mizaj		
• Balghami	18	60.0
• Damvi	12	40.0

Table 2: Effect of *Sikanjabeen Lemooni* on NVP

NVP	**Before Treatment**	**Day 7**	**Day 14**	**After Treatment**	**% difference**
Absent	0(0%)	4(13.3%)	21(70%)	26(86.7%)	86.7%
Mild	9(30%)	25(83.3%)	9(30%)	4(13.3%)	16.7%
Moderate	21(70%)	1(3.3%)	0(0%)	0(0%)	-70.0%
Total	30(100%)	30(100%)	30(100%)	30(100%)	-

Table 3: Effect of *Sikanjabeen Lemooni* on NVPQOL

Nausea and vomiting in pregnancy Quality of life questionnaire	**Before Treatment**	**Day 7**	**Day 14**	**After Treatment**
30-50 (QoL Much higher than average)	1(3.3%)	16(53.3%)	29(96.7%)	30(100%)
51-100 (QoL Higher than average)	27(90%)	14(46.6%)	1(3.3%)	0(0%)
101-140 (QoL Average)	2(6.75)	0(0%)	0(0%)	0(0%)
141-190 (QoL Lower than average)	0(0%)	0(0%)	0(0%)	0(0%)
191-210 (QoL Much lower than average)	0(0%)	0(0%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	30(100%)	30(100%)

Table 4: Mean and SD of PUQE/ NVPQOL before, during and after treatment

Pregnancy unique quantification of emesis (PUQE)/ Nausea and vomiting in pregnancy Quality of life questionnaire	**Mean ± SD (P value)**	
	PUQE	NVPQOL
Before treatment	7.50±1.33	79.63±15.32
Day 7	4.93±1.17 <0.001**	49.43±8.99 <0.001**
Day 14	3.37±0.56 <0.001**	36.60±5.17 <0.001**
After Treatment	3.13±0.35 <0.001**	32.63±2.55 <0.001**

Table 5: Treatment Outcome

Outcome	**No. of patients**	**%**
Relieved	26	86.6
Not Relieved	04	13.3
Total	30	100.0

Table 6: Effect of *Sikanjabeen Lemooni* on pregnancy outcomes

Parameters	**No. (N=18)**	**%**
Apgar Score		
One minute		
No depression	16	88.8
Mild depression	02	11.1
Five minute		
No depression	18	100
Mild depression	0	0
Wt.(kg) of baby at the time of delivery		
<2.5	2	11.1
2.5-3	15	83.3
3.5	1	5.5
Infant Gender		
Male	5	27.7
Female	13	72.3

IV. Discussion

The present study "Efficacy of *Sikanjabeen Lemooni* in *Qay'al-Haml*" was carried out on 30 patients in NIUM hospital, Bengaluru. All patients having nausea and vomiting during pregnancy were assessed with the help of objective parameters –PUQE Index and NVPQOL Questionnaire. Patients having mild and moderate NVP were only considered.

3.1 Age:
In present study the mean age of participants was 22.03, with extremes of 18 and 28 years. Majority of participants i.e. 24 out of 30 were in the age group of 18-24 years and 6 in the age group 25-29 years**. (Table 01)**
Studies conducted by Chan et al.[16] and Kuo et al.[17] correlates with findings of our study.
In a study conducted by Pukkila et al. mean age of those participants was 30.5 years. This is contradictory to our study, which may be due to older age of participants in that study.[18]

3.2 Socioeconomic status:
In present study 15 out of 30 patients belonged to upper lower class followed by 11 in lower middle class, 2 in lower class, and one each in upper middle and upper class. **(Table 01)**
A study conducted by Kuo et al.[17] 80 out of 150 belong to middle class, followed by 40 in low class and 30 in high class; this is contradictory to the present study, this might be due to different study settings .

3.3 Diet:
In this study most of the patients had mixed dietary habits except one vegetarian. **(Table 01).** This finding is supported by the study conducted by Pepper et al.[19] who proved that NVP rate is positively related to meat, alcohol and oil crops consumption.

3.4 BMI:
In present study 24 patients out of 30 were of normal weight, followed by 3 overweight patients, 2 underweight and 1 obese. **(Table 01)**
In studies conducted by Chartatos et al.[20] and Lacasse et al.[21] majority of the participants had normal weight, followed by overweight, obese and underweight participants which correlates our study.
In a study conducted by Koren et al.[22] 97 patients out of 259 were obese, followed by 77 patients of normal weight, 71 were overweight and only 9 were underweight. This is contradictory to our study which might be due to different study setting and race of participants.
Two studies conducted by Aroya et al.[23] and Jinabi [24] proved that lower BMI is associated with higher frequency of nausea and vomiting in pregnancy. This is contradictory to our study, which might be due to different study setting.

3.5 *Mizaj:*
Most of the patients in this study possesed *balghami mizaj* 18 (80%), followed by *damvi* mizaj 12 (40%).**(Table 01)** Our findings partially correlates with the concept mentioned in unani literature, where *qay'al-haml* is caused by accumulation of *balgham* and *safra*. This difference may be due to lack of authentic tool for proper assessment of *mizaj* of an individual.

3.6 Nutritional status:
In present study most of the patients had average nutritional status 23 (76.7%) and only 7 had good nutritional status (23.3%). **(Table 01)** NVP results in reduction in appetite and overall energy intake; however nutritional status of pregnant women having NVP depends upon the severity.[25]

3.7 Gestational age at onset:
In present study mean gestational age at the onset of symptoms was 6.70±1.78 weeks. **(Table 01)** In a study conducted by Mazzota et al.[26] mean gestational age of American patients were 6.0±2.8 weeks and Canadian patients were 5.70±2.8 weeks. In a study conducted by Koren et al.[22] mean gestational age at the onset of NVP in Diclectin and placebo group were 5.5±1.8 and 5.46 ±1.7 weeks respectively. In a study conducted by Jamigorn et al.[27] gestational age at the onset of symptoms in acupressure group was 6.2±1.0 weeks and in vitamin group was 6.8±1.5 weeks. The findings of all these studies are well correlated with our study findings. In general NVP appear between 4th and 6th week of gestational age.[28]

3.8 Severity of NVP:
In present study at the time of enrolment 21 out of 30 patients had moderate and 9 patients had mild NVP. **(Table 02)**
In a study conducted by Raheem et al.[29] 66 out of 150 of participants had moderate NVP, followed by severe 50 , mild only 34.These findings are similar to our study.
In a study conducted by Lacasse et al.[28] at the time of enrolment majority of the patients had mild NVP 145 out of 278, followed by moderate NVP 126, then severe NVP only 7. This is contradictory to our study, which might be due to large sample size of this study.

3.9 Parity:
Most of the patients in the present study were primiparous 17 (56.7%), and 13 were multiparous (43.3%). **(Table 01)** In studies conducted by Chhetry et al.[30] and Kuo et al.[17] majority of the patients were primiparous which correlates with our study.
In studies conducted by Lacasse et al,[31] Faramarzi et al.[32] and Mazotta et al. most of the participants were multiparous.[26]
The findings of all these studies are contradictory to our study which might be due to different study settings and race of the participants. In a cohort study by Gadsby et al.[33] showed that there was no association between parity and NVP.

4.0 Previous history of NVP:
In present study out of 13 multiparous women, 8 had history of NVP in their previous pregnancies. **(Table 01)** A study conducted by Lacroix et al.[34] which shows that women having previous history of nausea and vomiting in pregnancy are more likely to develop NVP in the present pregnancy. Another study conducted by Chartatos et al.[20] in this study out of 17070 patients having NVP 5919 had previous history of NVP.
In a cohort study conducted by Gadsby et al.[33] showed that NVP is common among patients who had NVP in previous pregnancy. Our study findings are well correlated with the above studies.
In a study conducted by Chhetry et al.[30] only few patients 16 out of 68 had previous history of NVP. This is contradictory to our study findings.

4.1 Previous history of motion sickness:
In this study 6 patients out of 30 had previous history of motion sickness. **(Table 01)** NVP shares, many characteristics with motion sickness, because both are vestibular dependent. [35]

4.2 Family history:
In the present study family history of NVP was absent. **(Table 01)** In studies conducted by Raju et al.[35]and Chhetry et al.[30] majority of the patients had no family history of NVP; this correlates with our study findings.
In a survey conducted by Vellacott et al.[37] showed that women who had family history of NVP have more chances to develop NVP. These finding are contradictory to our study. According to ACOG guidelines higher levels of NVP have been found in women who had mothers who experienced trouble with nausea in their pregnancy.[38]

4.3 Subjective parameter:
In the present study at the time of enrolment 21 out of 30 had moderate nausea and vomiting, and 9 had mild nausea and vomiting according to the PUQE score. On first follow up on D7, 4 patients got complete relief from nausea and vomiting and 25 patients had mild and only 1 patient had moderate symptoms. On second follow up on D14, 21 patients had no symptoms and 9 patients had only mild NVP. On follow up after treatment, 26 patients achieved complete relief, and in 4 patients symptoms were mild.

4.4 Objective parameters:
Pregnancy Unique Quantification of Emesis (PUQE)
The effect of *sikanjabeen lemooni* in NVP was assessed using PUQE index. Mean±SD of PUQE score before treatment, on D7, D14 and after treatment was 7.50±1.33, 4.93±1.17, 3.37±0.56, 3.13±0.35 respectively; the PUQE score progressively decreased from D7 through D14 and follow up after treatment with p value <0.001 at each follow up. In majority of the cases it reached to normal value.
In one study conducted by Koren et al.[22] in which Diclectin led to significant improvement in NVP symptoms compared with placebo. In that study mean difference in PUQE score before and after treatment was -4.8±2.7 and p value <0.006.
In one pilot study conducted by Maina et al.[39] Tansdermal clonidine shows a significant change in PUQE score from 13.8 to 6.3 and p value is <0.001.
Another study conducted by Kia et al.[40] which shows reduction in PUQE score by lemon inhalation in NVP patients with p value <0.001.
The efficacy of *sikanjabeen lemooni* in NVP is comparable with the above treatment options.

NVPQOL score:
The effect of *sikanjabeen lemooni* on quality of life in patients with NVP was assessed using NVPQOL questionnaire. Mean ± SD of the NVPQOL score before treatment, on D7, D14, and after treatment were 79.63±15.32, 49.43±8.99, 36.60±5.17, 32.63±2.55 respectively; the NVPQOL score progressively decreased

from D7 through D14 and follow up after treatment with p value <0.001 at each follow up. Quality of life in patients was much higher than average during final assessment after treatment.

In a study conducted by Mendoza et al.[41] compression stockings in NVP shows reduction in NVPQOL score, with p value is <0.001.

There was a significant reduction in NVPQOL score which indicates improvement in QOL in our study which shows that *sikanjabeen lemooni* is comparable with compression stockings in improving quality of life in women with NVP.

4.5 Pregnancy outcome:

In present study 18 patients were delivered during study period, most of the babies at birth had normal weight 2.5-3 kg and had no depression on Apgar score assessment. Out of 18, 13 were females and 5 were males. **(Table 07)** In studies conducted by Lacasse et al.[28] and Chan et al.[16] most of the newborns delivered were females which correlate with our study and showed association between female gender of fetus and NVP.

In a study conducted by Pukkila et al.[18] most of the babies' weight at the time of birth was between 3.50-3.65 which is contradictory to our study which might be due to different study settings.

Strength, limitations of the present study and future recommendations:

Long term follow up is the strength of present study and limitations are small sample size and observational study. Studies with large sample size and RCT's are recommended.

V. Conclusion

There was a significant decrease in PUQE and NVPQOL scores on day 7, continued through day 14 and after treatment with a *P* value <0.001. 86.6% patients achieved complete relief from NVP and accomplished much higher than average quality of life at the end of treatment period *Sikanjabeen lemooni* is effective in management of *Qay'al-Haml* and is comparable with other existing treatment options. Long term follow-up of the patients until delivery showed no adverse effect of *sikanjabeen lemooni* on the newborns. However, further randomised controlled trials are needed.

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