

Original Article

# The Effect of Chamomile Oil on Pain and Anxiety Intensity of IUD Insertion in Women Referring to Karaj Health Centers: Ridit Analysis

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## Abstract

**Introduction:** Intrauterine device (IUD) is a safe, effective and reversible method of family planning. Unfortunately, IUD insertion causes anxiety and pain. The aim of study was to compare ridit analysis and Kruskal-wallis test in pain and anxiety intensity of IUD insertion in women referring to health centers of Karaj (Iran).

**Materials and Methods:** In this randomized clinical trial study, 150 eligible women candidate intrauterine device insertion entered the study and were randomly divided into three groups: chamomile, placebo and control groups. Data was collected from women who came to health centers in Karaj (Iran) in 2017. Data collection tools included demographic information, Spiel-Berger questionnaire and pain visual analogue scale. The intensity of pain and anxiety were measured afterwards. Finally, ridit analysis and Kruskal-wallis test were used to rank the intensity of pain and anxiety in patients. The R-3.4.3 and Microsoft's Excel software were used for statistical analysis.

**Results:** The results showed that the mean±SD of age in three groups was 29.7±7.01, 28.68±8.15 and 31.6±7.71, respectively. Ridit analysis and Kruskal-wallis test showed considerable decrease of the anxiety and pain intensity, induced by IUD insertion in Chamomile, Placebo and Control groups respectively. Ridit analysis and Kruskal-wallis test statistics are significant. The value of the ridit statistic was  $\chi^2 = 20.23, P < 0.001$  and the value of Kruskal-wallis test is  $\chi^2 = 18.67, P < 0.005$  in pain intensity. Moreover, the value of the ridit statistic is  $\chi^2 = 3.92, P < 0.001$  and the value of Kruskal-wallis test is  $\chi^2 = 21.37, P < 0.005$  in anxiety intensity.

**Conclusions:** The results of this study suggested that, there is less significant difference in ridit analysis than Kruskal-wallis test among the three groups in decreasing pain and anxiety intensity.

**Key words:** Ridit analysis, Pain, Anxiety, IUD insertion

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## 1. Introduction

Methods of contraception have a long history, dating back to many years ago; however, voluntary control of fertility is more important nowadays. IUD is a safe and effective method with low defeating percentage [1]. There are a great number of

contraceptive methods such as oral tablets, injections in one month and three months, IUD and Norplant as term methods. The use of IUD has a few side effects and decreases with the logical techniques and screenings [2]. Among women of reproductive age, using IUD varies from 8 to 15 percent [3].

According to the Ministry of Health in 2005, the use of contraceptive methods in Iran was 73%, while the amount of using IUD is about 8.1% [4].

Ridit, as a likert scale data analysis, was derived from letters relative to an Identified Distribution. The test has been used in automobile accidents, cancer, schizophrenia, various business management, behavior and convexity and parasagittal meningioma with the DTS studies [5-6]. In this method, the distribution of item scores is compared with a reference distribution [7]. Ridit analysis for each item reflects the probability that this particular research topic received a higher priority score than another randomly selected topic of the list [8].

Kruskal-wallis is a non-parametric test, equivalent to one-way analysis of variance [9]. The test compares the means of more than two groups of cases. The Kruskal-wallis analysis tests whether several independent samples are from the same population [10].

Ridit analysis was originally developed by Bross for ordinal data in 1958 [11]. The study was performed over the crash-injuries in highway accidents and dependent variable was as an ordinal scale (none, minor, moderate, severe, fatal). Fleiss in 2011 applied ridit analysis in a dental clinical study based on a data extracted from a comparative clinical trial of ibuprofen, aspirin and placebo in the relief of post-extraction pain [8]. Berry et al. in 1985 surveyed the effect of the addition of zinc to 2 popular non-gamma-2 dental alloys [12]. They carried on ridit analysis and rank ordering; then, two evaluators rated the performance of the 5 alloys. Chien-Ho Wu in 2007 investigated two methods, grey relational analysis and ridit analysis, to analyze data based on Likert scale [6]. Coenegracht et al. in 2007 compared the single-shot diffusion-weighted echo planar and single-shot T2 weighted turbo spin echo techniques. Sequences were compared by rank order

statistic (Ridit) and Kruskal-wallis test [10]. Khanzode et al. in 2010 examined injury severity assessment for underground coalmine workers [13]. In their study, ridit analysis was used to evaluate the associations between the ordinal and nominal variable pairs. Zhou et al. in 2013 surveyed severity of condylar fracture, as an ordered variable, according to the cause of the injury in eight groups [14]. They applied ridit analysis to assess the relationship between the risk of fracture severity and fracture aetiologies.

## 2. Materials and Methods

In this study, chamomile oil was attained from Salamat Gostar Co. from Tehran Market, Iran (2017) and the study was randomized by clinical trial single-blinding in three groups. These data were gathered from 150 women who referred to Health Services in Karaj in 2017. In Chamomile group (n=50), three drops of chamomile oil was poured on a cotton ball, put into cans with lids, the demographic and anxiety questionnaires were filled in, and measurement of pulse and blood pressure were registered. Afterwards, cans were used for 5 minutes, with 7-10 cm distance from the nose. Then, the anxiety questionnaire had to be answered, and pulse and blood pressure were again measured. Later, the IUD was inserted and the pain of IUD insertion using ruler's pain. Placebo group (n=50) of propylene glycol which is scentless, together with control group were used without any intervention (n=50). In the study, pain and anxiety intensity were measured in women who had intrauterine device insertion. The entrance criteria were: **1.** age from 18 to 48 **2.** Iranian race **3.** Persian language **4.** Having the least level of literacy in reading and writing **5.** Not suffering from mental illness (not recognized and treated) **6.** Non-use of any anti-anxiety medications or relaxant **7.** Lack of cold and olfactory dysfunction, **8.** Not using a tranquilizer within 24 hours before inserting IUD **9.** Not using tobacco and not

having drug addiction **10**. Not having asthma. The exclusion criteria were allergic symptoms during the study and abuse of chamomile oil. The blood pressure and pulse rate were also measured to check for vital signs, demographic information and Spielberger questionnaire were completed. Then, IUD was placed and pain score was measured by ruler pain in control group. In two other groups, pain intensity was measured twice, before and after using chamomile and placebo oils. According to these questions, anxiety score was obtained and then Kruskal-wallis test and ridit analysis were performed and were compared with one another.

Ridit analysis, an extension of the Kruskal-wallis test, is a non-parametric test, used to gain ordinal data [15]. Two groups (or more) were compared using ridit analysis. One distribution across the “m” categories is identified as a standard relative to which each of the “g” distributions will be compared. The average rank is the average per groups. Mean Rank is a weighted mean of the average ranks. Category’s ridit is the proportion of all patients in the standard group who fell into a lower ranking category, plus half of the proportion of patients who fell into the given category. Mean ridit of a group which is a probability estimation of a random observation from that group will be greater than or equal to a random observation from reference group. Moreover, mean ridit for “g” groups are weighted averages of the ridits for the individual categories [16-17]. The test statistic is:

$$\chi^2 = \frac{12n_0 \sum n_i(\bar{r}_i - \bar{r})}{(n_0 + 1)f}$$

Where  $\bar{r}_i$  is mean ridit in per group,  $\bar{r}$  is total mean ridit and f is adjustment factor.

If a group’s mean ridit is equal to 0.5, its members tend to end up neither higher nor lower on the scale than members of the standard group.

If a group’s mean ridit is greater than 0.5, its members tend to end up higher on the scale than members of the standard group.

If a group’s mean ridit is lower than 0.5, its members tend to end up lower on the scale than members of the standard group.

The Kruskal-wallis method tests whether several independent samples are from the same population. The Kruskal-wallis H test, an extension of the Mann-Whitney U test, is the nonparametric equivalent to one-way analysis of variance and detects differences in distribution location. The test statistic is:

$$\chi^2 = \frac{12 \sum n_i(\bar{r}_i - \frac{n_i + 1}{2})^2}{n(n+1)f}$$

Both of these tests have degree of freedom equal to g-1, where g is the number of groups.

## 2.1 Statistical Analysis

The results were statistically described as Mean±SD in continuous variables. Likewise, frequency and percentage of categorical variables were reported. Fisher exact test was used to evaluate the association between categorical variables. The normality of continuous variables was checked using the Kolmogorov-Smirnov test. Non-parametric statistics were applied for data analysis. The Kruskal-wallis test was used to compare the mean of more than two groups. Ridit package was applied for the purpose of selecting the arbitrary reference group. Level of significance for statistical tests was 0.05. The R-3.4.3 and Microsoft's Excel software was used for statistical analysis.

## 3. Results

In this study, the age of women ranged from 18 to 47 (29.9±7.96). The mean±SD of age in chamomile therapy, placebo and control groups were 29.7±7.01, 28.68±8.15 and 31.6±7.71, respectively. Important demographic and clinical characteristics were summarized in Table 1. To test the ranked variables, Kruskal-wallis test and ridit analysis were used. Mean ridits in pain intensity were 0.3615, 0.556 and 0.582 in Chamomile oil, placebo and control groups, respectively.

**Table 1.** Demographic and clinical characteristics

Variables	Chamomile oil	Placebo	Control	P-value
Age	29.7±7.01*	28.68±8.15	31.6±7.71	0.156
<b>Education</b>				
Elementary	11 (22)	5 (10)	8 (16)	0.151
Guidance	14 (28)	15 (30)	18 (36)	
High school	20 (40)	21 (42)	22 (44)	
Academic	5 (10)	9 (18)	2 (4)	
<b>Job</b>				
Housewife	44 (88)	42 (84)	43 (86)	0.836
Employee	5 (10)	6 (12)	4 (8)	
Free	1 (2)	2 (4)	3 (6)	
<b>Delivery type</b>				
Cesarean	28 (56)	28 (56)	29 (58)	0.16
Vaginal	17 (34)	20 (40)	19 (38)	
Both	4 (8)	2 (4)	2 (4)	
Forceps	1 (2)	0 (0)	0 (0)	
<b>IUD history</b>				
Yes	28 (56)	23 (46)	30 (60)	0.35
No	22 (44)	27 (54)	20 (40)	
<b>Lactation</b>				
Yes	23(46)	30(60)	19(38)	0.08
No	27(54)	20(40)	31(62)	
<b>Menstruation Situation</b>				
Yes	35 (70)	32 (64)	38 (72)	0.42
No	15 (30)	18 (36)	12 (24)	
<b>Pulse Rate</b>	96.3±13.62	91.54±13.91	95.38±12.84	0.176
<b>Diastolic BP</b>	7.14±0.83	7.35±0.75	7.28±0.72	0.386
<b>Systolic BP</b>	11.22±1.23	11.4±1.51	11.46±1.2	0.643
<b>Anxiety</b>	32.78±12.94	38.96±14.87	45.74±14.51	0.029
<b>Pain</b>	2.18±2.16	3.98±2.79	4.22±2.19	<0.001

\*: n (%)/ mean±SD

The results demonstrated that in pain intensity, the test statistic of the ridit statistic was  $\chi^2 = 20.23, P < 0.001$  and the test statistic of Kruskal-wallis test was  $\chi^2 = 18.67, P < 0.005$  with 2 degree of freedom. The test statistic of ridit analysis and Kruskal-wallis test were the same. Similarly, chi-square test revealed significant difference in pain intensity

among three groups. Furthermore, the result indicated that the mean ridit and mean rank of pain score in chamomile group were lower than placebo and control groups. It showed that chamomile oil were more effective than two other groups in reducing the pain. The results were given in Table 2.

**Table 2.** Ridit for degree of pain intensity in three groups

Group	Painless	Mild	Moderate	Severe	n <sub>i</sub>	Mean rank	Mean ridit
Chamomile oil	15	25	6	4	50	54.73	0.3615
Placebo	7	16	16	11	50	83.91	0.556
Control	2	18	24	6	50	87.86	0.582
Total	24	59	46	21	150		
Average rank	12.5	54	106.5	140		226.5	
Ridit	0.08	0.357	0.71	0.93			0.5

Moreover, Figure 1 indicated the value of pain intensity in each group:

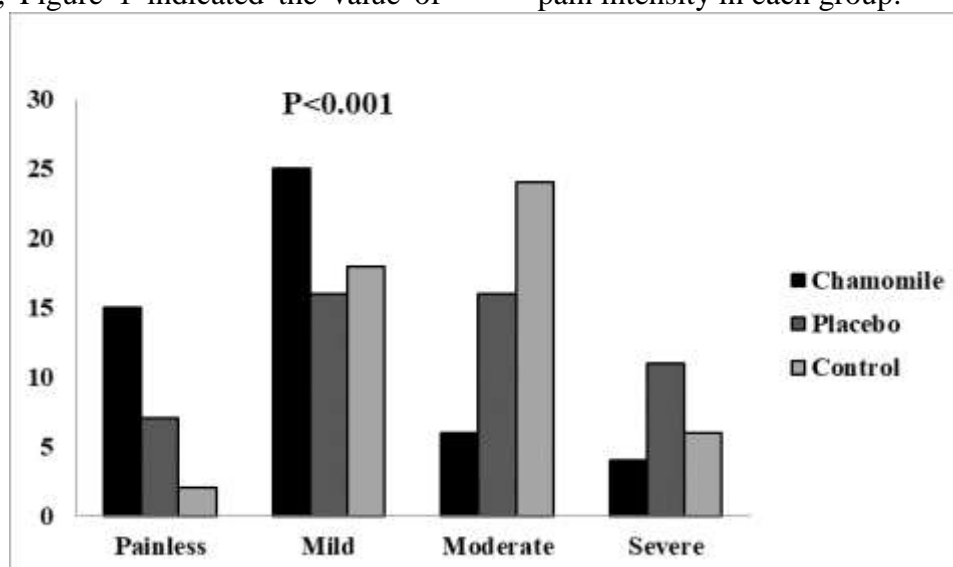


Figure 1. The value of pain level in three groups

Ridits mean in anxiety intensity were 0.3616, 0.522 and 0.6164 in three groups, respectively. Also, in anxiety intensity, the test statistic of the ridit test was  $\chi^2 = 23.92, P < 0.001$  and the test statistic of Kruskal-wallis test was  $\chi^2 = 21.37, P < 0.005$  with 2 degree of freedom. Ridit analysis and Kruskal-wallis test were the same. Moreover, chi square

test demonstrated significant difference in anxiety intensity between the three groups. Moreover, the results revealed that the mean ridit and mean rank of anxiety score in chamomile group were lower than placebo and control groups. It indicated that chamomile oil was more effective in reducing the anxiety than two other groups. The results are given in Table 3.

Table 3. Ridit for degree of anxiety intensity in three groups

Group	No anxiety	Mild	Moderate	Severe	$n_i$	Mean rank	Mean ridit
Chamomile	18	21	9	2	50	54.74	0.3616
Placebo	7	19	22	2	50	78.8	0.522
Control	2	17	26	5	50	92.96	0.6164
Total	27	57	57	9	150		
Average rank	14	54.53	112	145		226.5	
Ridit	0.09	0.37	0.75	0.97			0.5

Figure 2 shows the value of anxiety level in each group.

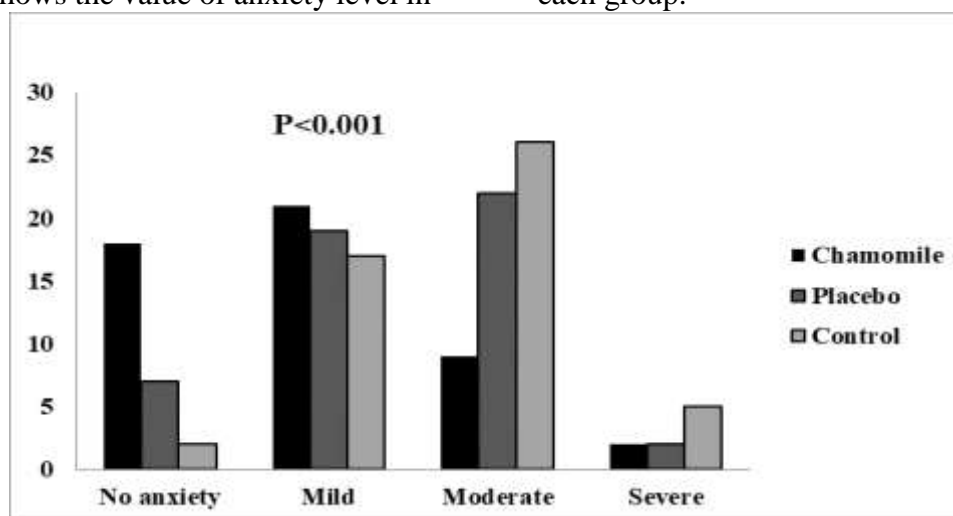


Figure 2. The value of anxiety level in three groups

#### 4. Discussion

In the present survey, we applied the ridit analysis and Kruskal-wallis test to compare pain and anxiety intensity among three groups of women in Karaj. These mean ridit and mean rank of ridit analysis revealed that pain and anxiety intensities were lower in chamomile group than placebo and control groups. The results of both tests were significant; however, ridit analysis was more significant than Kruskal-wallis test. The comparisons between ridit analysis and alternative methods were not performed over pain and anxiety intensity in other studies; however, the test was applied in other sciences.

One study investigated the effect of the addition of zinc to 2 popular non-gamma-2 dental alloys [12]. Two operators placed 247 amalgam restorations, using Dispersalloy non-zinc, Dispersalloy 0.9% zinc, Tytin (no zinc), Tytin 0.33% zinc, and Tytin 1% zinc. Using ridit analysis and rank ordering, the evaluators rated the performance of the 5 alloys. It was concluded that nongamma- 2 alloys including zinc had the lowest rate fracture at the margins of the restoration. In our survey, Kruskal-wallis test and ridit analysis were used to compare pain and anxious intensities. It was concluded that both of them had the same results. These methods

of analysis were the same and were used for ordinal dependent variable.

Another investigation surveyed two statistical methods: grey relational and ridit analysis. They were used to analyze data from Likert scale surveys and also Kruskal-wallis test was performed [6]. The data were extracted from an actual Likert scale survey regarding the life orientation (6 items) of respondents, used to illustrate the procedures for grey relational and ridit analysis. The calculation of grey relational grades for scale items was based on the scores assigned to the categories. The calculation of mean ridits for scale items was according to the response frequencies of ordered categories from a Likert scale survey. The results of the two methods were the same, showing that the two ordinal presented methods were consistent. In our study, two ordered approaches had the same results and more significant as in ridit analysis.

A study compared lesion conspicuity and image quality between single-shot spin echo planar imaging (SS SE-EPI) before, immediately and 5 min after intravenous injection of superparamagnetic iron oxide for detecting and characterizing focal liver lesions [10]. In this study, sequences were compared between Ridit and Kruskal-wallis

tests. Image quality and lesion conspicuity were compared for SS SE-EPI sets, using rank order statistic by ridit analysis. The results of the two statistical methods were identical. Both presented statistical methods had the same output.

A survey investigated the injury narratives to decide over the preliminary categories of incident attribute (P, S, IP or IS) for each of the injury event among coalmine workers using ridit analysis. The mean ridit values indicated relationship between injury severity and the incident attributes, injury severity (actual) and medium of injury as well as the injured body part, and the chi-squared statistic for job designation and activity at the time of injury were surveyed. Ridit analysis of the study revealed that the test may help to improve accident/injury survey reporting and devising preventive measures for decreasing injury severity [13]. Our results indicated the same results in two statistical methods and also preferred in Chamomile oil user.

An investigation assessed the pharmacological effects of traditional Chinese medicine, bear bile capsule and Huangqi granule, on recurrent parotitis in three groups of children [18]. They used one-way analysis of variance and ridit analysis. Their results showed that Huangqi and bear bile could be a novel clinical approach to treat recurrent parotitis in children. In our study, the same outputs of both ordered statistical methods, Kruskal-wallis and ridit tests was reached.

A study evaluated the relationship between the risk of fracture severity and fracture aetiologies [14]. They also performed logistic regression model for controlling the confounding variables. Their results revealed that there was no statistically significant association between aetiology and MacLennan classification of condylar neck and base using ridit analysis; however, the mean ridit value showed that fall from a height led to the most serious condylar fractures. Our findings showed identical

results in comparing pain and anxious intensity in women.

A recent study revealed that Wilcoxon rank sum test was followed by ridit analysis to depict the probability that a randomly selected subject from one average pain-severity level had a more favorable outcome on the specific pain DETECT item relative to a randomly selected subject from a comparator severity level [19]. They showed ridit analysis could be more exact than the chi-square statistic in comparing two independent samples when the dependent variable was ordered. Also, it had the benefit of enriched interpretation by providing a simple probability or likelihood of a more considerable outcome in one group vs another. Moreover, they showed ridit analysis and the Wilcoxon rank sum test were the same, which was identical with our results.

A study surveyed the importance of contrast-enhanced T1-weighted (T1W) MRI-based 3D reconstruction of dural tail sign (DTS) in meningioma resection [20]. They selected 18 cases of convexity and parasagittal meningiomas showing DTS on contrast-enhanced T1W MRI. Their result of ridit analysis revealed that incisions-designed 3D images were more accurate than those designed using MRI image. Our results showed less pain and anxiety intensities in Chamomile user and the same results as that of two order statistical methods, including Kruskal-wallis and ridit tests.

A recent study used ridit analysis to find the relative significance of each item to the survey respondents [21]. According to their ridit analysis, a priority ranking was assigned to each item and ridit analysis was then carried out at the degree to which the items grouped into each particular factor tended to have high or low priority rankings. Their finding of ridit analysis may be helpful to the managers of the private healthcare sector to focus their strategies and plan their efforts in line with the

findings to gain superior customer satisfaction and retention. Our results also showed the priority of using Chamomile oil by ridit analysis.

A survey performed ridit analysis in three groups of placebo-controlled trials in patients with fibromyalgia (FM), diabetic peripheral neuropathy (DPN), postherpetic neuralgia (PHN) and spinal cord injury (SCI) [22]. Their result showed that pregabalin is more often associated with clinically meaningful improvements in pain category in patients with FM, DPN, PHN, or SCI. In their study, pregabalin and placebo groups were compared and statistical significance was evaluated by a Cochran–Mantel–Haenszel test with modified ridit (modridit) transformation of the calculated ordinal shift scales. Our finding demonstrated the same results of ordering statistical methods.

In conclusion, decreasing anxiety and pain intensities in Chamomile, placebo and control groups respectively were significant. Both tests had the same results according to the significance of the difference; however, ridit analysis had less significance than Kruskal-wallis test.

## 5. Conclusion

It can be concluded that ridit analysis had less significance than Kruskal-wallis test based on decreasing anxiety and pain intensities in Chamomile, placebo and control groups.

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## Conflict of Interest

The authors declare no conflict of interest.

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