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# A SINGLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL OF LOCAL APPLICATION OF KOHL-CHIKNI DAWA-A UNANI COMPOUND FORMULATION IN THE PATIENTS WITH CORNEAL OPACITY

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**ABSTRACT**

**Objective:** The present clinical trial was undertaken to evaluate the safety, preventive/curative efficacy of the local application of Kohl-Chikni Dawa (KCD) in patients with corneal opacity (CO), to provide an economic, safe, and effective alternative treatment for it.

**Methods:** The present prospective single-blind, placebo-controlled trial was undertaken at Majeedia Hospital, Hamdard University, New Delhi. Ninety-two diagnosed patients of CO were randomly allocated to three groups for local application of KCD/placebo two sticks BID.

**Results:** Forty patients completed the 6-month duration of the study. KCD was found effective in the general amelioration of the signs and symptoms of CO. There was a statistically significant reduction in the CO score and improvement in vision on the reading of the Snellen chart in the test drug group in comparison to the placebo group in Grade-I (Nebular type) CO ($p>0.05$).

**Conclusion:** KCD was found very much effective to reduce the CO score, with clinical improvement of vision in the nebular type of CO. The dose of KCD in two sticks BID was found safe and tolerable with no side effects. A multicentric trial of the test drug on larger sample size for a longer duration is required to establish the efficacy of the formulation on CO.

**Keywords:** Kohl-Chikni Dawa, Corneal opacity, Unani medicine, Nebular opacity.

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## INTRODUCTION

Blindness due to corneal opacity (CO) presents an enormous problem worldwide. CO occurs when the cornea becomes scarred and it stops light from passing through it to the retina, and the cornea appears white or clouded over. Visual loss or blindness is a result of chronic keratitis, uveitis, cataract, secondary glaucoma, and rarely optic neuritis.

The treatment of CO is optical iridectomy, phototherapeutic keratectomy, keratoplasty, cosmetic colored contact lens, and tattooing of the scar.

There is no available treatment for CO, except keratoplasty/corneal transplants in modern medicine. The prognosis for visual restoration and maintenance of ocular health with corneal transplants is generally very good [1]. In a study, it was revealed that the survival rates at 1, 2, and 5 years for all corneal transplants performed for the 1st time in 1389 cases were 79.6%, 68.7%, and 46.5% (41.7–51.3%). Before the corneal transplant, 80.2% of the eyes were blind (visual acuity<3/60) whereas at the last follow-up, 41.8% of the eyes were blind [2].

CO is the 4th main cause of blindness globally (5.1%). According to the World Health Organization (WHO) definition of blindness, the patients with visual acuity of 3/60 or less are called blind. It is estimated that currently, there are 45 million individuals worldwide who are bilaterally blind, and another 135 million have severely impaired vision in both eyes [3].

In 1995, it was estimated that 38 million people in the world are blind (0.7% of the total population), while an additional 110 million people worldwide have a visual impairment [4]. In India according to the National Programme for Control of Blindness estimates, there are currently 120,000 corneal blind persons in the country. According to this estimate, there is an addition of 25,000–30,000 corneal blindness cases every year in the country [5].

Blindness due to CO presents an enormous problem in India not only in terms of morbidity but in terms of economic loss and social burden also. India emerges as a clear global priority as it has the world's largest corneal blind population and strong infrastructural readiness to rapidly scale its keratoplasty numbers [6].

In this situation, demand for herbal drugs as an alternate therapy is increasing in the world [7]. Kohl-Chikni Dawa (KCD) is a herbomineral compound formulation of Unani medicine for CO, and it is in the practice of Unani physicians for more than 200 years. This formulation is the part of GOI authenticated references books under the D and C Act 1940 namely, *Ilajul Amraz* and *Bayaz-e-Kabir* [8,9].

Hence, the present study was undertaken to evaluate the safety, preventive/curative efficacy of the local application of KCD in the patients with CO, and to provide an economic, safe, and effective alternative treatment for it.

## METHODS

### Study design

The present prospective study was carried out in the Department of Moalejat, Faculty of Unani Medicine, Majeedia Hospital, Jamia Hamdard, New Delhi. The clinical trial is a single-blind, randomized, placebo-controlled, comparative study of the efficacy of the local application of KCD. The duration of the study was 3 years, and the duration of the protocol therapy was 6 months. The study is designed in the light of methods adopted as per the WHO recommendations.

Ethical clearance was taken from Jamia Hamdard, Institutional Review Board before enrolling the patients for the study (JHIRB-Reference No.04/01 dated June 7, 2001).

**Diagnosis of CO**

Grading of CO:

Grade-I (Nebular Opacity): It is a faint opacity and difficult to visualize and it can be visualized only by careful examination with a focal surface.

Grade-II (Macular Opacity): It is dense enough to be visualized easily and it is possible to see the inner structures through it.

Grade-III (Leucomatous Opacity): It is a dense opacity through which the structures behind it cannot be seen [10].

In the selected patients with poor vision and suspicious CO, detailed history of the patient (general and specific for the eye) was recorded in the clinical record form (CRF). Detailed ophthalmological, visual field, bio-microscopy slit-lamp, and fundoscopy examinations were performed.

CO was recorded with photographs; pre- and post-treatment after 3 and 6 months. The changes in size, position, and density of CO were judged by examining the periodic sketches of the CO made from the visual impressions obtained by the bio-microscopy slit-lamp examination.

**Test drug**

Constituents of KCD;

1. Tootiya (Copper sulfate – S.D. Fine Chem. Ltd., Mumbai)
2. Sabun (Hard soap – M. S. Factory, Aligarh)
3. Raal (Resin of *Shorea robusta* Roth).

The ingredients were purchased from the local market and authenticated at the Department of Chemistry, Faculty of Science, Jamia Hamdard, New Delhi.

**Preparation of KCD**

The above ingredients were taken in a ratio of 1:20:1, and KCD was prepared after quantification of the constituents under aseptic conditions. Hard soap was cut into small pieces and heated in an iron pot. As the soap started to melt, copper sulfate powder was added, and complete liquefaction was allowed. Powder of resin of *Shorea robusta* Roth was then added and heated till the drug got burnt and converted into dry ash. After cooling, the drug was powdered using a grinder and filtered through a sieve (size 120 μ). The micro-fine powder was collected and stored in small bottles with a small glass stick and labeled as KCD with a single asterisk (*) [9,11].

**Placebo (mustered oil smog-ash)**

An earthen pot was filled with mustard oil; a cotton wick was immersed in the oil with the other end of it on the mouth of the pot. Cotton wick was burned, and another earthen pot was placed on it in such a way that the smoke is collected inside it. After complete burning of the mustard oil, the smoke ash was collected, stored in small bottles with a small glass stick, and labeled as placebo with a double asterisk (**) [12].

**Dose and administration**

The packs of KCD/placebo were provided to the patients with instruction to apply two sticks of the drug twice daily for 6 months. In selected cases of Group-I and Group-II, a placebo was applied on one eye (control eye) while the KCD was applied on the other eye (test eye). In Group III patients, KCD was applied on one side only and the response of CO was noted. Thereafter, they were compared to the similar stage of Group-I (control) and Group-II (control) or to the previous visits.

**Participants**

The patients with CO were selected based on the definition of CO under diagnostic criteria.

Patients of either sex in the aged between 20 and 70 years with all types of CO (nebular, macular, and leucomatous) who give voluntary written informed consent (approved by JHIRB) to participate in the study were recruited for the study. After the diagnosis of CO, all the patients were randomly allocated to the following groups:

Group-I: Nearly similar stages of CO in both eyes.

Group-II: Different stages of CO in both eyes.

Group-III: Those who did not have CO/other eye diseases on one side.

Patients with CO since childhood, corneal ulcer, glaucoma, using contact lenses for refractive errors, retinopathy, retinal detachment, color blindness, and any inflammatory condition of the eyelids and eyeball were excluded from the study.

Patients suffering from physical handicap or disability, pregnant women, with a history of serious head injury or neurological disorder, or psychiatric illness which may impair the ability to provide written informed consent, using any drug for any eye disease were also excluded from the study.

Patients with irregular follow-up or the application of the drug for more than 1 month were considered as withdrawn from the study. Patients with an allergy or hypersensitivity to KCD were also considered withdrawn cases.

The data were considered for analysis if at least 70% quantity of the drug was used by the patient. Otherwise, the data were not considered for analysis [13-15].

**Time frame**

February 1, 2000–May 31, 2003.

**Laboratory procedures**

Following laboratory tests were performed on day 1, after 3 months, and after 6 months of treatment.

Hemogram, blood sugar (fasting and post-prandial), LFT, and urine R/M examination.

**Follow-up schedule of patients and follow-up period**

After satisfactory examination and laboratory reports, each patient was issued a 1-week supply of the KCD/placebo and advised to report in OPD on Visit Number 2 (on day-3). During the study period at each visit, all the patients were evaluated by ophthalmological examination (Table 1).

**Outcome**

*Efficacy outcome*

Criteria of the assessment of effect of therapy

The results were recorded as follows;

1. The effect of treatment on signs and symptoms of CO: Signs and symptoms of CO patients pre- and post-treatment were recorded in CRF.
2. The effect of the treatment on CO score: The effect on CO score was recorded as follows;

0=No opacity, 1=Grade-I (nebular), 2=Grade-II (macular), and 3=Grade-III (leucomatous)

3. The effect of treatment on visual acuity: The effect of treatment on visual acuity was recorded as follows.
    i. Clinical improvement: Clinical improvement in visual acuity by at least one line by Snellen chart as compared to control eye or previous visit.

**Table 1: OPD visit schedule of patients**

| Visits | I$^{st}$ | 2$^{nd}$ | 3$^{rd}$ | 4$^{th}$ | 5$^{th}$ | 6$^{th}$ | 7$^{th}$ | 8$^{th}$ | 9$^{th}$ | 10$^{th}$ | 11$^{th}$ | 12$^{th}$ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Days | 1 | 3 | 7 | 11 | 15 | 30 | 45 | 60 | 90 | 120 | 150 | 180 |

ii. Stationary: No change in visual acuity.
iii. Deterioration: Fall in visual acuity by at least one line or more.
iv. Side effects: Any hypersensitivity, allergy to KCD, or any other side effects were noted during the study [13,14].

**Statistical analysis**

The data of each group were expressed as Mean±SD. Comparison of data within visits or previous readings was calculated by the Wilcoxon signed-rank test (on paired data). ANOVA was performed followed by Dunnett's t-test among the treatments groups. $p<0.05$ was considered statistically significant. The Student's pair t-test was performed to compare the visual acuity of patients pre- and post-treatment in different grades of CO. $p<0.05$ was considered statistically significant.

## RESULTS

A total of 92 patients with CO were enrolled in the study. Forty patients completed the 6-month duration of the clinical trial. In Group-I, four patients, in Group II, two patients, and in Group III, 34 patients completed the trial. Fifty-two patients did not complete the clinical trial due to various reasons.

**Demographic data**

The average age of the studied patients was of 38.55 years with a female-to-male ratio of 2:8. There were 33 cases of nebular, three cases of macular, and four cases of leucomatous type of CO. There were 21 cases with a history of signs and symptoms of CO from 6 months, 13 cases from 1 year, and six cases from 2 years.

*Effect of KCD and placebo on signs and symptoms of CO*

After 6 months of treatment with KCD, the results show that it is effective in the general amelioration of the signs and symptoms of the CO, especially foreign body sensation, and discharge (100%), followed by headache (83.3%), photophobia (81.8%), watering (63.7%), eye ache (41.3%), loss of vision (39.3%), and distortion of objects (22.1%). After 6 months of treatment with the placebo, the results show that it has no significant effect on the general amelioration of signs and symptoms of CO except for some effect on itching, headache, and loss of vision (Table 2).

*Effect of KCD/placebo on CO score in different grades of CO*

After 6 months of treatment, the results show that KCD has a significant effect on the nebular type of CO as out of 33 patients; CO score was nil in 13 patients (39.3%) in Grade-I CO but it did not affect Grade II and III CO (Table 3, Figs. 1 and 2).

After 6 months of treatment with a placebo, the results show that it does not affect all three grades of CO (Table 3).

*Effect of KCD/placebo on visual acuity in different groups of CO*

After 6 months of treatment with KCD, the patient's eyes in Groups I and II did not show statistically significant clinical improvement in the vision on the reading of the Snellen chart, but in Group III, there was statistically significant clinical improvement in the vision on the reading of Snellen chart ($p<0.05$). Fall of vision has not been reported in any patient. The patient's eyes of Groups I, II, and III, which were treated with placebo, show a statistically non-significant clinical effect on the vision on the reading of the Snellen chart ($p>0.05$) (Table 4).

*Effect of KCD/placebo on visual acuity in different grades of CO*

After 6 months of treatment with KCD, the patient's eyes in Grade I (nebular) CO, there was statistically significant clinical improvement in the vision on the reading of Snellen chart ($p<0.05$) but it shows statistically non-significant clinical effect in the vision on the reading of Snellen chart in Grades II and III of CO. The patient's eyes of Grades I, II, and III, which were treated with a placebo, show statistically non-significant clinical effect in the vision on the reading of the Snellen chart ($p>0.05$) (Table 5).

**Safety outcome**

The dose of KCD in two sticks BID was found safe and tolerable because no local or systemic adverse reaction was reported during the study period.

## DISCUSSION

Unani medicine is one of the oldest traditional medicines of India, having its origin in Greece. Eye diseases including Bayaz (CO) have been

**Table 2: The effect of KCD and placebo on signs and symptoms of CO in KCD and placebo groups**

| S. No. | Signs and symptoms | Number of cases in KCD group | | | | Number of cases in placebo group | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Pre-tre | Post-tre | Nos. of nil cases | % | Pre-tre | Post-tre | Nos. of nil cases | % |
| 1. | Loss of vision | 40 | 29 | 13 | 32.5 | 06 | 05 | 01 | 16.6 |
| 2. | Headache | 06 | 01 | 05 | 83.3 | 02 | 01 | 01 | 50.0 |
| 3. | Eye ache | 12 | 07 | 05 | 41.3 | 04 | 04 | 00 | 0 |
| 4. | Itching | Nil | Nil | 00 | 0 | 01 | Nil | 01 | 100 |
| 5. | Photophobia | 22 | 04 | 18 | 81.8 | 02 | 02 | 00 | 0 |
| 6. | Blepharospasm | Nil | Nil | 00 | Nil | Nil | Nil | 00 | Nil |
| 7. | Watering | 11 | 4 | 07 | 63.7 | 02 | 02 | Nil | 0 |
| 8. | Discharge | 02 | Nil | 02 | 100 | Nil | Nil | Nil | Nil |
| 9. | Redness | Nil | Nil | Nil | 0 | Nil | Nil | Nil | Nil |
| 10. | F.B. sensation | 02 | Nil | 02 | 100 | Nil | Nil | Nil | Nil |
| 11. | Distortion of object | 28 | 19 | 09 | 22.1 | 02 | 02 | Nil | 0 |
| 12. | Diplopia | Nil | Nil | Nil | Nil | Nil | Nil | Nil | Nil |
| 13. | Myokymia | Nil | Nil | Nil | Nil | Nil | Nil | Nil | Nil |
| 14. | Any other comp | Nil | Nil | Nil | Nil | Nil | Nil | Nil | Nil |

Pre-tre: Pre-treatment, Post-tre: Post-treatment, KCD: Kohl-Chikni Dawa

**Table 3: The effect of KCD/placebo on CO score in different grades of CO**

| Grades of CO | KCD group (Nos. of cases) | | | Placebo group (Nos. of cases) | | |
|---|---|---|---|---|---|---|
| | Pre-treatment | Post-treatment (Nil) | % | Pre-treatment | Post-treatment (Nil) | % |
| Grade-I | 33 | 13 | 39.3 | 03 | 0 | 0 |
| Grade-II | 03 | 00 | 0 | 02 | 0 | 0 |
| Grade-III | 04 | 00 | 0 | 01 | 0 | 0 |
| Total | 40 | 13 | | 6 | 0 | |

KCD: Kohl-Chikni Dawa, CO: Corneal opacity, grades of corneal opacity: Grade-I: Nebular, Grade-II: Macular, Grade-III: Leucomatous

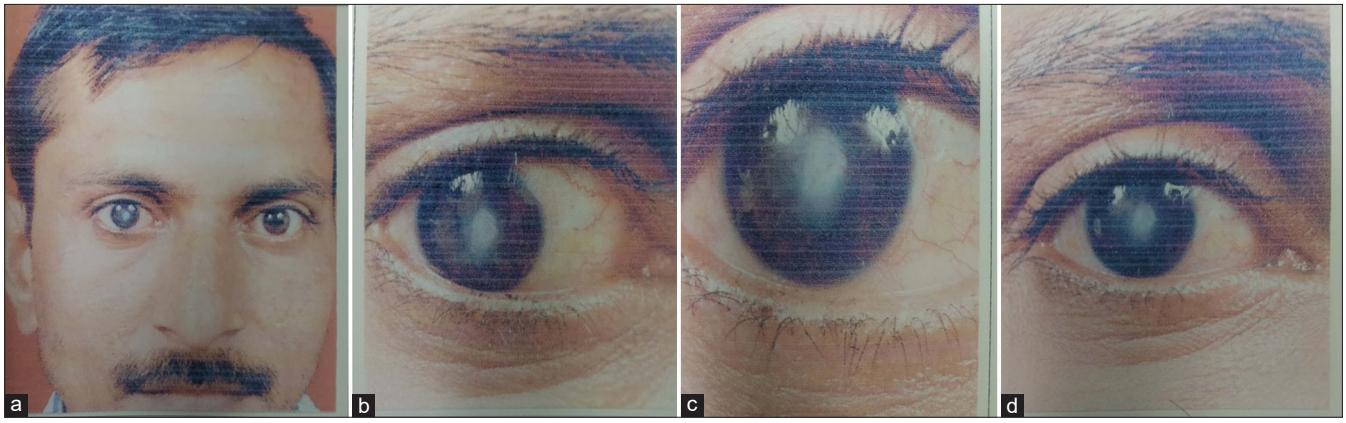


**Fig. 1: (a) Face of Patient (BT) (b) Rt eye (BT), (c) Rt eye after 3 months, (d) Rt eye after 6months**

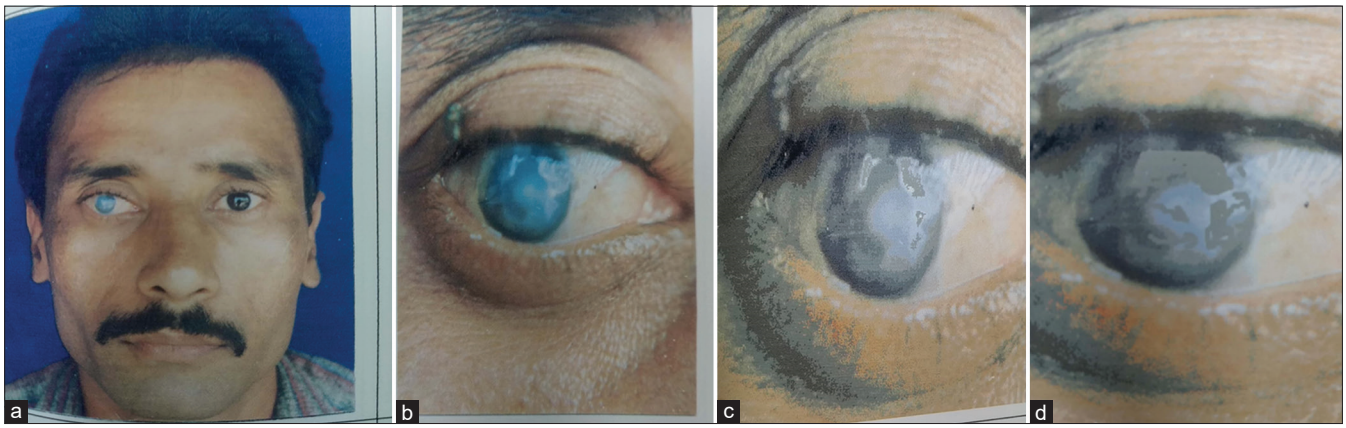


**Fig. 2: (a) Face of Patient (BT), (b) Rt eye (BT), (c) Rt eye after 3 months, (d) Rt eye after 6months**

**Table 4: The effect of treatment on visual acuity in different groups of CO**

| Vision | Mean of visual acuity (in lines) | | | | |
|---|---|---|---|---|---|
| | Group-I | | Group-II | | Group-III |
| | KCD-treated eye | Placebo-treated eye | KCD-treated eye | Placebo-treated eye | KCD-treated eye |
| Improvement | 1.5 (6) $^{NS}$ | 0.25 (1) $^{NS}$ | 2 (4) $^{NS}$ | 1 (2) $^{NS}$ | 0.94 (32)* |
| Fall | Nil | Nil | Nil | Nil | Nil |

*Statistically significant as compared to baseline at p<0.05, $^{NS}$Statistically non-significant as compared to baseline at p<0.05. KCD: Kohl-Chikni Dawa, CO: Corneal opacity

**Table 5: The effect of KCD/placebo on visual acuity on the reading of Snellen chart in different grades of CO**

| Grades of CO | Visual acuity | | p-value | Significance |
|---|---|---|---|---|
| | Pre-treatment Mean±SD | Post-treatment Mean±SD | | |
| Grade-I | 21.0000<br>09.19845 | 14.5455<br>09.1984 | 0.00002 | The result is significant at *P*<0.05 |
| Grade-II | 0.0000<br>0.6000 | 42.0000<br>10.3923 | Nil | The sample size is too small for calculation |
| Grade-III | 0.0000 | 0.0000 | Nil | The sample size is too small for calculation |

KCD: Kohl-Chikni Dawa, CO: Corneal opacity

described in Unani classical literature with its treatment with KCD [16]. Ingredients of KCD, that is, Tootiya (copper sulfate) has been described as having Mohallile auram, Mujaffif (desiccant), Dafe Taffun, and Qabiz (Astringent) properties. The second drug Sabun has Mohallile auram and Jali properties. The third drug Raal has Dafe Taffun and Mujaffif properties.

The dose of the KCD was found effective in the general amelioration of the signs and symptoms of the CO.

The effectiveness of KCD in the general amelioration of the signs and symptoms of the CO after 6 months of treatment may be due to the Mohallile auram (anti-inflammatory) effect of Tootiya, Sabun, and Raal [17-19], and Dafe Taffun (antiseptic) and Qabiz (astringent) effects of Tootiya and Raal [17-19]

Statistically significant reduction in CO score in the nebular type of CO after 6 months of treatment with KCD may be due to Mohallile auram

(anti-inflammatory), and Dafe Taffun (antiseptic) effects of Tootiya, Sabun, and Raal. Jali (detergent) effect of Sabun also contributed to the resolution of chronic keratitis by cleansing the corneal surface and reversing the chronic inflammation of the cornea to normal [17-19]

Statistically significant clinical improvement in the vision on the reading of the Snellen chart after 6 months of treatment with KCD in the nebular type of CO may be due to the synergetic Mohallile auram (anti-inflammatory) and Dafe Taffun (antiseptic) effects of the ingredients of KCD, that is, Tootiya, Sabun, and Raal which resolved the chronic keratitis. Thus, hazy cornea becomes transparent resulting in clinical improvement in the vision of the patients on the reading of the Snellen chart.

Because of the above results, the study shows that KCD has a preventive effect on CO by inhibiting the progress of CO as there was no increase in CO score and no deterioration of vision in any patient after 6 months of treatment. Moreover, it was also found that KCD has a curative effect on CO by reducing the CO score and improving the visual acuity in Grade-I (nebular) CO. However, it did not affect the Grade-II (macular) and Grade-III (leucomatous) types of corneal opacities.

## CONCLUSION

It can be concluded from the study that KCD is effective in the general amelioration of the signs and symptoms of CO. KCD was found very much effective to reduce the CO score, with clinical improvement of vision in the nebular type (Grade-I) of CO, and it did not reverse the macular/leucomatous types of corneal opacities.

The dose of KCD in two sticks BID was found safe and tolerable because no local or systemic adverse reaction was reported during the study period. The present study has proven that local application of KCD has a preventive/curative effect in the patients of nebular type of CO, and it can be an economic, safe, and effective alternative treatment for it.

A multicentric trial of the test drug on larger sample size for a longer duration is required to establish the efficacy of this formulation (KCD) on CO.

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## AUTHORS' CONTRIBUTIONS

Zehra Zaidi conceptualized the article, wrote the main manuscript text, and analyzed the data; Shehla Nazir prepared the tables and figures and reviewed the article.

## COMPETING INTEREST

The authors declare that they have no conflicts of interest.

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