

Full Length Research Paper

A preliminary study to assess knowledge, preferences, and perception of adult population of Karachi about scored and colored oral solid dosage form

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Beyond the pharmacological activity, the differences have been observed in the preferences of solid dosage form on the basis of color and swallowing difficulty in the studies conducted by a different researcher. The aim of the study is to insight the perception of the general population of Karachi about the color, scoring and splitting of tablets. A convenience sampling technique was used to collect data. Knowledge, attitude and practices of the participants regarding oral solid dosage form have been evaluated through a structured close-ended questionnaire. The color perception was pursued by asking questions to the participants about the association of color with effectiveness, identification, safety and onset of action. The scoring perception was also inquired focusing on the association of scoring on the convenience of splitting, their effect on the dose, type of tablet subjected to splitting and further consequences of splitting. Among 426 respondents, 248 participants were not aware of the type of medicine subjected to be splitting. Approximately half of the respondents (N=221) agreed with the point of view that ease of swallowing is one of the reasons for pill-splitting. The study provided preliminary data about color perception, scoring and splitting of tablet dosage form that can be beneficial for future research.

Key words: Scored tablet, color perception, pill splitting, oral solid dosage form, Karachi.

INTRODUCTION

The prevalence of oral solid dosage forms is more due to their relatively simple manufacturing procedure that leads to low cost as compared to other pharmaceutical preparations. Furthermore, stability issues are in

frequent and taste masking can be achieved conveniently. However, the swallowing ability is a prerequisite for the sufficient activity of solid oral dosage forms (Schiele et al., 2013). The size, surface area,

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shape and coating are the attributes related to the ability of tablets to go through the esophagus and it is widely accepted that the utmost factor is the size of the tablets; therefore, it must be small to its possible level. It was also revealed in studies that the size and shape of medicine are not only the factors results in non-adherence of medication but also the color of medicine is associated with certain diseases such as non-compliance was reported in adult epileptic patient due to color change (Liu et al., 2014). Therefore, the present study focuses the knowledge, attitude and perception of the people of Karachi towards the solid dosage form in terms of color, scoring and cost.

Subdivision of a solid dosage form provides a convenient way for drug administration to geriatrics, pediatrics and patients with swallowing problems. Not only this, but low doses can also be obtained which are not commercially available by the manufacturer and it is also a source of cost containment (Habib et al., 2014). However, in some studies conducted by different researchers such as Chou et al. (2015) reported that unequal tablet splitting causes inaccurate dose titration and even result in toxicity. Another researcher also reported that the subdivision of tablets containing inert matrices greatly affects the kinetic release profile (Teixeira et al., 2020). In another study, the effect of splitting on levothyroxine has been discussed. Levothyroxine has a complex stability profile with photo and thermo sensitivity as well as susceptibility to moisture, pH and oxidation. Prior splitting of tablets and storage in the bottle may cause stability issues (Shah et al., 2010). It is also evident from the literature review that the number of studies exploring the patient preferences over scoring of the solid dosage form is very few especially no such data is obtained from Pakistan up till now. Therefore, the present study has been undertaken to insight the pitfalls associated with tablet splitting.

MATERIALS AND METHODS

Target population and sampling

This cross-sectional study will explore the knowledge, preferences and perception of the consumer about physical appearances of oral solid dosage form, thus the target population for this study is the general public of Karachi, who is literate, read and understands English. Mainly the target population of the study was students of different universities, colleges, working professionals, housewives and the persons who are health conscious. A non-restrictive selection criterion was used and it included all adults above 18 years irrespective of gender (Ahmed et al., 2018). The sample size was 426.

Data collection

Data collection was carried out through a self-administered

questionnaire by a convenience sampling technique (Ibrahim et al., 2012). It is the kind of non-probabilistic sampling technique and respondents are selected on the basis of convenience of researcher i.e. respondents who are easily accessible. A close-ended structured questionnaire was used to gather information from the respondents from July 2017 to December 2017.

Statistical technique

The data were entered and analyzed using the Statistical Package for Social Science (SPSS) version 20. Descriptive results were presented as frequencies, percentages and mean \pm SD. Chi-square statistical analysis was used for significant associations between each variable and preferences toward the color of the oral solid dosage form. A significant level was accepted at $p < 0.05$. The responses of the purpose of scoring perception among respondents were collected on Likert 5 point scale anchored by 1=strongly disagree to 5=strongly agree. Data were analyzed by the Mann-Whitney U test, as the data were not normally distributed (Zaid et al., 2019).

RESULTS

Demographic information

Most of the respondents were female (61.7%; N=263). The largest proportion of the participants were aged 18-29 years (72.1%; N=307), followed by 30-44 years (16.4%; N=70), and 45+ years age group (11.5%; N=49).

Perception and preferences of solid dosage form

In Figures 1 to 4 preferences of solid dosage form, their perception of cost, indication and ease of swallowing have been compared with respect to gender. Out of 426 participants, 60% male and 67% female preferred tablet, 26% male and 18% female preferred capsule, followed by 9% male and 6% female preferred powder, while 6% male and 8% female preferred soft gel capsules. In view of 102(39%) male and 158(61%) female respondents, capsules are easily swallowed as compared to tablets. A total of 61(37%) male and 105(63%) female respondents never experience ease in swallowing of capsule as illustrated in Figure 2. Different perceptions of participants have been observed in response to the question assessing knowledge of participants towards the type of dosage form in case of serious disease (Figure 3). Less than a quarter proportion of participants that is, male 33(34%) and female 65(66%) believed that capsule is prescribed in serious diseases. Moreover 45 (39%) male and 71(61%) perceived that dosage form does not matter with type of illness. According to 31 (27%) male and 82(73%), female respondents soft gel capsules are more costly as compared to hard gelatin capsules as well as tablets. However, both male and female respondents equally experienced tablet as more economical than

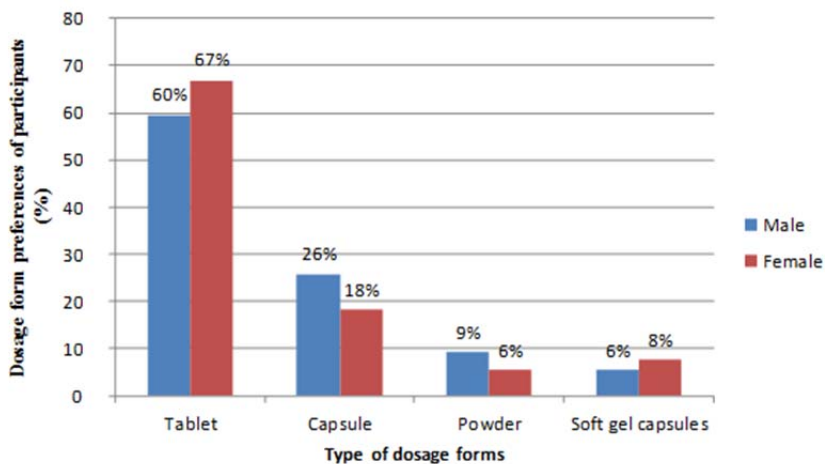


Figure 1. Gender preferences of oral solid dosage form.

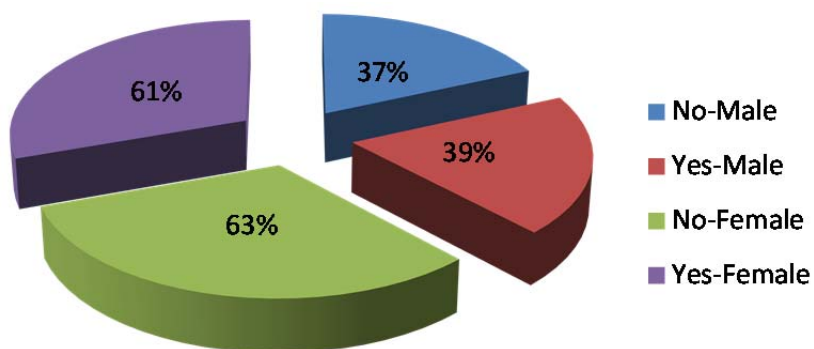


Figure 2. Experiences of male and female regarding swallowing of capsule.

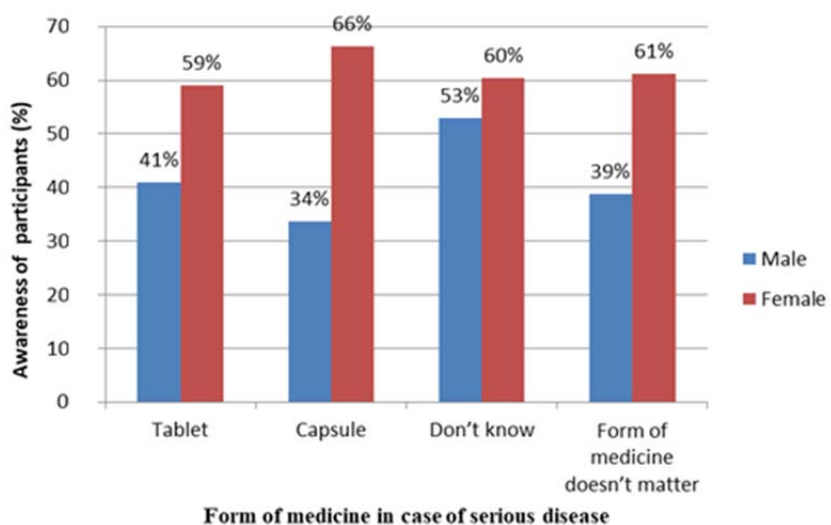


Figure 3. Preferences of the oral solid dosage form in case of serious disease.

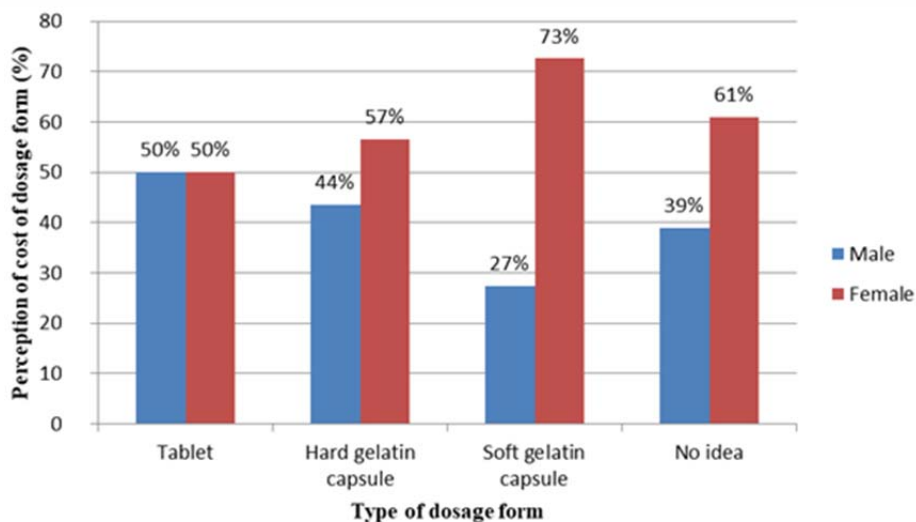


Figure 4. Perception of the cost of an oral solid form of medicine among male and female.

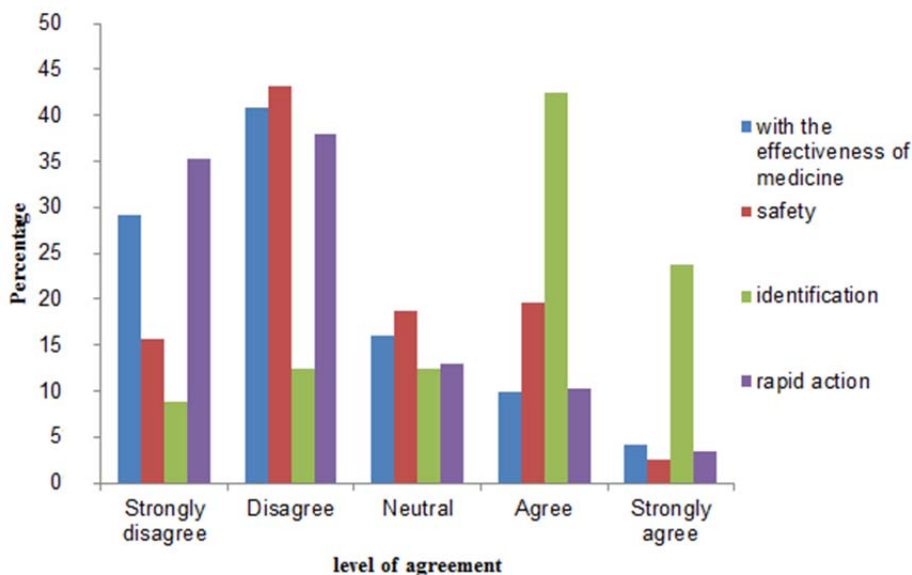


Figure 5. Respondents level of agreement with color association.

other dosage forms while 39% male and 61% female have no idea about cost of medicine with respect to its dosage form (Figure 4).

The color perception among respondents:

The level of agreement of color perception among respondents has been illustrated in Figure 5. It showed

that 124 respondents were strongly disagreed from the point of view that color is associated with the effectiveness of the medicine. Furthermore, 68 respondents neither agree nor disagree with the relation of color with effectiveness while 42 and 18 participants agree and strongly agree respectively. The vast majority of the population perceived that color is not associated with the safety of the medicine. Few respondents that is, N=84 and N=11 agree and strongly agree respectively

Table 1. Respondent's knowledge about the scoring of tablets.

Null hypothesis	p-value*	Result
1. Observation of splitting mark (scoring) in the center of the tablets is independent of gender discrimination	0.075	Accepted
2. Experience of subdividing the tablet into two halves is independent of gender	0.160	Accepted
3. Problem encountering in subdividing a tablet is independent of gender	0.384	Accepted
4. Perception of Splitting an unscored (without a central mark) tablet is a difficult task is independent of gender	0.421	Accepted
5. Perception regarding the variation of a dose of medicines due to splitting is independent of gender	0.037	Rejected
6. Awareness of the type of medicine that should not be subjected to splitting is independent of gender	0.857	Accepted
7. Perception of the breaking of tablet facilitate swallowing is independent of gender	0.642	Accepted
8. Perception of deterioration of split tablet due to environmental exposure is independent of gender	0.007	Rejected
9. Awareness of the fluctuation in the administered dose of the uneven broken tablet is independent of gender	0.896	Accepted
10. Usage of kitchen knives or scissors to subdivide tablets is independent of gender	0.008	Rejected
11. Perception of tablet splitting is a difficult task for elder patients suffering from impaired hand function and rheumatic disease is independent of gender	0.390	Accepted

*Statistical significance of differences was calculated using Pearson's chi-squared test; Degree of freedom = 5%; Sample size = 426.

with the opinion of color association with safety.

Most of the respondents were of the opinion that the incorporation of color in the dosage forms is not meant for increasing their efficacy. Only 44 people agreed, followed by 15 people strongly agreed with the point of view that color is added in the formulation in order to increase its action.

Respondent perception about the purpose and practice of scoring

In Table 1, the respondent's knowledge and perception about scoring and splitting have been compiled. Our results showed that among 263 female participants and 163 male participants, 234 (89%) females and 140 (85.9%) males have often observed scoring in the center of the tablet. Only 12 (4.6%) female and 16 (9.8%) male participants have never observed splitting marks over the tablet. As the p-value (0.075) is more than the significance level (0.05), we accept the null hypothesis. Thus, we conclude that there is no relationship between gender and splitting mark (scoring) of the tablet.

The experience of tablet splitting or observation of splitting has been found to be very common among participants, 163 (62%) female respondents and 87 (53.4%) male respondents have either experienced the tablet splitting by themselves or observed splitting carried out by others several times. On the other side, only 19 (7.2%) female respondents and 18 (11%) male respondents have never such experienced while 81 (30.8%) females and 58 (35.6%) male respondents have rarely practiced or observed tablets splitting. The results were not statistically significant ($p=0.160$). Most of the respondents believed that the dose of drugs is affected

by pill splitting but most of them are less knowledgeable about the type of drug that should not be subjected to splitting. The results were found to be statistically significant ($p=0.037$) that revealed the perception regarding the variation of a dose of medicines due to splitting is not independent of gender discrimination. More than half of the respondents that is, 88 male and 133 female had a view that ease of swallowing is the reason for the subdivision of tablets.

In the current study, most of the participants were aware of the instability of the tablet on exposure to the environment after splitting. Statistically significant results were obtained ($p=0.007$) that indicate the dependency of gender on the perception regarding the variation of a dose of medicines therefore null hypothesis is rejected. Respondents were also asked about their perception of the influence of tablet subdivision overdose of the drug. Almost half of the respondents ($N=225$) believed that only moderately serious effects can be produced due to the fluctuation of dose as a result of splitting. In response to the question of whether kitchen knives and scissors are suitable for subdivision, 56 males and 125 females perceived their unsuitability while only 9 males and 21 females had strongly believed that knives and scissors can be used for tablet splitting. The gender attitude and practice regarding kitchen knives or scissors in order to subdivide tablets were dependent on each other, as the p-value is less than 0.05 ($p=0.008$). In addition to this participants were also asked about their opinion whether splitting is a tedious task for geriatrics or not. More than a quarter of respondents male ($N=59$) and female ($N=108$) participants had the opinion that elder patients suffering from impaired hand function and rheumatic disease feel difficulties during tablet splitting. A significant association was found in the attitude of the

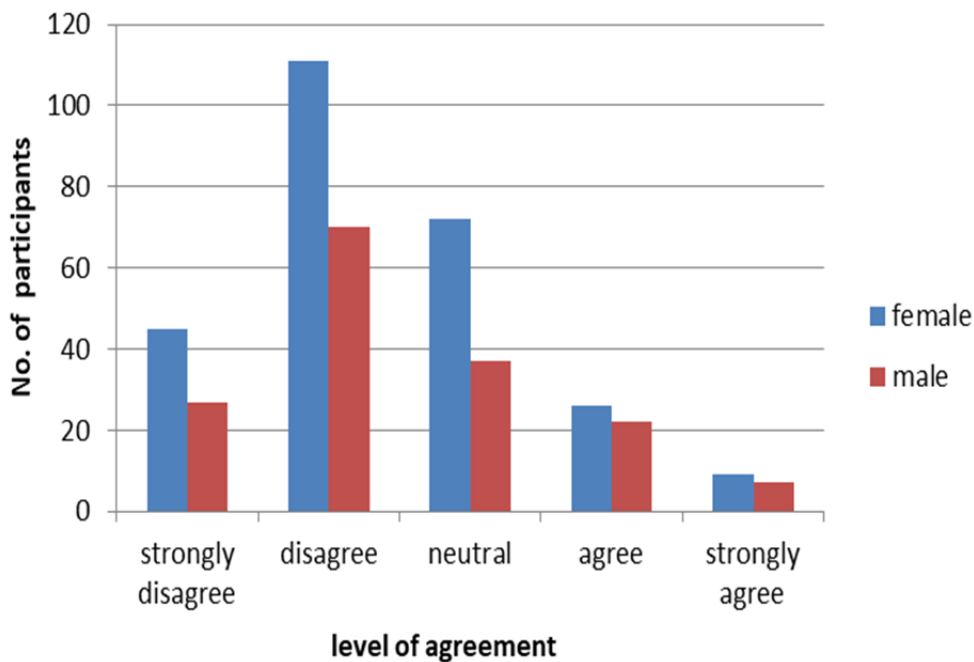


Figure 6. Level of agreement of male and female respondent towards the need for tablet scoring.

Table 2. Attitude of the male and female participant towards the need for scoring.

Statement	Knowledge score Median (interquartile range)	p-value*
Identification purpose	3(4-2)	0.032
To divide the tablets into two halves	4(3-5)	0.653
For attractive appearance	3(2-4)	0.737
No significant function at all	3(2-3)	0.044
No need for scoring	2(2-3)	0.679

Female: N= 263, Male: N= 163; Level of significances: 0.05; *Statistical significance of differences was calculated using Mann-Whitney U test.

male and female participants towards the need for scoring for identification purposes ($U= 18862.5$, $p=0.032$). The median attitude score among male and female participants was 3 (IQR: 4-2). Moreover, a significant association was also observed in the views of respondents that believed no significant function of scoring ($U=19045.5$, $p=0.044$). The median perception score was 4 (IQR: 5-3). Most of the participants were disagree with the view that there is no need for scoring (Figure 6). A non-significant association was found between male and female perception regarding the need for scoring for the purpose of splitting ($U=20906$, $p>0.05$) and attractive appearance ($U=21032.5$, $p>0.05$) (Table 2).

DISCUSSION

Literature review revealed that there are different approaches, perceptions and practices of the general population regarding the physical appearance and swallowing characteristics of oral solid dosage form (Ibrahim et al., 2012). The overwhelming majority of the respondents in the present study preferred tablets as a dosage form. In contrast to the study conducted by Ibrahim et al., the majority of the participants preferred capsule (Ibrahim et al., 2012). In our study, most of the people reported swallowing difficulties. The result of the study is consistent with the previous study conducted by Schiele et al. (2013) reported 37.4% of the participants

suffered difficulties during swallowing of solid drugs while 21.1% of the participants showed reluctance to drug intake due to swallowing difficulties. In another study conducted in Jordan, out of 1250 patients, 130 patients experienced swallowing difficulties (Tahaineh and Wazaify, 2017).

In the previous studies, it has been found that 45 (90%) of the doctors believed that color of solid dosage form has a great impact over the treatment compliance and more elegant product gains more patient acceptance (Hasamnis et al., 2010). One study also explored different color preferences depending on the age and gender of patients. A statistically significant result was obtained ($p=0.0351$) that revealed a strong correlation of color preferences among different age groups and gender (Alyami et al., 2017). According to Ibrahim et al. (2010), it is misunderstood that the colors of the different oral solid dosage forms are responsible for their pharmacological activity such as efficacy, the onset of action and their target organs inside the body (Ibrahim et al., 2010).

In the present study, it has been observed that people are well aware of the purpose of color incorporation into the solid dosage form. Most of them perceived that the purpose of color incorporation mainly for identification rather than improving the efficacy. These results are in agreement with the study conducted by Lenahan et al. (2013) that showed 67.3% of patients identified medications via visual appearance, but in such patients, uncontrolled blood pressure had been found more prevalent as compared to those who identified medications by name.

The current study showed that out of 426 respondents, 221 respondents believed that ease of swallowing provokes the splitting of the tablet. Another study also reported that 16.9% of patients either crush or split oral solid dosage form in order to overcome swallowing difficulties (Tahaineh and Wazaify, 2017). In our study, the problem encountered during splitting was found to be independent regarding gender variation ($p=0.384$). Contrarily to another study that showed a significant difference between the proportion of tablets broken by the male as compared to female ($p=0.035$) (Notenboom et al., 2016). In view of 181 participants, kitchen knives and scissors are not appropriate to carry out the splitting of the tablet. A study conducted by Verrue et al. (2011) concluded that a splitting device was found to be more suitable in terms of less weight deviation and weight loss compared to scissors, a kitchen knife or by hand. Another study provides similar findings and indicated that low variation in friability and weight loss of tablets was found with the usage of pill-splitter compared with a knife (Teixeira et al., 2017). The current study indicated a non-significant difference between male and female participants regarding the usage of kitchen knives and scissors. However, it was proved in another study that

the handgrip of the male was found to be higher than female participants (Schenk et al., 2019).

A total of 39% of the participants in the study believed that splitting is a difficult task for the elder patient having impaired hand movement and suffering from rheumatic arthritis. These results are in agreement with the comparative study conducted in the Netherlands that illustrated the capability to split tablets by elder participants was found to be low as compared to young adults (Notenboom et al., 2016). In the current study, most of the participants were aware of the importance of scoring. Other studies also elaborated on the importance of scoring. Teixeira et al. (2017) reported that weight variation of scored tablets was found to be low (8.6%) as compared to non-scored tablets (12.6%).

Conclusion

It is concluded that tablet is the most preferred dosage form but splitting is an issue for most of the respondents. There is a dearth of information of the participants about the type of drug and dosage form that should not be subjected to splitting. The study emphasized the availability of pill splitting devices since most of the participants considered tablet splitting a tedious step for elder patients especially with functional impairment of hands and arthritis. Furthermore, most of the participants condemn the use of knives and scissors to aid splitting. It indicates the need of scoring of tablet that could facilitate splitting or a splitting device provided by the manufacturer. The consumers should be provided with sufficient knowledge of the storage of half-tablets as well as the type of drug that could be affected by dose variation after pill-splitting. This information should be mentioned either on labels/leaflets or it has to be provided by pharmacist.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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