Assessment of knowledge, attitude, and practices on fixed dose combinations among postgraduate dental students

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Objective: To assess the knowledge, attitude, and practices of fixed dose combination drugs among postgraduate dental students.

Materials and Methods: A cross-sectional study was carried out among postgraduate dental students of dental colleges in coastal Andhra Pradesh. Three colleges were randomly selected and students of all the three years were included. Data was collected from the specialties of oral medicine and radiology, oral surgery, endodontics, pedodontics, periodontics, and public health dentistry. The total sample was 90 postgraduate students; informed consent was obtained from the participants, and a pretested questionnaire was distributed to them. Data was analyzed using the Statistical Package for the Social Sciences version 20 software.

Results: Out of 90 postgraduates, 33 were males and 57 were females. Thirty-five percent were aware of the essential medical list (EML), among them 11% were from oral medicine and radiology and 6.7% were from pedodontics. However, most of them were unaware of the number of fixed dose combination drugs present in the World Health Organization EML. None of them were able to name at least a single banned fixed dose combination drug. Most of them were unaware of the advantages and disadvantages of using fixed dose combination drugs. Amoxicillin with clavulanic acid was the most common drug prescribed by students (73.3%) followed by ofloxacin with ornidazole (54.4%), ibuprofen with paracetamol (53.3%), and sulfamethoxazole with trimethoprim (6%). Most of them were unaware of the rationality in using fixed dose combination drugs. Common sources of information were medical representatives 43 (47.8%), internet 39 (43.3%), and 12 (13.3%) reported using WHO EML.

Conclusion: There is an urgent need to improve knowledge on the rationality for using fixed dose combination, EML, and banned fixed dose combination in India to promote rational use of fixed dose combination.

Key words: Essential medical list, fixed dose combinations, knowledge

INTRODUCTION

Fixed dose combinations of drugs are combinations of two or more active drugs in a single form. 

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a biological product.\textsuperscript{[2]} The basic aim of drug therapy was to treat the ailment with minimal drugs that are safe and effective. Fixed dose combinations rationality are usually based on certain criteria, i.e. the drug in the combination state acts by different mechanisms, the pharmacokinetics should not be widely different, the combination should not have any supra-additive toxicity of the ingredients.\textsuperscript{[3]} The main concern of fixed dose combinations includes adverse consequence of drugs and adverse interactions of drugs. Usually, in dental colleges, during their routine practice prescribe antibiotics and pain killers to relieve suffering from dental pain. Unfortunately, many fixed dose combinations that are available in the market are irrational. Without adequate knowledge, prescribing these drugs can result in adverse drug reactions; therefore, adequate knowledge should be imparted to all medical and dental professionals right from their graduation and postgraduation itself. There are only a few studies that have been conducted to assess the knowledge, attitude, and practices among medical and dental students, and no study has been done so far on dental postgraduate students. Keeping this in view, the present study was conducted to evaluate the knowledge, attitude and practices about prescribing fixed dose combinations among postgraduate dental students in coastal Andhra Pradesh.

Objective

To assess the knowledge, attitude, and practices of fixed dose combination drugs among post graduate dental college students in coastal Andhra Pradesh, India.

MATERIALS AND METHODS

A descriptive cross-sectional study has been carried out on postgraduate dental students of dental colleges in coastal Andhra Pradesh. Among them three colleges were randomly selected and students of all three years were included. Data was collected from the specialties of oral medicine and radiology, oral surgery, endodontics, pedodontics, periodontics, and public health dentistry who prescribe medicines frequently. Sample size was calculated based on a previous study\textsuperscript{[4]} to be 90 postgraduate students; the study was carried out in the month of July 2015 over a period of one month. Ethical clearance was obtained from the institutional ethical board of SIBAR Institute of dental sciences, and informed consent was taken from all the participants.

Data collection

A pretested proforma containing a structured questionnaire with both open-ended and closed-ended questions was used in the study. A modified questionnaire was prepared from previous studies,\textsuperscript{[4,5]} and validity of the questionnaire was checked using Cronbach’s alpha (0.7). The questionnaire was distributed to the postgraduate students, and sufficient time was given to complete the form. Cross verification was done by the investigator to confirm that all the questions were answered.

Statistical analysis

The collected data was entered in the Microsoft Excel Sheet and analyzed using the Statistical Package for the Social Sciences version 20.0 statistical package (IBM, USA). Categorical data was analyzed using Chi-square test. $P$ value of $\leq 0.05$ was considered to be statistically significant.

RESULTS

The present study was carried out among postgraduate dental students of various departments of the two teaching dental hospitals in Andhra Pradesh. A total of 90 postgraduate students, which included 33 (36.7\%) males and 57 (63.7\%) females; of which, 33 (36.7\%) were in the first year, 29 (32.2\%) in the second year, and 28 (31.1\%) in the third year. Figure 1 shows the distribution of study participants according to speciality in postgraduation with higher percentage of participants from the department of oral medicine.

While only 35.6\% of the participants responded that they were aware of essential medical list, 54.4\% were aware of fixed dose combinations \textsuperscript{[Table 1]}, and the difference observed was not significant. Table 2 shows awareness on the essential medical list and fixed dose combinations according to the year of study and the difference was observed to be statistically significant. First year (47.5\%) and third year students (63.3\%) believed patient compliance as advantage of prescribing fixed dose combinations; second year students believed that enhanced drug effect (54.5\%) to be an advantage of prescribing fixed dose combinations; the difference observed was not statistically significant \textsuperscript{[Table 3]}.

All the students believed that multiple formulations, increased cost, difficulty in dose adjustment, and adverse drug reactions are the common disadvantages of fixed dose combinations \textsuperscript{[Table 4]}.

Figure 2 shows commonly prescribed drugs by postgraduate students. Most commonly prescribed drug
was amoxicillin and clavulanic acid (73.3%) followed by ofloxacin and ornidazole (54.4%) and the least was sulfamethoxazole and trimethoprim (0.6%).

It was observed that medical representatives are playing a key role on information regarding fixed dose combinations 43 (47.8%), followed by internet 39 (43.3%), while reliance on continuing dental education (CDE) programmes for information was the least [Figure 3].

**DISCUSSION**

The triad of knowledge, attitude, and practices are useful for finding the areas where deficiencies are present, and working on those areas help in awareness creation, as it will allow the study to be carried out according to the needs of community. WHO introduced the concept of essential drug list in 1977 and updates the list every year;[6] the government of India under the ministry of health and family welfare also recommended the list of essential medicines in India.

The present study observed that only 35.6% of the participants were aware of essential medical list, with postgraduate students from oral medicine and radiology (61.1%) being the most aware. This is possibly because oral medicine and radiology students have more knowledge on drugs. It was observed that 57.1% of third year postgraduate students were aware of fixed dose combinations given in EML but they could not name the number of fixed dose combinations given in the list. As the year of study increases, knowledge also increases, which might be the reason why third year students were more aware of fixed dose combinations.

Overall 45.6% of postgraduate students were unaware of the fixed dose combinations. Knowledge about essential medical list helps in rationally prescribing drugs for better treatment outcome; however, this lack of sensitization of doctors may be the one of the important factor for errors.[7]

It was observed that none of the postgraduate students could name a single band fixed dose combination in India, which is in contrast to the study conducted by Goswami et al.[4] and Kopal Sharma et al.[5,8] Knowledge about the banned fixed dose combination is very important as lack of this knowledge and prescribing these agents may lead to serious, adverse drug reactions. Recently, the government of India has banned 333 fixed dose combination drugs available in the market.[9]

| Specialty           | Awareness on EML* | Awareness on FDC** |
|---------------------|-------------------|--------------------|
| Oral Medicine       | 11 (61.1%)        | 12 (66.7%)         |
| Oral Surgery        | 7 (43.8%)         | 14 (87.5%)         |
| Endodontics         | 4 (20.7%)         | 7 (46.7%)          |
| Pedodontics         | 1 (6.7%)          | 1 (6.7%)           |
| Periodontics        | 4 (20.7%)         | 10 (66.7%)         |
| Public health dentistry | 5 (45.5%)     | 5 (45.5%)          |
| Total               | 32 (35.6%)        | 49 (54.4%)         |

χ²=0.98, P=0.612 (Not Significant), χ²=0.203, P=0.904 (Not Significant)

| Year                | Awareness on EML* | Awareness on FDC** |
|---------------------|-------------------|--------------------|
| First year          | 11 (33.3%)        | 17 (51.5%)         |
| Second year         | 9 (31.0%)         | 16 (55.2%)         |
| Third year          | 12 (42.9%)        | 16 (57.1%)         |
| Total               | 32 (35.6%)        | 49 (54.4%)         |

χ²=12.56, P=0.028 (Significant), χ²=23.56, P=0.000 (Significant)
It was observed in the present study that improved patient compliance and enhances drug effect were the most commonly reported advantages of fixed dose combinations. These results were similar to the study conducted by the Goswami et al. whereas were contrary to those reported by Kopal Sharma et al. 2014. It was observed that 39.8% believed that multiple formulation, increased cost, difficulty in dose adjustments, and adverse drug reactions were most common disadvantages of fixed dose combinations. Dissimilar results were observed in the study conducted by Goswami et al.

It has been observed in the present study that only two fixed dose combination drugs out of all commonly prescribed drugs were in accordance with the WHO essential medical list. When the rationality in prescribing fixed dose combinations in dentistry was questioned, none of them could explain the rationality. Amoxicillin/amoxicillin are effective against gram negative bacilli but not against beta lactamase producing staphylococci, whereas cloxacilline is antistreptococcal penicillin with no effect on gram negative bacilli, because these infections rarely co-exist combining them is irrational. Adding paracetamol to non-steroidal anti-inflammatory drugs, such as ibuprofen and aceclofenac, does not offer additional benefit but increases the chances of nephrotoxicity. Fixed dose combinations such as diclofenac plus seratiopeptidase has no added benefit above the single drugs regardless of the assertion that seratiopeptidase promotes quick resolution of inflammation. In spite of which patient are at higher risk of gastro intestinal irritation and bleeding from unknown peptic ulceration.

Fixed dose combinations of quinolones and nitromidazoles (Ofloxacin with Ornidazole) have not been recommended by any standard books but continue to be heavily prescribed drugs in gastrointestinal infections, pelvic inflammatory diseases, and dental infections. Injudicious practice of fixed dose combination antibiotics results in development of resistant strains that is a serious in health care problem in our country.

Because peptic ulcer is not always in association with vomiting, it is not advisable to prescribe an antiemetic in combination with peptic ulcer drugs (H₂ blockers and proton pump inhibitors).

In the present study it was observed that almost all the drugs except (amoxicillin + clavonic acid and sulfamethoxazole + trimethoprim) were irrational and not according to the essential medical list. Most commonly prescribed drug was amoxicillin + clavonic acid by all the postgraduate student of all the departments.

Table 3: Distribution of responses on disadvantages of fixed dose combinations according to the year of study

| Year            | Multiple formulation | Increased cost | Difficulty in dose adjustment | Adverse drug reaction | All the above |
|-----------------|----------------------|---------------|-------------------------------|----------------------|--------------|
| First year      | 5 (13.8%)            | 5 (13.8%)    | 11 (30.5%)                   | 4 (11.1%)            | 11 (30.5%)   |
| Second year     | 7 (18.4%)            | 5 (13.1%)    | 5 (13.1%)                    | 8 (21.0%)            | 13 (34.2%)   |
| Third year      | 1 (2.90%)            | 8 (23.5%)    | 9 (26.3%)                    | 3 (8.80%)            | 13 (38.2%)   |
| Total           | 13 (11.1%)           | 18 (15.0%)   | 25 (21.0%)                   | 15 (12.0%)           | 47 (39.8%)   |

χ²=10.124, P=0.251 (Not significant)

Table 4: Distribution of responses on advantages of fixed dose combinations according to the year of study

| Year            | Patient compliance | Enhanced drug effect | Patient demand | Less cost | Convenience |
|-----------------|--------------------|----------------------|----------------|-----------|-------------|
| First year      | 19 (47.5%)         | 17 (42.5%)           | 0 (0%)         | 2 (6.1%)  | 2 (5%)      |
| Second year     | 10 (22.7%)         | 14 (54.5%)           | 3 (6.8%)       | 1 (3.4%)  | 6 (13.6%)   |
| Third year      | 45 (63.3%)         | 16 (22.5%)           | 3 (4.2%)       | 2 (2.8%)  | 5 (7%)      |
| Total           | 74 (47%)           | 57 (36.3%)           | 6 (3.8%)       | 5 (3.1%)  | 15 (9.5%)   |

χ²=10.324, P=0.243 (Not significant)
which was rational. It was observed prescribing irrational combinations such as Ofloxacin with Ornidazole more in dental infections and similar finding were observed in study conducted by Kopal Sharma et al.\textsuperscript{[5,8]}

Most common answers given by the students regarding source of information on fixed dose combinations were medical representatives and internet and the least common were essential medical list and CDE programmes. Medical and dental college students as well as faculty and practitioners were under continuous influence by persuasive behavior of medical representative, which eventually leads to an irrational use of medicines. This shows that medical representatives are influencing the doctors and marketing their irrational products in the Indian market.

Limitation

Probable limitation of this study is that it was carried out in a particular area of the country involving few dental college students. In the future a larger study can be carried out on large sample involving all the dental college student throughout the country, and based on results regulation can be framed by the government to avoid irrational prescription of fixed dose combinations.

CONCLUSION

Irrational prescription of fixed dose combinations not only results in adverse drug effect, drug interactions, and impose unnecessary financial burden but also pose a problem to those practitioners who cultivate the habit of prescribing such combinations, which may lead to controversy when subjected to litigation in consumer forum.\textsuperscript{[14]} Time has arrived to think and act about this issue as patients’ health lies in the hands of health care professionals. Creating awareness among resident doctors is very vital regarding the advantages, disadvantages, and rationality in prescribing of fixed dose combinations, and it should be started from the undergraduate level of teaching.

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Conflicts of interest

There are no conflicts of interest.

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