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Original Research Article

Self-medication practices in urban and rural areas of western India: a cross sectional study

Dnyanesh Limaye[1,2,3,4]*, Vaidehi Limaye[1], Gerhard Fortwengel[1], Gerard Krause[3,4,5]

[1]Faculty III, Hochschule Hannover, [3]Hannover Medical School, [4]Hannover Biomedical Research School, Hannover, Germany
[2]PhD Programme, Epidemiology, Helmholtz Centre for Infection Research, Braunschweig, Germany
[5]Department of Epidemiology, Helmholtz Centre for Infection Research, Braunschweig, Germany

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***Correspondence:**
Mr. Dnyanesh Limaye,
E-mail: dnyanesh.limaye@hs-hannover.de

ABSTRACT

Background: Concerns about practice of self-medication (SM) world across are based on associated risks such as adverse reactions, disease masking, increased morbidity, wastage of resources and antibiotic resistance. SM is likely to differ between rural and urban areas of India. Systematically retrieved evidence on these differences are required in order to design targeted measures for improvement.
Methods: We conducted a cross sectional study among the general population in urban (Matunga) and rural (Tala) areas of Maharashtra, India to explore SM practices and its associated factors. Face to face interviews were conducted using the validated study questionnaire. Data was analyzed by using descriptive and analytical statistical methods.
Results: A total of 1523 inhabitants from 462 households were interviewed between [June/2015] and [August /2015], 778 (51%) of them in rural and 745 (49%) in urban areas. Overall self-medication prevalence was 29.1% (urban; 51.5%, rural; 7.7%, OR 12.7, CI 9.4-17.2) in the study participants. Participants having chronic disease (OR: 3.15, CI: 2.07-4.79) and from urban areas (OR:15.38, CI:8.49-27.85) were more likely to self-medicate. Self-medication practices were characterized by having old prescription (41.6%) as the main reason, fever (39.4%) as top indication and NSAIDs (Non-Steroidal Anti Inflammatory Agents) as the most self-medicated category of drugs (40.7%).
Conclusions: The present study documented that the prevalence of self-medication is associated with place of residence, and health status of the study participants. Self-medication is still a major issue in western Maharashtra, India and is majorly an urban phenomenon. Status of implementation of existing regulations should be reconsidered.

Keywords: Self-medication, Matunga, Tala, Mumbai, Raigad, Maharashtra, India

INTRODUCTION

Concerns about practice of self-medication (SM) world across are based on associated risks such as adverse drug reactions, disease masking, inaccurate diagnosis of disease, increased morbidity, drug interactions, wastage of healthcare resources and antibiotic resistance.[1-6] The World Health Organization (WHO) has defined self-medication as the use of drugs to treat self-diagnosed disorders or symptoms, or the intermittent or continued use of a prescribed drugs for chronic or recurrent disease or symptoms.[7]

Practiced globally, SM is an important public health problem, with a reported prevalence of 0.1% in northern and western Europe, 21% in Eastern Europe, 27% in USA.[1,8-12] In developing countries reported SM prevalence rates are much higher with e.g. 84% in Pakistan, 78% in Saudi Arabia, 67% in Nigeria and 79% in India.[8,13-15]

Antibiotics are commonly self-medicated drugs worldwide, with over 50% purchased and used without a prescription.[16,17] In line with Rather antibiotic SM constitutes internationally the most common and obvious contributing factor of antibiotic resistant pathogens.[18] Antibiotic resistance is a major challenge on healthcare system to balance between high burden of infectious diseases and remaining limited choices of active antibiotic therapy.[17]

Focus on India

In India there is no over the counter (OTC) category and medicines should be sold by pharmacists against the prescription of the registered medical practitioner. The Central Drugs Standard Control Organization (CDSCO)–India introduced starting from March 1, 2014 schedule H1 to control sale of medicines without prescription. Presently there are 46 drugs under schedule H1.[19,20] The H1 list includes twenty four antibiotics such as 3rd and 4th generation cephalosporins, carbapenems, antituberculosis drugs, newer fluoroquinolones, and certain habit forming drugs.[19]

The packaging of these drugs have mandatory Schedule H1 warning printed on the label in a box with red border and the Rx symbol in red. The pharmacist will maintain a separate register where identity of the patient, contact details of the prescribing doctor and the name and dispensed quantity of the drug will be recorded. This register has to be retained for at least three years. The drugs control authority has the responsibility to enforce the order. Government drug inspectors can conduct surprise checks on these registers and monitor sale of these 46 drugs under Schedule H1.[19,20]

Despite the existing rules and regulations, failures in the pharmaceutical regulatory environment in India have contributed to ease of access to various medications.[21-23]

A pharmacy based survey done in Berhampur, one of the major cities in eastern India, reported SM prevalence of 18%.[24] While fever, pain and gastrointestinal upset were the most common indications, nonsteroidal anti-inflammatory drugs (NSAIDs) (38%), gastrointestinal drugs (16%), cough remedies (14%), and antimicrobials (10%) were the commonly used drugs for self-medication. A study done in urban area of New Delhi in 2013, reported a 93% prevalence of SM.[6] Common cold (61%) and fever (51%) were the most common ailments for SM and previous use (39%) was the main source of knowledge for SM. A study done in 2012 reported SM prevalence of 50% from the rural areas of Northern India.[25] Primary reasons for practicing SM was high treatment costs in hospitals (40%) and family, friends and neighbors (33%) was the main source of information for SM. Jogdand et al found self-medication prevalence of 49% among rural people of Lohgaon, Pune in western part of India.[26] Antibiotics self-medication prevalence was 10% while ciprofloxacin (41%) and amoxicillin (29%) were the two most commonly self-medicated antibiotics. It is evident that there is a large variation in self-medication prevalence, indications, drugs used, reasons etc. in Indian studies. This might have resulted from varying self-medication definitions used, recall periods, region selected, study population, and methodology adopted.[6,24-26]

India is still predominately rural in terms of its population concentration. Out of a total 1210.2 million Indian population, the size of the rural population is 833.1 million or 69%.[27,28] There is clear divide between urban and rural areas in terms of socioeconomic factors. Rural India is far behind urban India in every indicator of progress like livelihood, employment, poverty, literacy, gender disparity and health.[27,28] Mumbai known as financial center of India is the capital city of India's wealthiest state called Maharashtra.[29,30] It is one of India's fastest growing, most densely populated districts and has India's best private hospitals and healthcare facilities.[31] Raigad district which is on the doorsteps of rich Mumbai considerably lags behind in terms of health parameters. Out of 1860 villages in Raigad district, only 659 villages (35.4%) host functioning medical institutions (primary health centers, sub-centers, and dispensaries).[29,32]

We found only few studies done to determine SM prevalence in Maharashtra, no studies done in Raigad district and none to compare the SM prevalence in rural and urban areas of Maharashtra. The present study was carried out to estimate and characterize the overall self-medication prevalence and antibiotic self-medication prevalence in the urban (Matunga, Mumbai) and rural (Tala, Raigad) areas of Maharashtra, India. The demographic and socio-economic characteristics associated with self-medication, indications, reasons, types of drugs used, the sources of self-medication, use of prescribing information, dosage compliance, etc. were also examined. If differences exists those could help to develop the targeted strategies to improve the situation.

METHODS

Study design

We conducted a cross-sectional study involving face to face interviews in urban and rural areas to determine the prevalence of self-medication and its associated factors. It was conducted through a household survey from 1st of June 2015 to 31st August 2015.

Study setting

The study was conducted in the urban area of Mumbai i.e. F/North ward - Matunga (district: Mumbai, state: Maharashtra, country: India) and rural area of Raigad i.e. Taluka Tala (district: Raigad, State: Maharashtra, country: India). Population of Matunga is 5,29,034

(1,13,779 families) and that of Tala is 40,619 (9,844 families).[32]

Sampling method

We used 2 stage cluster sampling method for our study as shown in fig 1. For rural Maharashtra SM prevalence has been reported as 49% by Jogdand[26]. As no information was available for urban counterpart, we assumed a prevalence rate of 60% in urban area in order to ensure a secure basis for the sample size calculation. Based on 95% confidence interval, 80% power, design effect of 2, and considering 10% non-response, our overall estimated sample size was calculated with 1490 subjects (745 each for Matunga and Tala). Consequently we decided to interview 300 families each from urban and rural area, taking into account varied family sizes. Thirty clusters were randomly selected each from Matunga and Tala. At second stage, we randomly selected 10 families from each cluster.

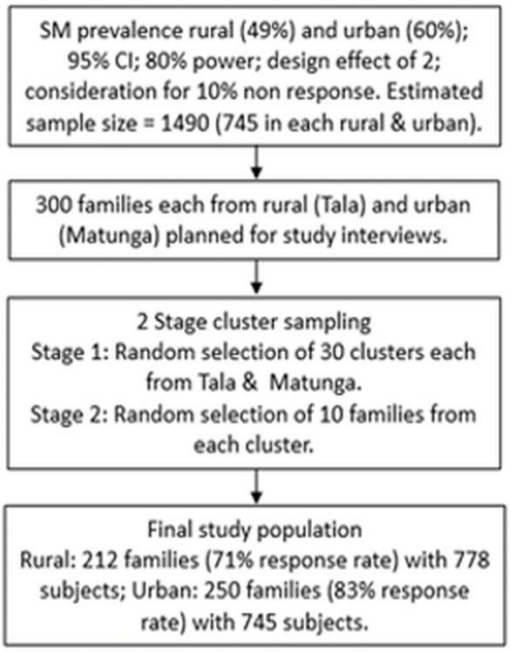

Figure 1: Sample size and recruitment flow.

Participants

Inclusion criteria

Subjects with address proof of residency in Matunga or Tala, ready to sign the informed consent, who understood Marathi, Hindi or English were eligible to participate in the study.

Exclusion criteria

Subjects having communication problem, severe illness or mentally challenged were excluded from the study.

Ethics committee approval and subject's consent

The study was approved by the Independent Ethics Committee from Maharashtra, India. The purpose and details of the study were explained to subjects and only those willing and ready to sign the informed consent were included in the study. The participants were assured that records and data identifying the subject are kept confidential and are not made publicly available. If the results of the study are published, the subject's identity remains confidential.

Study questionnaire

A structured study questionnaire was developed in English (A copy of the questionnaire is available from the corresponding author on request). It was translated to Marathi and Hindi (local languages) by a qualified and accredited translator. Marathi and Hindi versions were back translated to English by another translator to ensure the content uniformity. The study questionnaire consisted of 3 sections: socio-demographics, general self-medication habits, and antibiotic self-medication practices.

Self-medication for this study was defined as "use of medicines in last 3 months without the prescription of registered medical practitioner". Questionnaire's content and face validity was checked by a team consisting of epidemiologists, pharmacists, a statistician and also a lay person. We conducted a pilot study in 15 families each from Mumbai and Tala to ensure that the questionnaire would be appropriate, and understandable among the prospective respondents. The pilot testing allowed wording modifications in questions and provided an estimate of the average time required for interview and questionnaire completion. The pilot population was not included in the dataset of the final analysis.

The questions included demographic, socioeconomic characteristics of the respondents, and use of self-medication in the last 3 months. Detailed data referring to the sources of information, reasons, and the underlying indications for self-medications were obtained. Further questions about any existing chronic diseases, occurrence (s) of adverse drug events during self-medication, and whether subjects read and properly understood the information in patient leaflet about the drug used for self-medication were part of study questionnaire. In particular respondents were asked about antibiotic self-medication practice in the last 3 months. Information covered in this part included e.g. data on indications, source(s) of information for dosage decision, compliance with dosage, and practice of changing antibiotics during self-medication.

Data collection

Interviews with subsequent data collection were conducted by 10 qualified and trained local sub-

investigators (5 each for Matunga and Tala). After obtaining signed informed consent from the subjects, face to face interviews were conducted with each family member independently and data was recorded into a paper based questionnaire. Response to the questionnaire was obtained from the parents on behalf of their children who were below the age of 12 years. Data from paper questionnaires was entered into Microsoft Excel and cross checked against the entries in the questionnaire by the authors (DL and VL). Any inconsistency was clarified, corrected and noted next to the concerned data field in the paper questionnaire. After completion of data checks the Microsoft Excel file was locked for the final biometrical analysis.

Focused group discussions with pharmacists

Ten pharmacy shops from urban and 2 from rural study area were randomly selected to understand opinion of pharmacists towards selling medicines without prescription. Pharmacist from each shop was interviewed by 2 trained sub investigators (one from urban and one from rural). Pharmacists were asked 5 questions as mentioned below, related to sale of drugs without prescription and this data was recorded in the printed forms which was later on entered into Microsoft Excel and was saved for analysis.

1. Do you sell medicines without prescription?
2. If yes, then what are the reasons for sale of medicines without prescription?
3. Are you aware of risks associated with self-medication?
4. Are you aware of recent schedule H1 by Indian drug authorities and has it impacted your sale without prescription?
5. Have you slowed down or stopped selling medicines without prescription in the light of recent raids by Indian drug regulatory authorities?

Statistical analysis

Date was analyzed by using descriptive statistical methods for socio-demographic data, and self-medication variables such as indications, reasons, sources etc. A bivariate analysis was conducted with all relevant independent variables and Odds Ratios (OR) and their respective 95% Confidence Intervals (CI) were calculated. A binary logistic regression model was constructed from the variables that were significant in the bivariate analysis. $P<0.05$ was considered as significant. We used IBM SPSS version 23 for statistical analysis.

Data from focused group discussion was interpreted in relation to self-medication practices of study participants from urban and rural area. Descriptive analysis was performed for the data arising out of questions 1 and 3 to 5. For question 2, responses were clustered and then qualitative analysis was performed.

RESULTS

A total of 462/600 families i.e. 212/300 rural (Tala) and 250/300 from urban (Matunga) area participated in the study. The overall response rate was 77% (rural; 71%, urban; 83%).

Table 1: Socio-demographic characteristics of rural and urban participants.

Variables	Total (1523) n (%)	Rural (778) n (%)	Urban (745) n (%)
Gender			
Male	727 (47.7)	376 (48.3)	351 (47.1)
Female	796 (52.3)	402 (51.7)	394 (52.9)
Occupation			
Farmer	60 (3.9)	60 (7.7)	0
Student	555 (36.4)	298 (38.3)	257 (34.4)
Housewife	336 (22.1)	207 (26.6)	129 (17.3)
Retired	45 (3)	14 (1.8)	31 (4.2)
Business	167 (11)	72 (9.3)	95 (12.8)
Employee	360 (23.6)	127 (16.3)	233 (31.3)
Marital status			
Married	833 (54.7)	398 (51.1)	435 (58.4)
Unmarried	628 (41.2)	346 (44.5)	282 (37.8)
Others	62 (4.1)	34 (4.4)	28 (3.8)
Religion			
Christian	30 (2)	0	30 (4.1)
Hindu	1311 (86.1)	695 (89.3)	616 (82.6)
Muslim	119 (7.8)	49 (6.3)	70 (9.4)
Others	63 (4.1)	34 (4.4)	29 (3.9)
Qualification			
Illiterate	71 (4.6)	51 (6.5)	20 (2.7)
School	504 (33.1)	417 (53.6)	87 (11.7)
Graduate	796 (52.3)	272 (35)	524 (70.3)
Postgraduate	152 (10)	38 (4.9)	114 (15.3)
Chronic disease			
Yes	259 (17)	114 (14.6)	145 (19.4)
No	1264 (83)	664 (85.4)	600 (80.6)
Health insurance			
Yes	634 (41.6)	7 (0.9)	627 (84.2)
No	889 (58.4)	771 (99.1)	118 (15.8)
Age (years)			
<20	401 (26.3)	248 (31.8)	153 (20.5)
21-39	517 (33.9)	242 (31.1)	275 (36.9)
40-59	507 (33.3)	230 (29.6)	277 (37.2)
≥60	98 (6.5)	58 (7.5)	40 (5.4)
Monthly income (Indian rupee)			
<2000	50 (3.3)	50 (6.4)	0
2000-4999	236 (15.5)	236 (30.3)	0
5000-9999	190 (12.5)	162 (20.8)	28 (3.8)
10000-19999	290 (19)	163 (21)	127 (17)
20000-49999	344 (22.6)	129 (16.6)	215 (28.9)
≥50000	413 (27.1)	38 (4.9)	375 (50.3)

One thousand five hundred twenty three subjects i.e. 778 from rural and 745 from urban area made themselves available for the interviews and provided the required data. The family size median was 4 (range 2 to 5) in rural and 3 (range 1 to 5) in urban area. The mean age of the study participants was 33.3 years (SD=17.9) in rural and 36.1 years (SD=15.6) in urban area. Similar male to female ratio (1:1.1) was observed for total, rural and urban participants. Thirty three percent (259/778) rural and 44% (328/745) urban participants had source of income through their occupation as an employee, or a business, or being a farmer (only in case of rural). Fifty one percent (398/778) and 58% (435/745) of the participants in rural and urban area were married, respectively. Thirty percent (236/778) of the rural participants had monthly family income of 2000 to 4,999 Indian rupees whereas 50% (375/745) of the urban participants had monthly family income of ≥50,000 Indian rupees. Majority of the participants from rural (695/778; 89%) and urban area belonged to Hindu (616/745; 82%) religion. Nearly 14% (114/778) of rural participants and 19% (145/745) of urban participants reported having chronic disease. Eighty-four percent (627/745) of the urban participants had health insurance, while it was almost negligible in case of rural participants. (0.9%; 7/778). Forty percent (310/778) of the rural and 85% (638/745) of the urban participants had completed at least graduate level education. Further details related to socio-demographic characteristics are presented in Table 1.

Bivariate analysis

Total study population

Table 2 shows self-medication prevalence according to socio-demographic variables for all participants. Overall self-medication prevalence was 29.1% (444/1523). The prevalence of self-medication was highest among participants who were from urban study population (384/745; 51.5%; χ^2=354; p≤0.000; OR=12.7; $CI_{95\%}$=9.4-17.2), retired (21/45; 46.7%; χ^2=67.2; p≤0.000), married (293/833; 35.2% χ^2=37.3; p≤0.000), Christians (20/30; 66.7%; χ^2=26.3; p≤0.000), post graduate educated (67/152; 44%; χ^2=111.7; p≤0.000), having chronic disease (109/259; 42%; χ^2=25.3; p≤0.000; OR=2.01; $CI_{95\%}$=1.5-2.6), having health insurance (335/634; 52.8%; $\chi^{2=}$295.03; p≤0.000; OR=8.01; $CI_{95\%}$=6.2-10.3), in the age group of 40-59 years (175/507; 34.5%; $\chi^{2=}$22.2; p≤0.000) and having monthly income of ≧50,000 Indian rupees (180/413; 43.6%; $\chi^{2=}$157; p≤0.000). There was no statistically significant difference in self-medication prevalence among male (215/727; 29.6%) and female (229/796; 28.8%) study participants.

Table 2: Self-medication prevalence according to sociodemographic variables for all participants (n=1523).

Variables (n)	Use of self-medication		χ^2value	P-value	Odds ratio	$CI_{95\%}$
	Yes; n (%)	No; n (%)				
Place of residence						
Urban (745)	384 (51.5)	361 (48.5)	354	0.0001*	12.7	9.4-17.2
Rural (778)	60 (7.7)	718 (92.3)				
Gender						
Male (727)	215 (29.6)	512 (70.4)	0.12	0.74	1.04	0.8-1.3
Female (796)	229 (28.8)	567 (71.2)				
Occupation						
Farmer (60)	4 (6.7)	56 (93.3)	67.2	0.000*		
Student (555)	123 (22.2)	432 (77.8)				
Housewife (336)	88 (26.2)	248 (73.8)				
Retired (45)	21 (46.7)	24 (53.3)				
Business (167)	56 (33.5)	111 (66.5)				
Employee (360)	152 (42.2)	208 (57.8)				
Marital Status						
Married (833)	293 (35.2)	540 (64.8)	37.3	0.000*		
Unmarried (628)	130 (20.7)	498 (79.3)				
Others (62)	21 (33.8)	41 (66.2)				
Religion						
Christian (30)	20 (66.7)	10 (33.3)	26.3	0.000*		
Hindu (1311)	359 (27.4)	952 (72.6)				
Muslim (119)	43 (36.1)	76 (63.9)				
Others (63)	22 (34.9)	41 (65.1)				
Qualification						
Illiterate (71)	12 (16.9)	59 (83.1)	111.7	0.000*		
School (504)	66 (13.1)	438 (86.9)				
Graduate (796)	299 (37.6)	497 (62.4)				
Postgraduate (152)	67 (44)	85 (56)				

Continued.

Variables (n)	Use of self-medication		χ^2value	P value	Odds ratio	$CI_{95\%}$
	Yes; n (%)	No; n (%)				
Chronic disease						
Yes (259)	109(42)	150(58)	25.3	0.000*	2.01	1.5-2.6
No (1264)	335(26.5)	929(73.5)				
Health insurance						
Yes (634)	335 (52.8)	299 (47.2)	295.03	0.000*	8.01	6.2-10.3
No (889)	109 (12.3)	780 (87.7)				
Age (years)						
≤20 (401)	82 (20.4)	319 (79.6)	22.2	0.000*		
21-39 (517)	157 (30.4)	360 (69.6)				
40-59 (507)	175 (34.5)	332 (65.5)				
≥60 (98)	30 (30.6)	68 (69.4)				
Monthly income (Indian rupee)						
<2000 (50)	0 (0)	50 (100)	157	0.000*		
2000-4999 (236)	15 (6.4)	221 (93.6)				
5000-9999 (190)	26 (13.7)	164 (86.3)				
10000-19999 (290)	92 (31.7)	198 (68.3)				
20000-49999 (344)	131 (38.1)	213 (61.9)				
≥50000 (413)	180 (43.6)	233 (56.4)				

Table 3: Self-medication prevalence according to the socio-demographic variables for rural participants (n=778).

Variables	Self-medication		χ^2value	P value	Odds ratio	$CI_{95\%}$
	Yes; n (%)	No; n (%)				
Gender						
Male (376)	29 (7.7)	347 (92.3)	0.000	1.0	1.0	0.69-1.69
Female (402)	31 (7.7)	371 (92.3)				
Occupation						
Farmer (60)	4 (6.7)	56 (93.3)	25.7	0.000*		
Student (298)	8 (2.7)	290 (97.3)				
Housewife (207)	20 (9.7)	187 (90.3)				
Retired (14)	1 (7.1)	13 (92.9)				
Business (72)	6 (8.3)	66 (91.7)				
Employee (127)	21 (16.5)	106 (83.5)				
Marital status						
Married (398)	46 (11.6)	352 (88.4)	20.3	0.000*		
Unmarried (346)	10 (2.9)	336 (97.1)				
Others (34)	4 (11.7)	30 (8.8)				
Religion						
Hindu (695)	56 (8.1)	639 (91.9)	1.3	0.502		
Muslim (49)	3 (6.1)	46 (93.9)				
Others (34)	1 (2.9)	33 (97.1)				
Qualification						
Illiterate (51)	3 (5.9)	48 (94.1)	15.1	0.001*		
School (417	32 (7.7)	385 (92.3)				
Graduate (272)	16 (5.9)	256 (94.1)				
Postgraduate (38	9 (23)	29 (76)				
Chronic disease						
Yes (114)	19 (16.6)	95 (83.4)	15	0.000	3.03	1.6-5.4
No (664)	41 (6.2)	623 (93.8)				
Health insurance						
Yes (7)	1 (14.3)	6 (85.7)	0.4	0.43	2.01	0.2-16.9
No (771)	59 (7.7)	712 (92.3)				

Continued.

Variables	Self-medication		χ^2value	P value	Odds ratio	$CI_{95\%}$
	Yes; n (%)	No; n (%)				
Age						
≤20 (248)	8 (3.2)	240 (96.8)	13.6	0.003*		
21-39 (242)	20 (8.3)	222 (91.7)				
40-59 (230)	28 (12.2)	202 (87.8)				
≥60 (58)	4 (6.9)	54 (93.1)				
Monthly income						
<2000 (50)	0 (0)	50 (100)	19.6	0.001*		
2000-4999 (236)	15 (6.4)	221 (93.6)				
5000-9999 (162)	14 (8.6)	148 (91.4)				
10000-19999 (163)	10 (6.1)	153 (93.9)				
20000-49999 (129)	12 (9.3)	117 (90.7)				
≥50000 (38)	9 (23.7)	29 (76.3)				

Table 4: Self-medication prevalence according to the sociodemographic variables for urban participants (n=745).

Variables (n)	Use of self-medication		χ^2value	P-value	Odds ratio	$CI_{95\%}$
	Yes; n (%)	No; n (%)				
Gender						
Male (351)	186 (53)	165 (47)	0.5	0.464	1.116	0.8-1.5
Female (394)	198 (50.3)	196 (49.7)				
Occupation						
Student (257)	115 (44.7)	142 (55.3)	9	0.061		
Housewife (129)	68 (52.7)	61 (47.3)				
Retired (31)	20 (64.5)	11 (35.5)				
Business (95)	50 (52.6)	45 (47.4)				
Employee (233)	131 (56.2)	102 (43.8)				
Marital Status						
Married (435)	247(56.8)	188 (43.2)	14.8	0.000*		
Unmarried (282)	120 (42.6)	162 (57.4)				
Others (28)	17 (60.7)	11 (39.3)				
Religion						
Christian (30)	20 (66.7)	10 (33.3)	10	0.018*		
Hindu (616)	303 (49.2)	313 (50.8)				
Muslim (70)	40 (57.1)	30 (42.9)				
Others (29)	21 (72.4)	8 (27.6)				
Qualification						
Illiterate (20)	9 (45)	11 (55)	7	0.07		
School (87)	34 (39.1)	53 (60.9)				
Graduate (524)	283 (54)	241 (46)				
Postgraduate (114)	58 (51)	56 (49)				
Chronic disease						
Yes (145)	90 (62)	55 (38)	7.9	0.002*	1.7	1.17-2.4
No (600)	294(49)	306 (51)				
Health insurance						
Yes (627)	334 (53.3)	293 (46.7)	4.7	0.03*	1.5	1.04-2.3
No (118)	50 (42.4)	68 (57.6)				
Age (years)						
≤20 (153)	74 (48.4)	79 (51.6)	4.1	0.250		
21-39 (275)	137 (49.8)	138 (50.2)				
40-59 (277)	147 (53.1)	130 (46.9)				
≥60 (40)	26 (65)	14 (35)				
Monthly income (Indian rupee)						
5000-9999 (28)	12 (42.9)	16 (57.1)	16	0.001*		
10000-19999 (127)	82 (64.6)	45 (35.4)				
20000-49999 (215)	119 (55.3)	96 (44.7)				
≥50000 (375)	171 (45.6)	204 (54.4)				

Rural study population

Table 3 shows self-medication prevalence according to sociodemographic variables for rural participants. Self-medication prevalence for rural study population was 7.7% (60/778). The prevalence of self-medication was highest among participants who were employed (21/127; 16.5%; χ^2=25.7; p≤0.000), married (46/398; 11.6%; χ^2=20.3; p≤0.000), post graduate educated (9/38; 23%; χ^2=15.1; p=0.001), having chronic disease (19/114; 16.6%; χ^2=15; p≤0.000; OR=3.03; $CI_{95\%}$=1.6-5.4), in the age group of 40-59 years (28/230; 12.2%; χ^2=13.6; p=0.003) and having monthly income ≥50,000 Indian rupees (9/38; 23.7%; $\chi^{2=}$19.6; p=0.001). There was no statistically significant difference in self-medication prevalence by gender, health insurance or religion of the participant.

Urban study population

Table 4 shows self-medication prevalence according to sociodemographic variables for urban participants. Self-medication prevalence for urban study population was 51.5% (384/745). The prevalence of self-medication was highest among participants who were married (247/435; 56.8%; χ^2=14.8; p≤0.000), belonging to other religions (21/29; 72.4%; χ^2=10; p≤0.018), having chronic disease (90/145; 62%; χ^2=7.9; p≤0.002; OR=1.7; $CI_{95\%}$=1.17-2.4), having health insurance (334/627; 53.3%; χ^2=4.7; p≤0.03; OR=1.5; $CI_{95\%}$=1.04-2.3), and having monthly income of ≥10,000 to 19,999 Indian rupees (82127; 64.6%; $\chi^{2=}$16; p=0.001). There was no statistical significant difference in self-medication prevalence by gender, occupation, qualification, or age of the participant.

Binary logistic regression analysis

Total study population

The binary logistic regression analysis for the total study population revealed, that participants from urban area were 15 times more likely (OR: 15.38; p≤0.000, $CI_{95\%}$=8.49-27.85) to self-medicate than their rural counterparts. Unmarried participants were less likely (OR: 0.35; p=0.002, $CI_{95\%}$=0.18-0.68) to self-medicate as compared to married participants. Those having chronic disease were 3 times more likely (OR: 3.15; p≤0.000, $CI_{95\%}$=2.07–4.79) to self-medicate than participants not having chronic disease.

Rural and urban study population

Results were similar to those seen for total study population. Among rural study population, participants having chronic disease were 6 times more likely (OR: 6.84; p≤0.000, $CI_{95\%=}$3.21-14.58) to self-medicate than participants not having chronic disease. Among urban study population, unmarried participants were less likely (OR: 0.35; p=0.008, $CI_{95\%}$=0.16-0.76) to self-medicate as compared to married participants. Those having chronic disease were twice more likely (OR: 2.15; p≤0.002, $CI_{95\%}$=1.34–3.46) to self-medicate than participants not having chronic disease. There was no statistical significant association between self-medication and any other variable.

Characteristics of self-medication

Among the study participants who self-medicated, keeping old prescription(s) (rural: 32/60; 53.3%, urban: 153/384; 39.8%), and saving the time (rural: 14/60; 23.3%, urban: 138/384; 35.9%) were the main reasons for self-medication. Acidity (rural: 54/60; 90%), cough & cold (urban: 131/384; 34.1%), followed by fever (rural: 47/60; 78.3%, urban: 128/384; 33.3%) and headache (rural: 45/60; 75%, urban: 114/384; 29.6%) were the top indications for self-medication. Antacid (rural: 57/60; 95%), antibiotic (urban: 131/384; 34.1%) followed by NSAID (rural: 51/60; 85%, urban: 130/384; 33.8%) were the most commonly self medicated types of drugs among the study participants.

For rural participants pharmaceutical company (49/60; 81.6%), whereas for urban participants price (125/384; 32.5%), was the main factor while selecting drugs for self-medication. Pharmacy shop (rural: 54/60; 90%, urban: 357/384; 92.9%) was the main source of obtaining drugs for self-medication among study participants.

When enquired about reading the prescribing information, 53.3% (32/60) of the rural and 73.4% (282/384) of the urban participants reported reading always or at least sometimes before self-medication. Full understanding of prescribing information was defined as understanding the indication, dosage & administration, contraindications and adverse reaction section of prescribing information by study subjects. Failing to understand any of these sections was considered as partial understanding of the prescribing information by the study subjects. Of those who always or at least sometimes read the prescribing information before self-medication, 56% (18/32) of the rural and 75.5% (213/282) of the urban participants understood it partially or fully.

Thirteen point three percent of the rural (8/60) and 4.7% (18/384) of the urban participants reported of suffering from adverse drug reactions after self-medication. Consulting the doctor (rural: 4/8; 50%, urban: 9/18; 50%) and stopping the medication (rural: 1/8; 12.5%, urban: 10/18; 55.5%) were the measures taken after experiencing side effects associated with self-medication.

Focused group discussions (FGD) with pharmacists from pharmacy shops

All urban pharmacist (10/10; 100%) and none (2/2; 100%) of the rural pharmacist sold drugs without prescription in spite of being aware about risks associated

with self-medication. All of the interviewed urban as well as rural pharmacists were aware about schedule H1, accepted its impact on drug sale without prescription and admitted slowing down the sale without prescription in the light of recent raids by Indian drug regulatory authorities.

Regarding the reasons for sale of the medicines without prescription, the first theme to emerge from focused group discussions (FGD) with rural pharmacy shop personnel was related to conduct of business without competition. They do not have any pressure to sell drugs without prescriptions and can sustain their business.

"I do not have any competition in this area, why should I sell scheduled drugs to consumer who do not have doctor's prescription? It might cause them more harm".

The second theme to emerge out of the FGD with rural pharmacy shop personnel was related to implementation of schedule H1. Pharmacists described recent strict implantation of drug rules specifically schedule H1 by FDA and felt that it is too risky to dispense drugs without prescription.

"My business is going on well, I do not want to land in trouble by selling prescription only drugs to consumers without prescription. Are you aware of recent raids by FDA officials, they are becoming stricter and cancelling licenses. I do sell sometime drugs without prescription, but to only very known person".

The third theme to emerge out of FGD with urban pharmacy shop personnel was related to fear of losing business because of fierce competition.

"I have to run my business well and make profit for my family. If I do not sale it, next medicine shop (Pharmacy) will sell it for sure, then why shouldn't I"?

The fourth theme to emerge out of FGD with urban pharmacy shop pharmacist was related to having many customers at same time making prescription demand difficult.

"In fact I am helping my customers who are in so much hurry, they have lots of work. Also I do not have any time to look for prescription, I am too busy. Whatever they ask I do give them unless something like diazepam is requested".

DISCUSSION

Self-medication prevalence

The prevalence of self-medication in our study was found to be 29.1%, 51.5%, 7.7% in total, urban and rural study population respectively. A study done by Saharan in Mumbai, Maharashtra reported self-medication prevalence of 85%, which is higher than present study (51.5%).[33] This could be explained in part by the fact that Saharan study did not have a specific recall period for self-medication, as compared to 3 months in our study, neither it did define self-medication. Rural SM prevalence (7.7%) from our study is substantially lower than the study done by Jogdand et al (49%) in Lohagaon, Maharashtra, India.[26] This difference could be explained by number of factors. First, different recall periods used in the studies i.e. 3 months in present study, whereas no recall period in Jogdand study. Second, failure to define what is meant by self-medication in Jogdand study. It is a known fact that the longer recall period are related to more inaccuracies, and are potential bias for collecting information on self-medication practices.[34] Third, Jogdand study was done between December 2011 to January 2012 much before implementation of schedule H1. Instead our study was done (1st of June 2015 to 31st August 2015) one year after implementation of Schedule H1. This difference might have in part originated because of implementation of schedule H1 across India, enforcing sale only on prescription for number of medicines, as well as close monitoring by Indian state FDA.[19,35-37]

When statistically significant factors from bivariate analysis– place of residence, socioeconomic factors, and chronic disease were fitted into binary logistic model, only place of residence and chronic disease increased the likelihood of self-medication. Also compared to odds ratio of 12.7 in bivariate analysis, binary logistic regression model had OR of 15.38 for urban participants. Socioeconomic factors like education, occupation, and income are interlinked. The ability to have health insurance is linked to socioeconomic factors. At the same time, people with higher education, better jobs and higher income tend to be more in urban areas as seen in present study. We are of the opinion that, all these variables exerted synergistic effect which was responsible for increase in odds ratio from 12.7 (Bivariate) to 15.38 (binary logistic regression).

As stated above most important factor triggering self-medication based on results in our study are discussed below.

Place of residence

The higher prevalence of self-medication in urban participants (urban; 51.5%, rural; 7.7%) found in present study is in agreement with the studies from other parts of India i.e. from Andhra Pradesh (urban; 37%; rural; 17%) and Punjab (urban; 87%, rural; 82.5%).[38,39]

A contradictory result was reported in a study from South India, which reported urban self-medication prevalence (71%) lesser than that of rural 86 (%) participants.[40] This could be explained by the fact that this study was done only in literate population (graduates, software professionals, bank employees, and teachers) thus negating any possible effects of education, occupation, income on self-medication behavior between urban and

rural. Also this study did not specify the recall period leading to potential bias in the interpretation of results.

Our results are also in concordance with the studies from other countries like Sri Lanka (urban; 12.2%, rural; 7.9%), Pakistan (urban; 68.3%, rural 54%), and China (urban; 31%, rural; 25.3%).[41-43]

Some authors have attributed this difference to the fact that people in the economically weak rural area are more likely to consult a medical practitioner for a medical condition, than unnecessarily spending money on self-medication. This behavior seems to be a way of rationally and efficiently spending hard-earned money on health in low-and middle-income areas.[41]

This difference can also be attributed to the implementation of schedule H1 by FDA. Our rural study area had only 2 pharmacy shops as compared to more than 20 in the urban study area. It is very easy for state FDA to visit and monitor these pharmacies in rural area as compared to large number of pharmacies in urban area. Recent Food and Drug Administration, India (FDA) reports show that, FDA inspected maximum pharmacy stores (7143) in Raigad, Maharashtra (Rural) and also cancelled maximum number of (1384) pharmacy shop licenses in the same region as compared to other regions in Maharashtra.[35-37] This might have acted as a deterrent to pharmacy shops in our rural study area, so preventing sale of drugs without prescription making self-medication difficult for study participants.

The higher prevalence in urban areas may also be linked to easily accessible pharmacies in urban areas. In recent years, the infrastructure of communities has changed in India. Strategies are now being employed with better marketing of the pharmacies by locating them at easy access places. This change has prompted the urban population towards using non-prescription in their busy life schedule.[40]

Another possible reason for this difference could be, unavailability of family physicians in urban areas. During the last years, much of the medical care has fragmented into organ-based specialty domains. In India, this trend has become more prominent with arrival of "super specialist" and "super specialty hospital" culture. In cities such as Mumbai, Chennai, Kolkata, and Pune the older generation of general practitioners are retiring in their 70s and 80s, while no one is opening new practices in their localities.[44]

Today, there is no "one" doctor who is responsible for the whole person. People often find it frustrating when their small health-related questions are not answered by the single treating doctor, as they have to visit multiple health care providers. People want solutions which only family physicians can provide, who are capable of generalist care.[45] In urban area people try to manage their own diseases (cough, cold, fever, pain, acidity) due to unavailability of general practitioners. At the same time, high inflation rate in India has also increased doctors' fee which have further deepened the problem of self-medication.[40]

Chronic disease

Results of the present study indicated that self-medication prevalence was higher among participants having chronic disease. It appears that self-medication was not so much used for chronic health conditions as for acute minor common conditions, such as fever, cough/cold, headache, acidity.

Similar trend has been observed in a community based study done in Alexandria, Egypt, which reported that participants having chronic diseases mainly self-medicated for acute diseases (colic, dyspepsia, headache, flu, and fever) than for chronic conditions.[46]

A study done in Ankara, Turkey found that, the percentage of those storing medicines other than those required continually to treat chronic diseases at home was 74.4%. The medications stored at home were analgesic/anti-inflammatory drugs in 92.7%, cold medication in 45.7% and antibiotics in 28%.[47]

The higher prevalence of self-medication among participants with chronic disease can be attributed to pathophysiological reasons. Chronic diseases affect the person, cause pain and disability and reduce quality of life, hence, raising their need for medication.[48] Also it is known that people with chronic diseases need regular medicines and, consequently they might be more confident to make choices regarding consuming medicines i.e. self-medication. They might also want to avoid the physician fees as they are already spending money on medicines for chronic diseases.[49]

Reasons for SM

Our study indicated that having old prescription(s) (rural; 53.5%, urban; 39.8%), and saving the time (rural; 23.3%, urban; 35.9%) were the main reasons for self-medication among study participants. This highlights the practice of doing away with the need to go to a doctor for illnesses and providing quick, easy and convenient relief.

Based on the reasons identified for self-medication our results are similar to those reported in Indian studies done in Harayana, Pudducherry, Mumbai, and Tamil Nadu.[33,50-52] Our results differ from studies done in Pakistan, and Bangladesh which reported cost saving and unavailability of health services respectively as reason other than minor illness for practicing self-medication.[42,53] The observed difference might be due to variation in study settings, health seeking behavior of people, socio-cultural factors, differences in health infrastructure and community health practices.

Indications for SM

Our results are similar to those reported in Indian studies done in Maharashtra, India i.e. rural areas of Pune, rural Karad and Mumbai.[33,54,55] Our results differ from studies done in other Asian countries. Pain, respiratory symptoms, and allergy were the top symptoms in a study from urban and rural population of Islamabad, Pakistan.[42] Pain (17%) fever (15%) and gastritis (15%) were the main symptoms in a study from urban & rural areas of Bangladesh.[53] While headache and fever were the most common indications for self-medication in a study done in Pokhara valley, Western Nepal.[56] Although there is difference in self-medication indications which might have resulted due to differences in disease prevalence, dietary habits, health seeking behavior of people, still pain and fever were commonly seen indications in these studies.

Source of information for self-medication

Our study revealed that pharmacy shop (90%; rural; 92.9%; urban) was the main source of obtaining drugs for self-medication among study participants. Similar results have been reported in Indian studies from rural Tamil Nadu, South India; urban Nagpur and rural Karad from West India.[52,55,57] It is also worth mentioning that despite a lack of training in diagnosis and prescribing medications, pharmacists dispense medications to consumers based on the patient's symptoms or request for particular medications.[58-60] In these instances, the pharmacist's choice of medication is often based either on availability or on perceived prescribing practices of doctors rather than on current guidelines. This can lead to misuse, overuse, polypharmacy, adverse drug events, drug interactions and antibiotic resistance.[61,21]

Study strengths

Present study had statistically very sound design based on the considerations such as prevalence based sample size, and 2 stage cluster sampling method to have a more representative sample of the population. To our knowledge, this is the first study exploring the prevalence of self-medication in Raigad district of Maharashtra and also to compare self-medication in urban and rural area of Maharashtra.

Study limitations

Several limitations should be considered while interpreting the results of the present study.

Nature of the study: The main limitation of this study is, it's cross sectional nature which has inherent weakness in inferring causality. Cross sectional studies are unable to provide conclusive temporal association (cause and effect). However, the factors associated with SM (i.e. socioeconomics, place of residence and presence of chronic disease) are important while planning the future public health strategies in India.

Recall period: We used a 3 month recall period, which might have led to a recall bias. We tried to minimize the recall bias by adapting a well formatted, simple, and easy-to-understand questionnaire. Also, reporting on self-medication over a period of 3 months has been used in recent studies conducted in different parts of the world.[6,17,62-71] We would also like to mention that, it is not logical to simply generalize that shorter recall periods are more beneficial. This may also give false negative information as chances of sickness in shorter time frame and hence associated self-medication may be minimal. Longer recall periods may also give additional time points to respondents to give data regarding adverse events, self-medication diseases.[72]

Generalizability: This study was done only in Mumbai (Matunga Tahsil) and Raigad district (Tala Tahsil) of Maharashtra. However, owing to the similarities in socioeconomics, health seeking behaviors, and pharmacy sales practices throughout India, our findings are applicable to other Indian urban and rural areas. Observations of this study may not be extrapolated to remote rural areas of India which have very less or no health care facilities.

Study period: The seasonal occurrence of certain diseases could affect prevalence estimates. Although Maharashtra does not have extreme differences in climatic conditions, the study periods for this study included the rainy as well as summer season.

CONCLUSION

This study revealed that being from urban areas and having chronic disease was associated with likelihood of consuming medicines without prescription of a medical practitioner. Self-medication was also seen to be based on income, occupation and education. Higher education did not prevent people from harmful habit of self-medication. It is evident that education curriculum is missing to pass on the message that self-medication involves risk. Pharmacist was the main source of obtaining drugs for self-medication in this study. It is clear that there is a need to implement strict monitoring, supervision, inspection and audit of the business. As presence of old prescription with the patient was the main reason for self-medication cited in this study, pharmacist should retain the old prescription from the patient. On the similar lines, Indian ministry of health has proposed e-enabled structure for regulating sale of medicines.[73]

Subjects of the present study have self-medicated for minor indications such as acidity, fever, headache, cough-cold. However even for these indications there are risks involved as they take drugs without any medical knowledge. This could be critical in case of antibiotics leading to antibiotic resistance. There is a pressing need

to have better campaigns with pack modifications like red line campaign to give signal or pass on the message to people about risks associated with self-medication.

Thus from the present study it is evident that the prevalence of self-medication is a function of place of residence, socio-economics and health status of the study participants. Self-medication is a complex phenomenon and requires in depth research. We hope that the findings of this study will not only help further research but also help regulators, planners, health professionals to understand the targets of future interventions and to come out with integrated strategy to control the practice of self-medication.

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