INNSPUB

International Journal of Biosciences | IJB |
ISSN: 2220-6655 (Print), 2222-5234 (Online)
http://www.innspub.net
Vol. 19, No. 5, p. 100-121, 2021

RESEARCH PAPER OPEN ACCESS

Health risk assessment of residents of the industrial estate around pharmaceutical industries near Lahore, Punjab

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Key words: Exposure, Risk factor, Pharmaceutical residues, Health assessment.

http://dx.doi.org/10.12692/ijb/19.5.100-121 Article published on November 30, 2021

Abstract

The main objective of the study was an assessment of potential health risks associated with pharmaceutical residues in drinking water. The study was based on a multi-method perspective, i.e., visits, surveys and questionnaires. Near the area of Sundar Industrial Estates, respondents from four different villages around pharmaceutical industries were selected for the collection of data. The present study focuses on the fate, occurrence and toxicity of pharmaceutical drugs on human health. The findings of the study revealed that 59.2% village residents were suffering from different health issues due to drinking pernicious water. Reproductive problems and gastrointestinal illnesses were found to be the most common health problems among respondents. About 64.92 % of the respondents had reproductive problems from which pregnancy complications and menstrual disorders were majorly found in females. Socio-economic factors such as education, income and age were found to be the other contributing factors in deciding the health status of respondents. Sources of drinking water and their average distances from pharmaceutical industrial estates were assessed as crucial factors for the occurrence of health problems. The Mean±SEM value of BMI of respondents was measured as 24.60±0.246 and a range was measured as 17.6-33.8 kg/m². Hormonal changes causing reproductive problems among females were found to be the most prominent health effect due to drinking water contaminated with pharmaceutical residue. The most dominant reproductive problems were found to be pregnancy complications and menstrual disorders. The sources of drinking water and their average distances from the pharmaceutical industrial estates are the most crucial factors for determining the poor health status.

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Introduction

Pharmaceuticals are a group of inherently bioactive chemicals used for the promotion of growth, treatment and prevention of disease in humans. Pharmaceutical products contain active ingredients intended to cause pharmacological impacts and bring substantial advantages to society. The use of pharmaceutical drugs continues to increase as a result of improved healthcare systems around the world and people's expectations for longer lives (Leung *et al.*, 2013).

Due to the continuous detection of pharmaceuticals in the water setting, they have gained increasing attention from environmental and health organizations throughout the globe and have become one of the apparent pollutants (Jones *et al.,* 2005). The fact that pharmaceuticals are generated with the intention of causing biological effects may have raised concerns regarding the effects of unintended pharmaceutical exposure on the health of human beings (Kumar *et al.*, 2010).

There is increasing attention and concerns regarding the risk of pharmaceuticals in water causing human health effects. Since human beings began experimenting with drugs and medicines, pharmaceuticals have been present in our water setting. The ready access to product proliferation and pharmaceuticals combined with the thriving human population has substantially boosted the entry of such harmful compounds into the environment (Khanna, 2012).

Pharmaceutical products and their residue play a crucial role in environmental pollution. Many kinds of pharmaceutical substances were found in surface water, groundwater, household wastewater, municipal sewage and industrial disposal with significant concentrations which indirectly affect the quality of drinking water. Pharmaceutical companies produce various kinds of massive-scale pharmaceutical products and by-products of diverse non-biodegradable hazardous waste. They also produce untreated or partly processed waste throughout the environmental settings in the absence of powerful legislation. These waste contaminants were polluting all drinking water sources both directly and indirectly (Chander *et al.,* 2016).

Sources such as inappropriate disposal of expired or unused drugs and discharge of treated or partly treated industrial wastewater residues, etc. have discovered pharmaceutical compounds to enter the environment. Pharmaceuticals mainly enter surface and groundwater systems through drug contamination of solid waste and land-based pharmaceutical waste leaching (Daughton, 2007). Most of the drugs that are likely to be found in a waterfall into the high-use category because they are the substances that are present in the environment in the greatest amount (Caldwell *et al.,* 2014).

Contaminated drinking water may link to the transmission of various diseases. Despite the evidence that comparatively few pharmaceuticals have been identified and their lesser concentrations than the therapeutic doses greatly alarmed the regulators about the idea of pharmaceutical incidence in drinking water (Ashbolt, 2004). Pharmaceutical compounds in drinking water supplies directly influence the health of consumers through gastrointestinal disease, reproductive issues, waterborne diseases and congenital problems including physical abnormalities and mental retardation. (Morteani *et al.*, 2006).

The presence of pharmaceuticals in drinking water may have potentially harmful effects on human health. The presence of prescription drugs is a significant concern in ground and surface water routing to drinking water (Kolpin *et al.,* 2002). Following long-term exposure and trace quantities of pharmaceutical substances in drinking water can have serious adverse effects on human health (Wang *et al.*, 2010). This has resulted in a modification in reproductive health, such as menstrual disorders, declined fertility and pregnancy complications (Salgado, 2012). The existence of particular pharmaceuticals in a water supply varies from site to

site based on the type of pharmaceutical and the magnitude of their discharge into water sources. Key variables include the pharmaceuticals prescribed, used, or produced in the region and population density in the catchment area. Treatment options are either ineffective or insufficient due to differences in effluent input properties and pharmaceutical development. There are several approaches for screening and optimizing pharmaceuticals for risk assessment through potential health exposure to drinking water (Szymonik and Lach, 2012).

Preventive measures, such as guidelines or regulations governing health care disposal procedures, can decrease the substantial quantity of pharmaceutical waste that enters the water sources (WHO, 2004). The perspective of the present study is designed to conduct the evaluation of several pharmaceutical products by comparing potential intake values from drinking water with health-based guidance values. The evaluation of pharmaceutical exposure through drinking water was calculated on the basis of peak and average pharmaceutical levels, standard bodyweight estimates and daily water intake for adolescents, kids and infants (Boxall *et al.,* 2014). The only contaminants in the environment that have undergone significant human clinical testing were human pharmaceuticals. Although the toxicological databases are extensive, there is a need for exposure data to fulfill appropriate human-health risk assessments which would provide extensive information to determine whether regulations are appropriate. In order to minimize environmental risk, the disposal of unused pharmaceuticals will follow the best management guidelines. Improving the effectiveness of treatment systems and adequately managing risk impacts connected with the occurrence of pharmaceutical chemicals in drinking water supplies are the main commitments to prevent pharmaceutical contamination.

Materials and methods

The present study was designed to assess the potential health risk due to pharmaceutical residue in drinking water among residents of different villages near Sundar Industrial Estates, Lahore. This study is based on the survey, data collection related to health status and exposure, as well as assessment of disease-causing parameters among the selected population. Near the area of Sundar Industrial Estates, four different villages were selected for the assessment. The population from different villages was selected for the collection of data.

The residents of different villages drinking different sources of water were selected to assess the potential health risk. The population was selected and assessment was done on the basis of risk factors present in their drinking water. Comparison of the target group was done with the control group and it consisted of respondents that were living far from pharmaceutical residency and that were not exposed to a similar hazard.

Frequent surveys were conducted to the selected villages near Sundar Industrial Estates for data analysis and health risk identification among the selected community in order to design a questionnaire. Before the survey, written permission for interviews with the residents was pursued by the officials. The questionnaire was designed on the basis of observations and meetings with the selected population. Frequent visits were made in these villages to fill questionnaires on assessment of health risk. Only those village residents were selected who had gone to the interview. Various meetings were arranged to fill the questionnaire and to collect other relevant data. The questionnaire comprised of four sections, i.e., personal information, water quality assessment and hazard identification, general health status and health assessment. The data in the section of personal information assisted in evaluating the socio-economic status of residents. Water quality assessment included the main drinking water source, taste and smell of water, number of bores and drains in the area and hazard identification included the questions related to assessment, i.e., how far the selected population is living from pharmaceutical residency. This data was helpful in assessing the main source and quality of drinking water which is

important in determining the nature of water. Then, the section regarding general health status includes past incidence of disease, height, weight, BMI (Body Mass Index). The values were compared with the standard value in the range between 18.5-24.9 Kg/m^2 (WHO, 2004). This information was necessary to examine the health of the selected population, the occurrence of any past diseases, their cause and the contributing factors on their health. Next, the most important section of the questionnaire was health which includes the questions related to the prevalence of different diseases among them. Various questions for the assessment of health included common incidence of disease, frequency of disease and its treatment.

It was analyzed that contaminated drinking water with pharmaceutical residues could be the reason for the bad health among respondents. By providing the treatment and quality of drinking water, the possible causes and risks of health can be reduced. After data collection through a survey using a questionnaire and measurements of other parameters, the data was compiled in a tabulated form on Microsoft Excel Sheets. To calculate the percentages, the questionnaire responses were evaluated and statistical analysis was also done by calculating the mean/averages, standard deviation (SD) and standard error of mean (SEM) (Aparjit, Panwar and Sharma, 2011). Comparison of results of various parameters was done with control group as well as among the respondents from different villages and the data was presented in the form of tables, bar graphs and pie charts.

Results and discussion

This present study was based on the assessment of potential health risks due to the exposure of pharmaceutical residue in drinking water that is consumed by the residents from the vicinity of Sundar Industrial Estates. The findings of the study revealed that residents of villages were suffering from different health issues due to drinking detrimental water. The most determining health issue observed in respondents was reproductive issues. The results showed that drinking water contaminated with pharmaceutical residue is the most prominent factor contributing to several health issues such as reproductive and gastrointestinal problems.

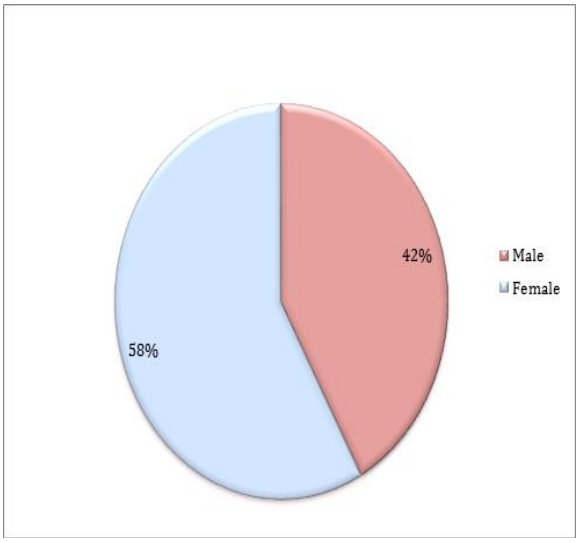

Fig. 1. Percentage of male and female respondents (n=250) from different villages.

The present study is concerned with the health risks among residents of different villages in which assessment was carried out to identify different health issues in the residents of the research area. Drinking water contaminated with pharmaceutical waste was found to be the most significant hazard contributing to health issues. These results were supported by a study that explained the existence of pharmaceuticals in potable drinking water that significantly concerns the risk on human health posed by their potential appearance in drinking water supplies (Khan and Nicell, 2015). Several factors influence community health as some conditions increase the risk and exposure to hazard. Socio-economic status such as age, sex, education level and monthly income played a vital role as a health indicator of respondents. From the data collected through the questionnaire in respect of potential health risk assessment, it was examined that these factors play a key role in determining the health risk and incidence of various diseases. From another study, it was revealed that socio-economic status, whether measured by income, literacy, or employment, is associated with a wide variety of health issues (Adler and Newman, 2002).

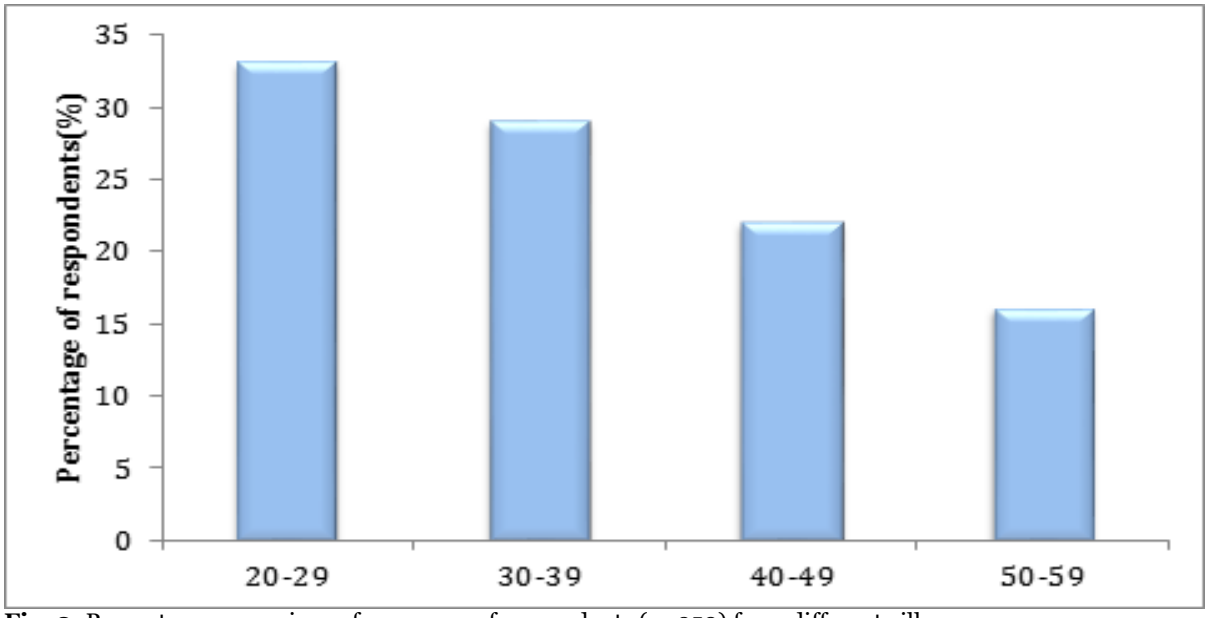

Fig. 2. Percentage comparison of age group of respondents (n=250) from different villages.

The main source of drinking water was found to be the water pumps in the residency that was believed to be a healthy source of drinking water. Other than that, tap water was another major source of drinking water there. As people were not much aware of the health problems associated with drinking water consumption and as they would not afford a filtration system, therefore they had to consume bore water.

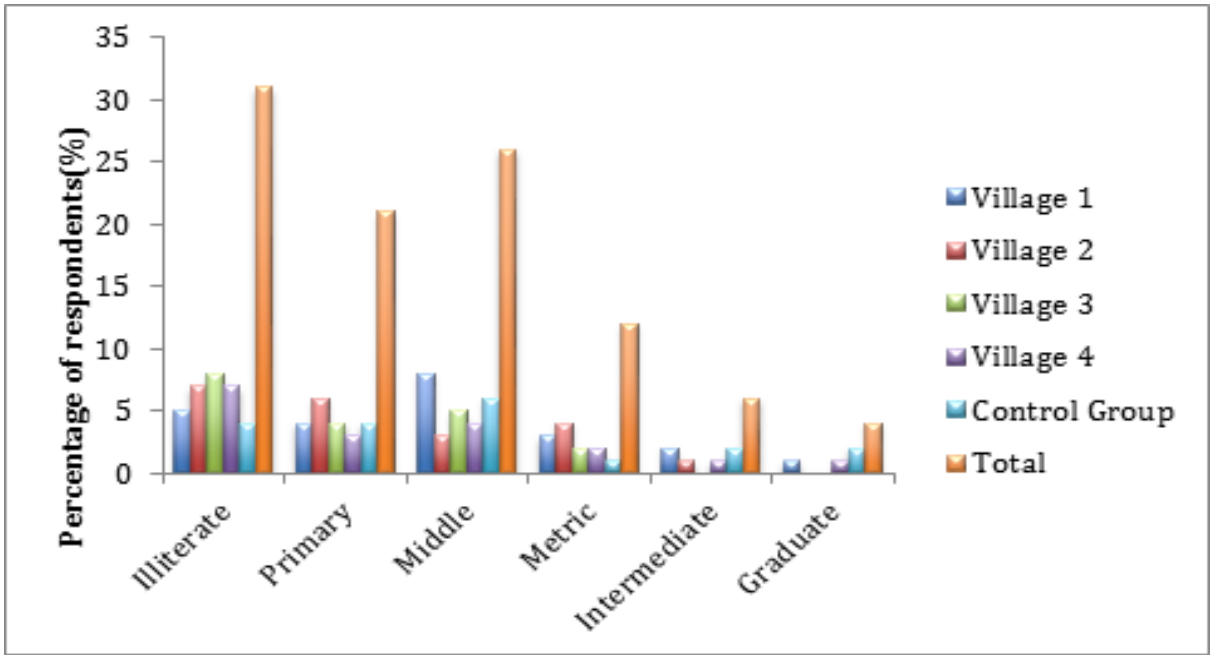

Fig. 3. Percentage comparison of education level in respondents (n=250).

It was also assumed that bores contain pharmaceutical content that may leach through the ground to the lower services then make drinking water contaminated and causes serious health effects. This study is supported by the results of one previous study conducted in Berlin explained that some pharmaceutical compounds do not completely remove and are released into the receiving waters as pollutants (Heberer, 2002).

During the study, 250 respondents were questioned of which (58%) were females and (42%) were male

(Fig. 1). Overall mean age was 65.92±9.7. Data from the age group reveals that (33%) of respondents belonged to the age group from 20-29 years, 29% belonged to age group 30-39 years, and 22% of the respondents ranged from age group 40-49 years and 16% belonged to 50-59 years of age group (Fig. 2).

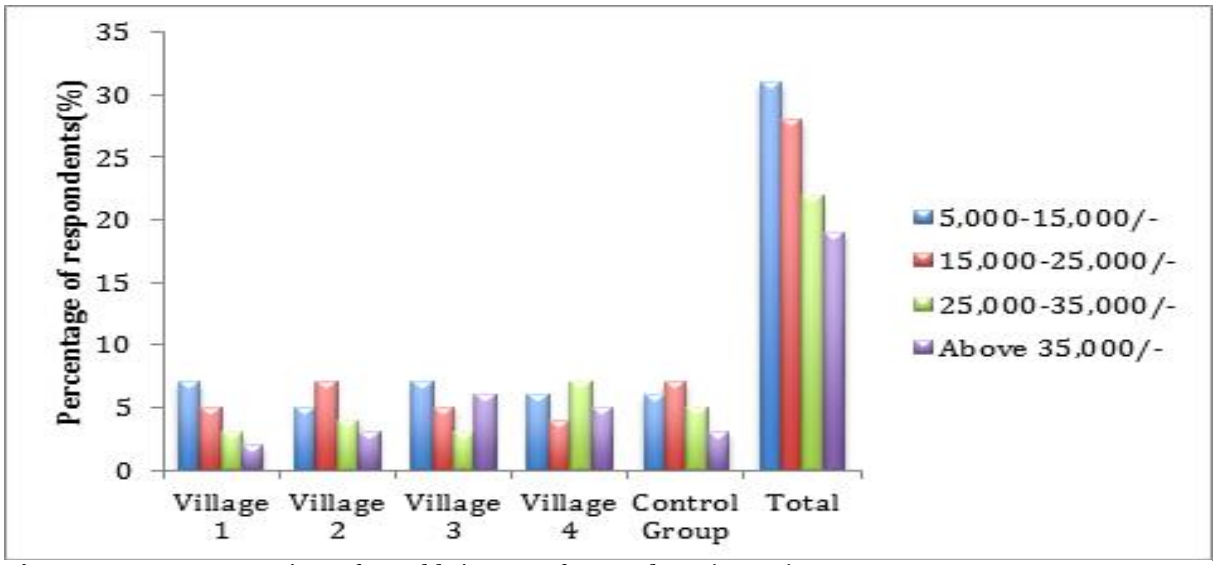

Fig. 4. Percentage comparison of monthly income of respondents (n=250).

Education statistics showed that 130 (52%) participants were educated and 120 (48%) were uneducated. Also measured during the study was the academic standard of the respondents. It was calculated from the data that out of total respondents (n=250), 31% were illiterate, 21% had primary education, 26% of respondents had the middle level of education, 12% had education up to metric level,6% had the education of intermediate level while 4% were graduate (Fig. 3).

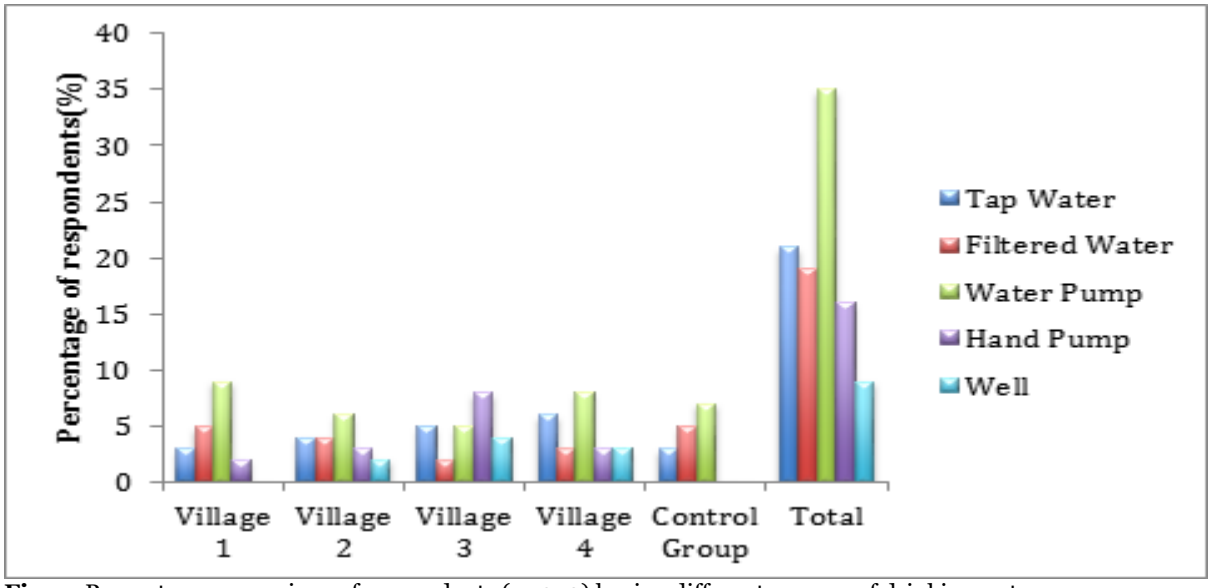

Fig. 5. Percentage comparison of respondents (n=250) having different sources of drinking water.

Water quality assessment and hazard identification

It was revealed from the result that most of the respondents were earning between 5,000-15,000 rupees per month, 19% mentioned their monthly income above 35,000 rupees per month, 28% of the respondents had 15,000-25,000 rupees and 22% of them were earning between 25,000-35,000 rupees per month (Fig. 4).

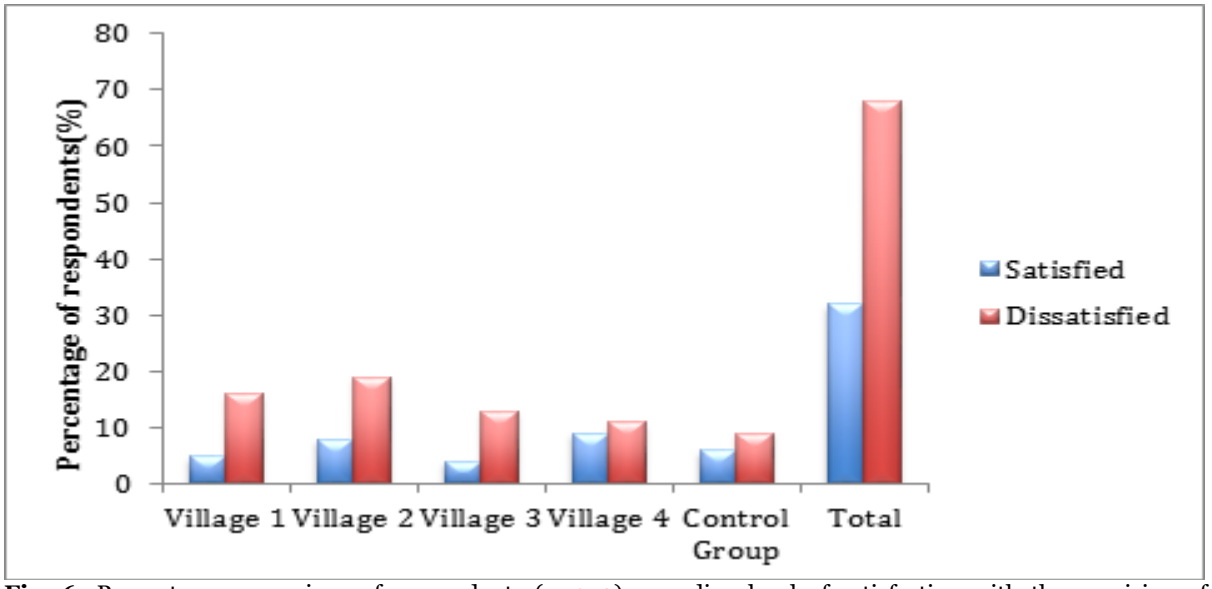

Fig. 6. Percentage comparison of respondents (n=250) regarding level of satisfaction with the provision of drinking water facility.

In the survey, 250 respondents were selected, out of which 200 were target group and 50 were the control group. Four different villages were also selected as target groups near the pharmaceutical area at Sundar industrial estates. The source of drinking water was analyzed among the respondents during the survey and assessed that 21% of the respondents were drinking tap water, 19% were drinking filtered water, 35% were using water pumps as a source of drinking water, 16% had hand pumps while 9% of them had well in their place as a source of drinking water (Fig. 5). The satisfaction level of respondents was also observed regarding the drinking water service and it was estimated that 32% of the respondents were satisfied with the drinking water facility while 68% were unsatisfied with the services (Fig. 6).

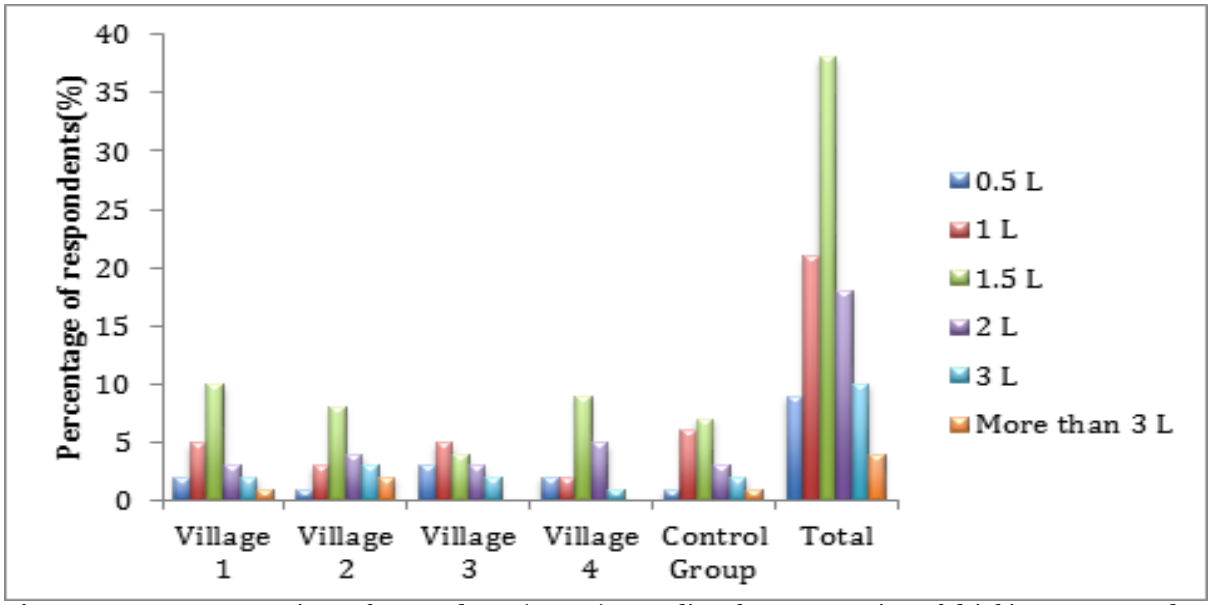

Fig. 7. Percentage comparison of respondents (n=250) regarding the consumption of drinking water per day.

During the survey, the quality of drinking water was also evaluated and it was observed that most of the respondents were not satisfied with the quality of provided drinking water. The present study is supported by the outcomes of one previous study conducted to analyze public perception regarding

drinking water quality and demonstrated the of various diseases due to the lack of awareness and knowledge in people related to groundwater issues and policy options (Foster *et al.,* 2002).

The number of bores in the residency was also identified as most of the respondents were using bore as the main source of their drinking water. It was found that most of the residents had only one bore in their nearby area and it showed difficulty among the residents regarding the provision of drinking water on a daily basis as only one bore in the residency was not enough to meet the need for drinking water for most of the community.

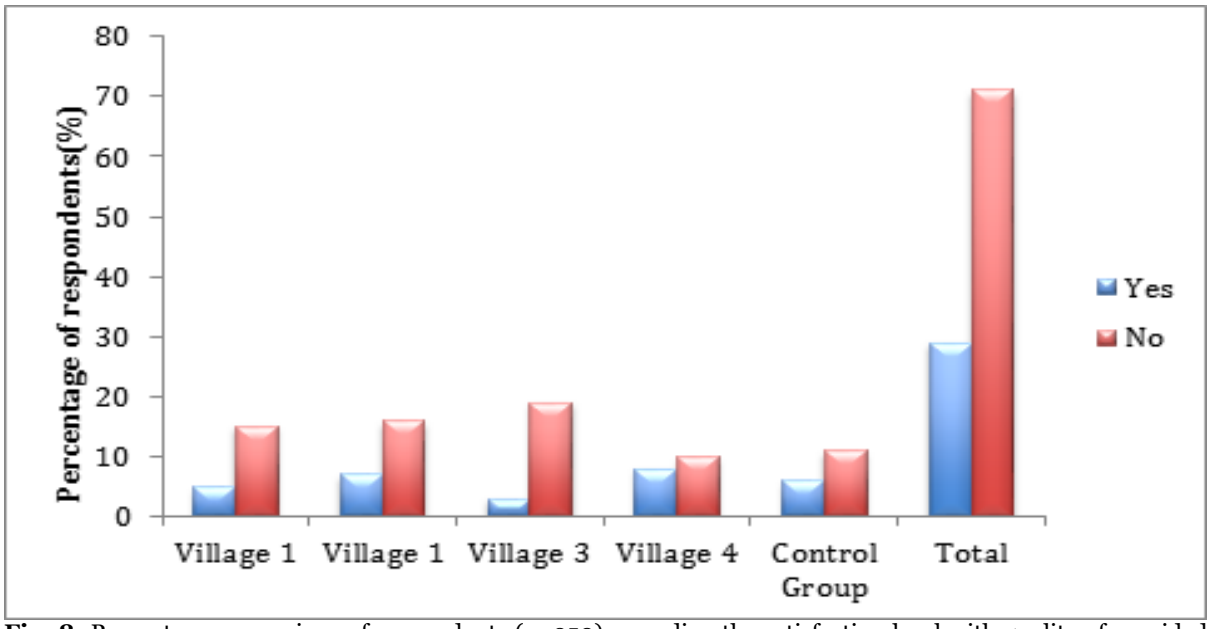

Fig. 8. Percentage comparison of respondents (n=250) regarding the satisfaction level with quality of provided drinking water.

The results of the present study supported by a previous study that assessed water shortage adaptation strategies, including technological innovation, use of tactical groundwater, and strategic planning to fulfill drinking water requirements (Iglesias *et al.,* 2007).

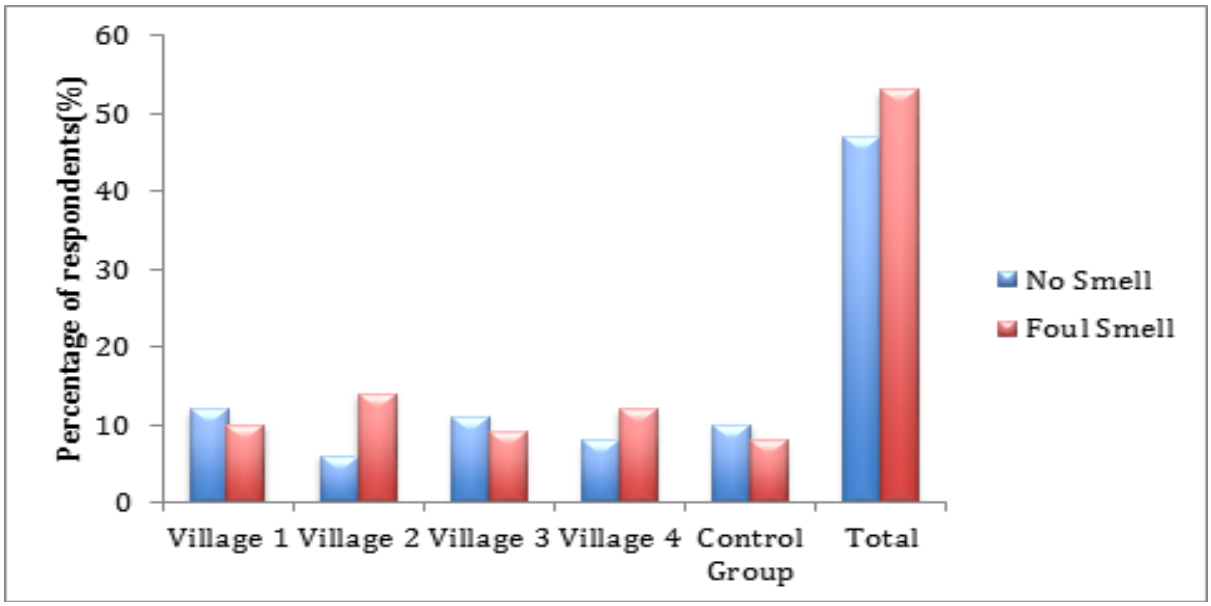

Fig. 9. Percentage comparison of respondents (n=250) mentioning smell in drinking water.

The survey also highlighted the average amount of water that one would drink per day. It was observed that 9% of respondents consume 0.5 L of water per day, 21% of them were drinking 1 L of water in a day, 38% were taking 1.5 L of water per day, 18% of respondents were drinking an average of 2 L water per day while 10% were taking 3 L by an average and only 4% of them were drinking more than 3 L of water per day (Fig. 7).

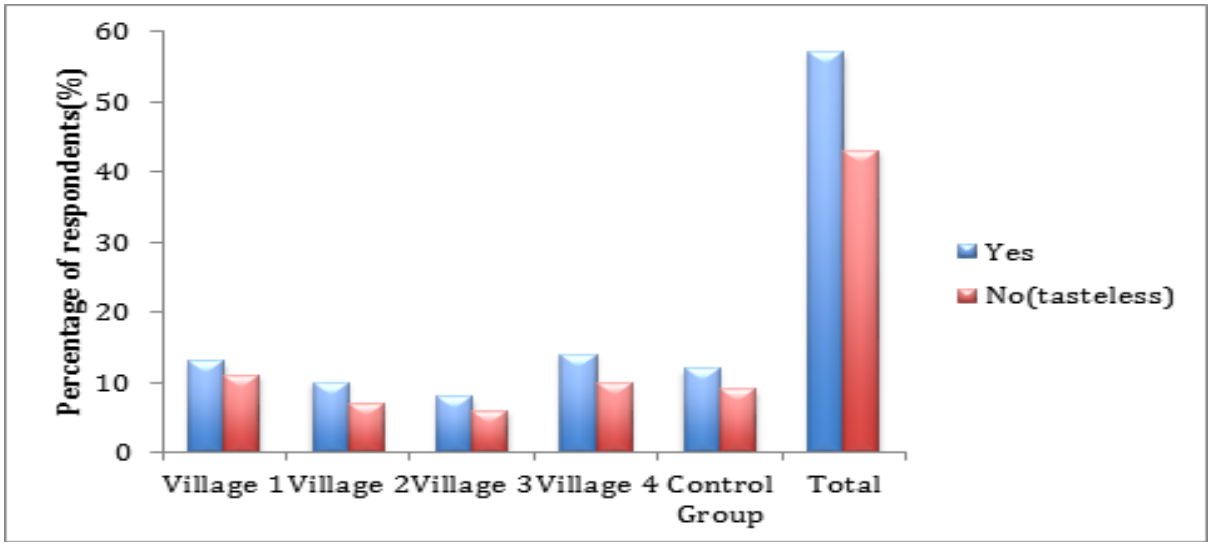

Fig. 10. Percentage comparison of responses of respondents (n=250) regarding the taste of drinking water.

Satisfaction with the quality of drinking water was also analyzed among respondents and it was estimated that only 29% of the respondents were satisfied with the quality of provided drinking water while 71% of them were not satisfied with the drinking water quality (Fig. 8).

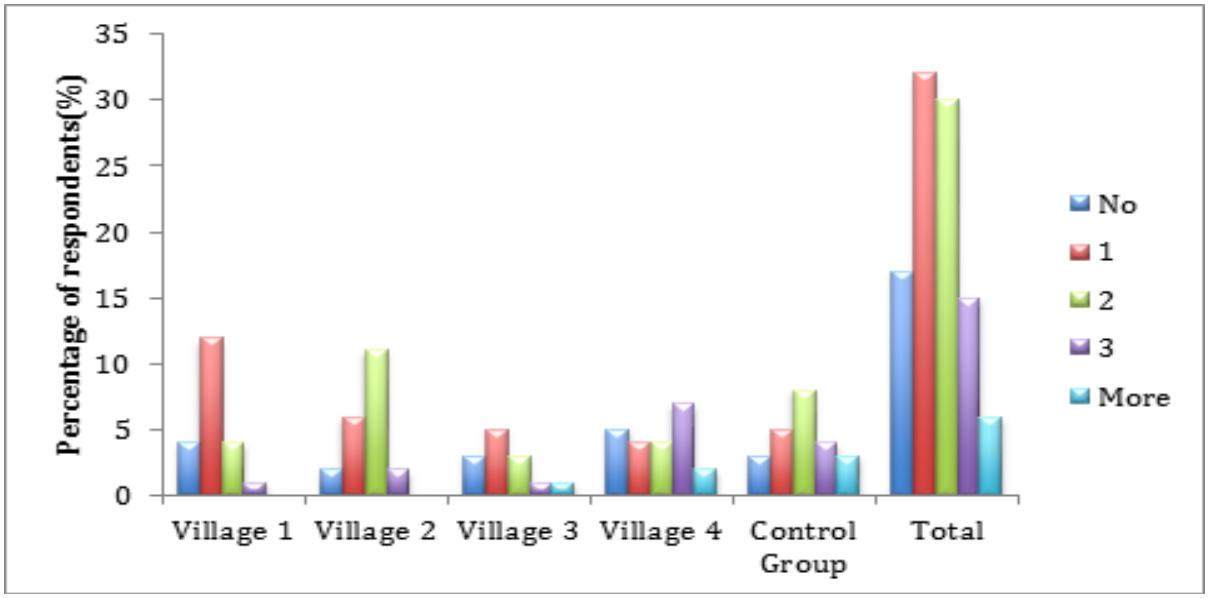

Fig. 11. Percentage comparison of respondents (n=250) having bores in their residency.

It was observed that the smell also contributes to the quality of drinking water and it was assessed that 53% of respondents complained about the foul smell in drinking water while 47% of the respondents did not mention the smell in drinking water (Fig. 9).It was assessed that taste also contributes to the quality of drinking water and estimated from the survey that 57% of respondents felt taste in drinking water while

43% felt no taste in drinking water (Fig. 10). The number of bores in the residency helped to assess the quality of drinking water and it was observed that 32% of the respondents had one bore in their residency, 32% had two bores in their residency, 15% had three bores in their residency, 6% of the residents had more than three bores in their residency while 17% of them had no bore in their residency (Fig. 11).

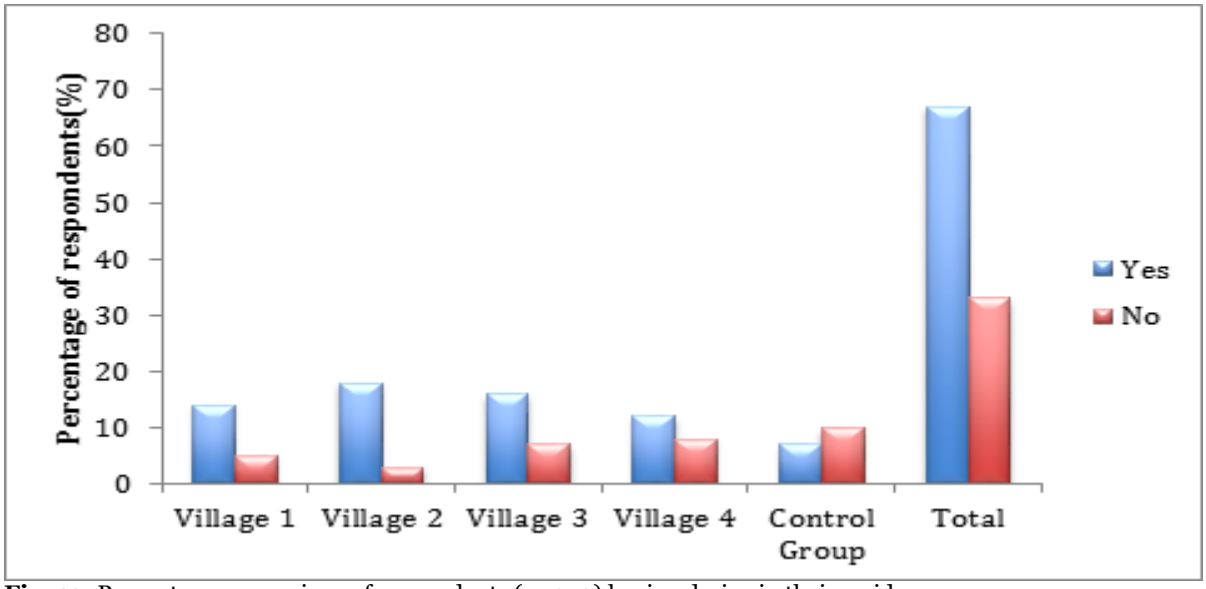

Fig. 12. Percentage comparison of respondents (n=250) having drains in their residency.

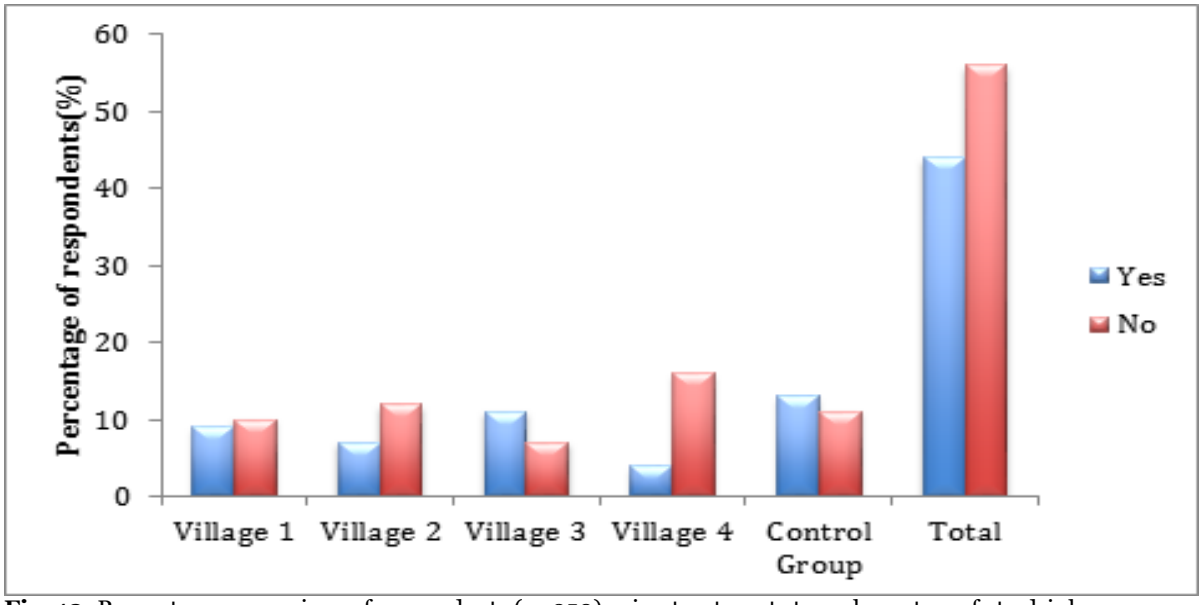

Fig. 13. Percentage comparison of respondents (n=250) using treatments to make water safe to drink.

It was also estimated that drains could affect the quality of drinking water and it was assessed that 67% of the residents had a drain in their nearby area while 33% of them had no drain (Fig. 12). Figure 13 is depicting the distances of selected residential areas lived from pharmaceutical industries and it was found that the residents of village 1 lived at the distance of 8.8km from pharmaceutical residency, village 2 residents lived at the distance of 7.3km, village 3 residents lived at the distance of 5.5km, village four residents lived 3.1km of distance from the pharmaceutical residency while residents of control group lived at more than 8.8km of distance from pharmaceutical residency. Among the respondents, it was also assessed that the water would be treated anyway to make it safer to drink and revealed that

only 44% of respondents used to treat water to make it safer to drink while 56% did not make any treatments to make water safer to drink Different ways for treating drinking water were analyzed and observed that 44% of the respondents used boiling to treat drinking water, 36% used filtering technique, 15% of them used to add chlorine to make water safer to drink, while 5% of them used other ways to treat the drinking water (Fig. 14).

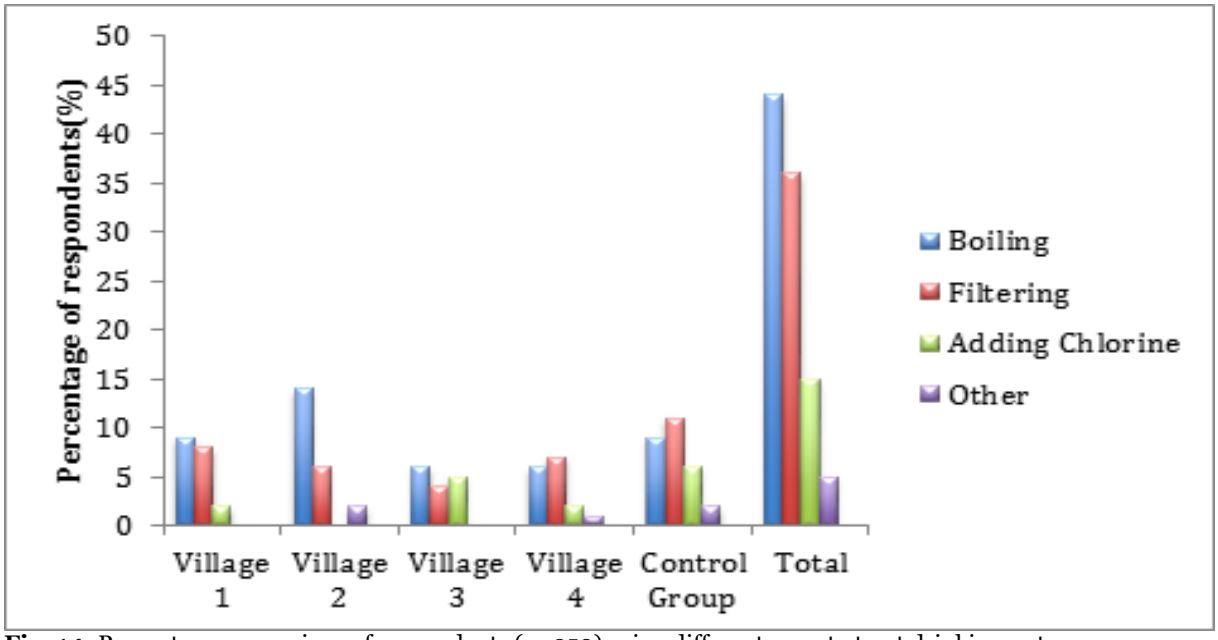

Fig. 14. Percentage comparison of respondents (n=250) using different ways to treat drinking water.

General health status

For the evaluation of general health condition Body Mass Index (BMI) of respondents from different villages and the control group (n=250) was also measured. The range of the respondents BMI value was calculated as 17.7-32.2kg/m² in village 1, 17.6-33.8 kg/m² in village 2, 17.6-33.2 kg/m² in village 3, 17.8-33.2 kg/m² in village 4 and 18.3-33.8 kg/m² among control group. The comparison was also made with standard values, i.e., 18.5-24.9 kg/m² (Fig. 15).

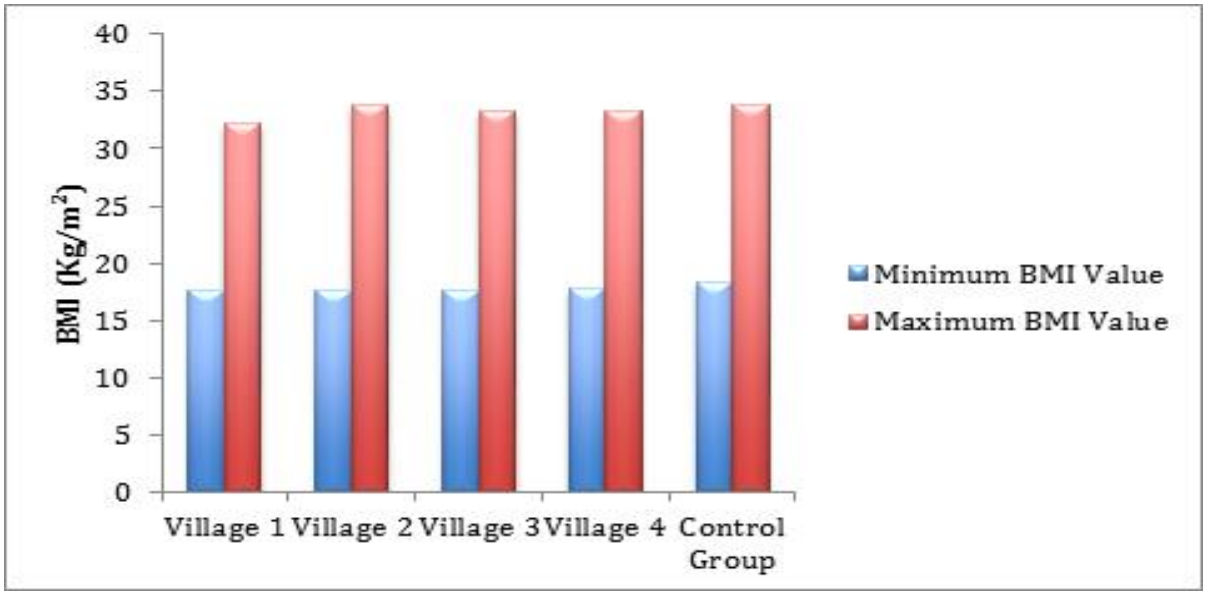

Fig. 15. Comparison of minimum and maximum range of BMI among respondents (n=250) from different villages.

The respondents mean BMI values from village 1, village 2, village 3, village 4 and control group were calculated as Mean ± SEM 24.1± 0.5730 kg/m², 24.5± 0.5821 kg/m², 24.8± 0.5549 kg/m², 24.4± 0.5257 kg/m² 25.1± 0.5174kg/m² respectively (Fig. 16).

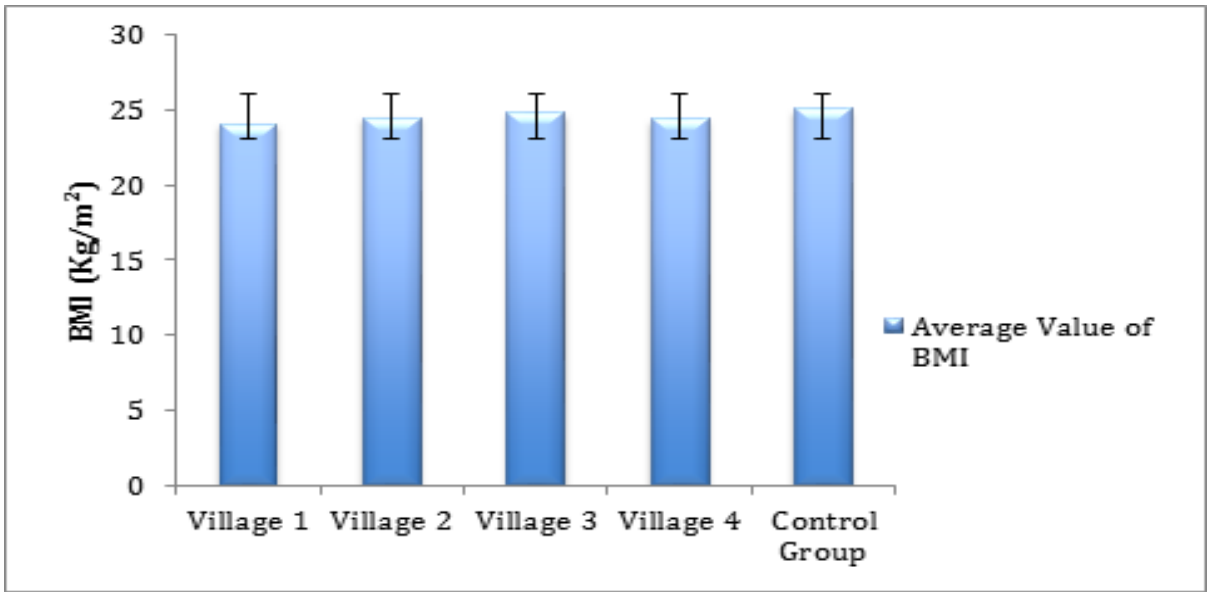

Fig. 16. Comparison of average value of BMI among respondents (n=250).

Identification of previous health conditions was necessary to assess the general health status among selected respondents. As far as the incidence of the past disease is concerned, 58.4% were assessed to have no past history of disease while 39.6% of them had a past incidence of disease (Fig. 17).

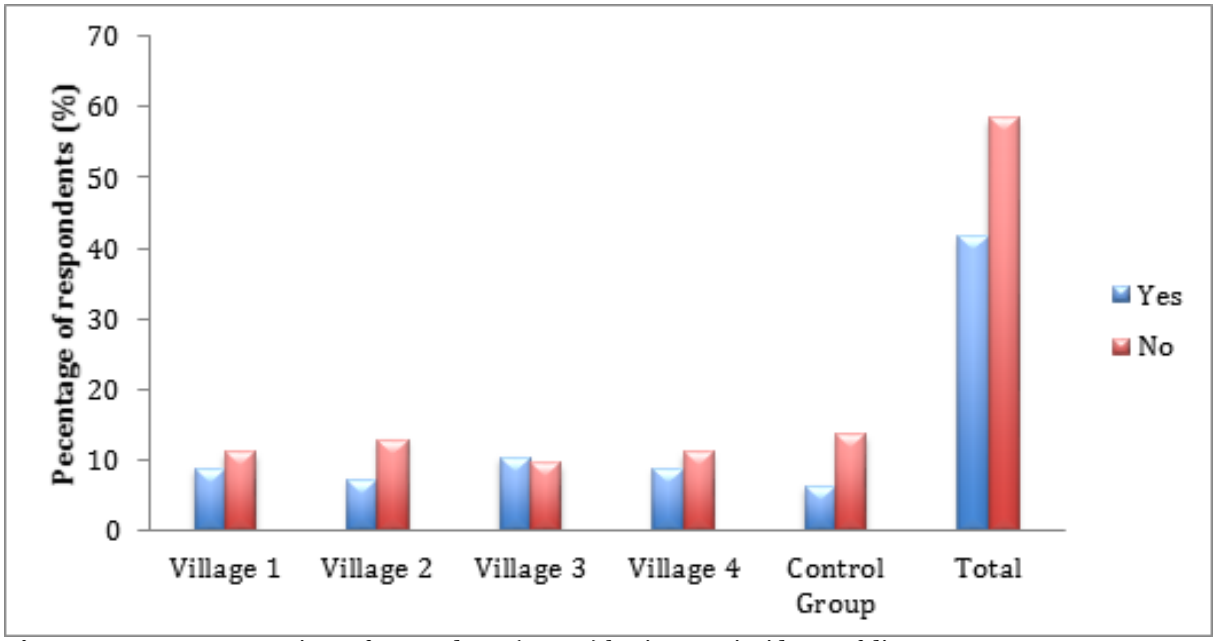

Fig. 17. Percentage comparison of respondents (n=250) having past incidence of disease.

Health assessment

Data was also collected regarding the health risk due to pharmaceutical exposure and it was assessed from the survey that 68% of the selected population mentioned have health risk due to pharmaceutical exposure and 32% of them did not mention any health risk due to pharmaceutical exposure (Fig. 18).

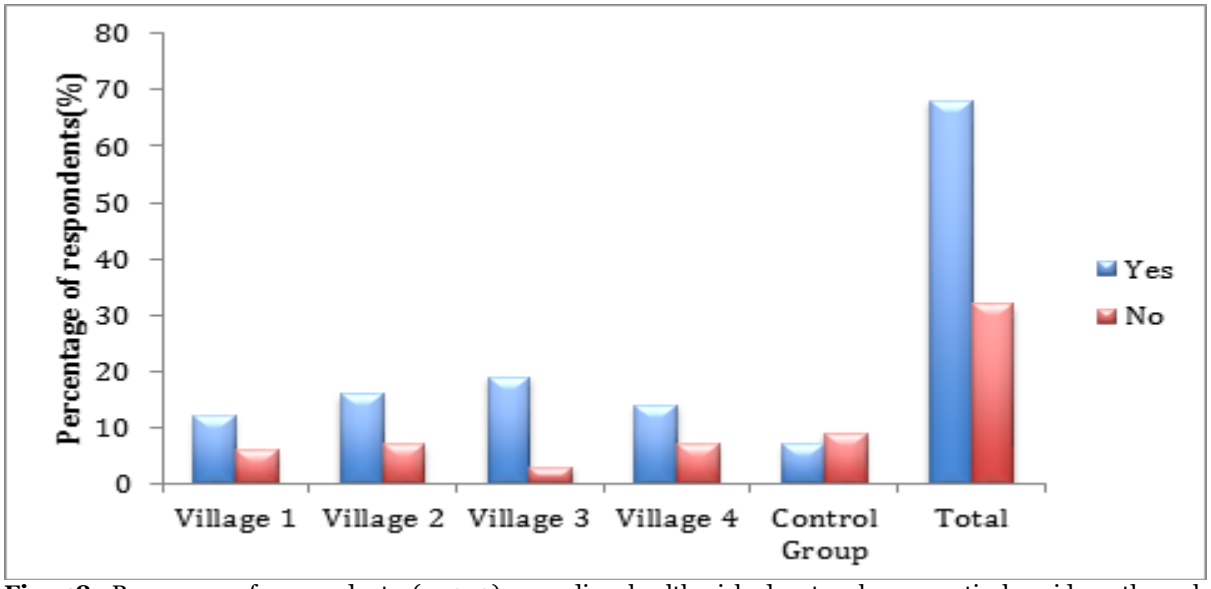

Fig. 18. Responses of respondents (n=250) regarding health risk due to pharmaceutical residues through drinking water.

It was also evaluated from the survey that respondents were suffering from any disease currently or not and it was estimated that 59.2% of the respondents were suffering from diseases while 40.8% of them did not mention any current incidence of disease among them (Fig. 19).

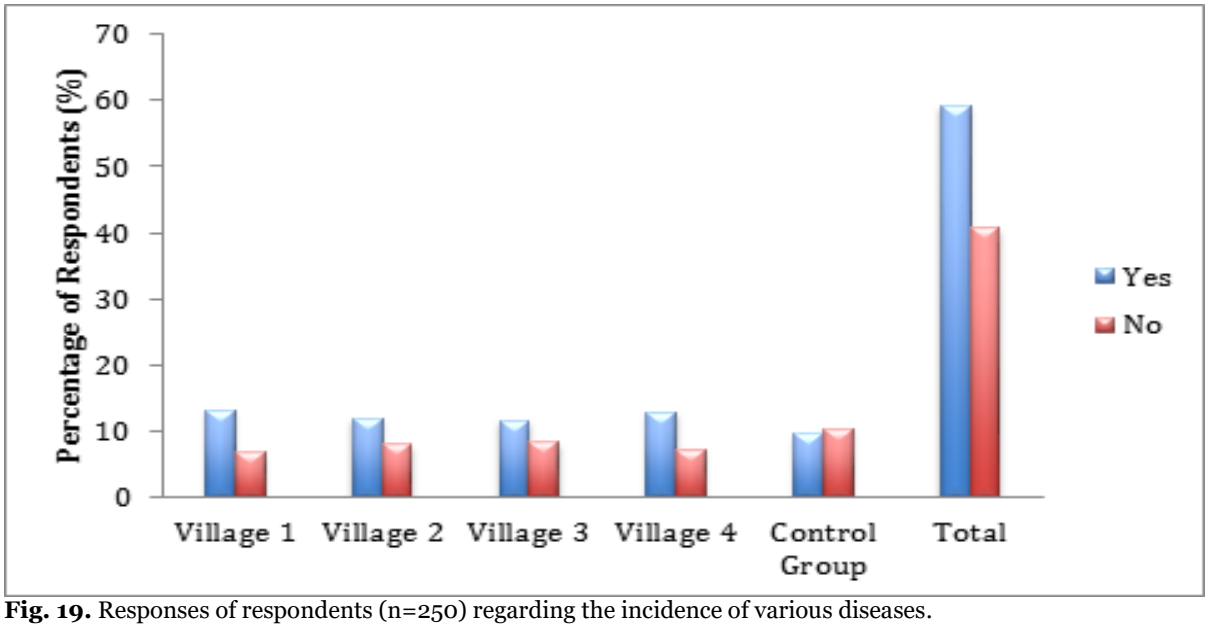

Fig. 19. Responses of respondents (n=250) regarding the incidence of various diseases.

Survey also emphasized the common diseases among respondents and the results of that survey concluded that out of 148 respondents 64.92% (n=96) were having reproductive problems, 36.22% were having the gastrointestinal problem and 16.86% mentioned susceptibility to other diseases like typhoid, cholera, hypertension etc. (Fig. 20). Percentage of reproductive problems among males and females were also observed during the survey and analyzed that 74% of females were having reproductive problems while only 26% of males said to have reproductive problems among them (Fig. 21).

Different reproductive problems in females were also observed as this problem seemed to be affecting a major population among females during the survey

and it was estimated that 46.3% of female respondents had menstrual disorders, 31% had pregnancy complications, 10% had infertility issues, 7% had issues due to hormonal imbalances and 8.4% of the females had other reproductive issues (Fig. 22). Data on the occurrence of disease were also collected due to the intake of poor quality water and it was revealed that 67.6% of the respondents said to have occurred diseases due to the drinking of contaminated water while 32.4% of them did not declare contaminated drinking water to be the cause of their disease (Fig. 23).

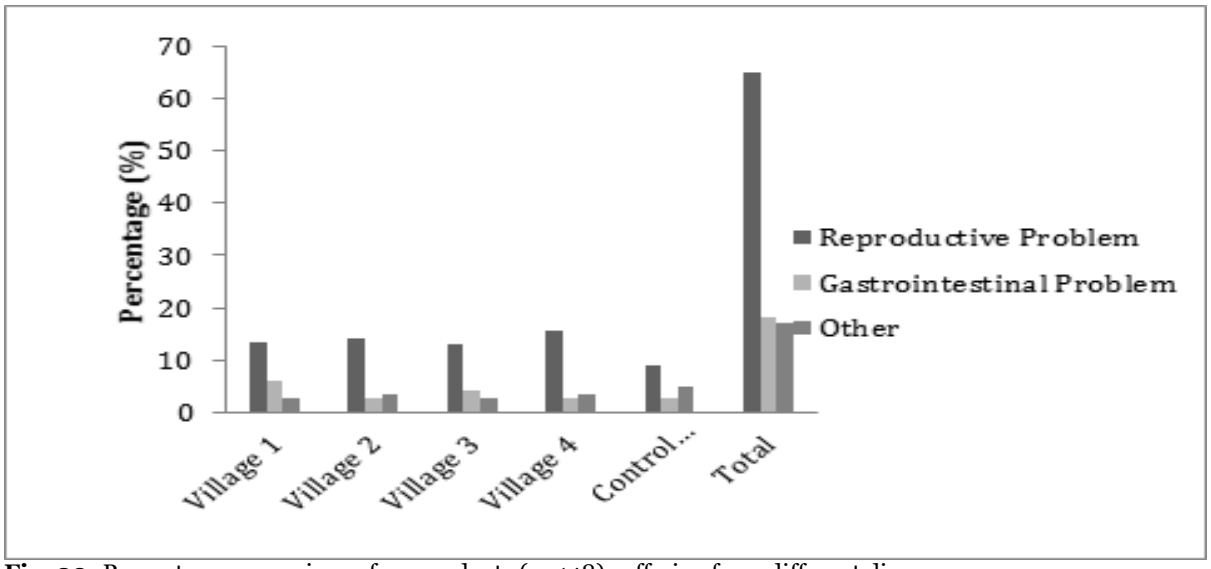

Fig. 20. Percentage comparison of respondents (n=148) suffering from different diseases.

The intensity of disease was also evaluated and estimated that 41.9% of the respondents had the mild intensity of disease caused by drinking contaminated water while 58.1% of them had the severe intensity of diseases among them (Fig. 24). It was also estimated from the survey that how frequent the disease is and evaluated among 148 respondents 33.8% of them felt disease rarely while 66.2% of respondents commonly felt the disease (Fig. 25).

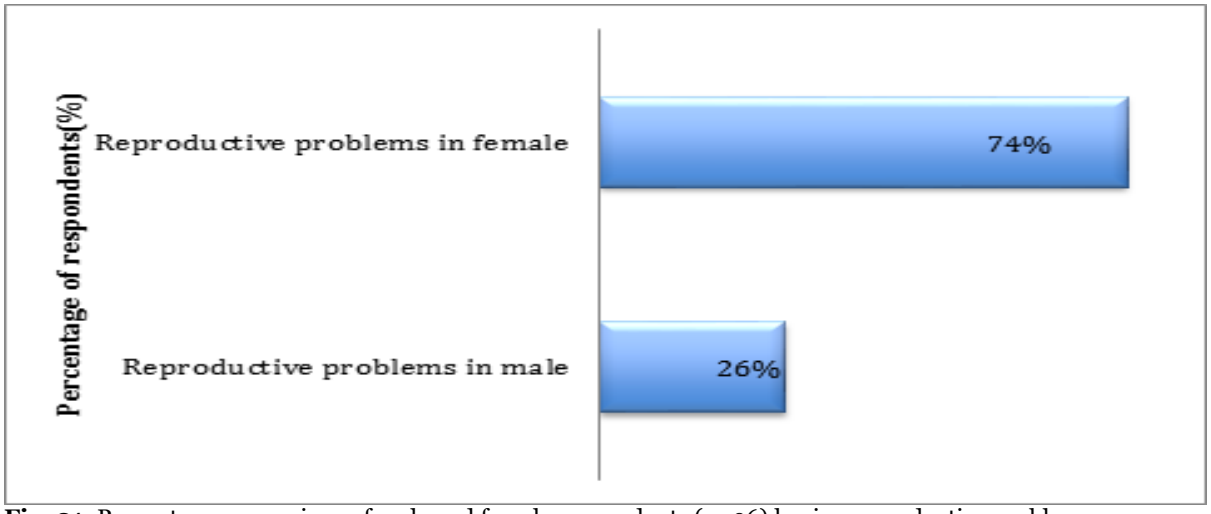

Fig. 21. Percentage comparison of male and female respondents (n=96) having reproductive problems.

The survey was done on the treatment of diseases as well. The results of the survey demonstrated that only 39.2% of the respondents were getting treatments against their diseases, while 60.8% of them did not get any treatments (Fig. 26). In the survey, recovery from disease after treatment was also analyzed among

the respondents and it was concluded that only 46.7% of the respondents felt recovery after the treatments while 53.3% did not feel any recovery even after the treatment (Fig. 27). The assessment was also made for the treatment and administration of drinking water and it was analyzed that most of the residents do not use any treatment to make their water safer to drink. As far as the treatment was concerned, they mostly used boiling methods to treat their water.

The present study is supported by another study that reported that drinking water at origin could be polluted and suggested that boiling can be sufficient to inactivate pathogens (Robertson *et al.,* 2008).

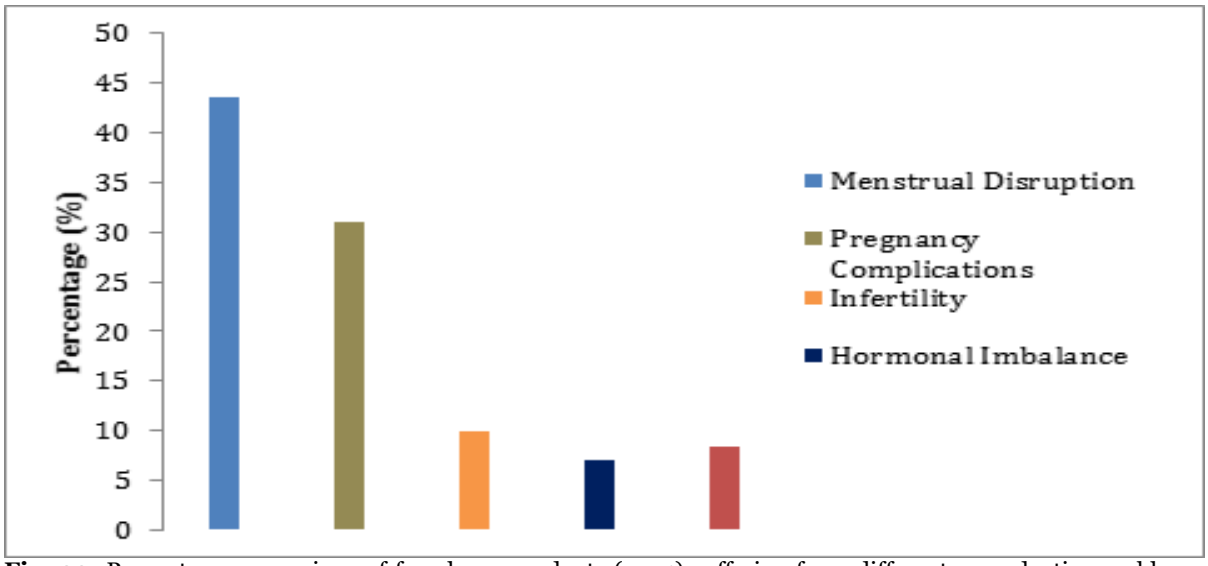

Fig. 22. Percentage comparison of female respondents (n=71) suffering from different reproductive problems.

Health assessment was the important part that was observed during the survey and it was initiated by the incidence of past diseases among the respondents. It was analyzed that most of them had no incidence of past diseases and some of them were even unaware of the incidence of any disease in their lifetime. A similar study was conducted to determine the health factors that occurred in different phases of life and took this framework of life course into account that helped to provide new lights in the development of disease and health situation of people (Spallek *et al.,* 2011).

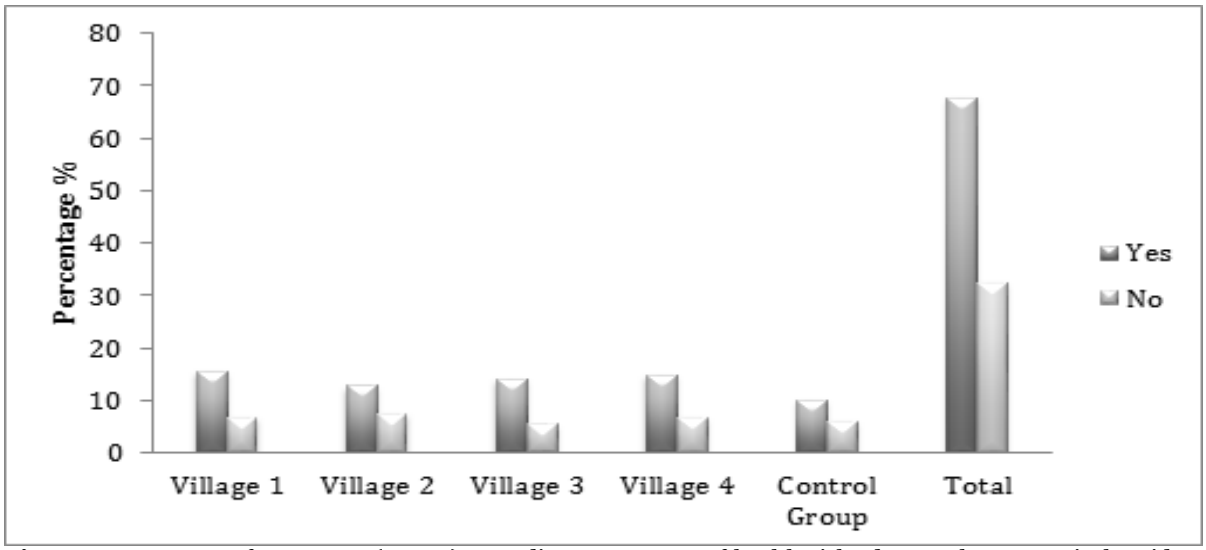

Fig. 23. Percentage of responses (n=148) regarding occurrence of health risks due to pharmaceutical residues exposure through drinking water.

Analysis was also carried out regarding the health risks due to the pharmaceutical exposure and it was observed that the respondents of those villages were more prone to health risks that were more nearer in the distance to the pharmaceutical industrial estates. It was estimated that an average of 68% of the respondents felt health risk and it was also assumed that it might be due to the consumption of water contaminated with pharmaceutical waste. From another study, it was also concluded that the involvement of pharmaceuticals in the aquatic environment and their influence on the ecosystem and humans are growing environmental health concerns (Bound and Voulvoulis, 2004).

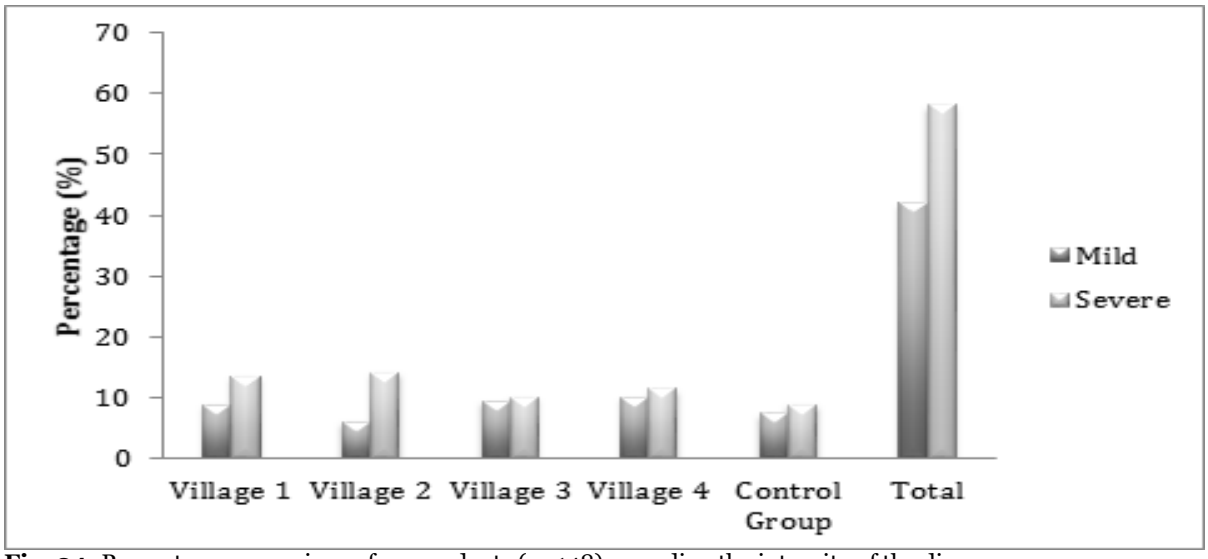

Fig. 24. Percentage comparison of respondents (n=148) regarding the intensity of the disease.

As per questionnaire data, reproductive problems and gastrointestinal illnesses were found to be the most prominent health consequences among the respondents. Reproductive problems due to hormonal changes were found to be most prevalent among the female respondents.

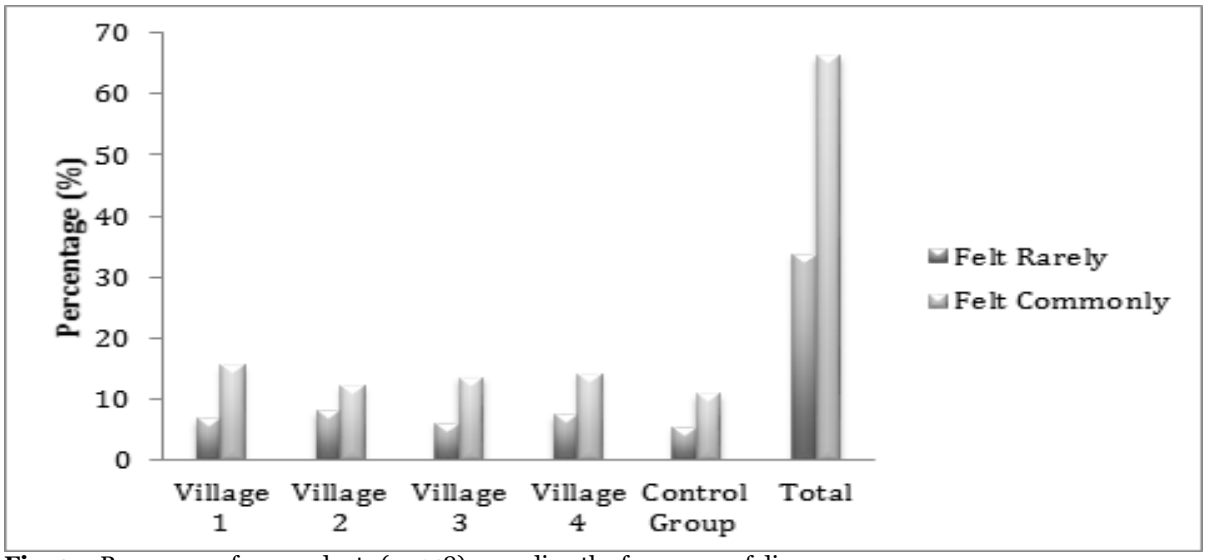

Fig. 25. Responses of respondents (n=148) regarding the frequency of disease.

The occurrence of this problem was significantly higher as compared to the control group. Different types of reproductive problems in females were analyzed in which the major issues observed were pregnancy complications and menstrual disorder among the female respondents. The reason could be

the drinking of contaminated water with pharmaceutical residue. The same study is supported by another study which indicated that women have a tendency of higher risk of unsuccessful reproductive outcomes and revealed that female fertility concerns the pregnancy complications and alterations of the menstrual cycle (Sharpe and Irvine, 2004). In the present study, BMI was measured as a general health indicator among the respondents in different villages and control groups. The average BMI (Body Mass Index) of respondents was found to be a little above the permissible limit, i.e., 18.5-24.9 kg/m². The reason might be the drinking water contaminated with pharmaceutical residues. The present study is supported by another study conducted by the Dars who evaluated BMI (Body Mass Index) as identifying anthropometric height/weight parameters and examined as a potential cause for the prevalence and growth of a number of serious health concerns (Dars, 2014).

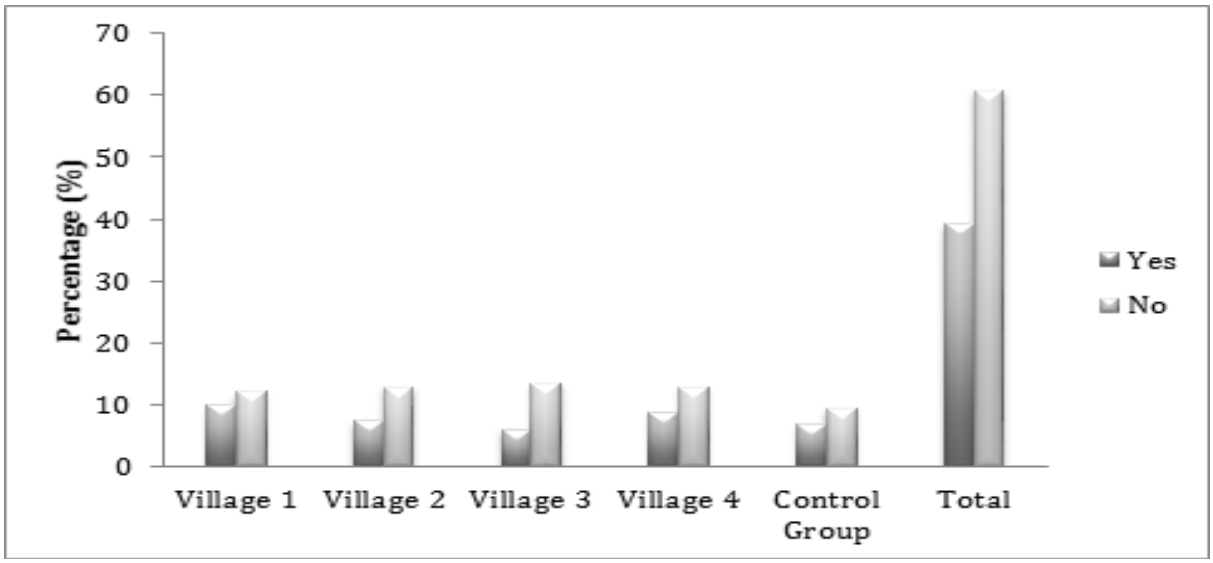

Fig. 26. Percentage comparison of respondents (n=148) getting treatment against their disease.

The presence of pharmaceutical compounds in drinking water has detrimental effects on health as there has been an increasing concern about the environmental quality and nature of toxic organic chemicals observed in drinking water.

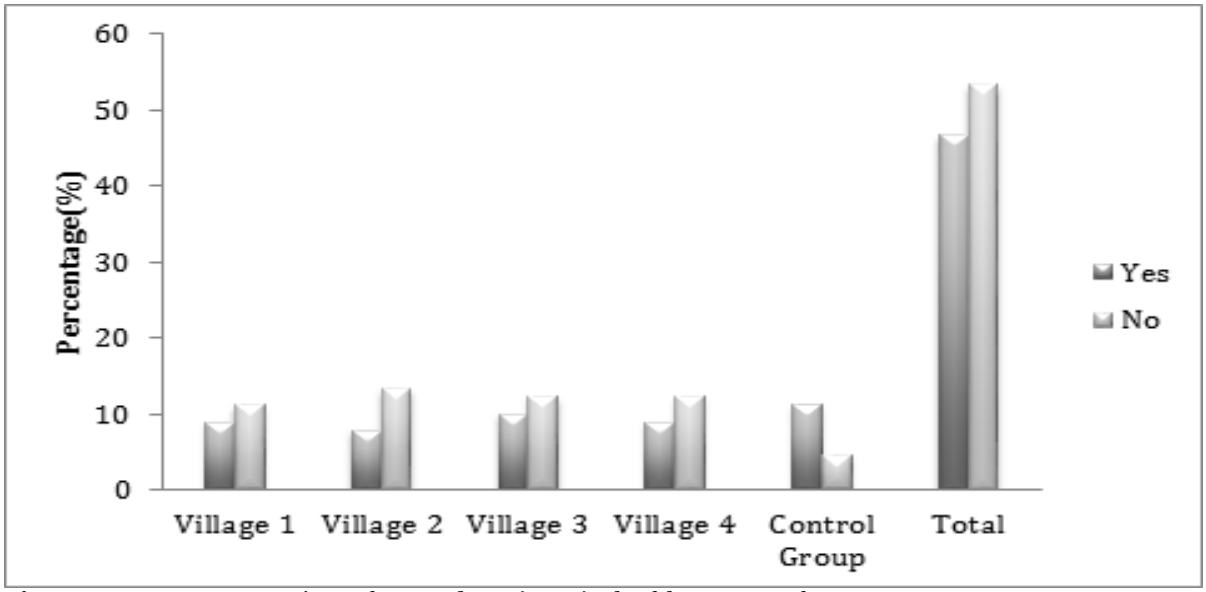

Fig. 27. Percentage comparison of respondents (n=90) who felt recovery after treatment.

The effects of drugs are growing and influencing the environment due to the constant release of pharmaceutical substances in substantial amounts.

People living nearer to the pharmaceutical residency are more exposed to the pharmaceutical compounds through drinking contaminated water, as different discharge and seepage activities from the pharmaceutical area were deteriorating the quality of drinking water. Factors that make the situation worse are lack of facilities, socio-economic status, unawareness and lack of commitments by the national level to provide healthy drinking water.

The findings of this study provide sufficient evidence for the development of an environmental monitoring program to be established in order to evaluate the continuous discharge of pharmaceutical products and to control their possible toxicological impact on the community.

Conclusion

Hormonal changes causing reproductive problems among females were found to be the most prominent health effect due to drinking water contaminated with pharmaceutical residue. The most dominant reproductive problems were found to be pregnancy complication and menstrual disorders. The sources of drinking water and their average distances from the pharmaceutical industrial estates are the most crucial factors for determining the poor health status.

Disclaimer/Acknowledgement

This article was presented at 7th International Conference "Positive Psychology: Developing a Flourishing Community" at NIP, Quaid-e-Azam University, Islamabad, Pakistan, November 2018.

Conflict of Interest/Declaration of Interest

One of the co-author of this research is member of research ethics committee.

Source of Funding

None. Grant support and Financial Disclosures: None.

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