

**CHANGING CONCEPTS: ROLE OF DIETARY FAT AS
A RISK FACTOR IN CORONARY HEART DISEASE IN
THE ARMED FORCES**

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ABSTRACT

The role of dietary fat as an important risk factor for Ischemic Heart Disease (IHD) in armed forces population is discussed in this paper. The findings highlight the importance of the type of fat eaten vis-a-vis risk of IHD when oils containing monounsaturated and polyunsaturated fatty acids are consumed.

A case control study with 108 cases and an equal number of controls showed that the IHD patients, contrary to the popular belief, had a significantly lower consumption of total fat as compared to the controls. The consumption of unsaturated fat energy was lesser than the recommended 10 per cent in 52.79 per cent of the cases as compared to 33.3 per cent of controls which was statistically significant. However, 44.5 per cent of the cases as compared to only 27.8 per cent of controls had a higher intake of dietary cholesterol and this was reflected in the levels of serum cholesterol being more than 200 mg per cent in 57.4 per cent of the cases and 43.5 per cent of the controls.

Coronary artery disease (CAD) is a multifactorial disorder. It is second only to injuries in hospital deaths and is an important cause of invalidment from services. An overall prevalence of 0.95/1000 for all ranks has been reported for the year 1990². The present study was carried out with the aim of delineating important risk factors operative in the armed forces population.

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MATERIALS AND METHOD

The study was conducted in a large tertiary care teaching hospital in the armed forces as a case control study with the study group consisting of confirmed cases of IHD and another comprising the control. The intake of dietary fat and associated factors were the exposure variables. The study population consisted of 108 cases with an equal number of controls. All confirmed uncomplicated cases of IHD treated either as outdoor or indoor patients formed the study group. Only incident cases occurring from March 1995 were included in the study. Cases were diagnosed based on history, ECG and enzyme studies. Controls were selected by a simple random sampling from the patients admitted to the hospital for diseases other than IHD. All cases of chronic diseases like rheumatoid arthritis, peptic ulcer, etc. and patients with neurological and psychiatric disorders were not considered as controls. One control was selected for each case. All the controls were matched for age, sex, socio-economic status and trade by frequency matching.

Nutritional parameters were assessed by standardized reweighted vessels of seven different sizes along with one table spoon and tea spoon, which were calibrated during the pilot study. History of food taken by the cases before the onset of disease was taken. Average quantities of different kinds of food taken per day in the preceding one year of the disease onset were recorded. Patients were assisted by showing vessels for different sizes to enable them to decide quantity of food intake. This method does have the handicap of recall bias which is to a great extent offset by the fact that all the cases are educated, elderly, experienced and are consuming military rations. Therefore, it is expected that information collected would be reasonably correct. Moreover, there was no other reliable method to study the dietary aspects prior to onset of illness; 24-hour recall being invalid for such studies.

Serum cholesterol estimation was done using standard diagnostic kits operated by semi-autoanalysers. The schedule was standardized after pretesting. Data were thereafter collected with the standardized questionnaire after examining each case. The data so obtained were analysed and necessary statistical tests were applied.

Age: 75 out of 108 cases were below 50 years of age with a mean age of 46.2 years. (Table 1).

TABLE 1
AGE-WISE DISTRIBUTION OF SUBJECTS

Age (in years)	Cases	Per cent
30 - 39 years	31	28.7
40 - 49 years	44	40.8
50 - 59 years	31	28.7
> 60 years	02	1.8
Total	108	100

Sex. 101 (93.5%) of the cases were males and only 7(6.5%) were females.

Family History. 82(75.9%) of the cases and 103 (95.4%) of the controls did not give any family history of CHD, hypertension, diabetes mellitus or angina. Only 12 (11.1%) of cases had a family history of IHD while only 3 (2.8%) controls gave a similar history. History of diabetes mellitus was seen in 11 (10.2%) of the cases and in 2 (1.8%) of controls. None of the cases had a combination of risk factors (Table 2).

TABLE 2
FAMILY HISTORIES OF CHRONIC ILLNESS AND OBESITY

Disease	Cases	Controls
None	82(75.9%)	103(95.4%)
IHD	12(11.1%)	03(2.8%)
Diabetes mellitus	11(10.2%)	02(1.8%)
Obesity	02(1.9%)	0
Hypertension	01(0.9%)	0
Total	108	108

$\chi^2 = 16.78$ $DF=2$ $p<0.01$

Index of Incidence: Maximum number of cases was other ranks, 73(67.6%). Officers and JCOs comprised only 13(12%) and 22(20.5%) of the cases respectively. However, since bulk of the armed forces comprise other ranks, 92.1 per cent approximately, the index of incidence among officers, JCOs and other ranks is 3.53, 4.40 and 0.734 respectively (Table 3).

TABLE 3
INDEX OF INCIDENCE OF IHD - ALL RANKS

Category	No. of cases	Per cent	Relative proportion (cases)	Proportional strength (in-service)	Index of incidence
Officers	13	12	0.12	0.034	3.53
JCOs	22	20.5	0.20	0.045	4.40
OR	73	67.6	0.676	0.921	0.734

Total Calorie Intake: 95 (88%) of the cases and 83 (76.9%) of the controls were taking lesser than 3000 kcals required for heavy work while only 13 (12%) of the cases and 25 (23.1%) of the controls were taking more than 3000 kcal (Table 4).

TABLE 4
TOTAL INTAKE OF CALORIES

Calorie intake	Cases	Control
< 2000	36(33.3%)	24(22.2%)
2001 - 3000	59(54.7%)	59(54.7%)
3001-4000	6(5.6%)	24(22.2%)
>4000	7(6.4%)	1(0.9%)
Total	108	108

X² = 6.19 DF = 2 p < 0.05 (Significant)

Consumption of Fat Energy. 90 (83.2%) of the cases were taking fat energy in the range of 500-900 kcals as compared to 83 (76.9%) of the controls. Only 18 (16.8%) of the cases and 25 (23.1%) of the controls had a fat energy consumption of more than 900 kcal/day (Table 5).

TABLE 5
CONSUMPTION OF FAT ENERGY

Fat Energy (Kcal)	Cases	Controls
<500 501 - 700 701 - 900 >900	19(17.5%) 39(36.1%) 32(29.6%) 18(16.8%)	2(1.9%) 39(36.1) 42(38.9%) 25(23.1%)
Total	108	108

$$X^2 = 16.25 \quad df = 3 \quad p < 0.01$$

Unsaturated Fat Energy. 57 (52.79%) of the cases and 36(33.3%) of the controls were taking less or equal to 10 per cent of energy from unsaturated fats while 51 (47.21%) of the cases were consuming more than 10 per cent of unsaturated fat energy as compared to 72(66.7%) of the controls (Table 6).

TABLE 6
INTAKE OF UNSATURATED FAT ENERGY

Energy (Kcal)	Cases	Control
< 150 151- 250 251- 300 >300	1(0.92%) 30(27.80%) 26(24.07%) 51(47.21%)	0 12(11.1%) 24(22.2%) 72(66.7%)
Total	108	108

$$X^2 = 12.06 \quad DF = 2 \quad p < 0.01$$

Dietary Cholesterol. 53 (49.1%) of the cases and 34 (31.5%) of the controls were consuming more than 251 mg/day of dietary cholesterol (Table 7).

TABLE 7
INTAKE OF DIETARY CHOLESTEROL

Dietary cholesterol (mg/day)	Cases	Controls	Total
251 mg or more	53	34	87
250 mg or less	55	74	129
Total	108	108	216

Odds Ratio = 2.10 (95% CL 1.16 - 3.80) $\chi^2=6.95$, df=1, $p < 0.01$

Serum Cholesterol: 62 (54.4% of the cases and 47 (43.5%) of the controls had serum cholesterol more than 200 mg per cent.

DISCUSSION

In the present study, 75 of the 108 (69.5%) cases were below 50 years of age with a mean age of 46.2 years and a standard deviation of 7.1. 44(40.8%) of the cases were males and only 7(6.5%) were females. Based on the index of incidence (Table 3), it was found that officers are 4.8 times and JCOs 5.9 times more prone to IHD as compared to the other ranks. 11.1 per cent of the cases gave a family history of IHD while it was 16.3 per cent in another study¹. 95 (88%) of cases and 83 (76.9%) of controls were taking lesser than 3000 kcals while only 13 (12%) of cases and 25 (23.1%) of controls were taking more than 3000 kcals. Taking 3000 kcals as the cut off, the odds ratio is 2.2 (95%CI 0.95-4.78) thereby, indicating increased risk of IHD in individuals consuming more than 3000 kcals (Table 4) required for heavy work.

WHO³ recommends that consumption of fat energy should not exceed 30 per cent of total calories, i.e. 3000 kcal. In this study 90 (83.2%) of the cases were taking fat energy in the range of 500-900 kcals as compared to 83 (76.9%) of the controls (Table 5). Only 18(16.8%) of the cases and 25 (23.1%) of the controls had a fat energy consumption of more than 900 kcal/day. This was statistically significant while controls taking higher fat energy and still not suffering from

disease. The finding is similar to that of seven countries studied wherein very low rates of coronary heart disease was observed in Crete where there were high levels of total dietary fat but low levels of saturated fat⁴. Consumption of monounsaturated fatty acids was higher in Crete. A similar situation prevails in the armed forces with mustard/rape seed/groundnut oil which are rich in monounsaturated acids being part of the armed forces' ration supply.

The comparative pattern of consumption of unsaturated fat energy by cases and controls was highly significant (Table 6). If 250-300 kcal is taken as cut off point (because unsaturated fats should provide at least 10 per cent of fat energy or 300 kcal approximately the odds ratio is 0.447 thereby showing that consumption of at least 10 per cent of unsaturated fat energy is protective against IHD. In the armed forces hydrogenated fat has been replaced by mustard oil/rape seed/groundnut oil which is desirable, as it is protective. Its consumption will provide the desired monounsaturated fatty acids. Mustard is also rich in n-3 fatty acids which protect against coronary artery disease and maintains a desired n-6/n-3 ratio of lesser than five⁵.

In regard to the intake of dietary cholesterol, taking 250 mg% as the cut of point 53(49.01%) of cases and 34(31.50%) of controls had an intake of cholesterol more than 251 mg/day (Table 7) giving an odds ratio of 2.1; which means that those consuming dietary cholesterol in excess of 250 mg per day are at more than double the risk of contracting IHD than those who are consuming less. In a prevalence study of risk factor of IHD, the author had reported 36 per cent with cholesterol intake over 300 mg/day⁶. If 300 mg/day is taken as the cut off limit, the odds ratio is 2.08 (95% CI: 1.14-3.82) indicating that the consumption of dietary cholesterol in excess of 300 mg/day is associated with almost similar risk. Increasing serum cholesterol is an important adverse effect of saturated fat⁷ therefore a diet low in saturated fat in conjunction with fruits and vegetables and legumes will be associated with a significant reduction in adverse cardiac effect. The Indian consensus group on prevention of hypertension and coronary artery disease has suggested a lower level of 100 mg/day as part of its dietary guideline for Indians.⁵

62(57.4%) of the cases and 47(43.5%) of the controls had serum cholesterol more than 200 mg per cent. While others have reported it to be 60 and 42 per cent respectively of their subjects with serum cholesterol more than 200 mg. Taking 200 mg as the cut off limit for serum cholesterol, odds ratio is 1.75 (95% CI:0.99.11) highlighting that serum cholesterol more than 200 mg is predictive of IHD. A similar observation was also made in a study⁹ wherein they

reported the risk of developing IHD with serum cholesterol level beyond 220 mg/dl was 1.87 (OR 1.87, 95 CI 1.37-4.93). The seven countries had also shown that on a population basis, the risk of CAD rises progressively with an increase in serum cholesterol above 150 mg^{4, 5}. It seems, therefore, that the concept of normal cholesterol has little meaning. Serum cholesterol levels in the low-risk rural population of India are around 160 mg/dl⁵⁷. The desirable serum cholesterol should therefore be lesser than 200 mg/dl. Values between 170 and 200 mg/dl should be considered borderline and levels over 200 mg/dl should be considered hypercholestermia⁵.

CONCLUSION

In regard to the intake of dietary fat, the type of fat consumed, viz. saturated, monounsaturated and polyunsaturated, is more important than the total fat calories intake, as a risk factor, for IHD. Therefore, it would be prudent to ensure that vegetable oils supplied in the armed forces are richer in monounsaturated and polyunsaturated fatty acids rather than saturated fats.

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प्रस्तुत लेख में सशस्त्र सैन्य बलों में अरक्तताजन्य हृदयरोग के लिए उत्तरदायी जोखिमपूर्ण घटक के रूप में आहारिय वसा की भूमिका के बारे में चर्चा की गई है। अध्ययन से प्राप्त निष्कर्षों में भोजन के लिए प्रयुक्त विभिन्न प्रकार की वसा तथा अरक्तताजन्य हृदयरोग से जुड़े जोखिम के संदर्भों में इसके महत्व पर प्रकाश डाला गया है, विशेष रूप से ऐसी स्थिति में जब भोजन में ऐसे तेलों का प्रयोग किया जाता हो जिनमें मोनो-अनसेचूरेटिड और पोली-अनसेचूरेटिड वसायुक्त अम्ल सेवन में आते हों।

एक केस नियंत्रण अध्ययन के अर्न्तगत एक ओर 108 केसों के बारे में तथा दूसरी ओर इतनी ही संख्या में आत्मसंयम रखने वाले केसों पर किए गए एक अध्ययन से पता चलता है कि प्रचलित धारणा के विपरीत अरक्तताजन्य हृदयरोग से ग्रस्त रोगियों द्वारा आत्मसंयम रखने वालों की तुलना में महत्वपूर्ण रूप से कम मात्रा

में वसा का सेवन किया गया था। आत्मसंयम रखने वाले 33.3 प्रतिशत व्यक्तियों की तुलना में 52-79% केसों में अनसेचूरेटिड वसा ऊर्जा का प्रयोग 10 प्रतिशत अनुशासित मात्रा से भी कम किया गया था, जो सांख्यिकीय दृष्टि से महत्वपूर्ण है। किन्तु 27.8 प्रतिशत आत्मसंयम वाले व्यक्तियों की तुलना में 44.7 प्रतिशत केसों में आहार में कोलेस्ट्रॉल की मात्रा का अधिक सेवन किया गया था तथा इसका पता इस तथ्य से चलता है कि 57.4 प्रतिशत केसों में तथा 43.5 प्रतिशत आत्मसंयम वाले केसों में सीरम कैलेस्ट्रॉल का स्तर 200 मि.ग्रा. प्रतिशत से अधिक पाया गया था।

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**ROLE OF SEMINAL GERM CELL MORPHOLOGY AND
SEMEN BIOCHEMISTRY IN THE INVESTIGATION AND
MANAGEMENT OF AZOOSPERMIC SUBJECTS**

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ABSTRACT

A significant proportion of male partners of infertile couples present with azoospermia. For proper investigation and management of such cases it is important to determine whether the condition is due to or is associated with obstruction in the reproductive tract. The study of seminal germ cell morphology (SGCM) and semen biochemistry has provided very useful noninvasive tools for differentiating between obstructive and non-obstructive azoospermia. Furthermore, the SGCM studies have been very valuable in objectively monitoring the response of the germinal epithelium to specific treatment in selected cases.

In about 50 per cent of infertile couples abnormal male factor is present, and a significant number of them show azoospermia. Some of them might have had varying degrees of oligospermia prior to development of azoospermia. Proper insight and a systematic approach are needed for elucidating the nature and etiology of such disorders'. First of all, it is to be determined whether the azoospermia is due to (a) an obstructive or (b) a non-obstructive cause then tries to find out the possible etiology for which other specific tests are to be carried out.

According to the W.H.O. Manual the diagnosis of obstructive azoospermia is made when it is associated with: (a) normal total testicular volume (>30 ml), (b) normal plasma level of FSH, and (c) when spermatozoa are present in testicular biopsy. "When the subject's azoospermia is of unknown origin, i.e. when he does not qualify for testicular biopsy because he has low testicular volume or elevated blood FSH, or the testicular biopsy reveals no

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Spermatozoa in the seminiferous tubules", this is diagnosed as "idiopathic azoospermia". But in actual practice, the above criteria and terminology are not always dependable, and neither do they clearly characterize the situation³.

During mid-1970s and early 1980s we were engaged in studies with cyproterone acetate (CPA) with or without testosterone as a potential male contraceptive. In order to elucidate the nature, site and mode of action of these regimens we studied among other parameters, seminal germ cell morphology (SGCM) and semen biochemistry - glycerylphosphorylcholine (GPC), acid phosphatase (ACP), and fructose.

At this time, we decided to use SGCM and semen biochemistry in the diagnosis and management of azoospermic subjects, and appropriate studies were undertaken. These proved to be very valuable non-invasive tools for differentiating between obstructive and non-obstructive azoospermia. More recently, studying the changes in the pattern of GCM has been found to be very valuable for monitoring the response of the germinal cells to specific treatments in selected cases.

METHODOLOGY

Considering the fact that such conditions may often have associated infection and/or inflammation of the secondary sex organs such as the epididymis, seminal vesicles and prostate, which may cause temporary blockage of ducts, the patients are administered a course of antibiotics and an anti-inflammatory drug with or without doing a prior semen culture. Then they are subjected to studies of SGCM and semen biochemistry. Various cellular and biochemical constituents of the semen, contributed by different reproductive organs are used as markers. The mature and immature germ cells are contributed by the testes, 70 per cent of glycerylphosphorylcholine (GPC) by the epididymis, fructose mostly or solely by the seminal vesicles and acid phosphatase (ACP) by the prostate.

Semen samples are collected after 3 to 4 days' abstinence to get adequate volume; sometimes 2 to 3 samples need to be pooled together because of low volumes. In subjects with marked androgen deficiency ejaculate volume may be very scanty. They may need weekly injections of testosterone for 2 to 3 months for obtaining adequate quantity of semen for carrying out these tests. The SGCM study is carried out as described in our earlier publication and in the WHO Manual⁴⁸. After centrifugation of the semen the deposit is properly smeared on glass slides and appropriately stained. The immature germ cells at various stages of differentiation i.e. spermatogonia, primary and secondary spermatocytes, and round and elongated spermatids are

Identified and their proportions determined. Sometimes the round spermatids share common cytoplasm and may appear as polymorph nuclear leucocytes. Great care is needed to differentiate the germ cells from the leucocytes and the Sertoli cell nuclei by the nuclear size and staining characteristics. As mentioned earlier, the germ cells serve as a marker of testicular contribution. As regards the semen biochemistry, the GPC, ACP and fructose are measured using the methods described in our earlier publication⁴, and these serve as markers of secretions from the epididymis, prostate and seminal vesicles respectively.

FINDINGS AND DISCUSSIONS

Over the years, these tests have been performed routinely on several hundred subjects, and these have provided very dependable results in differentiating between obstructive and non-obstructive azoospermia. The summary reports have been published earlier⁷. The author also had the opportunity of presenting the results of these studies at several advanced centres in U.K. and U.S.A. Everywhere; he has been urged to publish these results for wider use and the benefit of others. Recently, he had the privilege of delivering an oration based on this subject at the Second Asia Oceanic Congress of Andrology held at Chandigarh in November, 1996.

Here the diagnosis of obstructive and non-obstructive azoospermia has been based mainly on the absence or presence of immature germ cells, supplemented by low or normal GPC respectively. These correlated well with the 'correct' testicular biopsy findings in a good number of cases where the author had the opportunity of reviewing the biopsy slides. In obstructive azoospermia the level of GPC is low and there are no mature or immature germ cells in the semen, as is also observed in vasectomized individuals. The level of fructose and the ACP activity are not altered after vasectomy or in obstructive azoospermia, except in rare cases with non-development or maldevelopment of seminal vesicles where seminal fructose may be absent or very low. In rare cases of non-obstructive azoospermia due to Sertoli-cell-only syndrome, both mature and immature germ cells may be absent in the semen, but the seminal GPC is usually normal. In some of these cases immature germ cells have been observed in the semen; this may indicate the presence of islets of active spermatogenic tissue. Properly done and correctly interpreted testicular biopsy or even FNAC (fine needle aspiration cytology) can clinch the final diagnosis.

Sometimes the testicular biopsy procedure and/or fixing and processing of the tissue may not be proper, or despite being properly prepared it may not be interpreted appropriately. As for example, even in well equipped centres the advanced stages of spermatids (Scd) which may appear like tail-less spermatozoa, may be wrongly interpreted as sperms; and such testis biopsy

has been diagnosed as having normal spermatogenesis. Consequently, based on such wrong interpretation vaso-epididymal anastomosis may be attempted. However, in reality this may be a case of spermatogenic developmental arrest resulting in non-obstructive azoospermia. Several such cases have been referred to the author with the diagnosis of obstructive azoospermia based on testicular biopsy report. But studies of SGCM and semen biochemistry showed to the contrary, and a careful review of the biopsy slides by the author himself could not confirm the earlier claim. Similarly, in four other cases diagnosed elsewhere as obstructive azoospermia based on FNAC reports, immature germ cells were found in the semen and there was no evidence of any obstruction.

It has recently been observed that in majority of subjects with testicular failure caused either by maturation arrest, Sertoli-cell-only syndrome, cryptorchid testicular atrophy, or even Klinefelter's syndrome there are very tiny number of spermatozoa or spermatids which could be extracted from extensive testicular biopsies, and utilized for intracytoplasmic sperm injection (ICSI) 11.12.13.14. In the light of these observations, the presence of immature germ cells particularly the round or elongated spermatids in SGCM study in patients with Sertoli-cell-only syndrome or other cases of severe testicular atrophy could have a prognostic value. In such cases there would be greater chances of obtaining sperms from testis biopsies for ICSI. Furthermore, in certain patients with testicular atrophy having some clinical signs of hypoandrogenism, treatment with testosterone or HCG with or without HMG has caused stimulation of germinal epithelium often with progression in stages of spermatogenesis, and in some cases sperms have appeared in the semen. In addition, in some of these patients having initially very small testes the testicular volume has also increased following such treatment (Roy , 1993-98: unpublished observations). Consequently, such procedures not only enhance the prognostic value of the SGCM study, but also increase the chances of success in doing ICSI using sperms from testicular biopsy. We have had several such cases, and in three of them ICSI has already been successfully performed.¹⁵

In some cases of azoospermia due to spermatogenic maturation arrest at different cytological levels resulting from hypogonadotropic hypogonadism, hypoandrogenism, hyperprolactinemia or varicocele, the SGCM studies have been very helpful in objectively monitoring the response of the germinal epithelium to specific treatments. Sperms have appeared in their ejaculate, and some of them have impregnated their wives through natural sex act. Others have been able to produce varying numbers of sperms in the semen which could be appropriately utilized.¹⁵

CONCLUSION

In azoospermic subjects, we have studied the seminal germ cell morphology (SGCM) and semen biochemistry involving estimations of GPC, ACP and fructose, which served as markers of contributions from the testis, epididymis, prostate and seminal vesicles respectively. These proved to be very valuable non-invasive tools for differentiating between obstructive and no obstructive azoospermia. In cases with obstruction, the study of semen biochemistry could often indicate the possible site of the block. In some cases of azoospermia where testicular biopsy or fine needle aspiration cytology (FNAC) done in other centres had failed in establishing proper diagnosis, our studies with SGCM and semen biochemistry have clearly clinched the issue. The SGCM studies have also been very valuable in objectively monitoring the response of the germinal epithelium to specific treatments in selected cases.

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बांझग्रस्त दम्पतियों में बहुत बड़ी संख्या में पुरुष शुक्राणुहीनता से ग्रस्त पाये जाते हैं। इस प्रकार के केसों की जांच तथा उपचार के लिए यह पता लगाना महत्वपूर्ण होता है कि क्या वह स्थिति प्रजनन मार्ग में अवरोध के कारण है अथवा इससे सम्बद्ध है। अवरुद्ध तथा अनावरुद्ध अशुक्राणुहीनता की स्थितियों में अन्तर करने के लिए महत्वपूर्ण सूत्र प्राप्त हुए हैं। इसके अतिरिक्त, चयनित केसों में विशिष्ट उपचार करने हेतु जर्मिनल उपीथिलियम की अनुक्रिया का उद्देश्यपरक ढंग से प्रबोधन करने के कार्य में शुक्रिय जनन-कोशिका आकारिकी संबंधी अध्ययन बहुत लाभप्रद रहे हैं।

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**EXPERIENCE IN EARLY DEVELOPMENTAL STUDIES
WITH TWO FERTILITY REGULATING DRUGS:
THEIR CURRENT USES**

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ABSTRACT

In 1950s and 1960s there was a great surge of interest in the development of fertility control methods. Successful use of steroidal contraceptives in the human accelerated research on non-steroidal agents as well. Large number synthetic non-steroidal agents were screened for specific effects in reproductive biology and for ant fertility activity.

This presentation relates to early developmental studies-biological and clinical with two potential fertility regulating agents viz. clomiphene citrate and centchroman. Clomiphene was originally intended to be used for control of fertility in the female but subsequently proved to be a fertility promoting drug consistently inducing ovulation in anovulatory women. Its other clinical uses are also highlighted. Centchroman, which has somewhat similar biological actions, is primarily being used as an oral contraceptive. Its potential use in other clinical conditions is also indicated.

In early 1950s the hazards of uncontrolled population growth was visualized, and the urgent need for developing fertility control methods was recognized. At that time, it was also envisaged that different steps in mammalian reproduction, which are regulated by endogenous hormones, would be vulnerable to a variety of steroidal and non-steroidal agents. As a result of intensive research, a large number of orally effective progestogens and estrogens became available for investigation which led to the development of a good number of steroidal contraceptives for the female currently being used worldwide.

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Successful use of steroidal contraceptives in human accelerated research on non-steroidal agents as well. A large number of synthetic compounds and natural products were screened for specific effects in reproductive biology and for general anti-fertility activity¹. Of these synthetic non-steroidal agents, chloroethelene compounds formed an important group, and three of them viz. chlorotrianisene (or TACE), ethamoxytriphetol (or MER-25) and clomiphene citrate (or MRL-41) exhibited strong ant fertility effects in animal studies. Clomiphene citrate which was devoid of any significant side effects was particularly thought more promising for further development as an ant fertility agent.

One of the major attributes of the female ant fertility agents is their ability to prevent or interfere with implantation. A number of cytotoxic, alkylating, antimetabolic and antihistaminic agents, monoamine oxidase inhibitors, ergot alkaloids and tranquilizers have been tested for anti-implantation activity in animals with some success². However, because of their undesirable side effects further studies were discontinued.

Demonstration of anti-implantation activity of MER-25 presented an interesting lead³, following which a large number of compounds with anticipated similar biological attributes were synthesized. At the Central Drug Research Institute in India, more than 1500 non-steroidal compounds belonging to about 120 different structural types were synthesized and tested for anti-implantation activity since 1962⁴. Of these, compounds belonging to about 20 different structural series were found active, and of the most potential compounds, Centchroman was considered most promising for further development.

This presentation will be restricted to early biological and clinical studies with two of the then considered potential fertility Regulating agents viz. Clomiphene citrate and Centchroman.

(i) CLOMIPHENE CITRATE

Initial Experiments

The ant fertility effect of clomiphene in female rats was thought to be due to its gonadotropin-suppressing, ovulation-inhibiting and blastotoxic actions. In immature mice, it increased the uterine weight, but inhibited the uterotrophic effect of estradiol. Clomiphene was also reported to decrease the weight of the testis and accessory sex organs in immature and mature male rats. It was further reported that in immature rats

Clomiphene caused an inhibition of spermatogenesis at spermatic stage and a decrease in pituitary gonadotropin level.

Being encouraged by these findings in experimental animals clomiphene (MRL-41) was sent to some renowned investigators for clinical trial as a potential anti-fertility agent. Greenblatt and co-workers initially tried to inhibit ovulation in normally ovulating human volunteers by administering this compound from day 5 to 25 of menstrual cycle. Ovulation was not suppressed. On the contrary, in some of these women the life span of corpus luteum was probably somewhat prolonged, as indicated by a sustained rise in basal body temperature (BBT) beyond 20 or more days. This was considered to be a "pituitary modifying" effect. Based on this assumption this drug was administered to some anovulatory women and in 28 of 36 women an "ovulatory type of menses" were produced¹⁰. This was considered to be an important breakthrough in this difficult field of endeavour.

Studies by Roy, Greenblatt and Co-workers

At this juncture the present author joined Dr. Greenblatt's department, shifting from the University of Washington, Seattle, U.S.A. He was given this drug and was told, "this is the wonder drug, do whatever studies you would like to do with it". The author thoroughly reviewed the literature and observed the following:

- (1) In rats clomiphene exerted an ant fertility effect because of its gonadotropin-suppressing, ovulation-inhibiting and blastotoxic effects.
- (2) It did not interfere with gonadotropin action on the ovary in immature rats.
- (3) It exhibited estrogenic and anti-estrogenic actions in rats and mice, the exact nature of which was not known.
- (4) In women, it did not suppress ovulation; on the other hand it induced ovulatory menses in some of the anovulatory women.
- (5) No explanation was available for the discrepant findings in laboratory animals and women, and there was no knowledge about its mode(s) of action.

Systematic studies were undertaken in laboratory animals and the humans by Roy, Greenblatt and co-workers for elucidation of the problem (see 1). Special attention was given to design experiments to study:

- a. Whether graded doses of this compound would elicit differential response in gonadotropin secretion from the pituitary in the laboratory animals and women;
- b. Whether at the same dosage range it would exert estrogenic action in an estrogen-free system and an anti-estrogenic action in the presence of a potent estrogen; if that were so, could it be a competitive phenomenon;
- c. If it could counteract the uterotrophic effect of estrogen, could it also counteract the gonadotropin - suppressing and ovulation-inhibiting actions of estrogen in animals and women;
- d. What type of changes would be produced in the hormonal dynamics when used for induction of ovulation in anovulatory women; and
- e. The range of therapeutic efficacy in different clinical conditions.

Major observations of these studies' are highlighted below. Roy and coworkers were the first to show that:

- a. In the animal lower doses of clomiphene increased gonadotropin secretion from the pituitary and in relatively higher doses it suppressed gonadotropin secretion.
- b. While the hypothalamic-pituitary-gonadal axis in laboratory animals was readily suppressed by clomiphene, this drug failed to inhibit this axis in the human even in high doses.
- c. Clomiphene caused competitive inhibition of estrogen action at receptor level in the uterus, pituitary and hypothalamus and it counteracted the uterotrophic, gonadotropin- suppressing and ovulation-inhibiting actions of estrogen in rats.
- d. Clomiphene counteracted ovulation-suppressing action of estrogen in two normally ovulating women.
- e. During induction of ovulation in an anovulatory woman initially there was a rise in FSH secretion and then estrogen level rose, followed by a LH peak, ovulation occurred within 48 hours.

- f. Roy et al. were also the first to postulate that clomiphene by its competitive anti-estrogenic action prevented or mitigated the inhibitory influence of endogenous estrogen on the hypothalamic-hypophyseal axis and thereby helped in releasing gonadotropin and consequent ovulation. They further suggested a possible direct action of clomiphene on hypothalamic-pituitary axis, probably due to its estrogen-agonist property, and thus promoting gonadotropin release.

Studies by Other Investigators

Clomiphene was the first chemical substance which consistently induced ovulation in anovulatory women and it was devoid of any toxic effect. The nature and mode of its action were also complex and fascinating. The proposed concept of estrogen - competing property of clomiphene was novel. Because of its gonadotropin-releasing ability and its anti-estrogenic action, it had the potential for use in other clinical conditions also. Naturally, it aroused unusual interest and great enthusiasm among the basic scientists and clinical investigators throughout the world. This is well evident from more than 7,000 publications that have appeared to date on this subject⁸²⁰. All these studies have lent overwhelming support to the original observations made and the hypotheses propounded by Roy and co-workers, which have largely provided the fundamental base for subsequent developments'.

Clinical Uses of Clomiphene

There is only one indication for use of clomiphene in woman which has been approved by the Food and Drug Administration (FDA) in USA i.e. treatment of ovulatory failure in patients desiring pregnancy^{1, 9}. However, in several other clinical conditions clomiphene therapy has been tried with varying degrees of success and in some of these conditions it is still being used¹⁹⁻²⁷. These conditions are as follows

In Females:

(1) Induction of ovulation in anovulatory women; (2) Correction of luteal phase defect; (3) Regulation of menstrual cycles in cases with stress amenorrhea, post-contraceptive pill amenorrhea and dysfunctional uterine bleeding; (4) Chronic cystic disease of the breast and breast cancer; (5) Endometrial hyperplasia and endometriosis; (6) Ovarian hyperstimulation for in vitro fertilization and IUI; (7) Testing hypothalamic-pituitary function; (8) Prevention of post-partum breast enlargement; and (9) Non-steroidal estrogen replacement therapy in menopause.

In Males:

(1) Male infertility, particularly for oligospermia; (2) Male hypogonadism; (3) Testing hypothalamic-pituitary function; and (4) Treatment of painful gynecomastia.

Induction of Ovulation - Successful induction of ovulation with clomiphene citrate is considered to be one of the outstanding achievements in reproductive endocrinology. Clomiphene citrate is being extensively used for this purpose throughout the world. Initially, 50 mg is administered daily for five days from the 5th day of spontaneous or induced period. Ovulation usually occurs five to ten days after the last dose. If there is no positive response in two cycles, the daily dose is gradually increased usually upto 150 mg; but rarely still higher doses have also been used with caution for possible ovarian enlargement.

Clomiphene has sometimes been used in combination with other drugs such as estrogen, human chorionic gonadotropin (HCG), bromocryptine, dexamethasone, human menopausal gonadotropin (HMG) and GnRH.

Assisted Reproductive Technology. Combined use of clomiphene and HMG has become a common form of ovarian hyperstimulation in patients undergoing in vitro fertilization or intrauterine insemination (IUI). Following combined therapy the blood level of FSH remains markedly elevated in the follicular phase and this ensures maintenance of a good number of follicles for oocyte recovery (or for multiple ovulation in IUI), which otherwise would be destined to atresia.

Male Infertility. Certain patients with oligospermia due to hypo-spermatogenesis respond to clomiphene therapy favorably. However, better results have been obtained in subjects presenting with oligo-asthenospermia by combined therapy with clomiphene plus testosterone undecanoate (Roy, unpublished observation).

Testing Hypothalamic Pituitary Function: While GnRH test reflects on the pituitary function and its gonadotropin reserve, clomiphene test reveals the status of hypothalamic regulation of gonadotropin secretion. Normally, following administration of 50 to 100 mg clomiphene daily for five days there is a rise in blood levels of FSH and LH, the peak level reaching on the fifth day.

(ii) CENTCHROMAN

Initial Experiments

Centchroman, a non-steroidal substance synthesized and developed at the Central Drug Research Institute, Lucknow, had been reported to be a post-coitally effective ant fertility agent in rats, mice, dogs, and monkeys. In Phase II clinical trials with centchroman administered either post-coitally or in regular weekly regimens, it was reported to have good pregnancy protection. When administered to normally menstruating women, in some of them it produced menstrual irregularities the cause of which was not properly understood. In animal studies it was reported to have estrogenic actions in low doses and anti-estrogenic effects in high doses 28. It was further claimed to have anti-progestational property 28-30.

Studies by Roy and Co-workers

Systematic investigations were undertaken in laboratory animals as well as in the human by the present author for further elucidation of the nature of estrogenic, antiestrogenic and anti-progestational actions of centchroman. Because of its claimed biological actions, studies were also carried out to find out whether it would have any gonadotropin-modulating, ovulation-inducing, luteolytic and abortifacient effects.

In ovariectomized rats, graded doses of centchroman showed weak estrogenic property, but at the same doses it strongly counteracted uterine stimulating action of estradiol. This anti-estrogenic action of centchroman was specific, as it did not counteract the uterotrophic effect of testosterone. It was further shown that it prevented the uptake of radio-labelled estradiol by the uterus, fallopian tube, pituitary and hypothalamus. All these findings strongly suggested that centchroman, having estrogen agonist and antagonist actions at the same doses level, acted competitively with estrogen at receptor level. This was a new concept propounded by the present author. It also had gonadotropin-modulating action.

Centchroman failed to counteract progesterone-induced uterine stimulation in 'delayed implantation' rats; on the contrary, progesterone plus centchroman produced some additive effects in properly designed studies. It did not prevent the uptake of radio-labelled progesterone by the target tissues; in fact, it augmented its uptake in target tissues. All these findings clearly demonstrated that centchroman *per se* did not have any anti-progestational property, as was claimed earlier.

In the human, the nature of its estrogenic and anti-estrogenic actions was studied in estrogen-deficient patients with gonadal dysgenesis. In untreated subjects it caused mild estrogenic effect as revealed by mild stimulation of the vaginal epithelium, but it did not produce any withdrawal bleeding. On the other hand, it prevented stimulation of vaginal epithelium and withdrawal bleeding caused by 1mg of stilbesterol given daily for 20 days. These findings provided further clinical evidence for estrogen-agonist and antagonist actions of this drug at same dosage levels, indicating an estrogen-competing phenomenon at receptor level.

Its possible gonadotropin-modulating actions were studied in estrogen-deficient subjects with gonadal dysgenesis. Elevated levels of plasma luteinizing hormone (LH) were not suppressed with centchroman therapy on the contrary the LH levels were apparently further elevated. In one of these subjects centchroman not only counteracted the estradiol-induced suppression of plasma LH, but caused further stimulation of LH production.

From the foregoing presentations a close similarity between the biological attributes of centchroman and clomiphene may be noted. In view of these it was thought of interest to study whether centchroman would induce ovulation in anovulatory women. Centchroman was administered to eight women with ovulatory failure in daily doses of 15, 30 or 60 mg for 10 to 20 days in each course during a total period of 19 cycles. In 11 of 19 cycles in four subjects there was presumptive evidence of ovulation. In one of the two other patients urinary estrogen level was elevated indicating an ovarian stimulation; in the remaining two subjects urinary estrogen was not studied. It may be stated here that the total number of cycles in each subject treated with centchroman were too few to determine the real success rate.

Because of its claimed anti-progestational property, investigations were carried out to study its effect on corpus luteal function in two ovulatory women and also to study its effect in early pregnancy³⁸. No such actions were detected.

The above original observations of Roy and co-workers have been subsequently confirmed by a number of other investigators.

Clinical Use of Centchroman

Initially, contraceptive efficacy of centchroman in women was tested after post-coital administration of 60 mg of this drug and also in once-a-week schedules of administration of 120 mg, 60 mg and 40 mg of the drug. It was reported to provide good pregnancy protection.

Subsequently a multi-centre clinical trial using 30 mg centchroman once-a-week was conducted in 990 women over a total period of 13,965 women months with good pregnancy protection (Pearl Index: 2.84: life-table analysis at 12 months: 3.42 ± 0.63). In this study, it was noted that over 50 per cent of pregnancies in method-failure cases occurred during the first three months of drug use. This indicated that centchroman probably needed some initial period for fully acquiring contraceptive efficacy. It was, therefore, thought worthwhile to study whether twice weekly dose schedule in the first three months would provide better pregnancy protection.

At a later period another multi-centre trial was undertaken using a biweekly-cum-weekly mode of administration. Centchroman (30 mg) was taken orally on the first day of menses after registration and thereafter one tablet was taken twice weekly (every Wednesday and Sunday) for 12 weeks irrespective of the day of menses. This was followed by weekly administration of one tablet. In this study, 377 women received this treatment over a period of 3932 months and 3471 menstrual cycles. A better contraceptive efficacy was observed with a Pearl Index of 1.83 and Life Table Rate of 1.63 ± 0.74 , compared to 2.84 and 3.42 ± 0.63 respectively noted in the earlier weekly trial. Alteration in menstrual cycles was the main side effect; 2.7 per cent cycles were less than 20 days, 89.3 per cent were of 28 ± 8 days, 4.3 per cent of 36-45 days and 3.7 per cent were prolonged beyond 45 days. This drug is now being marketed in India under the trade names of 'Saheli' and 'Centron'.

The exact mode(s) of action of centchroman as a contraceptive or the mechanism of reported menstrual irregularities is not known. However, in the light of the observations in the studies by Roy et al. the following suggestions may be made:

- a. irregular and/or inadequate release of gonadotropins leading either to anovulation or premature or delayed ovulation may result in irregular and fluctuating levels of estrogen secretion;
- b. counteraction of estrogen action on the endometrium in the follicular phase may also prevent optimal estrogenic priming for progesterone action even if ovulation had occurred, and thereby cause asynchrony making endometrium unsuitable for implantation;
- c. the above effects are likely to decrease the chances of conception; whether the antiestrogenic action of this drug at the level of the cervix and fallopian tube would also contribute to the ant fertility effect needs further elucidation;

- d. the above changes may also account for the menstrual irregularities.

Other Potential Uses of Centchroman

1. Because of its estrogen agonist action it may be beneficial for women in menopausal age. Being a non-steroidal substance it would have advantages over other steroidal hormone replacement Therapies (HRTs).
2. Its potential for ovulation induction has not been thoroughly assessed.
3. It's possible use for testing hypothalamic-pituitary function or for treatment of breast cancer has not been systematically studied.

CONCLUSION

Research and development work on clomiphene citrate, which was originally intended to be used for control of fertility but subsequently proved to be a fertility promoting drug, is an important milestone in the development and progress of reproductive endocrinology. Although its mode of action is complex and many aspects of its action are not clear, very significant advances have been made in understanding the basic mechanisms involved, and based on these knowledge its rational use in various clinical disorders has been possible. It is heartening to note that the early developmental works and the hypotheses developed by the present author more than three decades ago have largely provided the fundamental base.

Extensive systematic research and development work over the decades carried out at C.D.R.I., Lucknow paved the way for the use of centchroman for female contraception. Being a non-steroidal substance it would be expected to have several advantages over steroidal contraceptives, particularly in regard to metabolic side effects. But menstrual irregularities associated with its use are a distinct disadvantage. Although considerable basic biological and clinico-pharmacological information are available, where the present author has made significant contributions, the exact mode(s) and site(s) of action of centchroman are far from clear. Systematic and well designed studies are warranted for clarifying various issues.

Another interesting aspect is that three antiestrogenic compounds namely, clomiphene citrate, tamoxifen and centchroman which have been reported to induce ovulation in anovulatory women, are being primarily used for three different purposes. Clomiphene is used for induction of ovulation, tamoxifen

For breast cancer and centchroman for contraception. What are the basic differences in their biological and clinico-pharmacological attributes that make this difference? These are some of the questions which need to be answered.

Lkkjk'k

1950 और 1960 के दशकों में प्रजनन नियंत्रण विधियों के विकास पर काफी रूचि प्रदर्शित की गई थी। मानवों में स्ट्रायड आधारित गर्भनिरोधकों के सफल प्रयोग के परिणाम स्वरूप गैर-स्ट्रायड कारकों संबंधी अनुसंधान में भी गति आयी थी। प्रजनन जैविकी तथा प्रजनन अवरोधक अनुक्रियाओं के संदर्भ में बड़ी संख्या में सिंथेटिक गैर-स्ट्रायड कारकों के विशिष्ट प्रभावों को जानने के लिए जांच की गई थी।

इस प्रस्तुति का संबंध क्लोमिफेन और सैटक्रोमन जैसी दो प्रजनन नियन्त्रक औषधियों के प्रारम्भिक जीव विज्ञानीय तथा क्लिनिकल विकासोत्पन्न अध्ययनों से है। क्लोमिफेन का प्रयोग मूलरूप से महिलाओं में प्रजनन नियन्त्रक हेतु किया जाना था, लेकिन धीरे-धीरे यह प्रजनन में सहायक औषधि सिद्ध हुई और लगातार नॉन-आवुलेटी स्त्रियों में डिम्बक्षरण के लिए इसका प्रयोग किया जाने लगा। यहां इसके अन्य क्लिनिकल प्रयोगों पर भी चर्चा की गई है। सैटक्रोमन जिसमें कुछ मिलते-जुलते जीव-विज्ञानीय लक्षण हैं, इसका प्रयोग ऑरल गर्भनिरोधक के रूप में किया जा रहा है। अन्य क्लिनिकल स्थितियों में इसके सामान्य प्रयोग पर भी चर्चा की गई है।

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**A STUDY ON TRAINING NEEDS ASSESSMENT OF
PANCHAYATI RAJ MEMBERS IN THE CONTEXT OF
LOCAL DECENTRALISED DEVELOPMENT
PLANNING INCLUDING HEALTH**

Renu Paruthi* and A.K. Sood**

ABSTRACT

The present paper identifies training needs of Panchayati Raj members in the context of local decentralised development planning including health in Gurgaon district of Haryana State. The Panchayati Raj members, administrators and trainees of Panchayati Raj institutions and community members were included in the study. Deficient areas were identified for training of Gram Panchayat, Panchayat Samiti and Zila Parishad members. They have knowledge about their roles and responsibilities in local planning, resource mobilisation, maintenance of records and reports, conducting of meetings, etc. Recommendations have been made by the authors in this paper regarding modifications in the training to include some areas for their effective involvement in local decentralised development planning including health.

In recognition of the Constitution (73rd Amendment) Act 1992, the Panchayati Raj members, estimated to be about three million in India, need to be equipped with necessary knowledge and skills to enhance their capabilities to take up new responsibilities in preparation of plans and implementation of schemes for economic development and social justice. Training to be successful, it has to be need-based and realistic. Therefore, the present study has been planned to identify the training needs of Panchayati Raj members in the context of local decentralised development planning, including health with a view to suggesting suitable modifications in their training. This study contributes towards providing basis for taking informed and rational decisions on the target groups to be trained and the nature and content of the training programmes to be designed for their benefit.

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MATERIALS AND METHOD

The present study was undertaken in Gurgaon district of Haryana State. The elections to the Panchayati Raj Institutions in Haryana were held during December, 1994 and since then these institutions have been operational. This district had 508 Gram Panchayats, nine Panchayat Samitis and one Zila Parishad.

All the 24 Zila Parishad members and 6 administrators of Panchayati Raj in the district (Gurgaon) were interviewed. Out of the nine blocks in the district, the block Gurgaon was selected by a simple random sampling and here all the 30 Panchayat Samiti members and 22 administrators of village and block level panchayats were interviewed.

Then five out of 63 Gram Panchayats were selected by a simple random sampling and all the 60 members of these Gram Panchayats were interviewed. 10 community members, including local informal leaders such as teachers, anganwadi workers, shopkeepers, etc. from each gram panchayat village were also interviewed.

Nilokheri in Gurgaon was included to study the State training institutions viz. the State Community Development Training Centre (SCDTC), Nilokheri; and Haryana Institute of Rural Development (HIRD), Nilokheri. All the ten trainers of these two institutions were interviewed. The total sample size was 202.

Secondary data collection was made from the *Constitution (73rd Amendment) Act, 1992*, *Haryana Panchayati Raj Act 1994*, executive orders and circulars of Haryana Government about PRIs, records and documents maintained by training institutes such as training curriculum, training load and records of Gram Panchayats and other relevant documents.

The primary data were collected through interviews with trainers, Panchayati Raj members, administrators and community members. Observations were also made at the training institutions and meetings of Gram Sabha, Gram Panchayat, Panchayat Samiti and Zila Parishad. Data so collected were analysed manually to identify the training needs of Panchayati Raj members for their effective involvement in local decentralised development planning, including health.

FINDINGS AND DISCUSSION

Gram Panchayat Members' Competencies

Majority of the gram panchayat members (58.4 per cent) were less than 50 years of age, 56.7 per cent were males, 70 per cent belonged to dominant caste and 58.3 per cent were up to middle pass. Majority (70 per cent) belonged to middle and lower middle socio-economic class. No one had previous experience of working with PRIs.

It was found that only 1/6th of the members were related to other elected members. Training courses on Panchayati Raj were attended by only 8 per cent of the members during the last three years. Out of these, a majority had attended only for 1-2 days at Gurgaon district. The contents covered in their training were provisions of the Act, duties and responsibilities of elected members and programmes/schemes of the government.

Knowledge of the Gram Panchayat members about almost all of the structural provisions of the Act was very poor. When asked about the deficiencies in the Act, 76.7 per cent could not reply. 13.3 per cent of the members opined lack of powers and demanded both powers and resources. Nearly seven per cent felt about the lack of educational criteria for the elected members and suggested the same for sarpanches (upto 6th or 10th pass). About three per cent of the members wanted the confidential report of government functionaries at the village level to be written by the respective sarpanches (Table 1).

Most of the Gram Panchayat members were not clear about their roles and responsibilities as they had not been provided with any copy of the Act or executive orders of the State Government on devolution of functions, powers and resources. However, the members thought construction works, sanitation and water supply were their responsibilities as they got grants marked for these works while 36.7 per cent did not know about their responsibilities. They were only aware of *Jawahar Rojgar Yojana* (56.7%), *Indira Awas Yojana* (43.3%) and *Apni Beti Apna Dhan* schemes (53.3%) (Table 2).

None of the Gram Panchayats had formed any sub-committee as mentioned in the Act. Most of them were not aware of them. Main difficulties faced by the gram panchayat members were in the release of gram fund due to bureaucratic delays and they suggested that procedures for the release of funds should be simplified.

The gram panchayat members faced problem in the removal of illegal encroachments and they had to attend to a number of court cases without any results. They suggested that more powers should be given to BDPO for removal of encroachments. Because the delays in removal of encroachments and ordeal of attending court cases in Gurgaon and Chandigarh would be avoided if BDPO had the power on removal of encroachments.

TABLE 1

**DEFICIENCIES AND SUGGESTIONS FOR THE HARYANA PANCHAYATI RAJ ACT
ACCORDING TO GRAM PANCHAYAT MEMBERS**

Deficiencies and Suggestions		Number of Gram Panchayat Members n = 60 (%)
1.	Deficiencies	
	Don't know much about the Act	46 (76.7)
	No deficiencies	6 (10.0)
	Act on paper is OK but no powers have been given practically	8 (13.3)
	No educational criteria is there in the Act for the elected members	4(6.7)
2.	Suggestions	
	Should get powers and resources	8(13.3)
	There should be educational criteria for sarpanches 6th pass or 10th pass	4 (6.7)
	Don't know	46 (76.7)
	Confidential report of Government functionaries at village should be written by the sarpanches	2 (3.3)

(Figures in parentheses indicate percentages)

Two meetings of Gram Sabha (Sawani) were observed. It was noticed that no agenda was prepared and the quorum was not fulfilled in both the meetings. The BDPO/SEPO had not attended the meetings in one village and no female member was present in the meetings. Even the female panches and sarpanches were absent and in their place, their husbands were participating. The participation of members was poor.

TABLE 2

MAIN RESPONSIBILITIES OF GRAM PANCHAYAT MEMBERS AND PROGRAMMES/ SCHEMES BEING IMPLEMENTED IN THE AREA AS TOLD BY THEM

Rsponsibilities and Programmes		Number of Gram Panchayat Members n = 60 (%)
1. Responsibilities		
	To solve the problems of the village	38 (63.3)
	Development works of the village	32 (53.3)
	Sanitation (through Safai Karamcharies)	28 (46.7)
	Water supply (tubewells)	28 (46.7)
	Construction of roads	22 (36.7)
	Construction of latrines, sewers	22 (36.7)
	Construction of chaupals, panchayat ghar	22 (36.7)
	Construction of school buildings	22 (36.7)
	Don't know/No responsibilities	22 (36.7)
2. Programmes/Schemes implemented		
	Jawahar Rojgar Yojana	34 (56.7)
	Indira Awas Yojana	26 (43.3)
	Apni Beti Apna Dhan	32 (53.3)

(Figures in parentheses indicate percentages)

On four occasions, visits were made to attend gram panchayat meetings on scheduled dates and it was observed that none of the meetings was held. On three occasions, it was found that the meetings were not held as Gram Sachiv had not come and on one occasion, it was due to some fights in the village groups the sarpanch and panches were busy at police station. It was told that the Gram Sachivs came irregularly, at their convenience, on any day at any time, filled up the proceedings book which was sent to panches for signatures.

Training Areas for Gram Panchayat Members

- Certain content areas for the training of gram panchayat members:
1. Provisions of Haryana Panchayati Raj Act 1994.
 2. *Role of gram panchayat members in development* Emphasis on health as an integral part of socio-economic development and formation of village health committee and its functions. Formation of village education committee and its functions.

3. Steps for local decentralised development planning, Resource inventory, socio-economic benchmark survey, identification of constraints to development, assessment of ongoing programmes, identification of goals and formulation of strategy, implementation planning and resource mobilisation.
4. Role of gram panchayat members in implementation of various activities under 29 subjects, including identification of beneficiaries for various schemes/programmes of the government, team building and leadership roles.
5. Monitoring of various activities and preparation of reports.
6. Financial management including budgeting, auditing and accounting.
7. Records maintenance.
8. Meetings and communication skills development.

Panchayat Samiti Members' Competencies

The knowledge of Panchayat Samiti members about the structural provisions of the Act was good. Most of them did not know about the constitution of district planning committee, State finance commission, sub-committees of gram panchayat, committees of Panchayat Samiti, meetings of gram sabha and gram panchayat, State election commission constitution and meetings of Zila Parishad and reservation of seats in Zila Parishad. When asked about the deficiencies in the Act (Table 3) , 66.7 per cent felt about the lack of powers and resources and 20.0 per cent stated lack of powers to inspect the government institutions. Their suggestions were that they should get powers and resources (66.7%) through proper executive orders from the government and joint meeting of the elected members with government (26.7%). (Table 3)

About their responsibilities, (Table 4) Panchayat Samiti members were not very clear as they had not been assigned any specific work. 36.7 per cent of them considered attending meetings as their responsibility while 16.7 per cent considered forwarding complaints of the sarpanches to the Chairman, Panchayat Samiti and solving disputes in the villages as their responsibilities. 13.3 per cent considered supervising the Gram Panchayats and construction works as their responsibilities.

Training Areas for Panchayat Samiti Members

- Certain content areas for the training of Panchayat Samiti members:
1. Provisions of the Haryana Panchayati Raj Act, 1994.
 2. Role of Panchayat Samiti members in development, emphasis on formation of Block co-ordination committee and its functions.

TABLE 3

DEFICIENCIES AND SUGGESTIONS IN THE HARYANA PANCHAYATI RAJ ACT ACCORDING TO PANCHAYAT SAMITI MEMBERS

Deficiencies and Suggestions	Panchayat Samiti Members n - 30 (%)
Deficiencies	
1. No powers and resources given	20 (66.7)
2. No power to inquire into records of Gram Panchayats and guide sarpanches	8 (26.7)
3. No power to inspect the government institutions	6 (20.0)
4. No deficiency	6 (20.0)
Suggestions	
1. Should get powers and resources	
2. No suggestions	20 (66.7)
3. Proper executive orders should be passed by government for greater powers	10 (33.3) 8 (26.7)
4. Joint meeting of Panchayat Samiti members should be organised with government departmental officers with BDPO and ADC to introduce and inform government functionaries about the role of elected members in supervision of the government employees	8 (26.7)

(Figures in parentheses indicate percentages)

3. Role of Panchayat Samiti in decentralised development planning, in consolidation of annual plans of Gram Panchayats and preparation of block development plan to be submitted to Zila Parishad.
4. Financial and executive management involving budgeting.
5. Behavioural aspects (Inter-personal behaviour and attitudinal change).
6. Meetings, leadership styles and communication skills development.

Zila Parishad Members' Competencies

Majority of the Zila Parishad members could tell about most of the structural provisions of the Haryana Panchayati Raj Act 1994, in details. None of them knew about the district planning committee and 3/4th did not know about State Finance Commission and sub-committees of gram panchayat. More than 1/2 did not know about the committees of Panchayat Samiti and the constitution of gram sabha.

The deficiencies in the Act as told by them (Table 5) were lack of powers over the government employees and Gram Panchayats, (83.3%) lack of funds for development, (75%) no provision for TA/DA (41.7%) and no staff under Zila Parishad (25%). They suggested adequate powers to be given to them by executive orders (62.5%) (Table 5).

Zila Parishad members (Table 6) had no responsibilities opined by 75.0 per cent of the members. Only the president and vice president talked about monitoring of utilisation of grants by the Gram Panchayats (8.3%) and solving the problems of the villages (8.3 %).

TABLE 4

MAIN RESPONSIBILITIES OF PANCHAYAT SAMITI MEMBERS AS TOLD BY THEM

Responsibilities		Panchayat Samiti Members n = 30 (%)
1.	To attend meetings	11 (36.7)
2.	No responsibilities	9 (30.0)
3.	Don't know	8 (26.7)
4.	To forward complaints of sarpanches (about encroachments) to Chairman P.S. and to BDPO	5 (16.7)
5.	To solve disputes in villages	5 (16.7)
6.	For development works in villages	5 (16.7)
7.	To supervise Gram Panchayats	4 (13.3)
8.	To supervise the construction works	4 (13.3)
9.	Inspection of PDS shops	1 (3.3)
10.	To educate illiterate members of P.S.	1 (3.3)
11.	To help in getting old age pension	1 (3.3)
12.	To help in P.S. work	1 (3.3)

(Figures in parentheses indicate percentages)

Training Areas for Zila Parishad Members

Content areas for the training of Zila Parishad members include: (i) Provisions of Haryana Panchayati Raj Act, 1994; (ii) meetings; (iii) behavioral aspects (attitudinal change and interpersonal behaviour); (iv) role of Zila Parishad members in development with emphasis on constitution of district co-ordination committee and its functions; (v) role of Zila Parishad members in decentralised development planning and (vi) financial and executive administration including budgeting, accounting, auditing, records, and reports.

In addition to the above topics vital statistics of the constituency, planning process in India, ability to prepare integrated and comprehensive plans based on a broad vision and knowledge of successes and failures of decentralised planning and implementation elsewhere were also identified.

TABLE 5
DEFICIENCIES AND SUGGESTIONS IN THE HARYANA PANCHAYATI RAJ ACT
ACCORDING TO ZILA PARISHAD MEMBERS

Deficiencies and suggestions	Zila Parishad Members n = 24 (%)
Deficiencies	20 (83.3)
1. No powers over the government employees or Gram Panchayats	
2. No funds for development, so felt helpless to solve the problems of villages (water, electricity, roads)	18 (75.0)
3. No responsibilities and no recognition	10 (41.7)
4. No TA/DA, honorarium	10 (41.7)
5. No staff under Zila Parishad.	6 (25.0)
Suggestions	
1. Government should give adequate powers by executive orders	15 (62.5)
2. Release of grants	14 (58.3)
3. TA/DA, honorarium	12 (50.0)
4. Political commitment was required, MPs and MLAs should not feel threatened.	8 (33.3)

(Figures in parentheses indicate percentages)

TABLE 6**MAIN RESPONSIBILITIES OF ZILA PARISHAD MEMBERS AS TOLD BY THEM**

Responsibilities		Zila Parishad Members n = 24 (%)
1.	No responsibilities	18 (75.0)
2.	Monitoring of utilisation of grants by Gram Panchayats	2 (8.3)
3.	To solve the problems of villagers	2 (8.3)

(Figures in parentheses indicate percentages)

RECOMMENDATIONS

Based on the findings of the study, the following recommendations are made to improve the performance of Panchayati Raj members so as to involve them effectively in local decentralised development planning, including health.

Policy Guidelines for the Training of Panchayati Raj Members

There is an urgent need to have clear cut and well defined policy guidelines for manpower development and training of Panchayati Raj members. The policy should envisage induction training for all the members elected for the first time. Orientation courses should be organised for the members with previous experience of working with PRIs. Refresher courses may be organised for all the members regularly to update their knowledge and skills. Policy decisions are also to be taken regarding venue, frequency and duration of training, allocation of financial resources, training infrastructure and facilities and establishment of evaluation procedures.

Manpower Development Cell for Panchayati Raj Members

Manpower development cell is needed at the State level. It should be headed by a full time senior officer with regular staff under the Director, Department of Development and Panchayats. Its main responsibilities should be to (i) assess the training load and the requirements of the elected members for training, (ii) prepare training manuals and guidelines, (iii) keep records of data about the training of the Panchayati Raj members, (iv) monitor the training programmes and (v) co-ordinate with the training institutes and provides feedback

for improvement. It will also review the training infrastructure and facilities from time to time so as to make necessary provisions on the basis of need.

State Training institutions

In Haryana, the State Community Development Training Centre (SCDTC) Nilokheri is responsible for providing training to village and block level panchayat members. It has eight faculty members and is conducting around 70 regular courses for government officials with around 4000 participants per year. The number of elected members in Haryana for village level is 60,117 and for the block level is 2528. In order to provide them induction training, around 1250 courses will be required to train 50 participants per course. As the training load is excessive to facilitate the training of elected members, it would be more practical to involve the district level training centres such as Krishi Gyan Kendra, District Training Teams and ANM training school. Institutes located in Gurgaon such as HIPA and SCERT (State Council of Educational Research and Training) can also be involved in providing training to the elected members. Besides, the SCDTC at Nilokheri needs to be strengthened by filling up of the vacant posts.

Haryana Institute of Rural Development, (HIRD), Nilokheri, has been assigned to train the Zila Parishad members whose number is 319. Around 10 courses will be required to train Zila Parishad -members within one year of their election. As the Institute has excellent infrastructure and facilities, it can provide both induction as well as refresher training courses to the Zila Parishad members.

Training Strategies

(i) The State level trainers after getting trained at the Central Institutes of .NIRD, Hyderabad or IIPA, New Delhi, should in turn train the trainers of district training institutions. Then the village and block level panchayat members should get training at the District Training Institutes. The duration of the induction training should be at least five days and for orientation and refresher courses^{4"5}, it should be two-three days. Refresher courses are needed once in every year. The number of participants per course should be limited to 40. The methodology of training should be through lectures, group discussions, role plays, case studies and demonstrations.

(ii) On the job training should be provided to the panchayat members during meetings and seminars by the Panchayati Raj administrators such as ADC, DDPO and BDPO.

(iii) A PRI newsletter should be started in local language for providing information on PRI activities covered by other PRIs as an experience sharing medium and also to provide information and guidelines on administrative procedures and rules.

Training Contents

Gram panchayat members need to be trained in (i) decentralization of planning, (ii) steps and mechanisms for implementation and monitoring of activities in sectors related to health and development, inter-sectoral co-ordination at local levels, (iii) resource mobilisation, (iv) communication skill development, and (v) organisation of meetings.

Panchayat Samiti and Zila Parishad members need training in (i) decentralised development planning, (ii) steps and mechanisms for inter-sectoral co-ordination of health and other development sectors, (iii) monitoring and supervision of implementation activities, and (v) behavioral aspects of personnel, particularly attitudinal change among them.

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प्रस्तुत लेख में हरियाणा राज्य के गुड़गांव जिले के स्वास्थ्य के साथ-साथ स्थानीय विकेन्द्रीकृत विकास योजना के संदर्भ में पंचायती राज सदस्यों की प्रशिक्षण संबंधी आवश्यकताओं का पता लगाया गया है। इस अध्ययन में पंचायती राज सदस्यों, प्रशासकों तथा पंचायती राज संस्थानों के प्रशिक्षार्थियों और सामुदायिक सदस्यों के शामिल किया गया था। जिन क्षेत्रों में ग्राम पंचायत समिति और जिला परिषद के सदस्यों को पूर्णतः प्रशिक्षित नहीं किया जा सका था उन क्षेत्रों की पहचान की गई थी। उन्हें स्थानीय स्तर पर नियोजन प्रक्रिया, साधनों की गतिशीलता, रिपोर्ट तैयार करने और आवश्यक रिकार्ड के रख-रखाव तथा बैठकों के आयोजन आदि के बारे में उनकी भूमिका और दायित्वों की जानकारी थी। प्रस्तुत लेख में आलेखकों द्वारा प्रशिक्षण संबंधी कुछ संशोधन करने का सुझाव दिया गया है ताकि स्वास्थ्य सहित स्थानीय विकेन्द्रीकृत विकास योजना के कुछ कार्यक्षेत्रों में उनकी सक्रिय भागीदारी सुनिश्चित की जा सके।

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A STUDY OF HEALTH PRACTICES AMONG THE ELDERLY IN FARIDABAD DISTRICT OF HARYANA

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ABSTRACT

This paper presents health practices related to smoking habits, alcohol taking habits and performance of regular exercise by the elderly persons in Faridabad district of Haryana State. The authors conclude that smoking was more prevalent among the rural elderly males as compared to their urban counterparts and bidi and hukkah were the popular forms among them. As far as alcohol taking habit was concerned, it was more prevalent among the urban elderly males but the frequency of intake was more among the rural elderly males. The performance of regular exercise by the elderly was much less prevalent in the rural areas.

During the past a few decades owing to several dynamic changes in the pattern and structure of the Indian society, breaking up of joint family systems, increasing cost of living, rapid urbanization and industrialization, the well-being of the elderly persons in India has been adversely affected. Various health practices prevalent among the elderly persons have definite impact on their status of health. Health is important in all phases of life irrespective of whether young or old. Smoking and alcohol intake are directly related to a number of diseases in the elderly population such as chronic bronchitis, lung cancer, coronary and artery diseases and liver disorders to quote a few. On the other hand, performance of regular exercise is known to guard against many diseases and help maintain a normal health.

MATERIALS AND METHOD

The study was carried out in the rural and urban areas of the district Faridabad of Haryana State. For the study in rural areas, Faridabad community

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development block was selected. Two primary health centres were selected from this community development block. Further, two sub-centres from each of the primary health centres were selected by a simple random sampling. For the study in the urban areas, New Industrial Town (NIT) zone of Faridabad complex was selected. From the New Industrial Town zone, six blocks were selected purposively to include all types of government health care facilities available in the area.

SAMPLE SIZE

Ten households with elderly couples and ten households with single elderly persons (widowed/divorced/separated) were selected by a systematic random sampling from each of the headquarter villages of the selected primary health centres, sub-centres and blocks in the urban areas (six villages and six urban blocks). Thus, in total thirty elderly persons from each of the six villages and six urban blocks (360 elderly persons) were selected for the study. Interview of the selected elderly persons was carried out using an interview schedule.

FINDINGS AND DISCUSSION

Smoking Habits

Regarding smoking habits of the elderly persons, they were divided into three groups viz non-smokers, current smokers and ex-smokers. Tobacco chewers were also included in the smoker groups. It was found that in the rural areas under the study, 57.6 per cent were current smokers and 13.7 per cent were ex-smokers. Among the elderly females, 21.5 per cent were current smokers. All of the rural elderly current smoker females were hukkah smokers except 2.7 per cent who were smoking both hukkah and bidi. In the urban areas, 27 per cent of elderly persons were current smokers and 20.9 per cent were ex-smokers (Table 1). Only 2.1 per cent of the urban elderly females were current smokers and were smoking hukkah.

Alcohol Taking Habits

The habits of alcohol taking among the elderly persons were divided into non-alcoholic, current alcoholic and ex-alcoholic. It was found that none of the elderly females both in the rural and urban areas had the habit of taking alcohol (Table 2). In the rural areas, 4.4 per cent elderly males were current alcoholics

TABLE 1
DISTRIBUTION OF ELDERLY PERSONS AS PER THEIR SMOKING HABITS

Rural						Urban				Total	
	Single		Couple			Single		Couple			
	Male	Female	Male	Female	Total	Male	Female	Male	Female	Total	
Non-Smoker	4 (2.2)	10 (5.5)	6 (3.3)	28 (15.5)	48 (26.5)	4 (2.2)	30 (16.6)	10 (5.0)	49 (27.2)	93 (51.0)	141 (38.2)
Current Smoker	21 (11.6)	9 (3.3)	48 (26.6)	29 (16.1)	107 (57.6)	11 (6.1)	1 (0.5)	34 (18.8)	3 (1.6)	49 (27.0)	156 (42.3)
Ex-Smoker	9 (5.0)	7 (3.8)	6 (3.3)	3 (1.6)	25 (13.7)	9 (5.0)	5 (2.7)	16 (8.8)	8 (4.4)	38 (20.9)	63 (17.3)
Total	34 (18.8)	26 (14.4)	60 (33.3)	60 (33.3)	180 (100)	24 (13.3)	36 (20.0)	60 (33.3)	60 (33.3)	180 (100)	360 (100)

(The figures in the parentheses denote the percentages)

and 8.8 per cent were ex-alcoholics while in urban areas 3.8 per cent were current alcoholic and 11.10 per cent were ex-alcoholic. Of the current alcoholics, 33.3 per cent were drinking alcohol rarely, 51.1 per cent were drinking only on social occasions, 11.1 per cent were drinking frequently and only 1.1 per cent was drinking daily.

TABLE 2
DISTRIBUTION OF THE ELDERLY PERSONS AS PER THEIR ALCOHOL TAKING HABITS

Rural			Urban			Total
	Single	Couple	Total	Single	Couple	Total
Non-alcoholic	52 (28.8)	104 (57.7)	156 (86.5)	45 (25.0)	92 (51.1)	137 (76.1)
Current Alcoholic	4 (2.2)	4 (2.2)	8 (4.4)	5 (2.7)	7 (3.8)	12 (6.5)
Ex-alcoholic	4 (2.2)	12 (6.6)	16 (8.8)	10 (5.5)	21 (11.1)	31 (16.6)
Total	60 (33.3)	120 (66.6)	180 (100)	60 (33.3)	120 (66.6)	180 (100)

(The figures in the parentheses denote the percentages)

The present study reveals that more elderly males and females in the rural areas smoked as compared to the urban areas. The current smokers (elderly females) in urban areas also had rural background. The finding is in agreement with the finding of the study conducted in Himachal Pradesh¹. Higher prevalence of smoking among the rural elderly may be attributed to the higher rate of illiteracy and ignorance of the harmful effects of smoking in the rural areas. Lack of various facilities for entertainment in the rural areas as compared to the urban areas also contributes to indulgence in smoking hukkah while the elderly persons in urban areas, they sit together and play cards. The prevalence of bidi and hukkah smoking among the rural elderly was high as compared to the urban elderly who smoked cigarettes more often. As far as smoking among the elderly females was concerned, it may be social stigma and better awareness among urban elderly females may have prevented them from smoking.

None of the elderly females in the rural and urban areas under study was taking alcohol. It may be due to socio-cultural values and stigmas prevalent in the Indian society. Among the elderly males alcohol taking habit was more prevalent among the urban elderly as compared to their rural counterparts. Most elderly males were taking alcohol on social occasions and habitual/regular drinking was not common among the urban elderly. Findings of the present study confirm the findings of another study which reported 5.14 per cent of the elderly males were addicted to alcohol². A study of elderly drug addicts of Haryana also found that only 7.0 per cent of the elderly were addicted to alcohol³. As found in various studies, alcohol intake was much less as compared to the smoking habit among the elderly. It may be attributed to the lower purchasing power and lower accessibility to alcohol by the elderly as compared to various means of smoking.

It was found that among the rural elderly males, only 5.0 per cent were performing regular exercise and none of the elderly females was performing regular exercise. On the other hand, in the urban areas, 34.3 per cent of elderly males and 13.8 per cent of elderly females were performing regular exercise. Commonest form of exercise among the elderly females was regular walks in the morning and after meals while the elderly males were performing yoga, walking, jogging and weight lifting, etc. (Table 3).

Very low prevalence of exercise performance among the rural elderly may be due to their low level of educational status, poor awareness of benefits of exercise and lack of health consciousness as compared to their urban counterparts.

CONCLUSION

Smoking was more prevalent among the rural elderly males as compared to their urban counterparts and bidi and hukkah were the popular forms among them. Alcohol taking habit was more prevalent among the urban elderly males but the frequency of intake was more among the rural elderly males. The habit of doing regular exercise by the elderly was much less in the rural areas.

TABLE 3
DISTRIBUTION OF THE ELDERLY PERSONS AS PER THE PERFORMANCE OF EXERCISE

Rural						Urban				Total	
	Single		Couple			Single		Couple			
Regular exercise	Male	Female	Male	Female	Total	Male	Female	Male	Female	Total	
Performers	3 (16)	-	6 (3.3)	-	9 (5.0)	10 (5.5)	7 (3.8)	52 (28.8)	18 (10.0)	87 (48.3)	96 (26.6)
Non-performers	31 (17.2)	26 (14.4)	54 (30.0)	60 (33.3)	171 (95.0)	14 (7.7)	29 (16.1)	8 (4.4)	42 (23.3)	93 (51.7)	264 (73.3)
Total	34 (18.8)	26 (14.4)	60 (33.3)	60 (33.3)	180 (100.0)	24 (13.3)	36 (20.0)	60 (33.3)	60 (33.3)	180 (100.0)	360 (100.0)

(The figures in the parentheses denote the percentages)

RECOMMENDATIONS

1. Regular health talks can be organised by the health functionaries at the village level, involving the Panchayat members, community leaders and voluntary workers where elderly persons can be invited and the importance of healthy lifestyle and health practices can be discussed.
2. Medical officers can also organize health talks for the elderly at the primary health centre level. During eye camps in the rural areas, health education can be given regarding health practices.
3. Mass media can be utilised to deliver messages regarding health care, importance of exercise and other preventive aspects of health care.
4. In the urban areas, counseling for healthy practices can be given through the geriatric clinics wherever they are available.

Lkkjk'k

प्रस्तुत लेख में हरियाणा राज्य के फरीदाबाद जिले में वृद्धजनों की धूम्रपान संबंधी आदतों, शराब पीने की आदतों और नियमित व्यायाम करने संबंधी स्वास्थ्य आचरण के बारे में उल्लेख किया गया है। लेखकों द्वारा यह निष्कर्ष निकाला गया है कि शहरी वृद्धजनों की अपेक्षा ग्रामीण वृद्धों में धूम्रपान का प्रचलन अधिक था और उन्हें बीड़ी तथा हुक्का अधिक पसन्द थे। जहां तक शराब पीने की आदत का संबंध था, शराब पीने की लत शहरी वृद्धजनों में अधिक प्रचलित थी, किन्तु शराब पीने की वारंवारता ग्रामीण वृद्धों में अधिक पायी गई थी। ग्रामीण क्षेत्रों के वृद्धों द्वारा व्यायाम कम ही किया जाता था।

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