Chapter-V
DISCUSSION

It is estimated that CVD will be the largest cause of disability and death in India, with about 2.6 million are predicted to die due to coronary heart disease (CHD), which constitutes 54.1% of all CVD deaths in India by 2020 (NNMB Technical report 2017). In addition, CHD in Indians has been showing to occur prematurely, that is atleast a decade or two earlier as compared to those in developed countries. Hypertension is important risk factor for CVD alongside overweight and obesity and is a major public health problem in developing countries around the world. Metabolic Syndrome is a complex web of metabolic risk factors that are linked with a 2-fold risk of CVD and a 5-fold risk of diabetes (NCEP ATP-III 2002, Sattar N et al, 2003). Individuals with Metabolic Syndrome have a 30%–40% likelihood of developing CVD within 20 years (NNMB Technical report 2017). Interest has increased in the use of diet and lifestyle rather than drugs for the prevention and management of hypertension and cardiovascular disease. Now a day’s reducing the incidence of CVD through dietary intervention is a major focus of health organizations worldwide as the dietary habits are highly modifiable and can be a potent risk factor for the development of CHD. But it is not easy to get people to make drastic changes in their eating habits, but specific foods can be helpful in preventing or treating these metabolic disorders.
Recently, the U.S. FDA allowed a claim for β-glucan soluble fiber from whole-grain barley and certain barley milling fractions for reducing plasma cholesterol levels and reducing the risk of heart disease (US FDA 2006). The claim for barley β-glucan is an extension to an existing U.S. FDA claim for oat soluble fiber in lowering cholesterol because both cereal grains are believed to contain soluble fiber with similar physiological effects (Nancy et al 2008). The National Cholesterol Education Program and the National Academy of Sciences in the United States recommending 20–30 g/d of dietary fiber and at least 5–10 g/d of soluble fiber (NCEP ATP-III 2002). Barley foods could help peoples to achieve these dietary goals. The role of barley β-glucan in reducing risk factors associated with CVD (e.g. high cholesterol) is the focus of many studies. Another motivation for advancing barley research is the potential for barley foods to improve consumer health and reduce the risk of prevalent diseases such as cardiovascular disease (CVD) or heart disease. Modifying risk factors through dietary intervention offers great potential for reducing the incidence of CVD. The consumption of dietary fiber, especially water-soluble fiber, has been shown to be inversely associated with coronary heart disease (Anderson JW 1995, Pereira et al 2004).

Therefore keeping in view the magnitude of Non communicable disease, this study has been carried out to know whether the addition of barley (a grain not frequently consumed by Indians) having high amount of soluble fiber (β-glucan) as a part of the heart healthy can affect the risk factors related to cardiovascular diseases. The findings of this study are being discussed under the following heads.
5.0: General characteristics of the respondents who were included in this study after screening for stabilization.

5.1: Baseline characteristics & disease profile of the study subjects.

5.2: Lifestyle (behavioral) determinants of study subjects at baseline and during of the trial.

5.3: Differential patterns of food & nutrient intake at screening, baseline and throughout the intervention.

5.4: Effect of intervention on blood pressure, body composition, blood lipid profile and glucose metabolism.

The present study was completed in three phase.

Phase I (Enrollment): Recruitment of participants having metabolic Syndrome.

Phase II (Stabilization): Stabilization of diet of all respondents (selected after screening) for four week.

Phase III: Randomization, introduction of barley in the intervention group and monthly follow up for three month.

Flow diagrams showing the process of inclusion of respondents.
During the first phase a total of 1020 patients were screened as they were suspected to have metabolic syndrome, only 278 met the inclusion criteria and they were stabilized for four week. Only 258 were successfully completed the stabilization phase and still met all inclusion criteria. At the end of this study (after 12 week) overall 205 patients were successfully completed all the follow-ups.

5.0 General Characteristics of the Respondents who were included in this study after Screening for Stabilization (n=278)

[I. Participants included in this study for stabilization (n=278)]

Out of 278 respondents, more than half 58.6% of the respondents were males and 41.4% were females. On the contrary, a study in urban healthy population of Eastern India by Prasad et al (2010) reported age-standardized prevalence rates of metabolic syndrome was 33.5% overall, 24.9 % in males and 42.3% in females. Another study carried out in Chennai proportion of metabolic syndrome reported higher proportion among male by using WHO definition (Deepa et al 2007). NNMB technical report (2017) showed that prevalence of hypertension and diabetes increased with age in both the genders. However in the present study, highest proportion of metabolic syndrome patients belonged to the age group of 41-50 years followed by 29.1% in the age range between 51-60 years, and 19.4 % in the age range of 31-40 years. (Deepa et al 2007) reported the mean age of metabolic syndrome patients was 47± 12 years which is very close to the findings of the present study in which the mean age of the respondents was found to be 51 years. Likewise in another study, mean age was found to be 46 years among adult male with Metabolic Syndrome (Madan et al 2015). One more study which was conducted in eastern India patients
with metabolic syndrome having the mean age of 51.66 ± 11.9 years (Prasad et al 2010).

Majority of the respondents belonged to Hindu religion (91.2%) followed by (8.8%) were either Muslim or belonging to other religion. It may be due to that this region was predominant with Hindus. Nearly half of the respondent’s belonged to rural area (48.9%) followed by more than one third 35.6% from urban area and only 15.5 % respondents from slum area. As per the family type, more than half (56.1%) of the respondents belonged to the nuclear family structure and 43.9 % respondents were from joint family. Literature seems to be silent about such distribution in the trials of nutrition. This was studied here to understand the demography of the respondents who were included for this study.

In the present study, nearly one-third (27.7%) of the respondents with metabolic Syndrome belonged to upper-middle class followed by 21.6% from lower-middle, 18.7% from upper socio-economic class, 17.3% were from middle class and 14.7% from lower socio-economic status. However a study from eastern India showed highest proportion of metabolic syndrome patients belonged to middle class (76.8) followed by 12.4% were belonged to Lower class and only 10.8% were from Upper class (Prasad et al 2010). Majority (88.8%) of the respondents were married. In the present study, metabolic syndrome was more prevalent in upper socioeconomic classes compared to lower socioeconomic strata. Accordingly, upper socioeconomic status has emerged as an independent risk predictor for metabolic syndrome. Similar observations were noted in persons belonging to middle income groups who had significantly higher prevalence of metabolic syndrome from a study in urban south
India (Mohan V et al 2001). In this study more than one third (37.0%) respondents were educated up to graduation and above. Likewise another study also supported the present findings with (34.8%) metabolic syndrome patients were graduated (Prasad et al 2010). With regard to the occupational status of respondents, about one-third (32.7%) of the respondents were engaged in either govt. or private jobs and very few were involved in business activities. On the contrary, an Indian study among diabetic patient reported that 46.67 % were involved in business activity while the remaining 53.33 % were in different jobs (Rupam et al 2011).

**Figure 5.0.1: Respondents' distribution according to their physical activity pattern.**

In this study only 15.1% indicated that they were involved in some form of physical activity (other than daily routine), while 84.9% respondents did not involve in any type of physical activity Figures 5.0.1. In a study among hypertensive patients reported 80% respondents were lead sedentary lifestyle while the remaining 20%
were moderately active. (Rupam et al 2011). Furthermore physical activity levels are decreasing in Asian Indians and a study reveals that 43% of the subjects with metabolic syndrome were physically inactive (Prasad et al 2009). Physical inactivity is a predictor of CVD events and related mortality. Many components of metabolic syndrome are associated with a sedentary lifestyle, including increased adipose tissue (predominantly central), reduced HDL cholesterol, and a trend toward increased triglycerides, blood pressure, and glucose in the genetically susceptible.

In this study nearly half (47.3%) of the respondents reported to have positive family history of hypertension followed by one-third (38.9%) of the respondents having positive family history of diabetes in their first degree relatives. Among 278 respondents nearly only one-fifth (18.6%) respondents reported to have heart disease in their family members. Such findings confirm that the genetic predisposition of hypertension may be higher than expected. On the contrary in most of the developing countries hypertension is strongly influenced by the lifestyle practices and environmental factors other than genetic predisposition (Forrester et al 1998, Salmond et al 1989).

Furthermore WHO (2010) reported the prevalence of daily tobacco smoking is 25.1% in Indian population while in this study 32.5% respondents were smoking different product of tobacco including cigarette/beedies/cigar and nearly one-third (29.6%) of respondents were consuming alcohol. This finding also corroborated with another study the prevalence of smoking was found to be 23% in eastern India (Prasad et al 2010).
Dietary intake pattern plays a significant role in human health. Cereals formed the bulk of the diet for Indian population; the consumption of cereals and grains was comparatively high. As shown in the figure 4.0.5. Nearly half 48% respondents consuming 9-15 servings of cereals per day and 18% were consuming >15 servings per day. While the recommendations for metabolic syndrome patients were 9-12 servings/day. Similarly for the pulses intake, very few 12% of the respondents were consuming adequate amount of pulses however majority 88% respondents were having below the recommendations. Green vegetables is a most important part of our diet but findings showed majority 91% respondents were having less than 2 servings per day that is too below the recommendations for metabolic syndrome patients that is 3-5 servings/day. On the contrary, about half of the respondents were came within the recommendation limit for root and tubers intake or higher and similar proportion (52%) of respondents were consuming lower than the recommendations. The daily intake of root and tubers was comparatively higher as compared to other vegetables in metabolic syndrome patients. Similarly, 2-3 serving of fruits were consumed by only 9% of respondents and 21% of the respondents were consuming <2 times servings. While the recommended servings are 2-3 servings/day, majority 72% were not in the habit of consuming fruits on a daily basis. For the consumption of milk and milk product, the recommended portions for metabolic syndrome patients is 2-3 servings per day however about more one third populations were not consuming milk on a daily basis followed by 34% were having < 2 portions of milk and 11 % were having >3 servings in a day before stabilization. The overall dietary intake of the respondents in this study was very poor, very few respondents were found to consume the recommended amount of pulses, green vegetables and fruits. Metabolic syndrome is a
heterogeneous outcome; thus, no single pathogenesis has been involved. Unhealthy eating practices were seen among the respondents in this study. It has been suggested that inclusion of more fruits and vegetables in a diet has been associated with lower blood pressure and may be associated with improved fasting lipid profile (Lichtenstein et al 2006). Findings from Bogalusa Heart Study, Young adults who had no risk factors consumed high fruits and vegetables and less sweetened beverages than those who had 1 risk factor (Yoo S et al 2004). A cross-sectional study which was conducted on 486 Tehranian adult females in the highest quintile of fruit and vegetable consumption showed a 10% to 40% and 14% to 38% lower likelihood of having metabolic syndrome compared to those in the lowest quintile of the Fruit and vegetables intake respectively (Esmailzadeh et al 2006).

II. Participants after Complete Follow-up: (n=205)]

5.1 Baseline characteristics and disease profile of the study subjects

This section deals with the baseline characteristics & disease profile of the respondents in the intervention and control group respondents hypothesising that “there is no significant difference between the intervention and control group with respect to the baseline characteristics and disease profile.

5.1.1 Socio-demographic Profile of the Respondents

In the present study, majority 57.1% of the respondents were male (59.6% in intervention and 54.5% in control) and 42.9% were female (40.4% in intervention and 45.5% in control. On the contrary in other study women were found in higher proportion 52.2% of metabolic syndrome compared to men 34.2% (Prasad et al
In NHANES III data, the prevalence differed little among men 24.0% and women 23.4% (Park et al 2003). However, in many of the studies worldwide and in Indian subcontinent, women had a higher prevalence of metabolic syndrome (Mabry RM et al 2010, Khanam MA et al 2011). It was mainly attributed due to the higher waist circumference among women.

In this study nearly one third (33.7%) of the respondents (34.0% in intervention group and 33.7% in Control group) were between the age range of 41-50 years followed by 31.2 % (30.1% in Intervention and 32.7% in Control) in the age range of 51-60 years. The mean age of the respondents was 49.4 ±9.2 years and 52.4±9.6 years, in Intervention group and Control group, respectively. There was no significant difference (p=0.40) between the two groups regarding the sex and age wise distribution. Prasad et al (2010) also found that the prevalence of metabolic syndrome increased with age in both sexes. This findings was consistent with other studies where mean age of metabolic syndrome patients was 52.1 ±16.7 years (Muzio et al 2007).

Majority 94.6% of the respondents were Hindus with the distribution of (94.2% in intervention & 95% in control). More than half (57.1%) of the respondents in both the groups belonged to rural area followed by 27.3%, who were from urban areas. Proportion of respondent’s belonged to rural area was higher (61.4%) in the control group as compared to 52.9% in the intervention group. However the residence wise distribution also showed insignificant (p=0.33).

This study found more than one-third (35.6%) of the respondents in both intervention and control group were educated up to graduation level or above and
36.1% (38.5% in intervention and 33.7% in Control group) were educated up to Secondary & higher secondary level. (Table 4.1.2) and nearly one third 34.1% respondents were housewives (34.6% in intervention group and 33.7% in Control group) followed by 30.7% (28.8% in intervention group and 32.7% in Control group) were doing govt. or private job. No significant differences (p =0.856) has been observed in both the group regarding their education and occupational status. In spite of thorough search, literature was not available to corroborate with the present findings out of other nutritional trial. Therefore, this study can be used in further interventional study as reference.

Figure 5.1.1: Socio-economic status of the respondents among intervention and control group

![Figure 5.1.1: Socio-economic status of the respondents among intervention and control group](chart)

On the basis of economic status more than one fourth 27.3% respondents (29.8% in intervention group and 24.8% in Control group) belonged to upper middle class followed by 22.0% were from lower middle class (Table 4.1.3). There was insignificant difference in both the group with reference to economic status. The
above findings confirm that both the intervention and control group were well matched as per the socio-demographic characteristics at baseline.

5.1.2 Present History of Diseases & Co-morbid Conditions

Among five components of metabolic syndrome the highest proportion of respondents were hypertensive which was 82.7% in the intervention group and 81.2% in the control group Figure 5.1.2. Likewise another study from eastern India among metabolic syndrome patients reported the proportion of increased Blood pressure was 89.2% which is very close to the present study (Prasad et al 2010).

Figure 5.1.2: Distribution of components of Metabolic Syndrome at Baseline

Another study by Muzio et al (2007) reported the prevalence of hypertension was 96%, high blood pressure was found to be most commonest component of metabolic syndrome in any population. Hypertriglyceridemia was the second most common component found in this study which was 78.8% and 79.2% in intervention and control group respectively. However high blood triglycerides were found among
56% of respondents (Muzio et al 2007). A similar study done in India by Prasad et al (2010) reported the prevalence of hypertriglyceremia was 67.0% and 83.9% were having central obesity (high waist circumference). However in the present study nearly three fourth 73.1% of the respondents in both the groups had central obesity which is comparatively lower in this study. (Muzio et al 2007) found 100% prevalence of central obesity followed by 64% were suffering from hyperglycemia which is very similar to the findings of our study where hyperglycemia was found among 69.2% and 63.4% of respondents in the intervention and control group respectively. Low proportion was observed for low HDL cholesterol in both the group (58.9%) however, (64%) of low HDL was reported by another study (Prasad et al 2010). In contrast to the present study low HDL is very common among Asian Indians and is corroborated also by various studies across South Asia (Khanam et al 2011, Basit A et al 2008). Nearly half of the respondents had three components of metabolic syndrome followed by 37.5% respondents in the intervention group and 28.7% had 4 components of metabolic syndrome. However another study carried out by Muzio et al (2007) found 46% respondents had 3 component followed by 38% had 4 component.

5.1.3 Treatment Profile and Family History of Diseases

Due to the ethical reasons, we could not ask the patients to stop using medicines to participate in this study, but there was no statistically significant difference between the groups when they were compared (Table 4.1.5). Overall 78% respondents were taking medicines at baseline however majority of them were on
anti hypertensive medications. All the respondents were asked to maintain a stable dose of medicines throughout the whole duration of the trial (Table 4.1.5).

As the genetic factors play a major role in the occurrence of chronic diseases, accurate knowledge of a patient's family history may identify a predisposition to developing certain illnesses, which can inform clinical decisions and allow effective management or even prevention of conditions.

**Figure 5.1.3: Participants family history of Hypertension.**

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=104)</th>
<th>Control (n=101)</th>
<th>total (n=205)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No family history</td>
<td>50%</td>
<td>42.6%</td>
<td>46.3%</td>
</tr>
<tr>
<td>Father</td>
<td>23%</td>
<td>31.6%</td>
<td>28.7%</td>
</tr>
<tr>
<td>Mother</td>
<td>15.3%</td>
<td>15.8%</td>
<td>15.6%</td>
</tr>
<tr>
<td>Siblings</td>
<td>19.2%</td>
<td>18.8%</td>
<td>19.2%</td>
</tr>
</tbody>
</table>

In this study out of 205 respondents, nearly half (46.3%) of the respondents reported negative history of hypertension in their first degree relatives (50% in intervention & 42.6% in control). Nearly one third 28.7% (23% in intervention & 31.6 % in the control) of all participants reported that their father had suffered from hypertension followed by 19.2% reported hypertension in their siblings and 15.6% respondents mother were suffered from hypertension. Likewise in another study (48.6%) respondents reported the presence of a family history of hypertension.
compared to (51.3%) who did not have a family history of the disease (Zungu et al 2008). Of those participants who reported a family history of hypertension, (77.8%) stated that it was related to their parents, (14.2%) to their grandparents (Zungu et al 2008). Another study by Mandal et al (2009) among hypertensive patients, reported 65.4% respondents had negative history of hypertension in their family. In the present study negative family history of diabetes was reported by majority 66.8% (69.2 % in intervention & 64.3% in control) of the respondents. Of all participants 15.1% (16.3% in intervention & 13.8% in control) stated that it was related to their father followed by 11.7% (10.5 % in intervention & 12.8% in control) to their mother. However the distribution was similar between the groups thus both the groups were comparable. Very few respondents reported having positive history of heart disease in their first degree relatives and insignificant differences was observed between the two groups regarding the family history of heart disease (p=0.82) (Table 4.1.8)

5.2 Lifestyle (behavioral) determinants of Study Subjects

Lifestyle characteristics such as physical activity pattern and substance abuse were also addressed in this study to know whether both the groups were followed the similar pattern as designed in the study protocol, as these risk factors can directly affected the primary outcomes of this study.

5.2.1 Physical Activity Pattern

There is definite epidemiological evidence that major four lifestyle risk factors such as smoking, heavy drinking, poor diet, and physical inactivity contribute to the development of metabolic syndrome and chronic diseases (McGinnis et al 1993, Mokdad AH et al 2000). Researches also suggest that these lifestyle risk factors are
Discussion

not randomly distributed, but that they tend to cluster with other unhealthy behaviors within individuals (Poortinga W 2007 Schuit et al 2002). Majority of the respondents in this study were reported to lead sedentary or lightly active life style although very small proportion, about one third, were engaged in moderate or strenuous activities (Tables 4.2.1). The proportion of respondents with sedentary lifestyle in the intervention and control group were 36.5% and 35.6% respectively followed by 35.6% were lightly active in the intervention group and 31.7% were in the control group, however the similar proportion of respondents with sedentary, moderate or heavy lifestyle were distributed between the intervention and control group at baseline.(p=0.60)

Physical activity pattern of the respondents revealed that in the intervention group only 24.1% were engaged in physical activity at baseline that shifted to 34.6 % at the end (12-week) (Table. 4.2.2). It was mainly because of the general recommendations by the physicians at each visit. Similarly in the control group this proportion increased from 22.7% to 30.6 % at the end. However within the group changes were not reached to significant level in any of the group similarly between group differences was also insignificant at baseline (p=0.48) and at the end (p=0.32).

As far as the type of physical activity was concerned, both the groups were similar on the basis of frequency of physical activity and no significant difference was observed. (p=0.71) Only 7.7% in the intervention group and 5.9% in the control group were regularly practicing physical exercise at baseline however at the 12-week this proportion increased to 9.9% and 8.9% in the intervention and control group respectively. Most of the respondents shifted to do physical activity 3-5 times in a week.
Furthermore the changes (within group) were very small in both the groups and it was found to be insignificant. However the recommendation for physical activity was brisk walking for 30-45 minutes at least 4-5 times in a week (NCEP 2002). Very few respondents were following the recommendations; it is due to the fact there was no strict protocol for the physical exercise in this study. This study was focused mainly on the diet intervention but lifestyle assessment were also carried out because these factors are directly associated with the primary outcomes. As expected and according to the protocol, both the groups were following the same pattern of physical activity and no significant differences were observed between the two groups at baseline and end of the trial.

Within group test also proved to be insignificant in both the groups indicated that respondents in the intervention and control group did not change their lifestyle pattern throughout the whole duration of the study. Thus physical activity pattern of the respondents could not change the primary outcomes of this study.

5.2.2 Addiction Pattern of the Respondents at Baseline and throughout the Trial

Prevalence of traditional risk factors for cardiovascular diseases are presented in Table 4.2.6. Out of 205, 37.1% of the respondents (39.4 % in intervention and 34.7% in control) were never addicted to any harmful substances in their life while half (50.0%) of the respondents (50.0% in intervention and 50.5% in control) were currently taking some type of harmful substances and 12.7% respondents were addicted in the past. Cigarette smoking is a well-established cause of CHD and the leading cause of death in the world. It may confer even greater risk of CHD in women than in men. The Nurses’ Health Study found a positive association between the
number of cigarettes smoked per day and risk of fatal CHD (RR of 5.5 for ≥ 25 cigarettes per day) and nonfatal MI (RR of 5.8) (Willett WC et al 1987). Smoking cessation substantially cuts the risk of CHD. Estimates indicate that it eliminates one third of the excess risk within 2 years and after 10 to 14 years returns risk levels to those of people who have never smoked (Kawachi et al 1997). Similar benefits have been seen for total mortality and people who stop smoking experience immediate and long term declines in excess risk of CHD and total mortality.

In the present study, 71% respondents in the intervention and 66.3% in the control group reported that either they never smoked or left in the past while 11.5% in the intervention and 11.9% in the control group were smoking ≥6 times in a week. No significance difference was observed between the two groups at baseline (p=0.89). This proportion reduced to 1.9% in the intervention and 4.9 % in the control group at the end of trial. Within group changes revealed insignificant (p=0.07) in the intervention group at 12 week however control group was not reached to the significant level (p=0.13).

Regarding the tobacco intake, at baseline 77.9 % in the intervention and 68.3 % in the control group reported either they never consumed or left in the past however this proportion increased to 86.5% and  81.1 % in the intervention and control group respectively. In the intervention group, 9.6% respondents were taking tobacco 4-5 times in a day followed by 6.7% were taking ≥6 times in a day. Differences between the groups were insignificant at baseline and 12 week while control group showed the significant differences after 12 week (p=0.02). While a study by Rupam et al (2011) reported that 43.3% male was consuming tobacco.
Nearly one fourth of the respondents stated that they were consuming alcohol. Among them 10.6% were occasional user in the intervention group and 12.9% in the control group. Most of the respondent who were consuming alcohol 4-5 times in a week, shifted to either occasional or formal users. Between group differences also proved insignificant at baseline (p=0.54) and at the end (p=0.65).

Numerous epidemiologic studies show an inverse association between alcohol consumption and risk of CHD in both men and women. In general, consumption of 1 or 2 drinks per day reduces risk by approximately 20% to 40% (Rimm EB et al 1996). Light to moderate alcohol consumption has also been associated with a lower risk of stroke. A meta-analysis of 42 published controlled studies estimated that the HDL-raising effect of 30 g/d of alcohol decreased CHD risk by 17%. In addition, a decline in fibrinogen lowered CHD risk by 13% (Rimm EB et al 1999). However, in the current study respondents were consuming more alcohol (4-5 times) but later shifted to occasional or never users at the end of this study.

5.3 Differential Patterns of Food & Nutrient Intake

Adherence to Dietary Protocol

Adherence to the dietary recommendations was good in both the group throughout the intervention trial. During the intervention, both groups reported to follow the similar dietary pattern as they were recommended on the basis of individual requirement and no significant differences was observed between the groups throughout the study period. In the intervention group, all the respondents consuming the recommended portions of barley with the controlled diet which was patterned according to the NCEP Step I diet plan for three month. During the
intervention period the reported daily intakes of barley in the intervention group was averaged 121±20.1 gm/day and zero in the control group. The average increase in soluble fiber through addition of barley (β-glucan) as compared to baseline intake was 3.19 g/d during the trial and it was shown to increase significantly from the control group. (p<0.001) Overall, the current evidence suggests that lifestyle interventions have beneficial effects on total and cardiac mortality, morbidity, and on behavior change in relation to modifiable cardiac risk factors. Lifestyle changes strongly reduced the prevalence of metabolic syndrome in the intervention group compared to controls, with an absolute risk reduction (ARR) of 31% (95% CI 21–41) and a relative risk reduction (RRR) of 47% (95% CI 33–58) (Simona et al 2000).

The results from this study showed that majority (61.9%) were non-vegetarian. The proportion of non-vegetarians was little higher among the intervention group 65.3% as compared to 58.4% in the control group, although the differences was not statistically significant (p=0.31). This findings were consistent with the other studies from India e.g. Khogare et al (2012) reported the proportion of non-vegetarians in this study are 69.2% in a sample of Hypertensive patients. The type of diet consumed also has various implications on Metabolic Syndrome. A vegetarian diet consists of mostly food items that are from plants and plant products.

The vegetarian dietary pattern has shown to lower the risk of Metabolic Syndrome. Rizzo et al (2006) studied various dietary patterns and looked at their association with Metabolic Syndrome and its risk. Among subjects of 30-94 years of age, dietary intake was assessed and classified them into three categories – as vegetarian (consuming meat, poultry or fish <1 time in a month), semi-vegetarian (consuming fish at any frequency but other meats <1 time in a month), and non-
vegetarians (consuming red meat or poultry ≥1 time/month). BMI was lowest in vegetarians and highest in non-vegetarians. Metabolic Syndrome was classified according to the ATPIII criteria, with maximum number of components (i.e. 5) for non-vegetarians. TG, FBG, BP, WC and BMI was significantly lower in vegetarians as compared to non-vegetarians (p<0.05). Similar finding by Toohey et al (1989) was observed in case of male and female vegans and lacto-ovo vegetarians; with significantly lower BMI, TG level, TC/HDL ratio among vegans as compared to lacto-ovo vegetarians (p<0.05). Vegans also demonstrated more favorable serum lipid profile as compared to lacto-ovo vegetarians.

In this study more than half 56.1% (52.9% in intervention and 59.4% in control group) indicated having meals 2 times on a daily basis followed by 39% having their meals three times in a day. It may be due to the fact that most of the respondents in this study belonged to rural areas and they preferred to take their meals two times in a day. However the proportion of 3 meals in a day was about 10% higher in the intervention group but this difference was not significant (p=0.42). Participants were also asked about the frequency of addition of salt to their cooked food. Less number 20% (18.3 % in intervention and 22.8% in control group) respondents indicated always adding salt in their food followed by 43.4% reported sometimes and remaining never in the habit of adding salt on a table. During the stabilization after the diet counselling most of the respondents who were always adding salt in their table were shifted to sometimes users. The proportion of sometimes users was comparatively higher (51% vs. 35.6%) in the intervention group although it was not significant statistically (p=0.08).
Based on dietary records, present study showed no significant differences in the mean intake of energy and nutrients between the two groups at baseline. However, the aim of this study was not to evaluate the food intake but to establish that the nutrient intake did not change significantly between the intervention and control group throughout the intervention periods. There were no significant differences regarding calorie intakes in the intervention group (2028±358 kcal/day) and control group (2052±390 kcal/day) during the trial.

In this study, both the groups slightly decreased energy intake over the 3-month of study period similarly for the protein intake, it was slightly decreased at 4-week in the intervention group but again it was increased at 8 and 12-week. Previous research suggests that consuming high amounts of dietary fiber may reduce energy intake as a result of reduced hunger and thus lead to weight loss Slavin JL (2005). Carbohydrate intake was decreased over the time but it was greater in the control group compared to intervention group (time effect=0.03). In both groups, consumption of total fat was decreased by the length of time and significant effect of time were observed for the percentage of energy provided by total fat (p=0.03) although there was no significant time by group interaction for calorie, protein and carbohydrate intake.

In this study saturated fat and percentage of energy provided by saturated fat decreased over time (p<0.001), whereas energy provided by polyunsaturated (PUFA) and monounsaturated (MUFA) fat was increased. Compared with the baseline values, ingested polyunsaturated fat, monounsaturated fat and percentage of energy provided by PUFA and MUFA increased over time in both groups. Increased intake of MUFA
and PUFA was observed because the intake of saturated fat was decreased over time. Although no significant differences were observed regarding type of fat intake between the intervention and control group throughout the intervention. In this study the percentage of energy provided by fat was averaged 25% of total energy intake and percentage of energy provided by saturated fat was 7% followed by about 8.3% from polyunsaturated fat and 10.4% from monounsaturated fats. The intake of different types of fat in this study was very close to the recommended level given by NCEP ATP-III step I diet plan which was ≤30% of total energy as fat, ≤10% of energy as SFA, and ≤300 mg dietary cholesterol/d. However, in 2001 the NCEP released revisions to the ATP III guidelines increasing total fat to 25–35% of energy, allowing a specific increase in MUFA intakes of up to 20% of energy, with a recommendation for replacing CHO with unsaturated fats for individuals with DM or Metabolic Syndrome (NCEP ATP-III 2001). Of interest, the current NCEP ATP III recommendations mirror the dietary fat profile of the Mediterranean diet (Willett WC et al 1995, Jimenez F et al 2002).

Recently, the Joint FAO/WHO Expert Consultation on Fats and Fatty Acids (2010) in Human Nutrition recommended that MUFA intakes be 15–20% of energy, according to total fat intakes. A number of prospective cohort studies have directly addressed associations between dietary fat and risk of CHD. Hu et al (1997) conducted a detailed prospective analysis among 80,082 women aged 34 to 59 years in the Nurses’ Health Study. Findings showed significant relations between CHD risk and types of fat rather than total amounts of fat. Higher intake of saturated and trans fatty acids was associated with increased CHD risk, whereas greater intake of polyunsaturated and monounsaturated fats was associated with decreased risk.
In fact, the nutrient and dietary fiber intakes did not markedly differ between the two groups at baseline whereas significant differences was found between the two groups at 4, 8, and 12 weeks of intervention. It was mainly due to the intervention strategy that barley was included in the intervention group after randomization which contains high amount of dietary soluble fiber (β-glucan). In this study both the groups significantly increased the intake of total dietary fiber during the intervention period. The mean total dietary fiber intake in this study was 31.5 gm in the intervention group and 28.5 gm in the control group. However the suggested intake of total dietary fiber is 25-40 gm/day or 12-14 gm/1000 kcal energy. (ICMR 2010) Intervention group approximately reached to recommended level because of addition of barley. Intervention group also attained the ATP III guidelines goal of at least 3 grams of viscous soluble fiber/day when the barley was added to the background dietary soluble fibre intake. 24- Hour food recall obtained at baseline and at each study visit indicated that subjects were generally compliant with overall diet recommendations.

There was a significant interaction of time × group for total dietary fiber and soluble fiber intakes (0.02 and 0.007, respectively); total dietary fiber and soluble fiber intake was significantly higher in the intervention group as compared to control group whereas no significant differences was found for the insoluble dietary fiber intake between the two groups. Thus, the primary outcomes (Blood pressure, fasting lipid profile and fasting blood glucose) and the secondary outcomes (Anthropometric measurements and body composition) were attributable to the barley diet in the intervention group.
Discussion

Regarding the micronutrient intake of the respondent at baseline (end of stabilization phase), it was found that no significant difference for any micronutrient at baseline except the zink intake. Zink intake was comparatively higher in intervention group (4.54±1.4) compared to control group (4.13 ± 1.1) (p=0.02). Although the findings of this study observed noticeable changes in dietary habits between the two groups, the objectives set for the subjects were not fully met for the sodium intake among both the groups but both the groups reduced their sodium intake over the duration of trial. In this study the intake of sodium was 2663 mg/day in the intervention group and 2674 mg/day in the control group whereas the recommended level of sodium intake is about 2500 mg/day. (WHO 2010)

Similarly the potassium intake also increased over time in the control group, although the changes were minimal. The average potassium intake in the intervention group was 2228 mg/day and 2186 mg/day in the control group which was within the range to the recommended level by ICMR (2010) which is 1875-5625 mg/ day. Enough potassium needs to be present in the diet to balance sodium intake. As losses of potassium are around 30 mmol/day, an intake of 50 mmol is suggested at the lower end. The recommended intake viewed as safe and adequate is 1875-5625 mg daily.

Unremarkable change was observed for calcium and magnesium intake whereas phosphorous intake was significantly increased during the trial but nominal changes in the control group. Some of the micronutrients increased in intervention group as compared to control group over the trial, it was because of higher content of these nutrients present in barley. Moreover the suggested intake of magnesium for Indians is 320 mg/day and the intake of magnesium in this study was averaged 341
mg in a day in both the group which is very similar to recommended intake for Indians (ICMR 2009).

Various epidemiological studies have suggested that magnesium can be an independent risk factor for the development of diabetes mellitus (Lopez et al 2004, Song Yet al 2004, Kao et al 1999), being a co-factor in number of enzymatic reactions that regulate glucose metabolism and insulin homeostasis (Barbagallo M et al 2003, Paolisso G et al 1997). In a cross-sectional study, an inverse association was reported between serum magnesium levels and Metabolic Syndrome (Romero et al 2002). In the CARDIA study, a total of 608 cases with Metabolic Syndrome were identified in young adults (18-30 years; n=4637), wherein, magnesium intake was found to be inversely associated with it. Of particular significance, were the inverse associations of magnesium with blood pressure and triglycerides which were subsequently attenuated with lifestyle and dietary factors adjustment (He K et al 2006).

Indeed, dietary records and nutritional markers showed insufficient intakes of several nutrients. Consumption of Iron did not change throughout the trial (effect of time was not significant) however the mean intake of manganese and zinc was significantly increased over the length of the time (p<0.001). There was a trend for a significant main effect of group for the zinc intake (p<0.001) as the significant differences for zinc intake among the two groups at baseline. In both groups, there was no variation in vitamin A, vitamin C, and folic acid intakes. During the intervention Vitamin A & C intake noticeably increased in the intervention group as compared to baseline. Moreover intake of folic acid was significantly increased over time (p=0.03) however the changes was nominal.
At last the caloric intakes and the proportions of carbohydrate, protein, and fat consumed by the intervention and control group was similar throughout the trial. Changes over time were not significantly different for any of the variables between the two groups except dietary fiber intake. These differences were only due to the methodological differences in the intervention group as barley was included in the intervention group and was observed at 4, 8 and 12-week which contains high amount of dietary soluble fiber.

5.3.2 Food Intake and Consumption Frequency

Individuals with metabolic Syndrome are at high risk of developing type 2 diabetes mellitus and cardiovascular disease, but the influence of dietary modification in the metabolism of glucose and insulin in these individuals is extremely important. Insulin resistance is a central component of metabolic syndrome, and replacing consumption of refined cereals increases insulin secretion in these individuals, and thus can reduce the risk of glucose intolerance and development of Type 2 diabetes Mellitus (Laaksonen et al 2005). This study, observed a significant improvement in the consumption pattern of different foods by all the respondents after the dietary counseling and all the respondents were highly motivated in their first visit. Analyzing the outcomes of this research we concluded that dietary counseling is a rich tool that is extremely important in the overall treatment of patients with metabolic syndrome. From the literature available, we confirmed that there are few studies that relate previous motivation, adherence to treatment and methods of nutritional intervention in patients with metabolic syndrome. We emphasize that
Discussion

Further studies are needed to assess adherence to treatment in patients with chronic diseases, so we can constantly improve health care in this population.

In this study the only difference between the two groups was the addition of barley food in the intervention group. None of the respondents were consuming barley before the study has been started. But after the recommendations all the respondents in the intervention group started to consume barley on a daily basis which is the main interventional food used in this study.

As we know that rice is the staple food of our country, in the present study about three fourth of respondents 72.1% in intervention and 74.3% in control group were reported eating rice on a daily basis (≥6 times/week) and only 10.6% in intervention and 7.9% in the control group were eating 4-5 times in a week at entry (screening visit). However during the intervention, daily eaters were reduced to 42.3% in the intervention group and 48.5% in the control group as they were shifted to either rarely or 2-3 times in a week. Although significant effect of counseling was observed in both the groups from screening to end of the intervention (p<0.001)

In this study, Pulses were eaten quite regularly. Sixty four percent in the intervention group and 55.4% in the control group reported to have pulses either six or more than 6 times in a week however one fifth respondents in both the group reported to have ≤3 times in a week. During the intervention daily users were significantly increased in both groups however respondents who were having ≤3 times were increased. However significant within group differences found in the intervention group (p=0.007) and control group (p=0.026).
As for green vegetables, about half (50%) in the intervention and 55.4% in the control group were having green vegetables in their daily diet before the counseling but this proportion shifted to 76% and 63.4% in the intervention and control group respectively. In the same way, at the screening visit green leafy vegetables were rarely consumed by 61.5% and 53.5% in the intervention and control group respectively however after the intervention this figure decreased to 15.4% in the intervention group and 19.8% in the control group. Significant proportion of respondents started to have green leafy vegetables on a weekly basis ($p<0.000$).

Fruit were not consumed as a regular part of the meal by majority of the people in this region as diet as they consumed seldom or never by 44.2% and 46.5% in the intervention and control group respectively. However this proportion reduced to 15.4% and 11.9% after the counseling. Only one fifth respondents from both the groups reported to consume fruits on a daily basis and about one quarter stated that they were consuming ≤3 times/week. Although majority of the respondents started to have fruits after the intervention and the proportions significantly differed before and after the intervention in both the groups ($p<0.001$).

As for dairy products was concern, before the diet counseling more than half of the respondents stated to consume milk on a daily basis while about one quarter were occasionally taking in both the groups. After the intervention most of the daily users were shifted to ≤3 times or 4-5/week. Significant proportion of respondents from both the groups were reduced the frequency or quantity of milk intake during the trial ($p<0.001$).
Respondents were also asked about the consumption frequency of non-vegetarian foods as they reported that 14.4% and 12.8% from the intervention and control group were taking flesh foods or eggs 4-5 times in a week while about a quarter of respondents (25%) from the intervention and 23.7% from the control group were consuming ≤3 times in a week. 34.6% from the intervention group and 41.5% from the control group were never consuming, however, a quarter was rarely consuming. Dramatic shift was observed in the consumption frequency of flesh foods after the diet counseling by intervention and control groups. On the contrary, consumption pattern of fish by respondents showed that very few respondents were eating fish on a weekly basis while one third respondents 35.6% and 29.2% from the intervention and control group were rarely users. After the counseling, most of them started to consume fish on a weekly basis. Within group changes in proportions was significantly different from screening visit in intervention group (p=0.02) while not reached to the significance level in the control group (p=0.33).

Similarly for the deep fried foods, Ten percent of the participants from the intervention group and 18.8% from the control group ate deep fried foods daily followed by 18.3% and 14.9% from the intervention and control group were consuming 4-5 times/week and ≤ 3 times /week were reported by 61.5% and 54.5% of the respondents. Similar pattern was observed by both the groups although none of the respondents were consuming deep fried foods on a daily basis in both the intervention and control groups and the proportion of rarely users were increased by 6-7 times after the counseling in both the groups.
At the initial visit, out of total only about one third respondents stated that they were seldom/ rarely consuming sweat dishes while more than one third respondents were having 4-6 times in a week. But after the counseling none of the respondents were in the category of 4-5 times or ≥ 6 times/week and rarely user were increased from 38.5% to 89.4% in the intervention group and from 27.7% to 87.1% in the control group.

5.4 Effect of Barley Consumption

5.4.1 Anthropometry and Body Composition

This study compared the effects of whole grain barley as an adjunct to a normal, heart healthy diet in free-living, men and women with metabolic syndrome. After 12 weeks of intervention with barley, intervention group significantly decreased body weight compared to control group. Mean body weight decreased by (-2.71) kg in the intervention group, significantly more than the (-1.22 kg) in the control group. Barley recommended in this study was whole grain and suggested intake was about 4-6 servings per day on the basis of individual calorie requirement.

The corresponding reductions in BMI were (-1.04) and (-0.48) kg/m² in the intervention and control group respectively. Mean reductions in waist circumference and waist/hip ratio were also significantly greater in the intervention group, compared with the control group. Similarly, Keenan et al (2007) compared the effects of two concentrated barley β-glucans in a self-selected diet in mildly hypercholesterolemia men and women and after six weeks of supplementation with higher molecular weight barley fiber significantly decreased body weight. Reduction in body weight was unwanted result in this study; because there was no calorie restriction in the present
Discussion

In this study, significant decrease in weight with the barley diet may have been attributable to a high amount of dietary fiber.

Figure 5.4.1: Mean % Reduction in anthropometry & Body composition from baseline to end of the intervention (12-week)

* Indicates the significant difference between the groups (Independent t-test)

Although in this study, subjects were not requested to do not change their usual physical activity programs because of ethical issues and subjects may have increased activity as the study progressed. Previous research suggests that consuming the recommended amounts of dietary fiber may reduce energy intake as a result of reduced hunger and thus lead to weight loss (Slavin JL et al 2004). Epidemiological studies tend to show that fiber is associated with reduced long-term weight gain (Banerjee P et al 2004, Liu S et al 2000). Clinical trials of soluble fibers find conflicting results. Kovacs et al (2007) fed soluble guar gum to overweight males on an energy-restricted diet. These subjects had significant decrease in their body weight.
and body fat percentages with no increase in hunger, although calories were restricted. Hunger at lunch was significantly reduced from baseline with consumption of barley in this study. Body weight (kg) decreased significantly from baseline to 12 weeks in the intervention group. This is interesting because there was no reported difference in nutrient intake from baseline to the end of the study.

Although the effect of barley or oats on visceral fat was not known. During the intervention, there was a trend toward reduced body fat and visceral fat % in both the intervention and control group and it significantly affected by the length of time (p<0.001). The reductions observed by group were not significantly different, whereas significant time by group interaction was observed for body fat % (p<0.001) & visceral fat % (p=0.007). According to the 2006 exercise guide from the Ministry of Health, Labour and Welfare, a 1-kg reduction of body weight induced by moderate exercise for the visceral fat loss corresponds to a 1-cm reduction of waist circumference. In another trial, Lierz G et al (2002) reported the net change of body weight in the test group at week 12 was correlated not with the reduction of the visceral fat area (r=0.065, P=0.791) but with that of the subcutaneous fat area (r=0.618, P=0.005). This suggests that the mechanism of the visceral fat reduction due to barley intake might be different from that of the weight loss due to exercise. The mechanism by which visceral fat is reduced thus seems to differ from the mechanism by which serum cholesterol levels are reduced and might vary with the genetic backgrounds of the subjects (Shimizu et al 2007). The low glycemic index of barley, which affects the lipid metabolism, might be one of the mechanisms of visceral fat reduction by barley intake. And barley contains other components than β-glucan that might affect lipid metabolism. Further research will be required to clarify the
mechanisms by which barley reduces visceral fat. In conclusion, barley intake significantly and safely reduced visceral fat area, BMI, and waist circumference. Barley with high amount of β-glucan has beneficial effects in preventing the metabolic syndrome (Shimizu et al 2007).

5.4.2 Blood Pressure

For the first time to our knowledge, that daily consumption of about 4-6 servings of barley food significantly decreased SBP after 12 week in middle-aged, men and women with metabolic syndrome. Both Systolic and diastolic blood pressure was significantly affected by the length of the time (p<0.001). Although reduction in systolic blood pressure was more rapid in the earlier weeks and became less pronounced as the study progressed (Fig. 4.4.4) At 12-week, the mean change in systolic and diastolic blood pressure were (-9.74,) mmhg in the intervention group as compared to (-5.00) mmhg in the control group. Two meta-analyses concluded that an increase in fiber intake of 10–15 g fiber/d for 8 wk was associated with a fall in SBP of between 1 and 3 mm Hg, and soluble fiber may be more effective than insoluble fiber (Streppel et al 2000). To date, dietary intervention trials that described significant decreases in BP have used extracted β-glucan from oats or barley or specifically formulated foods in overweight, obese, and hypertensive subjects. In contrast, our study used wholegrain barley widely available from Indian food retailers at low cost and was designed to be readily achievable by free-living individuals.

The reduction in BP observed with the treatments seemed to be also independent of the variation in daily sodium or potassium intake. However, accurate biochemical measurements of sodium and potassium intakes would be required for
this to be confirmed. But the sodium, potassium and other nutrients intake was similar
between both the groups throughout the trial so we could confirm that the observed
differences between the two groups were mainly due to the barley intake.

By simply replacing partially wheat and rice with barley this study was able to
lower blood pressure. Some of the difficulties in comparing studies are differences in
subjects, sources, and amounts of grains, length of consumption, and extent of dietary
control. Although in this study every effort were made to control diet, physical
activity, and other dietary factors that might affect blood pressure, including protein,
calcium, magnesium, sodium, and potassium. Some epidemiological studies have
reported an inverse association between dietary fiber and blood pressure (Appel L et
al 1997). Data collected from clinical trials suggest a small, anti-hypertensive effect of
fiber supplementation (Keenan et al 2002). Other studies show no effect on blood
pressure (Swain JF et al 1990).

A pilot trial including 18 subjects with hypertension and hyperinsulinemia
showed a significant reduction of systolic (-7.5 mmHg) and diastolic (-5.5 mmHg)
blood pressure after daily ingestion of 5.5 g of oat β-glucan as a cereal for 6 weeks
(Keenan JM et al 2002). The decrease in systolic blood pressure was also significantly
greater than in the control group, whereas the decrease in diastolic blood pressure was
not significantly different from the control group. In contrast, a study administering a
higher dose (7.7 g/day) of oat β-glucan to hypertensive patients for 12 weeks found no
significant changes in blood pressure compared with control (Maki KC et al 2007).

However, Diastolic blood pressure remained unchanged during this study.
Moreover the decrease was significantly greater in intervention group as compared to
control group for systolic blood pressure, the time × group interaction was significant. (p=0.01) Significant differences was found between the two groups at 12-week in systolic blood pressure (p=0.002) although the effect of group was insignificant. Davy et al (2002) reported no significant effects of oat consumption on blood pressure. In that randomized, parallel study, 36 men with elevated blood pressure consumed oat cereals, providing 5.5 g/day oat β-glucan, or wheat cereals for 12 weeks.

5.4.3 Fasting Lipid Profile and Fasting Blood Glucose

The amounts of barley recommended in this study were predicted to significantly lower serum cholesterol. After the 12 weeks of intervention with barley, it significantly decreased the fasting plasma total cholesterol concentration from their baseline values by a mean change of (-26.9 mg/dl, 10.7%) mg/dl in the intervention group and (-10.7 mg/dl, 4.4 %)) mg/dl in the control group. The cholesterol-lowering activity of oats and barley is thought to be due to the β-glucan in the fractions of soluble fiber found within these grains. On the contrary, another randomized crossover trial by Geraldine et al (2003) was unable to provide evidence of a significant improvement in CVD risk or type 2 diabetes risks in a group of mildly hypercholesterolemia, middle-aged men fed a highly enriched form of barley-derived β-glucan as part of a typical 38% fat diet. Total cholesterol decreased by only 1.3% over the 4-wk intervention period, which indicated a very modest improvement. Keogh et al (2003) also reported a poor cholesterol-lowering effect of a daily supplement of 10 g of barley β-glucans compared to a control diet and concluded that the lack of effect may be a consequence of structural changes in β-glucan that result from food processing or storage of the barley products.
The pattern of cholesterol-lowering action of β-glucan from barley in this analysis cannot be viewed as a dose dependent response. There are various reasons that may help to explain the lack of dose-dependent response. The Biorklund et al. (2005) in their study showed that the consumption of a beverage containing 5 g of β-glucan from oats lowered total cholesterol concentrations by 7.4% compared with a control beverage. However no cholesterol-lowering effect of a beverage with 5 g of β-glucan from barley was found which was attributed to the lower molecular weight compared with that of β-glucan from oats.

**Figure 5.4.2: Mean % change in blood Pressure and biochemical variables from baseline to 12-week**

* Indicates the significant difference between the groups (Independent t-test)

To date, most of the human studies investigating the hypocholesterolaemic effects of β-glucan have utilized diets rich in oat and oat products. However, human clinical trials have been conducted using barley foods as the source of β-glucan as well. (McIntosh et al. 1991) conducted one of the first trials comparing diets rich in
barley versus wheat in a cross-over design. Compared to the wheat period, the barley diet period resulted in a 6% lower total cholesterol level and a 7% lower LDL-C level. In 2004, Behall et al. reported that adding 6 g soluble fibre from barley per day for 5 weeks in addition to a Step 1 diet resulted in a 24% reduction in LDL-C (Behall et al., 2004b) which is very similar to the findings of present study. A meta-analysis by Ripple Talati et al (2009) including 8 randomized controlled trials, participants receiving barley had statistically significant reductions in total cholesterol (−13 mg/dL), LDL cholesterol (−10 mg/dL), and triglycerides (−12 mg/dL) compared with control group participants. Our findings are consistent with those of several studies reporting that an increase in the intake of total dietary fiber benefits lipid metabolism in normal subjects (Bruce et al 2000, Davidson MH et al 1991) and decreased the degree of blood lipids in patients with type 2 diabetes mellitus (Chandalia M et al 2000) and hypercholesterolemic adults (Spiller GA et al 1991, McIntosh et al 1991).

Moreover, the amount of dietary fiber showed no effects on plasma triacylglycerol in some studies of normal and hypercholesterolemic subjects (Behall et al 2004 &Brown et al 1991). However, the plasma triacylglycerol concentration decreased with the barley diet in the present study. A significant time by group interaction was observed in the reduction of triglycerides ($P=0.002$), with a greater decrease in triglycerides concentrations in the intervention group than in the control group. Intervention group significantly reduces fasting blood triglycerides from their baseline values with an average change of (-29.2 mg/dl, 14.3%) after 3 months which was about just two times higher than (-15.0 mg/dl, 5.25%) in the control group. In the meta-analysis of oats containing soluble fiber (β-glucan) by Brown and colleagues (1991) changes of 1.06 to 5.3 mg/dL were noted for triglycerides, another study
reported 12 mg/dL reductions in triglycerides compared with a control group which supported the present study.

In the current study, Low density lipoprotein cholesterol significantly decreased over time in both the groups (p<0.001) with the significant time × group interaction (p=0.01). Subjects consumed barley in the intervention group for a period of 12 weeks (averaging 22 grams of insoluble dietary fiber and 7.6 grams of soluble fiber) compared to the control group with the similar amount of insoluble dietary fiber but reduced amount of (average 4.63 gm) soluble fiber. The mean changes in intervention group were -14.1 mg/dl and -6.31 mg/dl in the control group with a difference in change between group was -7.84 mg/dl ((95% CI, −1.2 to −14.3, p=0.01). A viscous fiber intake of 10–25 gm/d is recommended by the National Cholesterol Education Program’s Adult Treatment Panel III as an additional diet option to decrease LDL-C while this study could not reached to the recommended level. McIntosh et al. (2001) showed that a 4-week diet enriched with barley foods containing 8 gm β-glucan per day reduced total and LDL cholesterol in moderately cholesterolemic men by 6.0 and 6.8%, respectively, compared with wheat foods containing 1.5% β-glucan. However in this study low density lipoprotein was reduced by (-9.94%) which is comparatively higher.

Another wheat-barley comparison showed 12% and 14% reductions in total and LDL cholesterol, respectively, when 14 normal cholesterolemic men were fed whole-grain barley flour products containing 9.6% β-glucan per day for 4 week, where both barley and control groups consumed equivalent levels of TDF per day (Newman et al 19991). Furthermore, Li et al (2003) compared a barley whole-grain diet with 8.9 g soluble fiber added to rice with 3.9 g soluble fiber in a 12-week
crossover study in normal cholesterolemic females. This barley diet resulted in 14.5% and 21% reductions in total and LDL cholesterol.

In a study by Behall et al. (2004), 7 men and 18 women were given test diets providing 0, 3, or 6 g/d of barley β-glucan with equivalent levels of TDF. Following both the 3 g/d and 6 g/d diet periods, reductions in the LDL cholesterol was 10% and 13%, respectively which indicates that general healthy dietary changes (low fat content, high total dietary fibre content and whole grain foods) have a positive effect on blood lipids, but can be even more augmented when adding soluble fibre. These varying results in human trials may be due to factors such as the dose of β-glucans, food processing, solid or liquid study products, the initial cholesterol concentrations of the subjects, or the study design. Second, differences in the molecular weight of β-glucan may influence the dose–response effect. Highly water-soluble β-glucan, with moderate to high molecular weight, may reduce serum LDL cholesterol levels better than β-glucan with a low water solubility and low molecular weight (Theuwissen and Mensink, 2008).

The consumption of about 8–12 g/day of barley β-glucan extract incorporated into baked products for 4 weeks did not improve the lipid profiles of hypercholesterolemic men (Keogh et al 2003). While, consumption of barley based baked products reduced LDL cholesterol in other studies (Newman et al 1989, McIntosh et al 1991). In spite of some conflicting results from individual clinical trials, pooling data from 11 studies in a analysis by Mweis et al (2010) showed that incorporating barley into different food products could be used as an efficacious way to increase the consumption of viscous soluble fibers in order to achieve the desired reduction in LDL cholesterol concentration.
Other studies have shown that the addition of barley to the diet reduced serum total and LDL-cholesterol. In a study of hypercholesterolemic men and women by Behall et al (2004), consumption of oat or barley products for 6 weeks reduced both serum total cholesterol and LDL-cholesterol, indicating that the source of the soluble fiber was not critical to reducing lipids. Adult male subjects consumed barley or wheat products for a period of 4 weeks (averaging 25 grams of insoluble fiber and 13.4 grams of soluble fiber) (McIntosh et al 1995). These subjects had significant reductions in serum total cholesterol and LDL cholesterol, without significant changes in triacylglycerol.

Barley intake did not affect HDL cholesterol in the present study. Similarly, the consumption of other soluble fibers, including those from oats, psyllium and pectin, have shown not to have an effect on HDL cholesterol and triacylglycerol concentrations (Brown et al 1999). Similar to that, the present study also showed no significant differences in high density lipoprotein cholesterol from baseline to week 12 in any of the group either in the intervention (p=0.57) or in the control group (p=.93). In the intervention group, minor increase was observed after the 12 weeks that was 0.70 mg/dl whereas it was negligible in the control group that was 0.07 mg/dl. Any way, 5.67% increase was observed in the intervention group compared to 3.96% in the control group.

Concerning the fasting blood glucose (FBS), within subject test indicate that there is a significant time effect (p<0.001). Mean % reduction in the fasting blood sugar from baseline to 12 weak was shown in (Table 4.4.21). Within group test reveals that fasting blood sugar significantly declined after the three month in both the groups. (p<0.001) Although between group difference was proved insignificant with a
**Discussion**

diff. in mean change of -3.95 mg/dl (95% CI, -0.5 to -3.7, p=0.15) even at the completion of intervention of 12 weak with barley indicated that recommended dose of barley was unable to detect a statistically significant differences as compared to step I diet. Previous studies (Anderson et al, 1990; Hallfrisch & Behall, 2000; Keogh et al, 2003) have shown that the delayed glucose absorption probably is due to the high viscosity of β-glucans. Bourdon et al (1999) demonstrated that there was no significant difference in the glucose response between a meal with enriched barley pasta (5 g of b-glucans) and wheat pasta, but the insulin response differed. Liljeberg et al (1996) showed that 2 gm of soluble fibers in a meal with oat or barley porridges had no influence on the postprandial glucose tolerance, but 8 gm of soluble fibre in high-fibre barley porridge had.

Many, although not all, of the animal and human trials that showed improvements in glucose control when a variety of soluble fibers were introduced into the diet were performed in prediabetic persons (Meyer et al 2000, Kestin M et al 1990, Bossello et al 1980, Liljeberg et al 1996, Hallfrisch et al 1995, Vuksan V et al 2000). Another study by Kestin et al (1995) reported significant improvement in glycemic response; Dietary fiber acts on glucose absorption and the rate of gastric emptying, which are determined largely by viscosity of fiber in solution. Reduction in postprandial glycemia has been attributed to the high viscosity of β-glucan.

Many studies have examined the effects of oats on glycemic response, but few have studied the effects of consumption of viscous barley fiber (Behall et al 2005). Wood et al (1988) described a significant reduction in postprandial insulinemia that appeared to be dependent on the amount of soluble fiber consumed. Other studies, however, have fed soluble fibers to normal and hypercholesterolemic subjects without
significant changes in glucose and insulin concentrations (Kestin M et al 1990). It is possible that the amount of soluble fiber used in these studies was not adequate to reduce glycemic response.

In the present study, there were no significant differences between the groups in fasting plasma glucose during the 12 week between diet regimens. These results suggest that barley intake over a short term does not influence fasting plasma glucose and glucose tolerance. Several studies have found that high-fiber diets decrease postprandial glucose. It is possible that the mechanism of improvement in fasting plasma glucose and glucose tolerance is not the same as that of postprandial glucose.

**Figure 5.4.3** Percentage reductions in Metabolic Syndrome components from baseline to end of the trial (12-week).

$^S$ # significantly different from baseline: $^{SP<0.05, #P<0.001}$ (chi-square). *Significantly different between groups (chi-square).
Hypertriglycerolemia and Hyperglycemia decrease significantly in both the group but more in the barley group than in the control group Figure: 5.4.3. High blood pressure decreased only with the barley diet. However low HDL and central obesity did not change significantly. This finding was similar with those of other studies reported that an increasing the intake of total dietary fiber improves cholesterol metabolism in healthy subjects (Bruce B et al 2000) and decreased the lipids concentrations in patients with type 2 diabetes mellitus (Davidson et al 1991). Many studies have provided evidence that dietary fiber especially viscous soluble fiber can interfere with the micellar solubility of lipids and decrease reabsorption of biliary cholesterol and increasing their fecal excretion or possibly alter the rate and site of absorption Schweizer et al 1991, Anderson et al 1998).

However, the mechanisms of the reduction in the blood lipid induced by increasing soluble fiber are controversial. Plasma triacylglycerol concentration decreased with the barley diet in the present study however, some studies showed no effects on plasma triacylglycerides (Behall et al 2000, Brown et al 1999). Greater reductions in triacylglycerides concentrations with the consumption of barley were not surprising on the basis of earlier studies that reported the same effect (Behall et al 2004, Li et al 2003). Interestingly these changes in the plasma lipid were obtained with minor modifications in the soluble fiber content, within the limits of heart healthy diets.

In this study, the barley diet lowered prevalence of high blood pressure by 12% compared to control group in which decreased by 3%. Numerous studies have reported that whole grains that are high in soluble fibers, such oats and barley are
more effective in decreasing plasma cholesterol than those in which fibers are predominantly insoluble such as wheat or rice (Lupton et al 1994, Dubois C et al 1995). In a review of the effect of fiber on the components of Metabolic Syndrome, Davy and Melby concluded that consumption of 20-35 g/day of total dietary fiber and at least 3 g/day of soluble fiber, as recommended by the American Dietetic Association, results in a greater reduction in risk factors for cardiovascular disease and diabetes (Davy et al 2003).

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