Action Research on Advocating Use of Fortified Foods amongst the parents of the students studying in the Faculty of Family and Community Sciences using Diffusion of Innovation Model

Synopsis of Ph.D. Thesis

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INTRODUCTION

Lactose intolerance is a condition in which humans are not able to digest milk sugar- lactose due to the lack of enzyme – lactase. Lactose is a disaccharide- composed of two mono saccharides- glucose and galactose. Lactase (b-galactosidase) enzyme is required for enzymatic hydrolysis of lactose (Szilagyi A and Ishayek N, 2018; Misselwitz B, 2019). Undigested lactose causes gastrointestinal symptoms such as bloating, nausea, flatulence, diarrhoea, vomiting etc. Intestinal injury can be one of the several causes leading to lactose intolerance (Matthews et al 2005 ; Misselwitz B et al 2019).

Various ethnic groups have varied intensity of lactose intolerance. In adults, white north Europeans, North Americans and Australasians have the lowest rates ranging from 5% in a British population to 17% in Finland and northern France. In South America, Africa and Asia, over 50% of the population has lactase non-persistence and in some Asian countries this rate is almost 100%. (Lomer MC, 2008; Solomons NW et al 2002 ; Kretchmer N, 1971; Swallow DM 2003; Olds LC and Sibley E 2003; Turnbull GK 2000; Lim LL et al 2003; Johnson JD, 1981; de Vrese M, 2001)

Lactose intolerance occurs as lactase production decreases. Undigested lactose passes into the colon, part of the large intestine absorbs water from stool and changes it from a liquid to solid form, upon colonic fermentation leading to gastrointestinal symptoms such as bloating, acidity, diarrhoea, vomiting, borborygmi etc. Headache and nausea might also occur as a result of indigestion. Severity of symptoms occur with severity in maldigestion of lactose.

Lactose intolerance can be categorised into primary lactose intolerance, secondary lactose intolerance, developmental lactose intolerance and congenital lactose intolerance (Rusynyk and Still 2001).

Lactose intolerance can be detected by various method. The methods are Lactose tolerance test, Hydrogen breath test, Biopsy and genetic test (Robles L and Preifer R, 2020)**.** Primary LI also known as lactase non-persistence is genetic, irreversible, and usually develops during childhood. Secondary LI is caused due to any existing intestinal injury or surgery that might lead to low lactase synthesis and lactose malabsorption. This can occur at any age (Harvey Lousie et al 2018) (Matthews et al 2005). Developmental lactose intolerance might occur in infants born prematurely- this usually last for a short period of time after a child is born.

Congenital lactose intolerance is extremely rare of genetic origin (genes inherited from parents causes this disorder).

Various modes of treatments are available such as avoidance of milk, consumption of plant based milk, introduction of yogurt and other probiotics and enzyme replacement therapy. The most common advice that physicians give patients with LI is to avoid dairy foods (dennis A et al 2013). The hydrolytic capacity of probiotic strains can be used to reduce the actual amount of lactose in the product, as occurs in yogurt. It can also be used to increase the overall hydrolytic capacity in the small intestine. Saltzman JR et al 1999 observed that 7 day supplementation with Lactobacillus acidophilus did not change hydrogen production or symptoms.

Lactose hydrolysed milk (LHM) is an excellent option to combat lactose intolerance. Lactose hydrolysed can be incorporated into all the recipes using dairy milk, as a measure to treat lactose intolerance.

RATIONALE

Milk is a one of the most important sources of nutrients for children, adults and elderly and plays a significant role in maintaining the health of the individuals.

Several children (at varying stages-early childhood, childhood, adolescence) suffer from lactose intolerance leading to occurrence of symptoms such severe abdominal pain, nausea, diarrhoea and dehydration, these symptoms eventually interfere with the growth of children.

However scarce literature is available on effect of consumption of Lactose Hydrolysed Milk (LHM) on QOL, nutritional status and BMI of various population groups suffering from lactose intolerance and the use of LHM to develop food products.

OBJECTIVES

Broad objective:

To identify lactose intolerant individuals and determine the effectiveness of supplementing lactose hydrolysed milk to children, adults and elderly suffering from lactose intolerance on reduction of their symptoms, quality of life(QOL) and changes in their nutritional status along with determining the feasibility and acceptability of food products developed from LHM.

Specific objective:

- To determine the presence of lactose intolerance (LI)among children, adult and elderly population of urban Vadodara.
- To collect detailed information on gastrointestinal symptoms and symptoms experienced due to consumption of various foods by means of semi-structured questionnaire.
- To conduct Hydrogen Breath Analyser Test for selection of lactose intolerant subjects for supplementation of lactose hydrolysed milk.
- To collect baseline information on BMI, dietary intakes, Quality of life of the LI subjects.
- To supplement lactose hydrolysed milk (LHM); 250ml once daily for a period of six weeks to LI subjects.
- To assess the impact of supplementation on the Quality of life, BMI and dietary intakes of LI subjects at the end of intervention.
- To study the organoleptic properties of food products developed using lactose hydrolysed milk.

REVIEW OF LITERATURE

This chapter will focus on the available literature under the following heads:

1. Milk and its benefits for children, adult and geriatric population.
2. Lactose intolerance and its prevalence, pathophysiology, types and its genetic predisposition.
3. Diagnosis of lactose intolerance.

    3.1 Lactose tolerance test

    3.2 Breath analyser test

    3.3 Biopsy

    3.4 Genetic analysis

4. Treatment of lactose intolerance

    4.1 Avoidance of dairy products

    4.2 Enzyme replacement therapy

    4.3 Probiotic inclusion in diet

5. Lactose intolerance and nutritional status

6. Lactose intolerance and Quality of life

    6.1 Social life compromise

    6.2 School performances

    6.3 Stress and anxiety

7. Product development from using milk alternatives

    7.1 Oats milk

    7.2 Soya milk

    7.3 Almond milk

    7.4 Coconut milk

METHODOLOGY

Lactose intolerance is an ailment resulting in the occurrence of gastrointestinal symptoms such as abdominal pain, vomiting, nausea etc. This chapter depicts the materials and methods used to conduct the study.

Phase I- Statutory clearance, study design and Screening and Identification of Lactose intolerant subjects.

Phase II- Collecting of information from the subjects with respect to anthropometry, dietary intake and quality of life before and after supplementation with lactose hydrolysed milk.

Phase III- Organoleptic evaluation of food products developed from standard and lactose hydrolysed milk.

Phase IV- Development of IEC material.

Phase I- Statutory clearance, study design and Screening and Identification of Lactose intolerant subjects.

Ethical clearance was obtained from the ethical committee- Institutional Ethics Committee for Human Research (IECHR), Faculty of Family and Community sciences, The Maharaja Sayajirao University of Baroda, Vadodara. Ethical approval number IECHR/2018/18 was obtained for conducting this study.

In this phase we determined the study design, sample size and identified lactose intolerant subjects using Hydrogen breath Analyser test.

Type of study and determining sample size

Study design used in this study is cross-sectional in nature and sampling technique applied here is purposive sampling technique.

Sample size is calculated using the following formula

$$n = Nx / (N-1)\,E^2 + x$$

Where, $x = Z^2_{(1-a/2)}\ p\,(1-p)$

p= Estimated proportion (from previous knowledge), E= % of error permitted

N= finite size of the population, (1- a)= confidence level (this formula is used when we have a finite population) ,Considering prevalence as 50% and error as 5%.

Total number of staff members in the university is 1742.

The sample size of adults, elderly and children are- Adults= 346,

Children= 346, Elderly= 183

Screening on the basis of gastrointestinal symptoms

Total of 503 adults, school going children (346) from 5th standard to 9th standard and 11th standard and 219 people from elderly population were screened. General information regarding age, gender, types of family, presence of disease, medication details was gathered. A detailed questionnaire was developed to gather information upon occurrence of gastrointestinal symptoms such as vomiting, diarrhoea, nausea etc post consumption of various food types like: milk and milk products, cereal products, pulses, fruits, vegetables and fermented foods.

Identification of lactose intolerant subjects by means of Hydrogen Breath Analyser test and their enrolment for the study.

Subjects who reported to suffer from gastric discomfort after consumption of milk and milk products and who met the inclusion criteria, provided consent to participate in HBT and lactose hydrolysed milk supplementation. were enrolled for conducting **Hydrogen breath analyser test** (HBT). HBT was conducted in the subjects from all three categories: children, adult and elderly population until a sample of 30 in each group was achieved.

Procedure:

In this test the individual is required to exhale out into the mouth piece of the breath analyser post consumption of specific substrate. In our study, Hydrogen breath analyser of WBM company was used. We administered orally 25gm of lactose powder dissolved in 250ml of water to subjects and they were asked to breath out six times into the device after a period of 30 minutes each.

Subject preparation- It is a vital aspect of conducting the test. Subjects were instructed not to have antibiotics four weeks prior HBT, not to consume laxatives one week before conducting HBT and prohibit from consuming high in fats and spicy food the night prior conducting test.

Collected data were entered into a Microsoft excel sheet. Data analysis was performed using Statistical Package of Social Sciences (IBM SPSS Statistics 25).

Phase II- Supplementation with lactose hydrolysed milk and collecting information upon BMI, dietary intake and Quality of life before and after supplementation.

In this phase, baseline information is taken upon anthropometry, dietary intake and Quality of life and then lactose hydrolysed milk were supplemented to the lactose intolerant subjects post obtaining their consent.

Study design : Quasi experimental design was used.

Sample size: 30 in each age group of children , adult and elderly population.

BMI of the lactose intolerant subjects

Height, weight were measured and BMI was calculated.

Height – Body height is the head to toe measurement of a human body, from the feet to the head of the individual.

A spring- loaded non-stretchable tape was used to measure the height of the subjects. we identified one convenient flat wall for the measurement of height. The subject was made to stand barefoot with the arms hanging freely by the side. Two consecutive reading were taken to avoid error.

Weight- Body weight is the most commonly used anthropometric measurement. Also convenient to execute. Karada scale (Omiron®) was used to calculated the body weight of the individuals. Subjects were asked to stand straight upon the weighing scale. Children's weight were analysed using the software WHO Anthroplus™.

BMI was calculated using the formula :

$$\text{BMI (kg/m}^2\text{)} = \frac{\text{Weight (kg)}}{\text{Height (m}^2\text{)}}$$

Dietary intake of the lactose intolerant subjects

Dietary intake of the subjects was performed using 24 hr dietary recall method. Individuals were asked to mention their daily food intakes for 3 consecutive days.

Nutrient content of diet was calculated using DietCal® Software (Gurdeep Kaur, RD, AIIMS) containing the data from the book- Indian Food Composition Tables (referred commonly as IFCT 2017) National Institute of Nutrition, Indian Council of Medical Research, 2017.(Longvah T, Ananthan R, Bhaskaracharya K, Venkaiah k.)

24 hour dietary recall method was administered before and after supplementation.

Quality of life of the lactose intolerant subjects

WHO defines Quality of Life (QOL) as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standard and concerns. A modified semi-structured questionnaire was developed with 10 questions in relation to lactose intolerance. Scores obtained, determined the subject's QOL. Higher scores indicated poor QOL whereas less scores referred to good QOL. This questionnaire was administered before and after supplementation with LHM.

Supplementation with Lactose Hydrolysed Milk (LHM)

LHM was procured from GCMMF, Anand, Gujarat, India; commercially available in the name of Lactose hydrolysed milk. 250ml of LHM was supplemented to lactose intolerant subjects daily for a period 6 weeks. The subjects were provided with a compliance sheet for a period of 6 weeks and telephonically asked for their intake every 3rd day. They were instructed to put a tick mark on the compliance sheet on each day they consumed the milk. A feedback form was developed to assess lactose intolerant subject's response post supplementation for taste, smell, sight, texture and desire to purchase.

Statistical analysis- Collected data was entered into a Microsoft excel sheet and data was analysed using Statistical Package of Social Sciences (IBM SPSS Statistics 25).

Phase III- Organoleptic evaluation of food products developed from standard and lactose hydrolysed milk

In this phase food products were developed from both lactose hydrolysed milk and standard milk and organoleptic evaluation of all the various food products namely: cold coffee, rose milk, white sauce pasta, vegetable au gratin, *sandesh* and *kheer* was conducted.

Selection and training of panelist for organoleptic evaluation

a. **Screening of semi-trained panelist**: Threshold test was conducted to determine the panel members. Threshold test was conducted among students and staff members from the department of foods and nutrition to determine the panellists.
b. **Threshold test:** Threshold is defined as a point on the stimulus scale at which a transition in a series of sensations or judgments occur. Subjects who pass the threshold test were included to conduct the organoleptic evaluations of the food products developed from standard milk and lactose hydrolysed milk.
c. **Score card is developed for organoleptic evaluation:** A score card was developed and was given to each panelist while conducting organoleptic evaluation of food products developed from both standard dairy and lactose hydrolysed milk .

Tools for organoleptic evaluation

Hedonic scale was used to score the food products developed from both standard and lactose hydrolysed milk. Panelists were asked to score the food products on criteria such as: texture, aroma, odour, aftertaste etc.

Procurement of Lactose Hydrolysed Milk (LHM) and standard milk, raw materials and selection of food products.

Procurement of Lactose Hydrolysed Milk (LHM) and standard milk

Lactose Hydrolysed Milk was procured from GCMMF (write full form), Anand, Gujarat, India in quantity of 250ml per tetra pack. It had beta galactosidase rendering less than 0.01g of lactose in it. However all the other nutritive features were same. Standard milk from the same company was procured commercially.

Selection of food products

Food products which are completely milk based were selected to understand the replacement of standard milk with lactose hydrolysed milk. Care was taken to select food products from each category: beverage, main course and dessert to make sure that lactose intolerance should not be a reason to prohibit individuals from consumption of milk based food items. All the food products prepared from standard milk and lactose hydrolysed milk were studied for their organoleptic features.

Procurement of raw ingredients

All the ingredients for the preparation of various food products were procured from local market and online market.

Development of food products from standard and lactose milk

In this section of the study two food products were developed from each category: beverage, main course and dessert; namely: cold coffee, rose milk, white sauce pasta, vegetable au gratin, *sandesh* and *kheer*.

Cold Coco- It's a cold beverage; using cocoa powder, milk, corn flour and sugar.

Rose milk- It's a cold beverage; using rose syrup, milk, sugar and chopped dry fruits.

White sauce pasta- White sauce pasta is an Italian savoury cuisine. Pasta, onion, garlic, milk, refined flour and some spices were used to cook this delicacy.

Vegetable au gratin- vegetable au gratin is an Italian savoury cuisine. In this vegetables are cooked in white sauce using milk, flour and spices.

Sandesh- It is a popular dessert from West Bengal in India. Sugar, cardamom powder and milk is being used.

Kheer- It is a dessert popular all over the country. Milk, sugar and vermicelli were used for its preparation.

Statistical analysis

Collected data was entered into a Microsoft excel sheet and data was analysed using Statistical Package of Social Sciences (IBM SPSS Statistics 25). Results were expressed in terms of Mean $\pm$ Standard deviation for nutrient consumed. Student t-test was applied to analyse the

organoleptic evaluation of food products developed from standard and Lactose Hydrolysed Milk (LHM).

Phase IV- Development of IEC material

It is being created to generate awareness, disseminate information and educate people about lactose intolerance and lactose hydrolysed milk.

The IEC material pictorially depicts the following components:

I. What is lactose intolerance

II. Causes and types of lactose intolerance

III. How to identify lactose intolerance

IV. Recipes developed from lactose hydrolysed milk

RESULTS and DISCUSSION

The results of the present study entitled "**Assessing the presence of Lactose Intolerance among Children, Adults and Elderly of Urban Vadodara and Evaluating the Impact of Supplementing Lactose Hydrolysed Milk on their Quality Of Life and Nutritional Status"** are presented, and discussed in this chapter.

5.1- Phase I: Screening and identification of Lactose Intolerant (LI) subjects

5.1.1 General information of the respondents

In this phase, semi-structured questionnaire was developed and 503 adults, 272 children and 219 elderly responded to the questionnaire given to them. Most subjects (39.93%) belonged to the age group of 18 to 35 years followed by 13 to 17 years (18.1%). The medical history of the subjects revealed that total adults respondents suffering from diabetes were 3.6% and total respondents suffering hypertension were 6.9% whereas total geriatric individuals suffering from diabetes and hypertension were 7.3% and 9.13% respectively. Around 42% respondents belonged to nuclear family and 15% belonged to joint family.

5.1.2 Gastrointestinal symptoms experienced by respondents upon consumption of the various food groups.

Gastrointestinal symptoms post consumption of food-groups such as milk and milk products, cereals, pulses, fermented foods, fruits and vegetables were assessed. It was observed that 27.5% of the subjects reported to have experienced gastrointestinal symptoms owing to the consumption of milk and milk based products followed by vegetables (14.2%), pulses (5.8%), fermented foods (6.9%), fruits (8.8%) and cereal products (3.2%). Nearly one third of the respondents didn't experience any adverse gastrointestinal symptoms after consumption of various foods (Table 1). Among milk and milk products, it was observed that majority of the subjects had gastrointestinal discomfort post consuming of milk followed by cheese (28%) and *kadhi* (20%) (Table 2).

Table 1- Number of adults, children and elderly suffering from gastrointestinal symptoms upon consumption of various foods (N=994)

Various food groups	Adult (n=503)	Children(n=272)	Elderly(n=219)	Total (N=994)
Milk and milk products	93 **(18.4%)**	99 **(36.4 %)**	82 **(37.4%)**	274 **(27.5%)**
Vegetables	68 **(13.5%)**	50 **(18.3%)**	24 **(10.95%)**	142 **(14.2%)**
Pulses	39 **(7.7 %)**	3 **(1.01%)**	16 **(7.30%)**	58 **(5.8%)**
Cereal products	15 **(2.9%)**	11 **(4.04%)**	6 **(2.73%)**	32 **(3.2%)**
Fermented foods	31 **(6.16%)**	16 **(5.88%)**	22 **(10.04%)**	69 **(6.9%)**
Fruits	26 **(5.16%)**	42 **(15.4%)**	20 **(9.13%)**	88 **(8.8 %)**

Table 2- Number of adults, children and elderly suffering from gastrointestinal symptoms upon consumption of various milk and milk products (N=994)

Milk and milk products	Adult (n=93)	Children (n=99)	Elderly (n=82)	Total -274 (N)
Milk	57 **(61.3%)**	15 **(15.15%)**	53 **(64.6%)**	125 **(45.6%)**
Lassi	6 **(6.45%)**	5 **(5.05%)**	2 **(2.43%)**	13 **(4.74%)**
Kadhi	7 **(7.52%)**	9 **(9.09%)**	4 **(4.87%)**	20 **(7.29%)**
Milk powder	5 **(5.37%)**	8 **(8.08%)**	0 **(0%)**	13 **(4.74%)**
Chaach	4 **(4.30%)**	8 **(8.08%)**	3 **(3.65%)**	15 **(5.47%)**
Milk sweets	2 **(2.15%)**	9 **(9.09%)**	2 **(2.43%)**	13 **(4.74%)**
Milk chocolates	0 **(0%)**	0 **(0%)**	0 **(0%)**	0 **(0%)**
Ice cream	3 **(3.2%)**	12 **(12.12%)**	1 **(1.21%)**	16 **(5.83%)**
Cheese	4 **(4.3%)**	17 **(17.17%)**	7 **(8.53%)**	28 **(10.21%)**
Fruit custard	2 **(2.15%)**	4 **(4.04%)**	6 **(7.31%)**	12 **(4.37%)**
Yogurt	3 **(3.22%)**	6 **(6.06%)**	4 **(4.87%)**	13 **(4.74%)**
Condensed milk	0 **(0%)**	6 **(6.06%)**	0 **(0%)**	6 **(2.18%)**

5.1.3 Screening for lactose intolerance among the subjects using Hydrogen Breath Analyser.

Respondents (N=220) who reported adverse gastrointestinal symptoms post consumption of milk and milk based products were enrolled and hydrogen breath analyser test was performed on the subjects who consented for HBT (N=181).

A total of 62 children, 65 adults and 54 elderly were screened using hydrogen breath analyser test and the results showed that 49.72% of them were lactose intolerant. (Table 3)

Table 3- Presence of lactose intolerance detected post HBT (N=181)

Presence of lactose intolerance	**Adult (n=62)**	**Children (n=65)**	**Elderly (n=54)**	**Total N (%) (N=181)**
Lactose intolerant	30 (48.3%)	30 (46.15%)	30 (55.5%)	90 (49.72%)
Non- lactose intolerant	32 (51.6%)	35 (53.84%)	24 (44.4%)	91 (50.27%)

5.1.3.1 Severity of Lactose Intolerance amongst the subjects.

The subjects with lactose intolerance were further divided into mild, moderate and severe categories depending on the severity of lactose intolerance. Hydrogen gas emitted into the breath analyser was measured in terms of ppm. Subjects producing hydrogen gas >21ppm, >60ppm, >80ppm belongs to mild, moderate and severe malabsorption respectively.
Majority of the subjects (80%) fell in the mild malabsorption category (Figure 1).

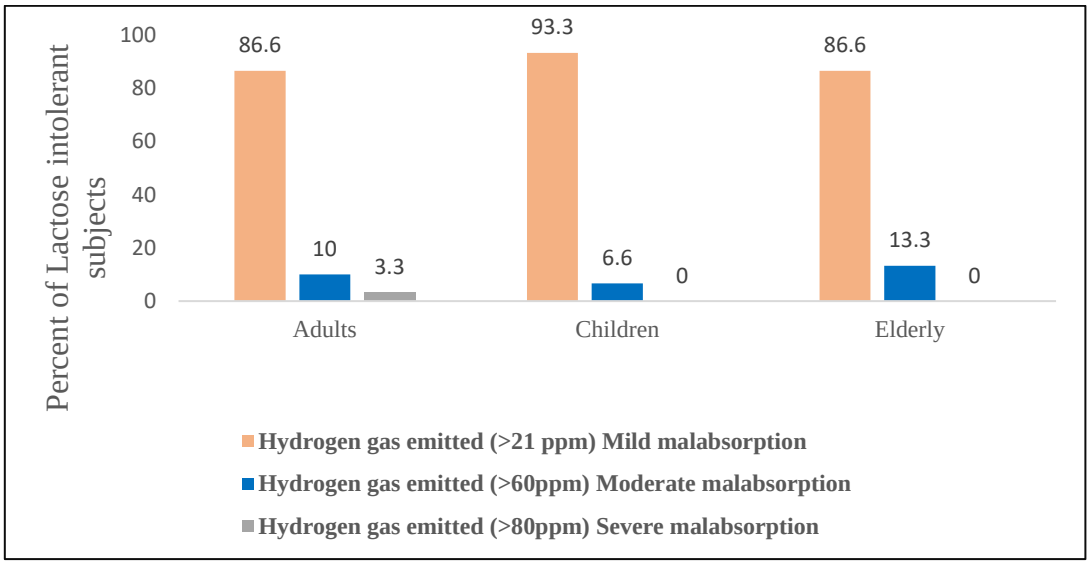


Figure 1- Severity of lactose intolerance amongst the subjects (N=90)

5.1.3.2 Symptoms suffered by lactose intolerant subjects during hydrogen breath Analyser test (HBT) (N=90)

Lactose intolerant subjects experienced symptoms such as flatulence, cramps, diarrhoea and other non-gastrointestinal symptoms like headache. Maximum children, adult and elderly experienced vomiting, diarrhoea and flatulence respectively. Whereas, adult and geriatric individuals suffered from diarrhoea whereas children suffered mostly from flatulence (Figure 2).

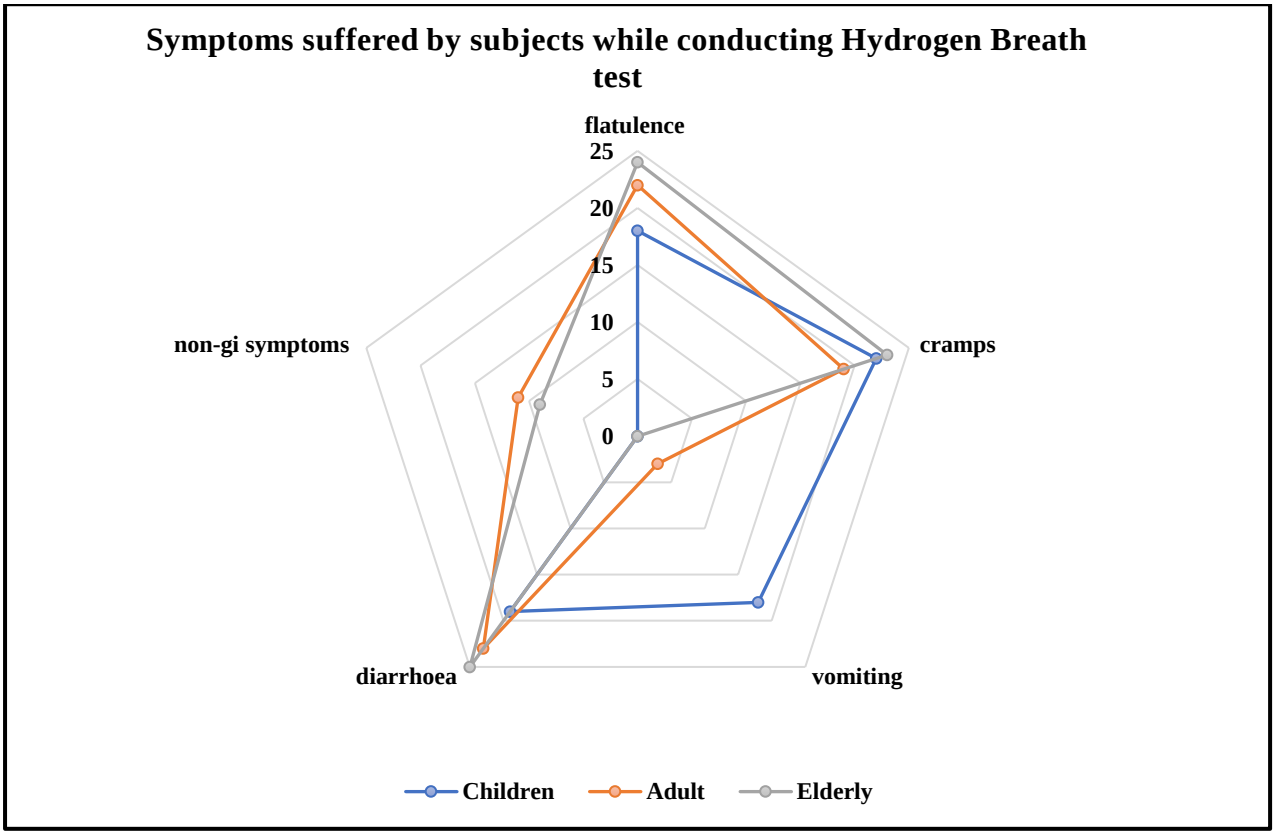


Figure 2- Gastrointestinal symptoms suffered by lactose subjects during hydrogen breath analyser test (HBT)

5.2- Phase II - Supplementation of Lactose intolerant subjects with Lactose hydrolysed milk and its effect on their Dietary intakes, Anthropometry and Quality of life.

In this phase 250 ml lactose hydrolysed milk (LHM) per day was supplemented for a period of 6 weeks to all the lactose intolerant subjects (children, adults and elderly) and the subjects were assessed for dietary intakes, BMI and Quality of life before and after supplementation. Feedback of the subjects upon consumption of LHM was taken post supplementation.

5.2.1 Dietary intake of the lactose intolerant subjects before and after supplementation with LHM

Among children, the percent difference of protein, carbohydrate, fat, calcium and carotenoid post consumption of lactose hydrolysed milk was 3.85, 7.08, 2.73, 5.76, 35.48, 0.61 respectively. Among adults, the percent difference of protein, carbohydrate, fat, calcium and carotenoid post consumption of lactose hydrolysed milk was 8.45, 3.76, 7.26, 58.9, 1.73 respectively. All the nutrients increased significantly post supplementation. Among elderly population, the percent difference of protein, carbohydrate, fat, calcium and carotenoid post consumption of lactose hydrolysed milk was 3.30, 6.54, 4.19,7.34, 43.62, 4.22 respectively ($p < 0.001$).

5.2.2 BMI of the lactose intolerant subjects before and after lactose hydrolysed milk Supplementation

There's an increase in the moderately overweight category post the supplementation among children by 3.4%. Based on the BMI score, adult subjects were categorised into underweight, normal, overweight and obese. It was observed there was a decrease in underweight category post supplementation by 3.5%, eventually improving subjects under normal category by 4%. Though there happen to be no changes in the overweight and obese categories.

In elderly, It was observed, there was an increase in normal category by 6.7% post lactose hydrolysed milk supplementation. Obesity and overweight remained the same whereas underweight decreased by 6% post lactose hydrolysed milk supplementation.

5.2.3 Quality of life of the lactose intolerant subjects before and after supplementation with LHM

Depending upon the severity of lactose intolerance, the subject's quality of life might get affected. Score was divided into 3 categories- poor, average and good. Majority (87%) of the lactose intolerant adults reported to have good quality of life as most of them had stopped completely consumption of milk completely. Since there was no consumption of milk. Therefore lactose intolerance did not affect their quality of life that explains the reason for them having good scores for quality of life. Majority 70% of the lactose intolerant elderly reported to have average quality of life and 16% had poor quality of life.

5.2.4 Feedback from lactose intolerant subjects regarding lactose hydrolysed milk

Lactose hydrolysed milk (LHM) was accepted unanimously from all the three age groups. 100% reported no gastrointestinal symptoms after LHM consumption. 33.3% of the subjects felt that the product is costly compared to normal milk to be consumed daily. Around 20 % subjects reported undesirable smell. On further enquiry it showed that these children disliked the smell of milk, whereas all the parents of the lactose-intolerant children showed willingness to purchase it (Table 4)

Table 4- No. of subjects opining about the organoleptic quality of LHM milk (N=30)

Parameters	**Children N (%) (n=30)**	**Adult N (%) (n=30)**	**Elderly N (%) (n=30)**
Smell – desirable	24 **(80%)**	30 **(100%)**	30 **(100%)**
Undesirable	6 **(20%)**	0 **(0%)**	0 **(0%)**
Sight	30 **(100%)**	30 **(100%)**	30 **(100 %)**
Taste	30 **(100%)**	30 **(100%)**	30 **(100 %)**
Texture	30 **(100%)**	30 **(100%)**	30 **(100 %)**
Desire to purchase	30 **(100%) (response of parents)**	20 **(66.6%)**	30 **(100 %)**

Phase III: Food Product development from Lactose hydrolysed milk and Standard dairy milk

Standard methods were used to develop six food products namely *cold cocoa, rose milk, white sauce pasta, vegetable au gratin, kheer and Sandesh* using standard dairy milk and lactose-free milk. Organoleptic evaluation was performed in duplicates using nine point hedonic scale by 50 semi-trained panel members who qualified the threshold test.

5.3.1 Organoleptic evaluation of beverages with lactose hydrolysed milk and standard dairy milk

No significant statistical differences were seen any of the organoleptic properties for cold cocoa. However there was statistically significant reduction in after taste and taste by 3.8% (p value < 0.05) and 5.1% (p value <0.01) respectively. No significant difference was observed in acceptability of rose milk developed from standard dairy milk and lactose hydrolysed milk.

5.3.2 Organoleptic qualities of white sauce pasta and veg au gratin with lactose hydrolysed milk and standard dairy milk

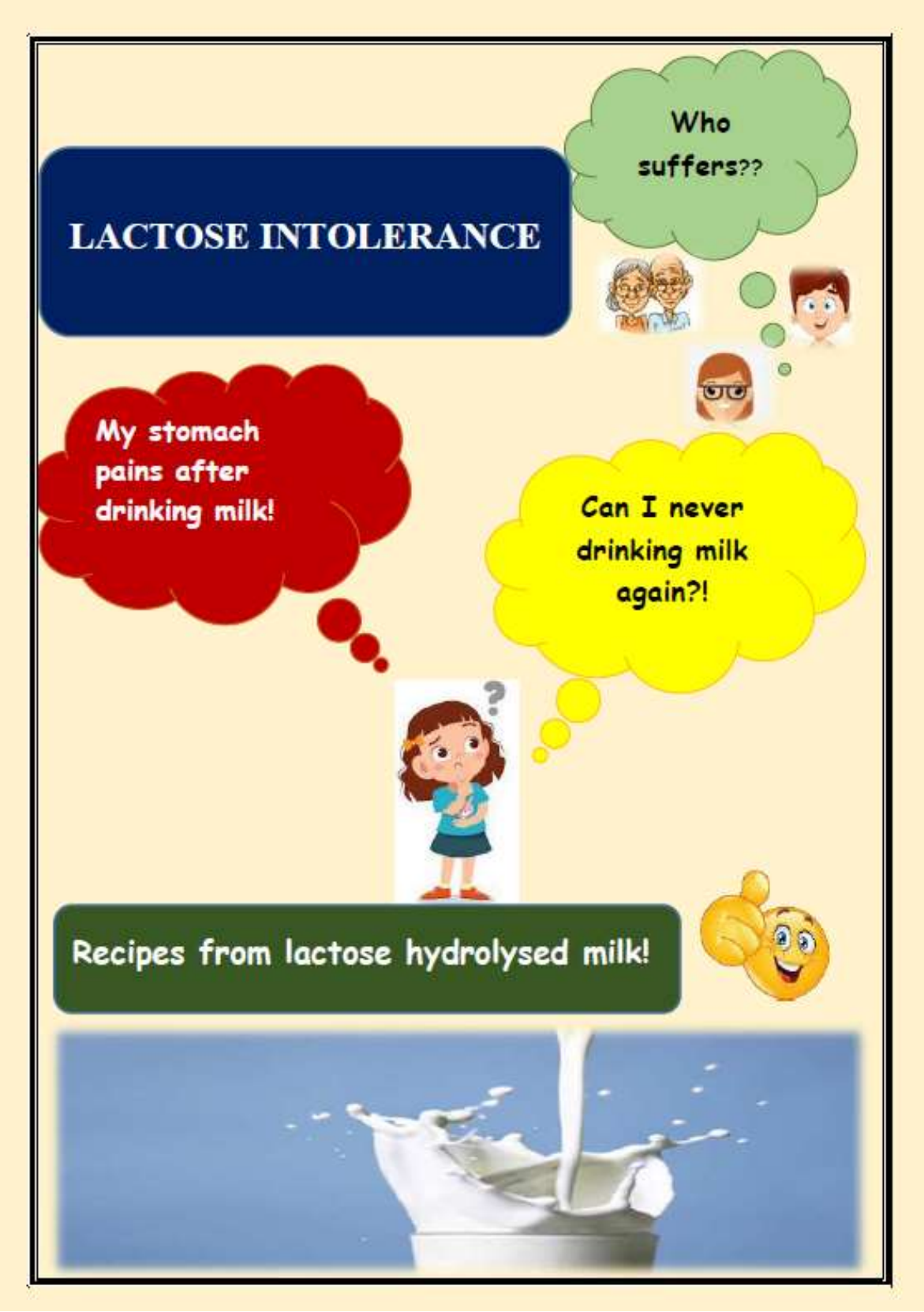
We have observed no significant difference between the organoleptic qualities between pasta made from both the standard milk and LHM, however mouth feel and overall acceptability of white sauce pasta prepared from LHM was significantly higher by 6.8% ($p < 0.001$) and 4.12% ($p < 0.05$) respectively. Likewise no difference were observed in veg au gratin prepared from both standard milk and lactose hydrolysed milk. However score of mouth feel of standard milk was higher than score of moth feel of veg au gratin prepared from lactose hydrolysed milk.

5.3.3 Organoleptic qualities of *kheer* and *Sandesh* with lactose hydrolysed milk and standard dairy milk

We have observed no differences between ***kheer*** and ***Sandesh*** prepared from standard milk and LHM. Yet, taste, after taste and over all acceptability characteristics of standard milk had higher score for *kheer*, texture and mouth feel received higher score for *kheer* made up of lactose hydrolysed milk. Visually, compared to standard milk *Sandesh* prepared from LHM was darker (brownish) in colour. Overall acceptability of *Sandesh* prepared from standard milk received higher score compared to Sandesh made from LHM.

Phase IV- Development of IEC material

The cover page of the IEC material developed is illustrated below:



DISCUSSION

Lactose is the carbohydrate present in milk. It is disaccharide, composed of one molecule of D-glucose and D-galactose. In human body digestion begins in mouth itself owing to the enzyme – salivary amylase. In the acidic environment of stomach digestion of milk starts, here pepsin starts protein digestion by breaking down milk proteins into smaller fragments. Lingual lipase breaks down milk fats into further smaller fragments. These smaller fragments then move further to the small intestine for further digestion. In small intestine lipases and proteases acts upon milk fat and milk protein respectively thereby converting it into diglycerides, monoglycerides, free fatty acids and small peptides and amino acids respectively (Vander A et al., 2001).

Lactose intolerance is caused due to reduced expression or activity of lactase in the small intestine. The undigested lactose accumulated in colon and its fermentation leads to the production of carbon dioxide, hydrogen, methane and short chain fatty acids resulting in the occurrence of gastrointestinal symptoms such as bloating, acidity, diarrhoea etc (Deng Y, Misselwitz B, Dai N, and Fox M., 2015). Symptoms of intolerance towards carbohydrates are caused mainly due to deficiency of enzymes or transporters or overloading of a transport system located on the brush border of the epithelium lining present in the small intestine.

Jones H F et al., 2011 mentioned in their study that the majority of infants with gastrointestinal symptoms exhibited fructose malabsorption, but the capacity to absorb fructose increased with patient age up to 10 years old. Food was considered to cause or worsen their gastrointestinal symptoms in 89.6% of IBS patients compared to 55% of healthy subjects ($P < 0.001$). Cereal-based foods, predominantly bread or its components, were the most frequently cited (53.3%), and spicy foods (39.3%), vegetables and fatty foods (35.6% for both) also featured prominently (Hayes P., Corish C., O'Mahony E and Quigley E., 2013).

In the presence study 22.1% respondents reported gastrointestinal symptoms from milk and milk products which was followed by vegetables (14.2%), pulses (5.8%), fermented foods (6.9%), fruits (8.8%) and cereal products.

Solomons NW et al., 1980 mentioned in their study that 50 g of lactose was used for the breath test but this caused diarrhoea and flatulence in patients during the test. Therefore another study was conducted by (Rana S., et al 1995) to modify dose of lactose for lactose hydrogen breath test. Patients positive with 50 g lactose were repeated with 25 and 12.5 g lactose in 1-week interval. 91.4 % patients were detected of LI with 25 g lactose and 42.8 % with 12.5 g lactose. Symptoms of diarrhea (63 %) and flatulence (97 %) for 50 g of lactose dose decreased to 22.8%

and 34.2 % respectively with 25 g lactose. Therefore, 25 g of oral lactose dose was used for detecting the presence of lactose intolerance in our study.

Another study by Oberacher M., et al 2011 indicated in their study, hydrogen breath analyser test conducted at hourly intervals over a 2 hour duration had an excellent (>95%) sensitivity and specificity to diagnose lactase deficiency.

In the present study lactose intolerance was detected by conducting hydrogen breath analyser test (HBT) among 181 subjects for 3hours, breath being measured at every 30 minutes interval by giving 25g of oral dose of lactose powder in a glass of 250 ml of water. HBT revealed that 49.72% of them were lactose intolerant and 88.8% fell into the mild intolerance category.

Lactose intolerance leads to the occurrence of gastrointestinal symptoms thereby preventing lactose intolerant individuals from consuming milk. Replacement of enzyme lactase can be a mode of treatment lactose intolerance. In one of the study, The feasibility of effective enzyme replacement therapy with a β-galactosidase from *K. lactis* was demonstrated by (Rosado J. L et al., 1984).

Lactase replacement by means of using exogenous enzymes, derived from yeast or fungi with microbial exogenous lactase obtained from the yeast or fungi might be considered as an dependable enzyme replacement therapeutic option (Ianiro G et al., 2016). In present study lactose hydrolysed milk is supplemented based upon the above mentioned concept that lactose when hydrolysed into glucose and galactose is easier to digest than standard dairy milk. Lactose hydrolysed milk supplemented in this study had lactose <0.01g, glucose and galactose present was 2.4 g and 2.4 g respectively in 100g.

Consumption of varieties of milk and milk products have been shown to have a positive effect upon the growth of school children in Kenya (Grillenberger et al., 2003). In another study by Wiley A. S., 2012, it was mentioned that those children who drank milk on a daily basis were taller (1.0 cm; $p<0.02$) compared to those who consumed less. In our study among adults there is a decrease in underweight category from pre consumption (6.9%) to (3.4%) post consumption of lactose hydrolysed milk, no changes were observed among obese or overweight category. In elderly, 33.3% belong to normal category before intervention, whereas post intervention it was 40%. There's an increase in the moderately overweight category post the supplementation among children by 3.4%. Children consumed excess of 7.5 g fat, 7.5 g protein and 12 g carbohydrate daily for a period 6 weeks thereby increasing total energy consumption – 147.5 kcal. This lead to increase in moderately overweight category. Calcium

intake increased by 5.76% post lactose hydrolysed milk supplementation. Kim, H. S et al., 2005 mentioned in their study, consumption of partially lactose digested and low fat milk for a period of 4 months lead to the increase in calcium, protein, fat, phosphorus, riboflavin etc.

The health-related quality of life (HRQOL) is a patient-focused concept, referring to an impairment of functional status (physical or mental) and the sense of well-being. The health-related quality of life was significantly impaired in subjects with GERD, un investigated dyspepsia and IBS in this community (Jeong J. J et al., 2008). Carlson M. J et al., 2014 mentioned in their study, Children reported that food-induced symptoms interfered with school performance, sports, and social activities. despite use of several coping strategies, food-induced symptoms can adversely impact children's QOL in several important areas.

Gopinath B et al., 2016 showed in their study that adolescent boys who remained in the highest tertile versus the lowest tertile of yogurt consumption from age 12 to 17 had higher overall quality of life and mental well-being scores at the 5-year follow-up.

In this study 100% of children supplemented with lactose hydrolysed milk had good quality of life. Majority (87%) of the lactose intolerant adults reported to have good quality of life as most of them had stopped completely consumption of milk completely. Since there was no consumption of milk. Therefore lactose intolerance did not affect their quality of life that explains the reason for them having good scores for quality of life. Majority 70% of the lactose intolerant elderly reported to have average quality of life and 16% had poor quality of life.

Lactose hydrolysed milk can be used in making fermented dairy products such as cheese, yoghurt, dahi and heat desiccated products such as Khoa. Lactose hydrolysis in milk produces better digestibility and sweet taste, thereby leading to the recent rise in the demand for lactose hydrolysed dairy products (Aggarwal A, Seth R, Gandhi K, Wangdare S., 2019).

Similarly results were obtained where higher sweetness in lactose hydrolysed gulabjamun (a deep-fried Khoa Indian dessert) compared with control was observed (Harini and Rao., 2011). In the present study also we see, *Sandesh* prepared from lactose hydrolysed milk had higher sweetness compared to *Sandesh* prepared from standard dairy milk. While heating, during *Sandesh* preparation a slight brown colour appeared due to mailard reaction in lactose hydrolysed milk compared to *Sandesh* prepared from standard dairy milk. From the above studies we can say that a wide variety of food products can be developed from lactose hydrolysed milk without compromising on its organoleptic properties at both household and commercial level.

CONCLUSION and RECOMMENDATIONS

This study has been able to establish successfully that lactose intolerance is a genuine gastric issue to be addressed and lactose hydrolysed milk can be consumed by lactose intolerant individuals in place of standard dairy milk. Lactose hydrolysed milk and standard dairy milk has the same nutritional properties exception being lactose hydrolysed milk has glucose and galactose in place of lactose.

It is concluded from this study that milk and milk products were the main reason to cause gastrointestinal symptoms followed by vegetables and fermented foods. Among milk and milk products, it was observed that majority of the subjects had gastrointestinal discomfort post consuming of milk followed by cheese and *kadhi*. Presence of Lactose intolerance was found to be 11.02% in children, 8.75% in adult 13.7% in elderly population respectively.

Lactose hydrolysed milk does help in increasing protein, fat and calcium intake however it shouldn't be used as means to treat underweight.

It is concluded from this study that lactose hydrolysed milk did not have a major significant impact on Quality of life. However, it should be noted that as subjects had stopped milk consumption prior supplementation and majority had good quality of life.

The sensory panellist accepted all the six food products prepared from lactose hydrolysed milk based upon organoleptic qualities. Thus, these products prepared from LHM can be recommended to lactose intolerant individuals for their consumption.

Detection of lactose intolerance by means of hydrogen breath analyser can be explored further and conducted pan-India to understand the variation within the same country. Hydrogen breath analyser test was used in our study. However, for further research methane and hydrogen breath analyser along with genetic analysis can be used to understand the prevalence of lactose intolerance in the country.

Lactose hydrolysed milk shall be explored further to develop more varieties of recipes to understand its efficacy further.

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