
**“NORMAL RANGE OF VALUES OF LIVER AND
SPLEEN SIZE BY ULTRASONOGRAPHY IN
CHILDREN IN BELAGAVI (NORTH KARNATAKA) –
A ONE YEAR HOSPITAL BASED CROSS
SECTIONAL STUDY”**

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LIST OF ABBREVIATIONS

USG	Ultrasonography
MRI	Magnetic resonance imaging
CT	Computed tomography
CI	Confidence interval
IQ range	Interquartile range
SD	Standard deviation
MHz	Megahertz
MCL	Mid-clavicular line
cm	centimeters
BSA	Body surface area
BMI	Body mass index

ABSTRACT

NORMAL RANGE OF VALUES OF LIVER AND SPLEEN SIZE BY ULTRASONOGRAPHY IN CHILDREN IN BELAGAVI (NORTH KARNATAKA) – A ONE YEAR HOSPITAL BASED CROSS SECTIONAL STUDY

ABSTRACT:

Background: The Liver and spleen are two of the most important intra-abdominal organs screened in paediatric population for any infection or any pathology. Ultrasound is usually the first-line imaging modality used for assessing the paediatric abdomen. Normative data for organ size are challenging in the paediatric population because of changes that occur with growth and development and the effects of the body habitus, including height and weight in contrast to adults.

Objectives: To establish normal range of values for liver and spleen size in terms of length in children in Belagavi (North Karnataka) and to correlate liver and spleen size with age and sex of children.

Materials and Methods: A hospital based cross sectional study was done on 312 children aged between one month to 12 years referred for ultrasound abdomen in a tertiary care institute from 1st January 2019 to 31st December 2019. Study was done using an ultrasonography machine G.E. VOLUSONP8 (GE Healthcare, USA). Liver measurements were performed in supine position. Spleen measurements were performed in right lateral decubitus position. Liver-Length and Spleen-Length were considered as primary outcome variables. Age and gender were considered as other explanatory variable. P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis. Regression coefficient, along with its 95% CI and p values were presented.

Results:There was an even distribution of study subjects across the age groups. Male children contributed to 55.77%. The mean Liver length was 9.2 ± 2.2 cm. Liver length increased by 0.481 cm for one year increase in age. **“Liver Length = 7.04 + 0.48 X age (years)”**. The mean Spleen length was 6.66 ± 1.63 cm. There was a statistically significant difference between mean spleen length at baseline compared to spleen length at various age groups except at 3 months to <6 months. Spleen length increased by 0.297 cm for one year increase in age. **“Spleen Length = 5.34 + 0.297 X age (years)”**. Sex was not a determining factor.

Conclusion:There was a statistically significant correlation between liver and spleen length and age of the child. Sex was not a determining factor for organ dimensions in the pediatric age group. Our study is one of the kind in creating a database for normal values of liver and spleen from this part of the country.

Keywords:Liver, Spleen, Length, Size, Ultra sonogram, Regression equation, Age, Children, Organ dimension, Correlation.

CONTENTS

SL. NO.	TOPIC	PAGE NO.
1.	INTRODUCTION	1-3
2.	OBJECTIVES	4
3.	REVIEW OF LITERATURE	5-26
4.	METHODOLOGY	27-30
5.	RESULTS	31-41
6.	DISCUSSION	42-50
7.	CONCLUSION	51-52
8.	SUMMARY	53-55
9.	BIBLIOGRAPHY	56-61
10.	ANNEXURES	
	ANNEXURE I – CONSENT FORM	62-66
	ANNEXURE II – ETHICAL CLEARANCE LETTER	67
	ANNEXURE III – PROFORMA	68
	ANNEXURE IV – FIGURES	69-71
	ANNEXURE V – KEY TO MASTER CHART	72
	ANNEXURE VI – MASTER CHART	73-80

LIST OF TABLES

TABLE NO.	PARTICULARS	PAGE NO
1	Couinaud classification of liver	7
2	Mid clavicular line longitudinal diameter of the liver in 310 healthy children as measured by ultrasound	9
3	Longitudinal length of the liver in various categories of body weight	10
4	Normative data for spleen size in various age groups	14
5	Various diameters and volume of spleen with respect to different age groups	15
6	Relation between various categories of body weight and longitudinal length of the spleen	16
7	Studies measuring liver size in healthy children	18
8	Studies measuring spleen size in millimeters in healthy children	22
9	Descriptive analysis of age groups in the study population	31
10	Descriptive analysis of gender in the study population	32
11	Descriptive analysis of liver- length, spleen-length in study population	33
12	Comparison of mean of liver - length and spleen - length between gender	34
13	Comparison of mean liver- length across the age groups	35
14	Comparison of mean spleen-length across the age groups	36
15	Comparison of mean of liver- length and spleen length between gender at different age groups	37
16	Simple linear regression between liver length and age.	41
17	Simple linear regression between spleen length and age	41
18	Comparison of our study results with other studies	43

LIST OF GRAPHS

GRAPH NO	PARTICULARS	PAGE NO
1	Pie chart of age groups in the study population	31

2	Pie chart of gender in the study population	32
3	Line chart for comparison of mean of liver - length and spleen - length between gender	34
4	Line chart for comparison of mean of liver - length across the age groups	35
5	Line chart for comparison of mean of spleen - length across age groups	36
6	Line chart for comparison of mean of liver - length and spleen - length of age group (1 month – <3 months) between gender	38
7	Line chart for comparison of mean of liver - length and spleen - length of age group (3 month – <6 months) between gender	38
8	Line chart for comparison of mean of liver - length and spleen - length of age group (6 month – <12 months) between gender	38
9	Line chart for comparison of mean of liver - length and spleen - length of age group (1 year – <2 years) between gender	39
10	Line chart for comparison of mean of liver - length and spleen - length of age group (2 years – <4 years) between gender	39
11	Line chart for comparison of mean of liver - length and spleen - length of age group (4 years – <6 years) between gender	39
12	Line chart for comparison of mean of liver - length and spleen - length of age group (6 years – <8 years) between gender	40
13	Line chart for comparison of mean of liver - length and spleen - length of age group (8 years – <10 years) between gender	40
14	Line chart for comparison of mean of liver - length and spleen - length of age group (10 years – <12 years) between gender	40

LIST OF FIGURES

Figure No.	Particulars	Page No.
1	Segmental anatomy of the liver	6

2	Gross anatomy of the Liver	7
3	The position of paediatric spleen	13
4	The position of paediatric spleen	13
5	Spleen size in various age groups	17
6	Linear liver measurements in longitudinal plane in studies from literature	18
7	Measurement of liver size in the largest craniocaudal diameter in mid-clavicular line	19
8	Diagram showing the method for measuring splenic length and width by ultrasound	21
9	Ultrasound measurement of longitudinal length of spleen	21
10	Comparison of liver length measurement by our study Vs Dhingra B et al	46
11	Comparison of spleen length measurement by our study Vs Konoş OL et al	48
12	GE VOLUSON P8 USG machine used for the study	69
13	USG image of liver in the right midclavicular line	70
14	USG image showing measurement of craniocaudal dimension of the liver in the midclavicular line	70
15	USG image of spleen, longitudinal view	71

16	USG image showing measurement of spleen length between the most superomedial and the most inferolateral points	71
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INTRODUCTION

The Liver and spleen are two of the most important intra-abdominal organs screened in paediatric population for any infection or any pathology. Ultrasound is a vital imaging technique in paediatric age group for assessing a variety of clinical conditions as it is safe besides being convenient, handy and fast. It can be used everywhere from outpatient care to emergency care to inpatient care. It is usually the initial modality of imaging used for evaluating the paediatric abdomen. Any abnormality in the size of the liver or spleen may denote a pathological disease. But its assessment is challenging, with change in the size of the organs with age. The normative published values also vary according to the population and the methods used for estimation.¹ It is important to measure the dimensions of abdominal organs in paediatric age group as it is vital for observing the growth patterns of abdominal organs and their diagnosis and management if needed.² The size of the organ is critical in the interpretation of the disease. A physical examination may not be sufficient to detect the minor changes in the size of the organs like liver and spleen. Also interpreting the normative data is perplexing in children due to the effect of various anthropometric characteristics such as weight and height besides age, their body habitus and various known, unknown factors. There are well established normal ranges in adults, but in the paediatric age group, there is no well established data.³ There are also a few studies in children that outline the normative data of organ size in healthy children.⁴⁻⁶ In cases like hepatomegaly, which is a relatively common clinical finding in children, it is necessary to identify the cause and treat at an earlier stage as it may be due to intrinsic liver diseases or due to hepatic steatosis or it could also be due to childhood obesity. Early detection is needed in critical cases to avoid premature liver failure. The spleen could be palpable in about 15% to 17% of healthy

neonates and in about 10% of healthy children.⁷ For the spleen to be palpable in most children, it must achieve a size that is double or triple its normal size.⁴ It is essential to measure the size of the spleen as various illnesses present by change in the size of the spleen. There may be increase or decrease in the spleen size. Serial measurements of the size of the paediatric spleen helps in tracing the normal growth pattern besides helping in following up of the pathological process. Hence establishing the normative spleen values by serial ultrasound measurements can help in establishing the diagnosis of locally endemic diseases. Syndromes such as Tropical splenomegaly, diseases such as malaria, sickle cell disease and lymphoma can be diagnosed comfortably if baseline values of spleen size are available. The sonographic assessment of spleen is also very important because of the essential functions done by the spleen. To completely understand the disease process, morphological details of the organ and laboratory parameters are essential. But in certain conditions like malaria, organomegaly could be the only feature on ultrasonography. And also not always the spleen, which is palpable clinically, is essentially pathological. In certain conditions, spleen may be palpable without any clinical significance, because it is pushed down due to any pathology present sub-diaphragmatically. The changes in the size of the abdominal organs is difficult to interpret clinically and is also not reliable.⁸ Hence imaging techniques play a key role in assessment of abdominal organs. Among the various modalities available, MRI is not readily accessible to everyone for routine use because of its cost while computed tomography is associated with radiation exposure and hence may not be suitable for serial measurements.⁹ But USG has the capacity to distinguish the disease by identifying the abnormalities in organ size. It may be the first choice for detecting the abnormalities in organ size in all settings. Ultrasonography is a non-invasive, recognised, safe and fast method for measuring

the size of the liver and spleen.^{1, 10} Spleen and liver sizes are integral part of routine abdominal ultrasonography as alteration in size can be indicative of a variety of pathological conditions.^{11, 12} In addition, false positive labelling of a patient as having organomegaly can lead to further investigations, causing anxiety to the patient as well as unnecessary expenditure. The ability to recognize abnormal enlargement of an organ, inevitably requires generally accepted reference values for a particular population as sizes vary with age, gender and ethnicity. Several studies have been conducted in different parts of the world including India to provide normal reference values for liver and spleen sizes to respective population.^{1, 3, 10-12}

Need of the study:

But the literature on normal range of ultrasound size of liver and spleen in paediatric population in north Karnataka is lacking. There are also no well-designed large scale studies in Karnataka to our knowledge in this regard. But a study is necessary to provide reference values for this population as well as to see how much it is par with the reference values being followed currently. This study will also help to avoid misdiagnosis of those pathological disorders affecting the liver and spleen size. There are variations in the size of the spleen and liver with regards to age of the subject, sex of the subject, anthropometric characteristics such as weight, height, body mass index (BMI) and body surface area (BSA) in paediatric age group. Hence, normal values of dimensions of liver and spleen in children in our area needs to be assessed. The availability of these figures from our study will go a long way in establishing normative values and help in establishing a more practical way of evaluating the size of liver and spleen sonographically. Hence this study was carried out with the objective of estimating the normal values for liver and spleen size in paediatric age group and to correlate it with their age and sex.

OBJECTIVES

1. To establish normal range of values for liver and spleen size in terms of length in children in Belagavi (North Karnataka)
2. To correlate liver and spleen size with age and sex of children.

REVIEW OF LITERATURE

LIVER – ANATOMY, NORMAL DIMENSIONS IN ADULTS, CHILDREN

The liver is a large organ located on the right side of the abdomen beneath the diaphragm extending up to the left side of upper abdomen. It is shaped like a prism or wedge. The apex is situated on the left while base is situated on the right. It is highly vascular and easily friable. Weighing about 1500 grams in adults, it is reddish-brown in color. It has a rubbery feel on touch. It is divided into two lobes – the right and the left. Under the liver, the gallbladder is situated. It is involved in filtering the blood from the digestive tract, detoxification of chemicals and metabolism besides manufacturing proteins needed for clotting and other essential functions.

PAEDIATRIC LIVER:

Anatomy:

Segmental anatomy of paediatric liver is very alike to that seen in adults. But the liver in children is larger in relationship to their body weight on comparison with adults. In adults, the liver contributes only 2 to 3% of the body weight compared to 4% in children.^{13, 14} In children, the right lobe of the liver anteriorly extends below the costal margin and posteriorly it is near to the iliac crest. In children, the left lobe of the liver extends to the lateral wall of the abdomen, covering spleen and the stomach.¹⁴ In adults, the abdomen is generally rectangular with the long axis vertical and the most common open surgical approaches are made through vertical incisions. In babies the abdomen is broader than it is long and open procedures are generally made through transverse supra umbilical incisions.

With regards to location, the liver is situated in the right sub phrenic space. It is maintained in its position by its connection with the vena cava and the folds of

peritoneum. These folds only continue on the liver surface as Glisson's capsule and on the abdominal cavity as parietal peritoneum. When healthy, these folds are thin and avascular. The liver is divided into two lobes and ultimately into eight segments. The left lobe comprises of segments two, three and four while the right lobe contains segments five, six, seven and eight.^{15, 16} These segments are supplied by their own portal radical and hepatic artery branches and a segmental bile duct. The adjacent segments are separated by hepatic veins. The vascular supply and its vascular anatomy is analogous in children as adults.¹⁷⁻¹⁹ The right and left lobes are separated by an imaginary line called cantlie's line, extending from the gallbladder base to middle hepatic vein.

Figure 1: Segmental anatomy of the liver:

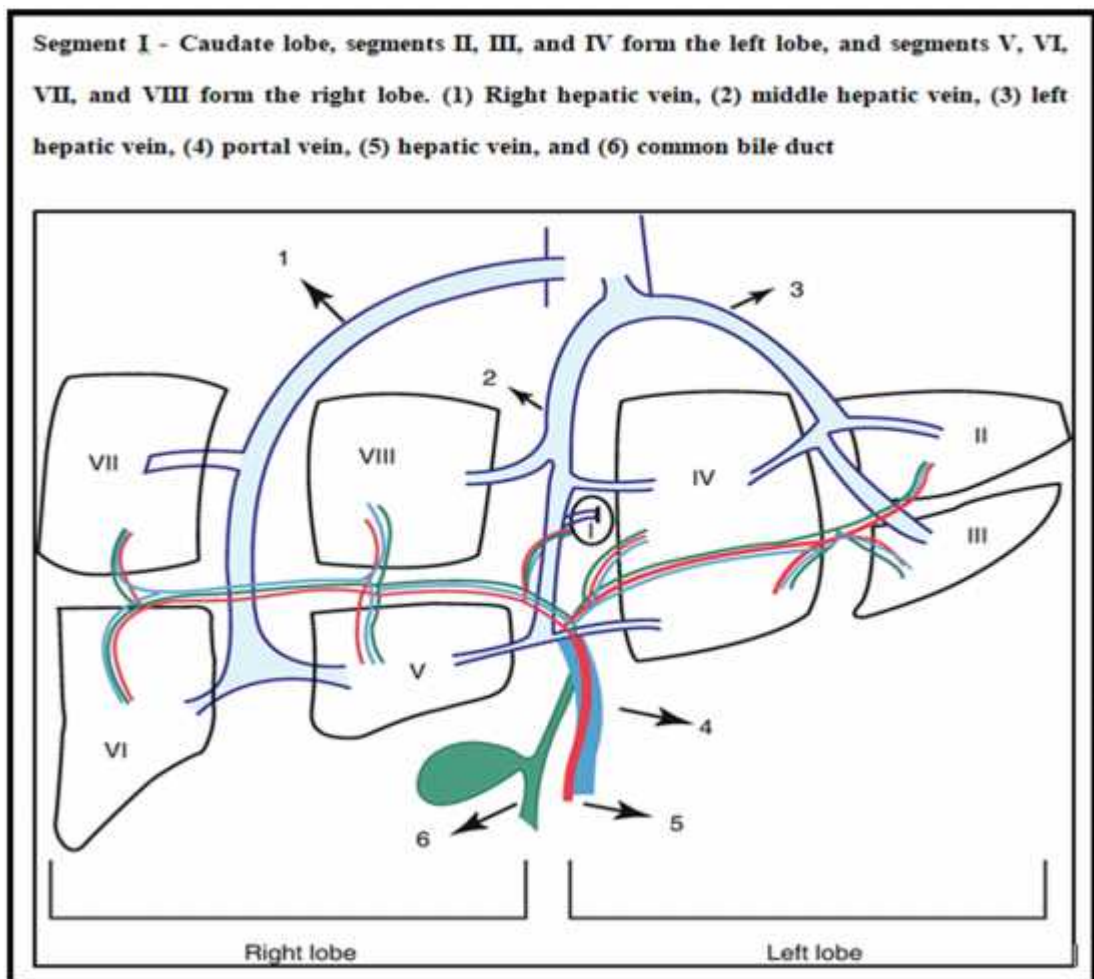
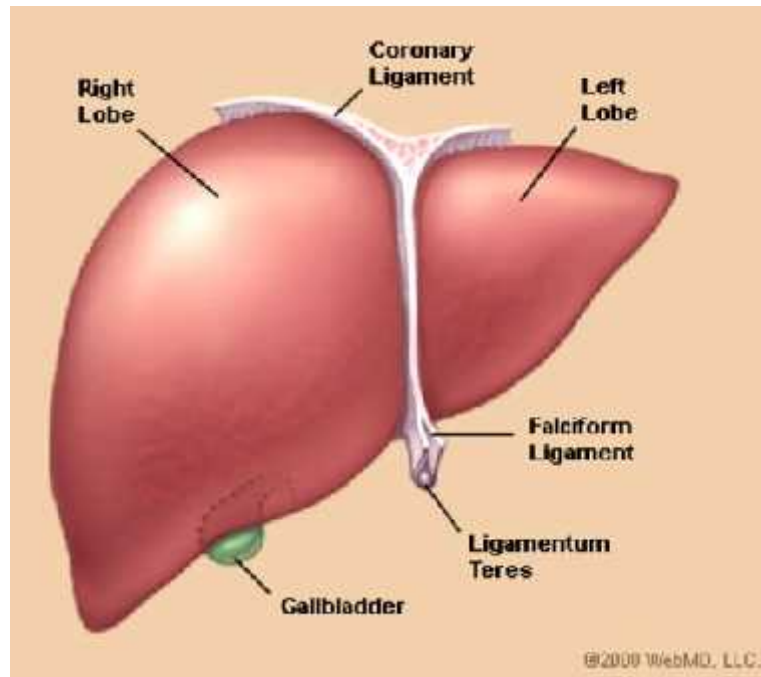


Figure 2: Gross anatomy of the Liver



Source: WebMD

Table 1 : Couinaud classification of liver ¹⁶

Couinaud classification of the liver			
Right lobe		Left lobe	
Right posterior section	Right anterior section	Left medial section	Left lateral section
Segments 6 and 7	Segments 5 and 8	Segment 4	Segments 2 and 3

NORMAL DIMENSIONS IN ADULTS, CHILDREN:

The liver isn't a proportional organ. Its lobes are different sizes and can be larger and smaller in areas depending on where the radiology professional is taking measurements.^{20, 21} These differences can cause some variance accuracy.

The size of the organ is critical in the interpretation of the disease. A physical examination may not be sufficient to detect the minor changes in the size of the organs like liver. Ultrasound is a very popular technique commonly used for liver

examination. There is no consensus on a single constant method for measuring the dimensions of the liver. The presently available normative data is grounded on surveys with smaller sample sizes^{22, 23}, populations which are highly selective²⁴ and from studies based on autopsy.²⁵ The effect of anthropometric variables such as height, weight, BMI needs to be assessed. There is also a lack of data on general populations or a community based population. Dietary factors may also play a role in size of the abdominal organs and their development with age. It is also challenging to bring the three dimensional liver volume into a single parameter which is measurable.²⁶ For assessment of the paediatric patient, there is a need for an easy, accurate and reliable way of measuring the organ size. “One of the most commonly applied methods of estimating liver size in routine diagnostic situations is measurement of the liver diameter in the midclavicular line (MCL)”.²⁷ Niederau C et al²⁴ (1983) in their study observed that in measurement of liver size, there is a need for estimating longitudinal as well as anteroposterior diameters. They observed that only measuring longitudinal diameter may result in higher or lower values than normal.

Men tend to have a larger liver size than women. This is usually because men’s bodies tend to be larger. While liver sizes can vary slightly, there are some studies about the average liver size by age.

The following are the results of the study measuring the average liver length for boys in the study by Dhingra B et al (2010).³ They performed ultrasound evaluation of 597 healthy children between the ages of 1 month and 12 years.

Age	Liver length (Boys)
1 to 3 months	2.6 in. (6.5 cm)
3 to 6 months	2.8 in. (7.1 cm)
6 to 12 months	3.0 in. (7.5 cm)
1 to 2 years	3.4 in. (8.6 cm)

2 to 4 years	3.5 in. (9.0 cm)
4 to 6 years	4.1 in. (10.3 cm)
6 to 8 years	4.3 in. (10.8 cm)
8 to 10 years	4.7 in. (11.9 cm)
10 to 12 years	5.0 in. (12.6 cm)

The following are the results for liver length in girls:

Age	Liver length (Girls)
1 to 3 months	2.4 in. (6.2 cm)
3 to 6 months	2.8 in. (7.2 cm)
6 to 12 months	3.1 in. (7.9 cm)
1 to 2 years	3.3 in. (8.5 cm)
2 to 4 years	3.5 in. (8.9 cm)
4 to 6 years	3.9 in. (9.8 cm)
6 to 8 years	4.3 in. (10.9 cm)
8 to 10 years	4.6 in. (11.7 cm)
10 to 12 years	4.8 in. (12.3 cm)

Liver size can vary by sex, body mass index, height, amount of alcohol consumed, and many other factors.

Table 2: Mid clavicular line longitudinal diameter of the liver in 310 healthy children as measured by ultrasound²⁸

Subjects		Longitudinal Dimensions (mm) of Right Lobe of Liver									
Age Group	No.	Mean	SD	Median	Minimum	Maximum	Percentile for Mean		95% Confidence Interval		
							10th	90th	Lower Bound	Upper Bound	
1	0-<3 mo	21	64	14	63	45	85	46	84	57	70
2	3-<6mo	24	72	14	75	47	90	50	87	66	78
3	6-<12 mo	24	79	10	78	61	100	68	96	75	83
4	1-<2y	30	85	11	84	65	104	69	100	80	89
5	2-<4y	27	92	11	93	70	111	75	106	88	96
6	4-<6y	27	100	15	104	70	120	77	118	94	106
7	6-<8y	31	105	14	108	72	125	80	121	99	110
8	8-<10y	26	110	14	112	81	130	85	127	104	115
9	10-<12y	27	115	12	117	87	130	94	127	110	119
10	12-<14y	38	118	12	122	90	133	97	131	114	123
11	14-<16y	35	121	12	127	95	137	99	133	117	125

MCL: Midclavicular Line Longitudinal Diameter

Table 3: Longitudinal length of the liver in various categories of body weight¹⁰

Weight group (Kg)	liver length (cm)						95% CI of the mean	
	Median	IQrange	Mean	SD	Min	max	Upper	lower
≤20 n = 126	7.40	6.90-7.87	7.44	0.93	5.10	10.4	7.27	7.60
21-30 n = 158	8.18	7.64-8.75	8.22	0.91	5.54	10.8	8.07	8.36
31-40 n = 11	9.39	8.63-10.20	9.42	1.26	5.42	11.8	9.02	9.81
≥41 n = 7	10.00	8.74-10.60	9.85	1.10	8.53	11.5	8.83	10.87

In the study by Kratzer W et al²⁹ in 2003, they measured the average liver diameter of more than 2,080 male and female participants between 18 and 88 years old at the mid clavicular line.

The study's results found the following:

Age	Average liver diameter
18 to 25 years	5.4 in. (13.6 cm)
26 to 35 years	5.4 in. (13.7 cm)
36 to 45 years	5.5 in. (14.0 cm)
46 to 55 years	5.6 in. (14.2 cm)
56 to 65 years	5.7 in. (14.4 cm)
Greater than 66 years	5.6 in. (14.1 cm)

This study represents one of the largest populations studied regarding average liver length, and it concluded that the average liver size in adults was 5.5 inches (in.), or 14 centimeters.

Increase in the size of the liver is called hepatomegaly. It can be either due to an intrinsic disease of the liver or due to a systemic disorder.³⁰

It is not always hepatomegaly when the liver is palpable. Clinically, hepatomegaly is assessed by percussion and palpation in the mid clavicular line. The upper edge is determined by percussion. The lower edge is identified by determining the amount of extension in the right side beneath the costal margin either by palpation or percussion. Auscultation can also be used to determine the lower border. Liver span is determined by measuring the distance between the upper edge and the lower edge. Radiologically, it is determined by its length measured vertically. In common practice, hepatomegaly is extension of liver edge beneath the costal margin on the right side by 2 centimetres in children and 3.5 centimetres in newborn.³⁰ The length or span of the liver has correlation with body weight more than the body height in paediatric age group. There is also correlation with age in children. With increase in age, the liver span increases. In a one week old child, the liver span is 4.5 to 5 centimetres, determined by percussion. It is around 6 to 6.5 centimetres in a twelve year old boy while it is 6 to 6.5 centimetres in a twelve year old girl.³⁰ Normally, in children who are healthy, the edge of the liver may be palpable along the mid clavicular line by atleast two centimetres beneath the costal margin. So estimation of liver span clinically is better correlated with diagnosis of enlarged liver than predicting the amount of extension beneath the costal margin alone. There is a curvilinear relationship between size of the liver with age and anthropometric variables.

Radiographic imaging plays a major role in estimating liver size and can supplement clinical examination. MRI, CT, USG and sulfur colloid scintigraphy are various modalities available to determine the size of the liver reliably. Radiographic and ultrasonic measurements were associated with up to 8% lower estimates of liver size compared to measurements made at autopsy.³¹

IMPORTANCE OF LIVER SIZE IN CHILDREN AND HEPATOMEGALY:

Hepatomegaly is a relatively common clinical finding in children. It is necessary to identify the cause and treat at an earlier stage as it may be due to intrinsic liver diseases or due to systemic disorders. It could be due to hepatic steatosis or it could also be due to childhood obesity. Early detection is needed in critical cases to avoid premature liver failure. It is not always hepatomegaly when the liver is palpable. The edge of the liver may be palpable beneath the costal margin in normal healthy children. But it feels soft on touch and moves easily with inspiration.³⁰ The causes of hepatomegaly in children may range from intrinsic storage disorders to obstructive causes to parasitic causes of infection.³²⁻³⁵ Hepatomegaly may be associated with other symptoms and signs. Dyspnoea, diarrhoea, tiredness, seizures, enlargement of spleen and jaundice may accompany hepatomegaly. Enlargement of liver may be due to various pathophysiological mechanisms like inflammation, congestion of liver, storage disorder related pathology, obstruction and infiltration. Hepatomegaly is defined as a liver edge 3.5cm below the right costal margin in newborns and 2 cm below the right costal margin in older children. The average liver span is 4-5 cm in newborns and 6-8 cm in children at 12 years of age. The border of the liver can be found by palpation, percussion and auscultation. Of note, the liver may be displaced downward by the diaphragm or thoracic contents leading to false impression of hepatomegaly.

SPLEEN – ANATOMY

In humans the spleen is purple in color and is in the left upper quadrant of the abdomen. The gross weight of the spleen is 15 grams at birth and it is lesser than six centimetres in length. The size of the spleen increases in a logarithmic scale with

increase in age of the children.⁴ The spleen is located in the left part of the abdomen under the diaphragm. It has a convex surface facing the diaphragm, below the 9th, 10th and 11th ribs. A ridge divides it into two parts on the other side, gastric part anteriorly and renal part posteriorly. Below this it is in contact with the tail of the pancreas. In adults, the spleen size varies from seven to fourteen centimetres. Accessory spleens are very common in the neonate and usually found in the greater omentum.⁴ Histologically, spleen is made up of white and red pulp and their ratio increases with age and antigenic stimulus.^{36, 37} Thus the anatomy of spleen is very unique and leads to observation of several variations in radiological imaging.

Figure 3: The position of paediatric spleen

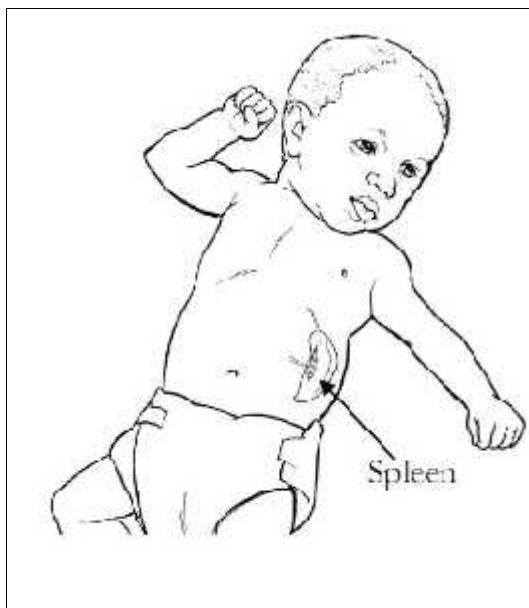
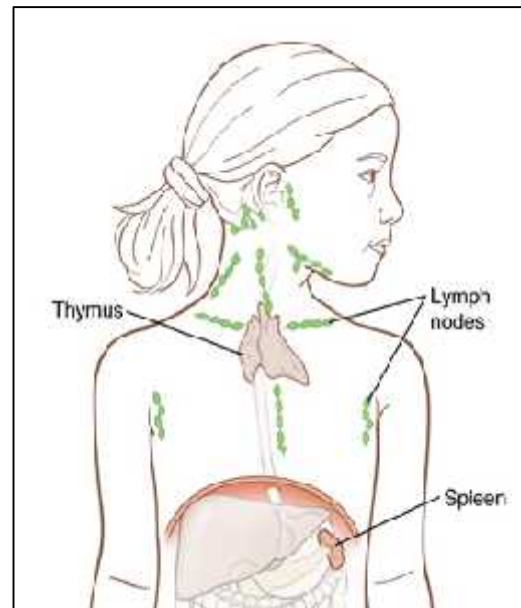


Figure 4: The position of paediatric spleen



NORMAL DIMENSIONS IN ADULTS, CHILDREN

The size of the spleen varies according to the age of the child. The length of the spleen is “measured by obtaining the greatest longitudinal distance between the dome of the spleen and the tip in coronal view that included the hilum, while the patient was breathing quietly”.⁴

Table 4: Normative data for spleen size in various age groups⁴

The three numbers below represent the 10th percentile, median, and 90th percentile for the long axis of the spleen (cm)

AGE IN MONTHS OR YEARS	LONGITUDINAL AXIS OF SPLEEN IN CENTIMETRES (10 th , 50 th and 90 th percentile)
0-3 months	3.3, 4.5, 5.8
3-6	4.9, 5.3, 6.4
6-12	5.2, 6.2, 6.8
1-2 years	5.4, 6.9, 7.5
2-4	6.4, 7.4, 8.6
4-6	6.9, 7.8, 8.8
6-8	7.0, 8.2, 9.6
8-10	7.9, 9.2, 10.5
10-12	8.6, 9.9, 10.9
12-15	8.7, 10.1, 11.4
15-20	
A. Female	9.0, 10.0, 11.7
B. Male	10.1, 11.2, 12.6

There are variations in the measurements of spleen with age. Spleen is usually not palpable. In pathological conditions, it may become palpable when it becomes enlarged twice or thrice its size.^{38, 39} In a normal healthy child or a neonate also, the spleen may be palpable as reported in the literature.^{3, 40} Thus clinical measurement of spleen by percussion and palpation may be inaccurate in detecting marginal increase in spleen size.⁷

Table 5: Various diameters and volume of spleen with respect to different age groups:³⁸

Variable	mean	SD	median	25th	75th	Kruskal Wallis p-value [& post-hoc comparisons]	2.5th	3rd	97th	97.5th
Volume (cm ³)						<0.001				
0-18 years	81.0	51.4	70.8	41.2	105.8		13.2	14.9	205.1	221.2
0-3 years	33.1	15.48	31.9	23.5	37.9	0-3 vs 4-10: <0.001	9.3	9.6	67.4	68.3
4-10 years	74.9	30.12	70.2	54.8	90.2	0-3 vs 11-18: <0.001	30.1	30.4	142.3	147.4
11-18 years	125.5	52.14	111.2	90.5	153.0	4-10 vs 11-18: <0.001	42.0	42.6	248.9	264.6
Transverse area (cm ²)						<0.001				
0-18 years	23.9	11.1	22.7	15.7	30.3		7.1	7.5	47.0	51.1
0-3 years	13.1	4.5	12.8	9.9	15.5	0-3 vs 4-10: <0.001	6.2	6.4	23.8	24.0
4-10 years	22.8	6.0	22.3	18.2	26.8	0-3 vs 11-18: <0.001	12.3	12.5	34.4	36.0
11-18 years	33.6	11.0	32.4	27.8	38.8	4-10 vs 11-18: <0.001	15.1	16.1	55.0	58.5
Longitudinal spleen diameter (cm)						<0.001				
0-18 years	8.4	1.8	8.4	6.9	9.7		4.6	4.7	11.4	11.7
0-3 years	6.2	1.1	6.4	5.7	6.8	0-3 vs 4-10: <0.001	3.5	3.7	8.6	8.7
4-10 years	8.4	1.0	8.3	7.7	9.1	0-3 vs 11-18: <0.001	6.4	6.4	10.6	10.6
11-18 years	9.9	1.2	9.9	9.1	10.8	4-10 vs 11-18: <0.001	7.8	7.9	12.4	12.5
Antero-posterior diameter (cm)						<0.001				
0-18 years	3.2	0.8	3.2	2.6	3.7		1.7	1.7	4.7	4.9
0-3 years	2.4	0.5	2.3	2.1	2.7	0-3 vs 4-10: <0.001	1.4	1.5	3.4	3.4
4-10 years	3.2	0.6	3.2	2.8	3.5	0-3 vs 11-18: <0.001	2.0	2.0	4.4	4.5
11-18 years	3.8	0.7	3.8	3.4	4.2	4-10 vs 11-18: <0.001	2.6	2.7	5.7	6.0
Ratio of spleen volume to abdominal volume (%)						0.17				
0-18 years	1.2	0.5	1.1	0.9	1.4		0.47	0.49	2.21	2.28
0-3 years	1.2	0.5	1.2	0.9	1.4		0.55	0.57	2.52	2.80
4-10 years	1.2	0.5	1.1	0.9	1.5		0.46	0.47	2.36	2.36
11-18 years	1.1	0.4	1.0	0.8	1.4		0.39	0.47	2.02	2.10
Ratio of antero-posterior spleen diameter to antero-posterior abdominal diameter						0.09				
0-18 years	0.17	0.03	0.17	0.15	0.19		0.12	0.11	0.22	0.23
0-3 years	0.17	0.03	0.16	0.15	0.18		0.11	0.11	0.22	0.22
4-10 years	0.18	0.03	0.17	0.15	0.19		0.11	0.10	0.22	0.23
11-18 years	0.17	0.03	0.18	0.15	0.19		0.11	0.10	0.21	0.23
Ratio of longitudinal spleen diameter to xipho-pubic distance (%)						<0.001				
0-18 years	35.8	5.5	35.5	32.6	38.8		25.7	25.8	46.0	47.4
0-3 years	37.8	5.7	37.2	34.3	41.4	0-3 vs 4-10: <0.001	27.1	27.4	51.1	51.9
4-10 years	35.2	5.9	35.2	31.8	37.7	0-3 vs 11-18: <0.001	25.5	25.6	48.9	52.1
11-18 years	35	4.3	34.4	32.1	37.9	4-10 vs 11-18: 0.94	26.2	27.3	45.0	45.2
Ratio of longitudinal spleen diameter to longitudinal left kidney diameter (%)						0.48				
0-18 years	105.6	13.4	105.1	96.6	113.6		83.0	83.6	135.6	136.3
0-3 years	105.6	14.7	105.3	93.7	115.4		77.3	79.5	140.4	145.1
4-10 years	106.6	12.9	107.2	97.8	113.7		85.1	85.8	137.2	139.0
11-18 years	104.4	12.9	103.8	95.8	112.1		82.2	83.2	133.0	134.5

Table 6: Relation between various categories of body weight and longitudinal length of the spleen¹⁰

Weight group (Kg)	Spleen length(cm)						95% CI of the mean	
	Median	IQ range	Mean	SD	Min	Max	Upper	lower
≤20 n = 126	6.90	6.38-7.52	6.93	0.84	5.0	9.70	6.78	7.08
21-30 n = 158	7.54	7.27-8.13	7.54	0.79	5.41	9.70	7.41	7.66
31-40 n = 41	8.55	7.76-9.17	8.46	1.04	5.72	10.7	8.13	8.78
≥41 n = 7	9.26	8.64-9.36	9.09	0.52	8.50	9.92	8.61	9.57

ALTERED DIMENSIONS OF SPLEEN AND CAUSES

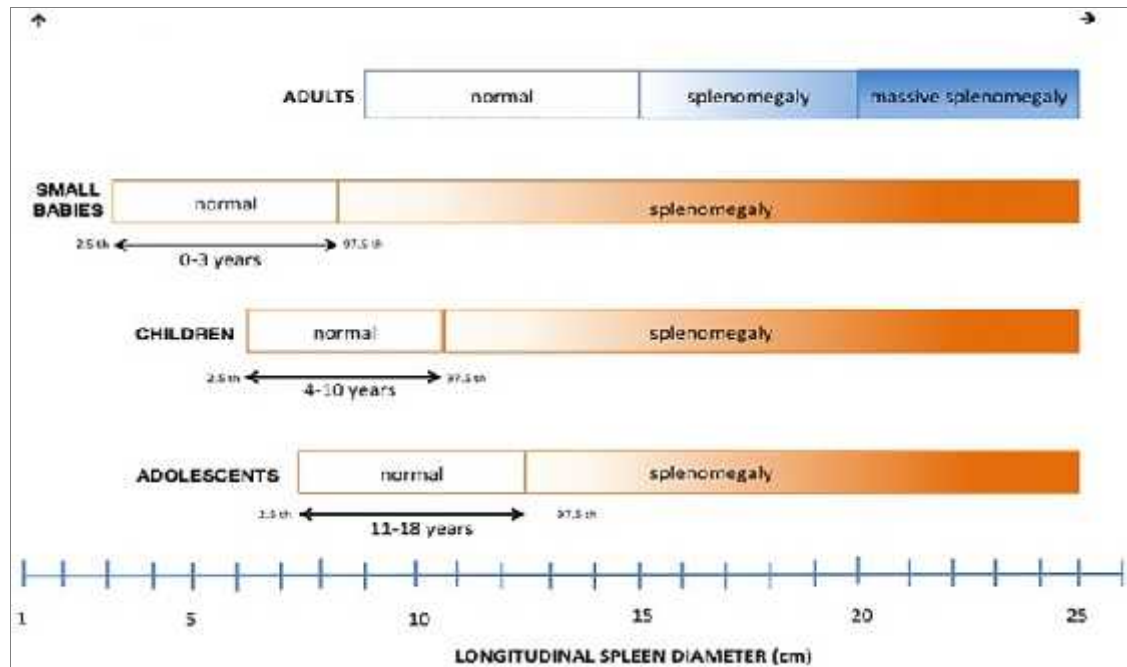
One third of newborns and 10% of children may normally have a palpable spleen. The tip of the normal, palpable spleen is soft, smooth, non tender and less than 1-2 cm below the left costal margin.⁴¹ An enlarged spleen may be due to:

- infectious disease (like mononucleosis)
- anemias
- tumors
- portal hypertension

The size of the spleen may be reduced in conditions such as sickle cell disease

ULTRASONOGRAPHIC MEASUREMENT OF LIVER AND SPLEEN:

Figure 5: SPLEEN SIZE IN VARIOUS AGE GROUPS^{38, 42, 43}



Imaging techniques play a key role in assessment of abdominal organs. Among the various modalities available, MRI is not readily accessible to everyone for routine use because of its cost while computed tomography is associated with radiation exposure and hence may not be suitable for serial measurements.⁹ But USG has the capacity to distinguish the disease by identifying the abnormalities in organ size. It may be the first choice for detecting the abnormalities in organ size in all settings. Ultrasonography is a non-invasive, recognised, safe and fast method for measuring the size of the liver and spleen.^{1, 10} Spleen and liver sizes are integral part of routine abdominal ultrasonography as alteration in size can be indicative of a variety of pathological conditions.^{11, 12} In addition, false positive labelling of a patient as having organomegaly can lead to further investigations, causing anxiety to the patient as well as unnecessary expenditure. The ability to recognize abnormal enlargement of an organ, inevitably requires generally accepted reference values for a

particular population as sizes vary with age, gender and ethnicity. Organs like spleen when grossly enlarged are easily picked up in USG while diagnosis may be difficult in cases of mild organomegaly such as in typhoid fever and also in malaria. Furthermore, racial dissimilarities in size of the organs also exist.⁴⁴

Figure 6: Linear Liver measurements in longitudinal plane in studies from literature (Adopted from Calle-Toro JS et al¹)

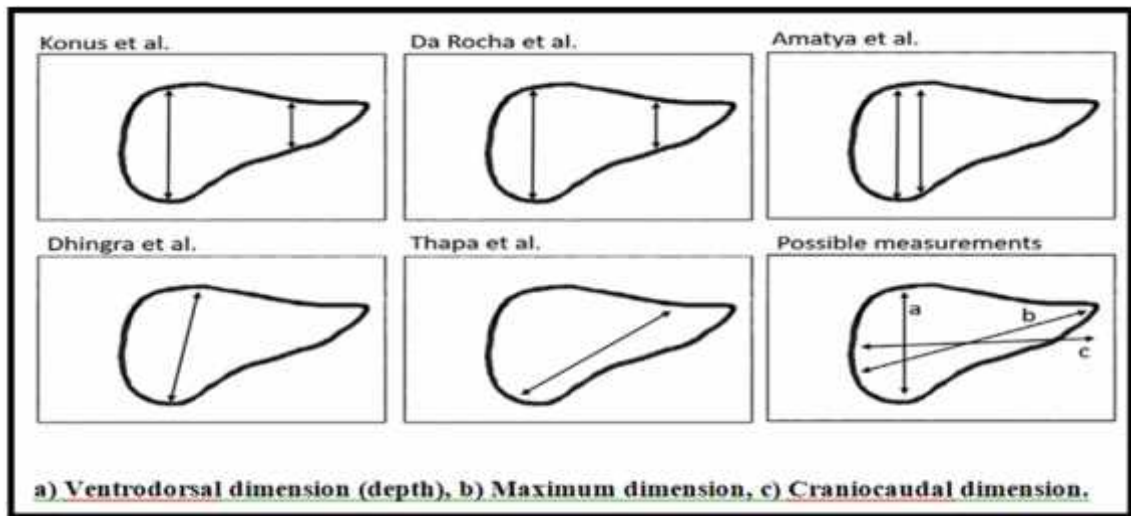


Table 7: Studies Measuring Liver Size in Healthy Children

(Adopted from Calle-Toro JS et al¹)

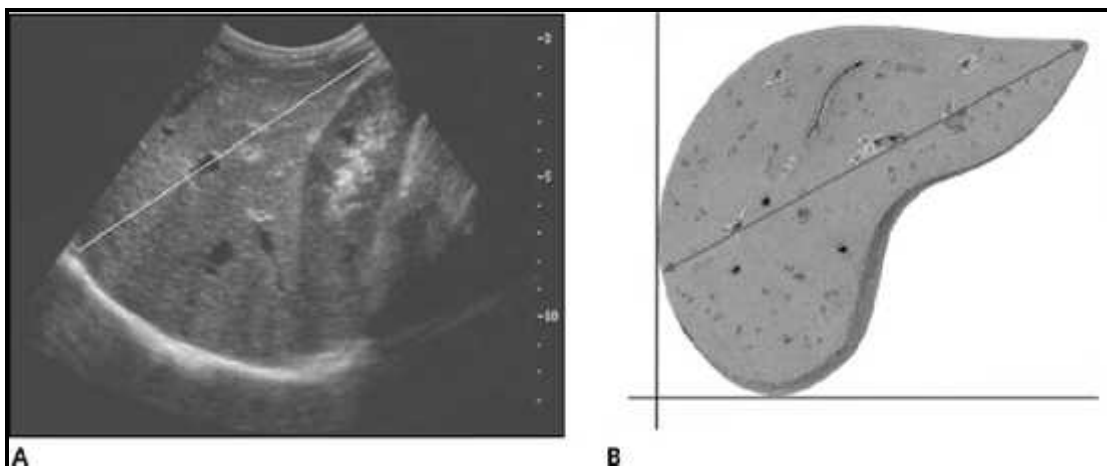
Age	Turkey, Konus et al, 1998					Brazil, da Rocha et al, 2009					India, Dhingra, 2010					India, Amatya et al, 2014					Nepal, Thapa et al, 2016				
	n	Mean	SD	5th	95th	n	Mean	SD	5th	95th	n	Mean	SD	3th	97th	n	Mean	SD	5th	95th	n	Mean	SD	5th	95th
0-<3 mo	53	61.0	10.4	48.0	90.0	32	66.0	5.7	47.0	75.0	21	63.5	9.3	48.5	80.5	45	53.0	5.2	44.0	57.0	36	68.0	7.0	54.0	80.0
3-<6 mo	40	73.0	10.8	53.0	86.0	34	76.0	7.2	58.0	90.0	35	71.5	8.6	56.0	84.5	45	64.0	9.2	49.0	83.0					
6-<9 mo	20	79.0	8.0	70.0	90.0	72	84.0	9.1	62.0	101.0	51	77.0	9.0	62.0	95.5						35	76.0	9.3	47.0	75.0
9-<12 mo						36	84.0	6.9	65.0	96.0															
1-<2 y	18	85.0	10.0	68.0	98.0	102	92.3	7.5	77.3	110.3	77	85.5	11.8	67.0	106.5	45	89	8.6	71	103	62	84.0	7.4	69.5	94.5
2-<4 y	27	86.0	11.8	63.0	105.0	48	99.0	6.7	78.0	11.0	132	89.5	11.4	70.5	116.0						43	87.3	8.9	73.4	105.2
4-<6 y	30	100.0	13.6	77.0	124.0	181	104.0	8.2	86.5	126.0	115	100.5	12.6	69.0	140.0	45	92.0	9.1	80.0	108.0	41	92.2	9.1	75.3	106.6
6-<8 y	38	105.0	10.6	90.0	123.0	109	109.0	8.7	91.0	133.0	51	108.5	11.2	86.0	128.0						25	98.7	8.7	84.6	117.6
8-<10 y	30	105.0	12.5	83.0	128.0						62	118.0	11.0	97.0	140.5										
10-<12 y	16	115.0	14.0	95.0	136.0						53	132.5	12.5	103.5	153.5	45	107	11.1	91	129	19	106.3	10.7	92.0	127.0
12-<14 y	23	118.0	14.6	94.0	136.0																11	116.1	8.8	104.0	130.0
14-<18 y	12	121.0	11.7	104.0	139.0																				

*Measurements are reported in millimeters

LIVER:

In the study by Warnakulasuriya DTD et al¹⁰, “Ultrasonographic examination was done using a high resolution real-time scanner (PHILIPS HD 6, Germany) with a 3.5 MHz convex transducer. Liver measurements were performed in a supine position. The longitudinal axis was measured after clear visualization of the liver in the midclavicular plane. The uppermost edge under the dome of the diaphragm was defined as the upper margin, and the lowermost edge defined as the lower margin”.¹⁰ Mid clavicular Line Longitudinal Diameter (MCLLD) is most commonly used for measuring size of the liver in routine diagnostic procedures. It has also been accepted as the best method for distinguishing diseased from healthy liver. In the study by Kratzer W et al²⁹, “examinations were carried out with the subjects in the supine position. For better access to the liver, subjects were instructed to raise their right hand behind their head, thus increasing the intercostal spaces and the distance from the lower costal margin to the iliac crest. The examination was carried out during deep inspiration and with a relaxed abdominal wall. In each case, the liver was examined in 3 planes, visualized longitudinally, cross-sectionally, and diagonally”.

Figure 7: Measurement of liver size in the largest craniocaudal diameter in mid-clavicular line. A, USG image B, Represented diagrammatically.²⁹



In the study by Börner et al⁴⁵, it was measured in the right MCL from hepatic dome till the inferior hepatic tip.

SPLEEN:

While many imaging techniques can be used to determine spleen size, ultrasonography is particularly useful because of ease of use and lack of radiation exposure. Diagnostic imaging to assess spleen size is routinely accomplished by ultrasonographic measurement along its long axis. However, there is variation among radiological texts in defining the upper limits of normal for longitudinal diameter, with values ranging from 12 to 14 cm in adults.⁴⁴

In the study by Pelizzo G et al³⁸, Esaote My Lab Twice ultrasound device was used. They estimated the spleen size in children aged above one year.³⁸ They used a 3.5 to 5 MHz convex probe to measure the spleen size in either supine or lateral decubitus position. In another study the longitudinal diameter was estimated by measuring the distance between highest superior-medial point of the spleen and the lower inferior-lateral point.⁴⁶ Organs were measured during the time of deep inspiration generally.¹⁰

Scanning technique⁸

Investigators had generally used coupling medium for good transmission. Right lateral decubitus position was used by several investigators and coronal plane was embraced. In this position, the measurements are easy to reproduce and the longest dimension can be measured.^{5, 6, 47} The Longitudinal diameter was estimated by measuring the distance between highest superior-medial point of the spleen and the lower inferior-lateral point in deep inspiration. The probe varies depending on the age of the subjects and their physique.

Figure 8: Diagram showing the method for measuring splenic length and width by ultrasound⁴⁴

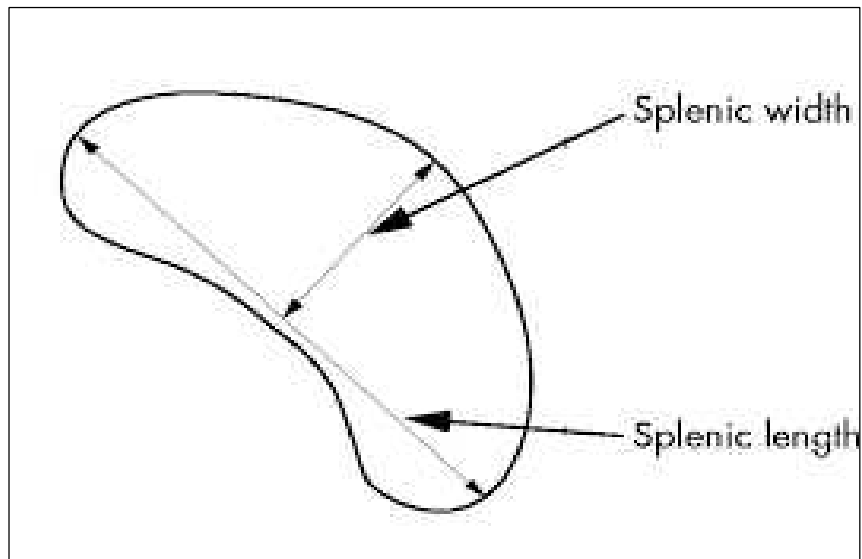


Figure 9: Ultrasound measurement of longitudinal length of spleen.⁸



Table 8: Studies measuring spleen size in millimeters in healthy children

(Adopted from Calle-Toro JS et al¹)

Age	USA, Rosenberg et al, 1991				Turkey, Kozan et al, 1995				USA, Megreus et al, 2004				India, Dhingra, 2010				Nepal, Thapa et al, 2016				Turkey, Öztürkci et al, 2018								
	n	Median	10th	90th	n	Mean	SD	5th	95th	n	Mean	SD	Min	Max	n	Mean	SD	3th	97th	n	Mean	SD	5th	95th	n	Mean	SD	5th	95th
0-3 mo	28	43.0	33.0	38.0	53	33.0	7.8	40.0	65.0	37	43.0	7.1	30.0	61.5	21	47.0	9.7	34.5	69.5	36	50.0	7.9	36.1	62.4	21	48	10	33	61
3-6 mo	13	53.0	49.0	64.0	40	39.0	6.3	47.0	67.0	16	55.0	5.6	47.0	63.0	35	54.5	5.1	45.5	65.5						24	54	5	47	62
6-9 mo	17	62.0	52.0	68.0	20	65.0	7.6	52.0	74.0	27	65.5	7.3	52.5	74.5	51	58.0	7.4	45.5	77.5	33	60.0	7.9	47.2	75.8	24	62	7	54	74
9-12 mo																													
1-2 y	12	69.0	54.0	75.0	18	70.0	9.8	55.0	85.0	35	65.5	7.1	53.5	82.5	77	62.5	8.8	46.0	87.0	42	61.0	8.2	48.5	78.5	30	70	8	57	80
2-4 y	24	74.0	64.0	86.0	27	75.0	8.4	61.0	88.0	46	75.5	9.5	58.0	94.0	132	68.0	8.8	47.0	88.0	43	68.1	9.2	54.2	81.6	27	75	11	62	89
4-6 y	39	78.0	69.0	88.0	30	84.0	9.0	70.0	100.0	54	80.5	8.8	65.5	97.0	115	72.5	9.5	51.0	101.0	28	69.3	7.0	55.4	80.6	27	79	10	67	94
6-8 y	21	82.0	70.0	96.0	38	85.0	10.3	69.0	100.0	51	85.5	9.5	70.0	102.5	51	77.5	9.7	59.0	98.0	31	95.5	8.3	79.0	110.5	31	86	11	74	101
9-10 y	16	92.0	79.0	105.0	30	86.0	10.7	70.0	100.0	41	88.5	9.7	69.0	108.5	62	82.0	10.2	66.5	103.5						26	92	12	78	107
10-12 y	17	98.0	86.0	109.0	18	97.0	8.7	81.0	108.0	53	94.5	10.7	70.5	113.5	53	87.0	15.2	65.0	115.0	19	106.3	10.7	92.0	127.0	27	97	14	73	111
12-14 y	26	101.0	87.0	114.0	23	101.0	11.7	85.0	118.0	48	100.0	9.2	82.0	116.5						11	116.1	8.8	104.0	130.0	38	100	10	85	114
14-18 y	17	101.0	95.5	121.5	12	101.0	10.3	88.0	115.0	26	130.0	8.0	91.0	117.5											35	104	9	94	118

MOST RELEVANT GLOBAL STUDIES:

Calle-Toro JS et al¹ (2020) in their systematic review evaluated the size of the paediatric liver, kidney and Spleen by USG. They concluded that the size of these organs increase consistently with age.

Rousan LA et al¹¹ (2019) carried out their study “to provide practical and reliable normal reference values for the size of the liver and spleen in children and to correlate the values with age, height and weight. 315 children (142 boys and 173 girls) were prospectively examined by ultrasound due to problems unrelated to the liver or spleen. All of the subjects had normal sonographic appearance of their organs. The ages of the subjects ranged from newborns to 14 years. The liver and spleen size was correlated with age, height and weight. The spleen size was compared with previous internationally published data. There was no statistical significant difference

in the size of the liver and spleen between boys and girls ($P>0.05$). There was steady increase in the size of the liver and spleen with good correlation with age and all the somatic parameters. The spleen size was in close proximity to those previously reported in the literature. They concluded that standard spleen and liver size reference values were obtained by ultrasound for Jordanian children and were in concordance with international values”.

Pelizzo G et al³⁸ (2018) in their study “determined the range of normal spleen dimensions evaluated by ultrasonography. They prospectively examined 317 caucasian children of both sexes. The patients were divided into three groups: 0-3 years; 4-10 years; 11-18 years. Sex, weight, height/length, body mass index (BMI), waist circumference and xipho-pubic distance were determined for each child. Ultrasound spleen evaluation included longitudinal/antero-posterior/transverse diameters, transverse area and volume. Spleen volume/abdominal volume, longitudinal spleen diameter/longitudinal left kidney diameter and longitudinal spleen diameter/xipho-pubic distance ratios were also calculated. For caucasian subjects, in different age groups spleen volume, transverse area and diameter increased while the spleen/abdominal volume ratio decreased significantly ($p<0.001$). A significant ($p<0.001$) decrease in longitudinal spleen diameter/xipho-pubic distance ratio was noted between the 0-3 years group and both 4-10 and 11-18 years group. Age and auxological data, except BMI, showed a high correlation with spleen dimension (r 0.8). They concluded that for pediatric surgeries, a dedicated classification of splenomegaly is needed”.

Özdikici M²⁸ (2017) in his study measured the normative values of paediatric liver size by USG.

Warnakulasuriya DTD et al¹⁰ (2017) conducted a study in school children of Sri Lanka for establishing normal reference values of abdominal organs like liver, kidneys and spleen on 332 subjects. They observed a statistically significant difference between the male and female liver. The size of the liver was higher in females. Only body weight has significant impact on deciding spleen size on multiple regression analysis.

Thapa NB et al¹² (2015) conducted a study among 272 children in Nepal. The objective of this study was to determine the normal range of dimensions for the liver, spleen and kidney in healthy children.

Ezeofor SN et al⁴⁸ (2014) conducted a study in South-East Nigeria in 1315 children (633 boys and 682 girls) between the ages of 5 and 17 years. The objective of this study was to establish the normal values of splenic length in healthy school children in South-East, Nigeria and to correlate them with body indices. Results showed there was a significant correlation between splenic length and age, $P < 0.001$. Males had statistically significant longer spleen length than females. They concluded that there was a clear racial variation between the established Nigerian values and results from other countries of the world.

Eze CU et al⁸ (2013) carried out their study to determine normative data for spleen size in 947 school going children aged between 6 to 17 years. They concluded there was a significant association between size of the spleen and height of the subject.

Johnson TN et al³¹ (2005) assessed the changes in liver volume (LV) from birth to adulthood in their meta-analysis. They developed a more general model to predict liver volume in pediatric populations and young adults, and have investigated a range of covariates. $LV = 0.722 * BSA(1.176)$.

Safak AA et al⁵ (2005) conducted a study at Duzce ,Turkey in 712 healthy school aged children (7–15 years). The purpose of this study was to determine the normal standards of liver, spleen and kidney dimensions and the relationship of each with sex, age, body weight, height, body mass index, and body surface area in healthy school-aged children. Results showed there were no significant differences in organ dimensions with respect to sex ($P > .05$). The mean right kidney length was shorter than the left kidney length and the difference was significant ($P = .009$). Body weight showed the best correlation with liver, spleen and kidney dimensions. The results were also supported by the variance and covariance of the correlation coefficients. They concluded that organ dimensions showed the best correlation with body weight.

Megremis SD et al⁴⁷ (2004) conducted a study in Greece on 512 healthy children aged from 0 to 17 years and concluded that there was a significant association between age, weight or BSA, height with length of the spleen.

Konu OL et al⁶ (1998) in their study concluded that body height should be considered the best criteria to correlate with longitudinal dimensions of these organs.

Kasales CJ et al⁴⁹ (1994) in their study described the imaging variants of liver, pancreas and spleen. They observed that in order to recognize the pathologic changes that affect each organ, one must have a detailed knowledge of the broad spectrum of normal variants that can be seen when imaging the upper abdomen. They explored the wide variability in appearance of the normal liver, spleen, and pancreas during cross-sectional imaging (CT, US, and MRI), stressing a thorough understanding of normal anatomy and the affect of physiologic variants.

Rosenberg HK et al⁴ (1991) in their study established normative data for spleen size in children of various age groups till twenty years using sonography.

Naveh Y et al⁵⁰ (1984) assessed the liver size in normal infants and children in their study.

MOST RELEVANT INDIAN STUDIES:

Amatya P et al⁵¹ (2014) in their cross sectional study observed that Palpation-percussion method was good (88%) in estimating size of the liver within \pm one cm of USG size.

Dhingra B et al³ (2010) conducted a cross sectional hospital based study to establish normal range for liver and spleen size by USG on 597 healthy Indian children between the age of one month to two years. They found significant correlation between organ size and height of the children.

LACUNAE OF LITERATURE

The literature on normal range of paediatric liver and spleen size measured by USG in north karnataka is lacking. There are also no well designed large scale studies in Karnataka to our knowledge in this regard. But a study is necessary to provide reference values for this population as well as to see how much it is par with the reference values being followed currently. The ability to recognize abnormal enlargement of an organ, inevitably requires generally accepted reference values for a particular population as sizes vary with age, gender and ethnicity.

METHODOLOGY

MATERIALS & METHODS:

Statistical Methods:

This study was conducted in the department of Radiodiagnosis at Jawaharlal Nehru Medical College, KAHER, Belagavi.

Study population:

All children who were advised USG abdomen as an investigation by the referring consultant to the Department of Radio-Diagnosis at The KLE'S Dr. Prabhakar Kore hospital & MRC, Belagavi between 1st January 2019 to 31st December 2019 were considered as study population.

Study design: The current study was hospital based cross sectional study

Sample size:

The present study is basically a cross sectional study. In the analysis comparisons will be done of liver length and spleen length in different groups like age, gender etc. The sample size calculation is based on the means of males and females in the age group of 4 to 6 years, the prominent group of the study. The reference article is "Normal values of liver and spleen size by ultrasonography in Indian children". Indian Pediatr. 2010.³

Sample size formula the minimum sample size formula based on mean and standard deviation is $n = \frac{(z_{\alpha} + z_{\beta})^2 (s_1^2 + s_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$ where z is linked with the level of significance and z is linked with the power of the test. For 5% level of the significance $z = 1.96$ and $z = 0.84$ for 80% power of the test. \bar{X}_1 is the mean of the first group (7.4) and \bar{X}_2 is the mean of the second group (7.1). s_1 is the standard

deviation of the first group (0.99) and s_2 is the standard deviation of the second group (0.90). With these values the formula gives the value of 156 in each group. Since it is a cross sectional study single group of $156+156 = 312$ is taken as sample size.

Sampling method: Universal sampling was used to reach the estimated sample size.

Study duration: The study was done from January 2019 to December 2019. The data was collected for a period of one year.

Inclusion Criteria:

- All children aged between one month to 12 years, who were advised ultrasonography of abdomen by the referring consultant from 1st January 2019 to 31st December 2019.

Exclusion criteria:

- Patients with any infective, inflammatory, hematological, malignant, congestive or collagenous conditions that can affect the size of the liver and the spleen.
- Non consenting patients.

Ethical considerations: Institutional human ethics committee approval was obtained. After explaining the procedure, objectives and all the details, only the willing participants were included in the study after getting informed consent from the parent/guardian. Their data was kept confidential.

Data collection tools: A structured study proforma was used to collect all data.

Methodology:

A detailed clinical history was taken using a proforma to exclude the presence of any infective, inflammatory, hematological, malignant, congestive or collagenous conditions that can affect the size of the liver and the spleen. Study was done using a USG machine G.E. VOLUSON P8 with a curved probe of 1.5 - 4.5 MHz (low frequency) and a linear probe of 4.5 - 13.0 MHz (high frequency).

“Liver measurements were performed in supine position. The longitudinal axis was measured after clear visualization of the liver in the midclavicular plane. The uppermost edge under the dome of the diaphragm was taken as the upper margin, and the lowermost edge as the lower margin. Spleen measurements were performed in right lateral decubitus position. The longitudinal measurement of the spleen was taken between the most supero-medial and the most infero-lateral margins”.

(i) Equipment: USG MACHINE G.E. VOLUSON P8 (GE healthcare, USA).

Statistical Methods:

Liver- Length, Spleen-Length were considered as primary outcome variables. Age, Gender were considered as other explanatory variable.

Descriptive analysis: Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram and pie diagram.

Categorical outcome: The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of

percentages. Odds ratio along with 95% CI is presented. Chi square test was used to test statistical significance.

For normally distributed quantitative parameters the mean values were compared between study groups using independent sample t-test (two groups).

The association between categorical explanatory variables and quantitative outcome was assessed by comparing the mean values. The mean differences along with their 95% CI were presented. ANOVA was used to assess statistical significance. Association between quantitative explanatory and outcome variables was assessed by Linear regression analysis. Regression coefficient, along with its 95% CI and p values are presented.

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.⁵²

RESULTS

A total of 312 subjects were included in the final analysis.

Table 9: Descriptive analysis of age groups in the study population (N=312)

Age Groups	Frequency	Percentages
1 month - <3 months	25	8.01%
3 months - <6 months	28	8.97%
6 months - <12 months	26	8.33%
1 year - <2 years	45	14.42%
2 years - <4 years	56	17.95%
4 years - <6 years	36	11.54%
6 year - <8 years	35	11.22%
8 years - <10 years	34	10.90%
10 years - <12 years	27	8.65%

Among the study population, 25(8.01%) participants were aged between 1 to <3 months, 28 (8.97%) were aged between 3 to <6months, 26 (8.33%) were aged between 6 to <12months, 45 (14.42%) were aged between 1 to <2years, 56 (17.95%) were aged between 2 to <4years , 36 (11.54%) were aged between 4 to<6years , 35 (11.22%) were aged between 6 to <8years, 34 (10.9%) were aged between 8 to <10years , 27 (8.65%) were aged between 10 to <12years(Table 9&Graph 1)

Graph1: Pie chart of age groups in the study population (N=312)

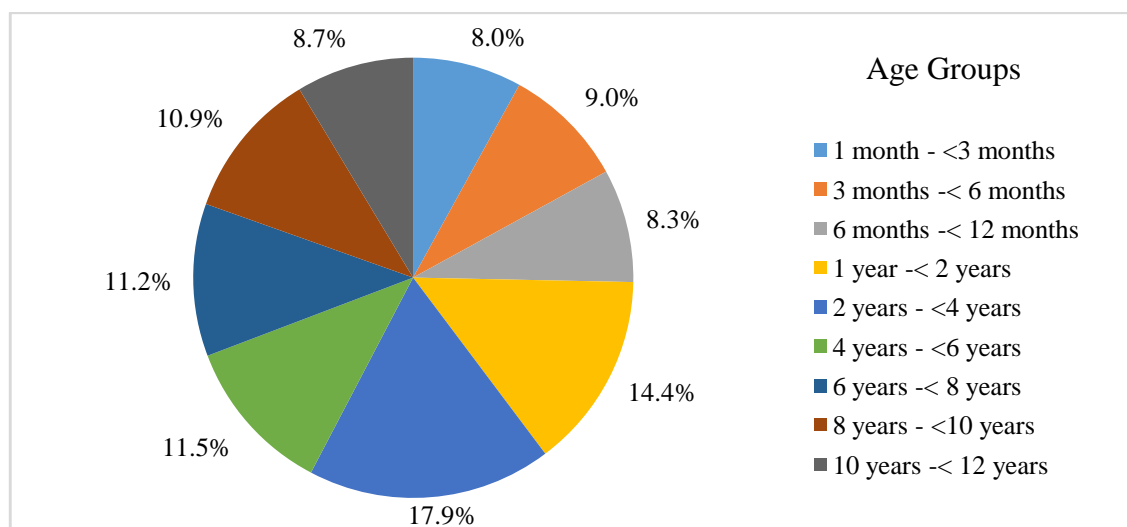


Table 10: Descriptive analysis of gender in the study population (N=312)

Gender	Frequency	Percentages
Male	174	55.77%
Female	138	44.23%

Among the study population, 174 (55.77%) were male and remaining 138 (44.23%) participants were female. (Table10&Graph 2)

Graph2: Pie chart of gender in the study population (N=312)

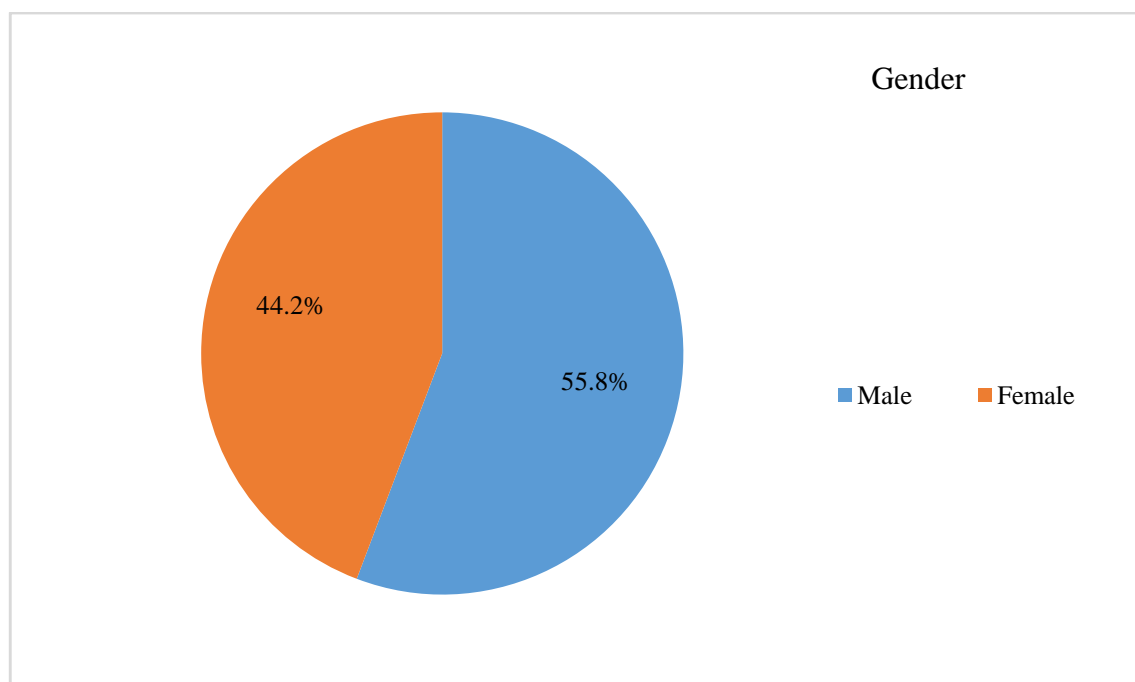


Table11: Descriptive analysis of liver- length, spleen-length in study population (N=312)

Parameter	Mean \pm SD	Median	Minimum	Maximum	95% C.I	
					Lower	Upper
Liver- Length	9.2 \pm 2.2	8.9	4.5	15.0	9.0	9.4
Spleen-Length	6.66 \pm 1.63	6.5	3.5	11.5	6.5	6.9

The mean Liver- Length was 9.2 \pm 2.2in the study population, minimum level was 4.5 and maximum level was 15 in the study population (95% CI 9 to 9.4).The mean Spleen-Length was 6.66 \pm 1.63in the study population, minimum level was 3.5 and maximum level was 11.5 in the study population (95% CI 6.5 to 6.9). (Table11)

Table12: Comparison of mean of liver- length and spleen - length between gender(N=312)

Parameter	Gender (Mean± SD)		P value
	Male (N=174)	Female (N=138)	
Liver- Length	9.17 ± 2.24	9.23 ± 2.15	0.815
Spleen-Length	6.7 ± 1.72	6.62 ± 1.52	0.696

There was no statistically significant difference in meanLiver- Length(P value 0.815) and meanSpleen- Length(P value 0.696) between Gender.(Table 12&Graph3)

Graph 3: Line chart for comparison of mean of liver- length and spleen - length between gender(N=312)

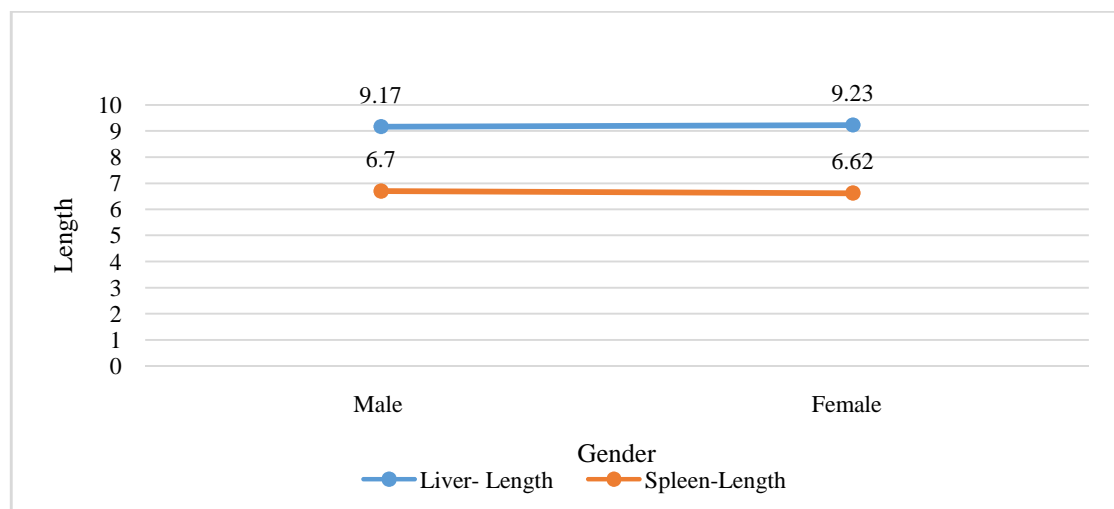


Table13: Comparison of mean liver- length across the age groups (N=312)

Age Groups	Liver- Length Mean \pm SD	Mean difference	95% CI		P value
			Lower	Upper	
1 month - <3 months	6.12 \pm 1.12				
3 months - <6 months	7.18 \pm 0.9	-1.06	-1.77	-0.36	0.003
6 months - <12 months	7.7 \pm 1.07	-1.58	-2.30	-0.86	<0.001
1 year - <2 years	8.51 \pm 1.12	-2.39	-3.03	-1.75	<0.001
2 years - <4 years	8.66 \pm 1.05	-2.54	-3.16	-1.92	<0.001
4 years - <6 years	9.84 \pm 2.22	-3.72	-4.39	-3.05	<0.001
6 year - <8 years	10.3 \pm 1.07	-4.17	-3.03	-1.75	<0.001
8 years - <10 years	11.9 \pm 1.04	-5.87	-3.16	-1.92	<0.001
10 years - <12 years	12.1 \pm 1.32	-6.02	-4.39	-3.05	<0.001

The Mean Liver- Length for 1 month - <3 months participants was 6.12 \pm 1.12, Taking as base line, the mean difference of Liver- Length (1.06) in 3 months - <6 months participants was statistically significant (P value <0.05) and the mean difference of Liver- Length in 6 months - <12 months (1.58), 1 year - <2 years (2.39), 2 years - <4 years (2.54), 4 years - <6 years (3.72), 6 year - <8 years (4.17), 8 years - <10 years (5.87), 10 years - <12 years (6.02) was also statistically significant (P value <0.05). (Table 13 & Graph 4)

Graph 4: Line chart for comparison of mean of liver- length across the age groups (N=312)

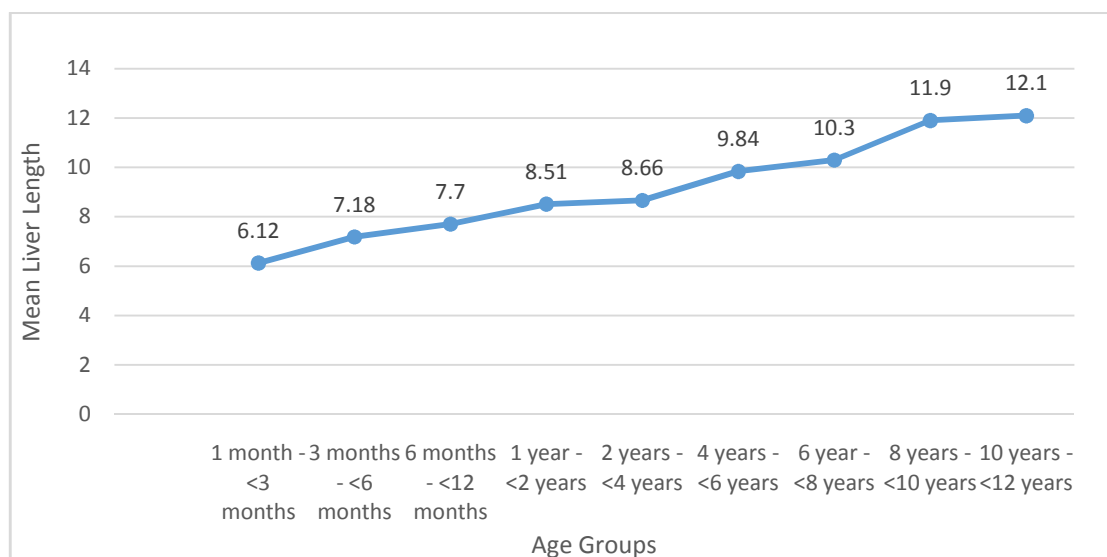


Table 14: Comparison of mean spleen-length across the age groups (N=312)

Age Groups	Spleen-Length Mean ± SD	Mean difference	95% CI		P value
			Lower	Upper	
1 month - <3 months	4.88 ± 1.15				
3 months - <6 months	5.38 ± 0.51	-0.50	-0.17	1.17	0.142
6 months - <12 months	6.08 ± 1.1	-1.20	-1.89	-0.52	<0.001
1 year - <2 years	6.32 ± 1.38	-1.45	-2.06	-0.84	<0.001
2 years - <4 years	6.06 ± 1.26	-1.18	-1.77	-0.59	<0.001
4 years - <6 years	7.01 ± 1.44	-2.13	-2.77	-1.50	<0.001
6 year - <8 years	7.52 ± 1.27	-2.65	-2.06	-0.84	<0.001
8 years - <10 years	8.37 ± 1.15	-3.50	-1.77	-0.59	<0.001
10 years - <12 years	8.31 ± 1.45	-3.43	-2.77	-1.50	<0.001

The Mean Spleen- Lengthfor 1 month - <3 months participantswas 4.88 ± 1.15, Taking as base line, the mean difference of Spleen- Length (0.5) in 3 months - <6 months participantswas statistically not significant (P value 0.142) andthe mean difference of Spleen - Length in 6 months - <12 months (1.20) , 1 year - <2 years (1.45) , 2 years - <4 years(1.18) , 4 years - <6 years(2.13) , 6 year - <8 years(2.65) , 8 years - <10 years(3.50) , 10 years - <12 years (3.43) was statistically significant (P value <0.05). (Table 14&Graph5)

Graph5: Line chart for comparison of mean of spleen- length across age groups (N=312)

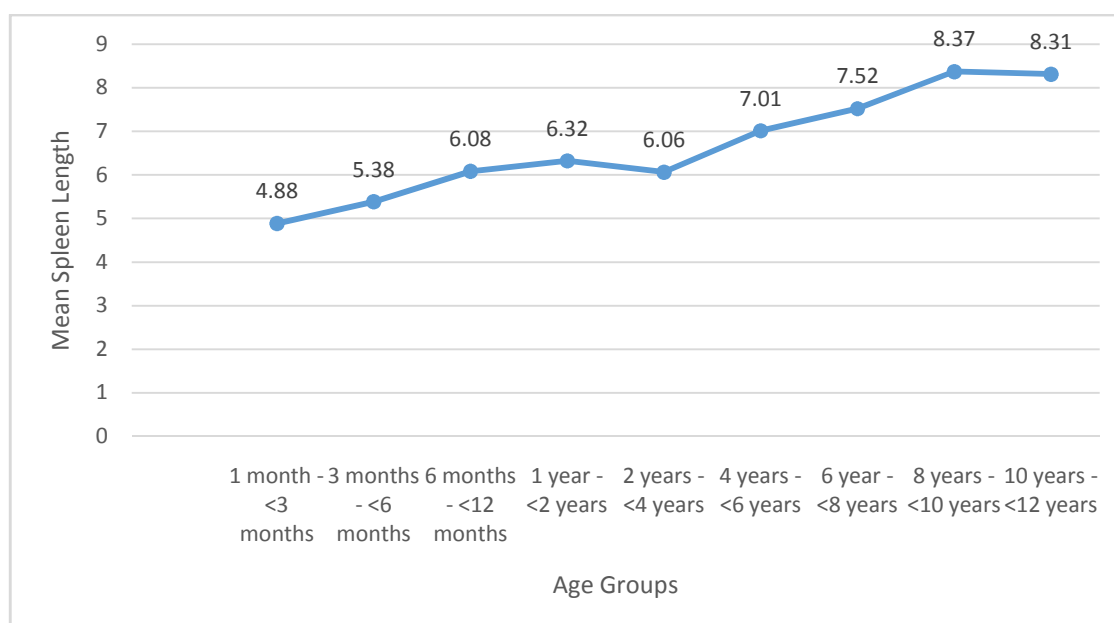
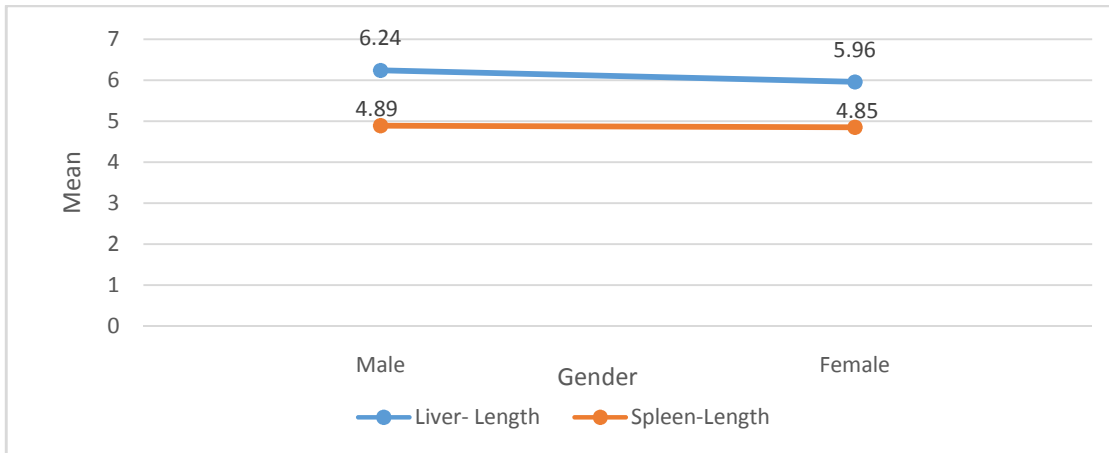


Table15: Comparison of mean of liver- length and Spleen length between gender at different age groups.

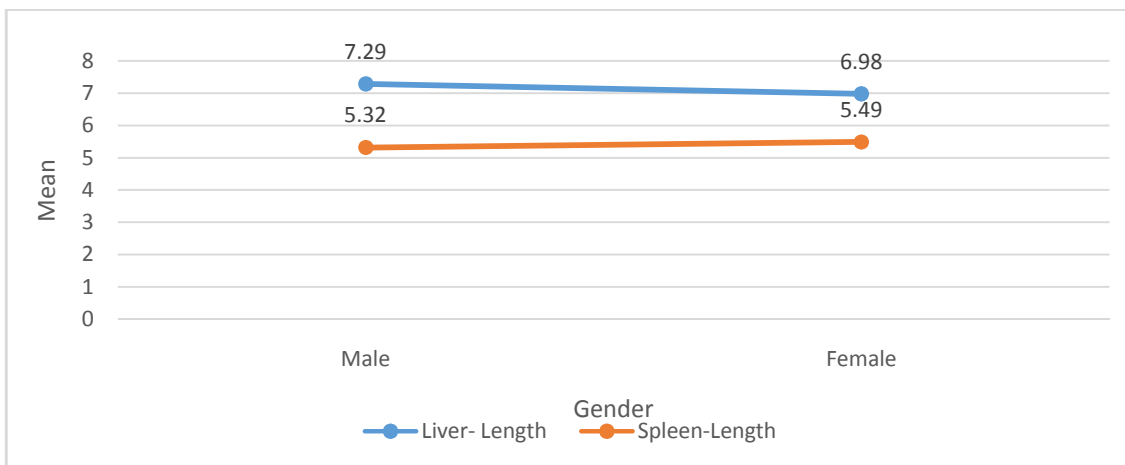
Gender	Frequency	Parameter	
		Liver- Length (N=312)	Spleen-Length (N=312)
Age Group (1 month – <3 months)			
Male	14	6.24 ± 1.22	4.89 ± 1.36
Female	11	5.96 ± 1.01	4.85 ± 0.9
P value		0.548	0.936
Age Group (3 months – <6 months)			
Male	18	7.29 ± 0.89	5.32 ± 0.48
Female	10	6.98 ± 0.94	5.49 ± 0.56
P value		0.386	0.395
Age Group (6 months – <12 months)			
Male	17	7.61 ± 1	6.22 ± 1.17
Female	9	7.88 ± 1.22	5.82 ± 0.97
P value		0.556	0.394
Age Group (1 year – <2years)			
Male	28	8.44 ± 1.05	6.48 ± 1.5
Female	17	8.62 ± 1.26	6.06 ± 1.14
P value		0.611	0.329
Age Group (2 years – <4years)			
Male	29	8.51 ± 0.92	5.92 ± 1.53
Female	27	8.82 ± 1.16	6.2 ± 0.9
P value		0.280	0.413
Age Group (4 years – <6years)			
Male	16	10.09 ± 2.5	7.28 ± 1.66
Female	20	9.65 ± 2.02	6.8 ± 1.24
P value		0.560	0.326
Age Group (6 years – <8years)			
Male	19	10.52 ± 0.82	7.67 ± 0.94
Female	16	10.02 ± 1.29	7.36 ± 1.6
P value		0.176	0.479
Age Group (8 years – <10years)			
Male	21	12.15 ± 1.36	8.52 ± 1.01
Female	13	11.49 ± 1.35	8.13 ± 1.35
P value		0.177	0.340
Age Group (10 years – <12years)			
Male	12	12.32 ± 1.22	8.41 ± 1.62
Female	15	12 ± 1.42	8.23 ± 1.36
P value		0.546	0.763

There was no statistically significant difference in meanLiver- Length and meanSpleen- Lengthfor participants of all type of Age Groupsbetween Gender.(Table 15&Graph6 to 14)

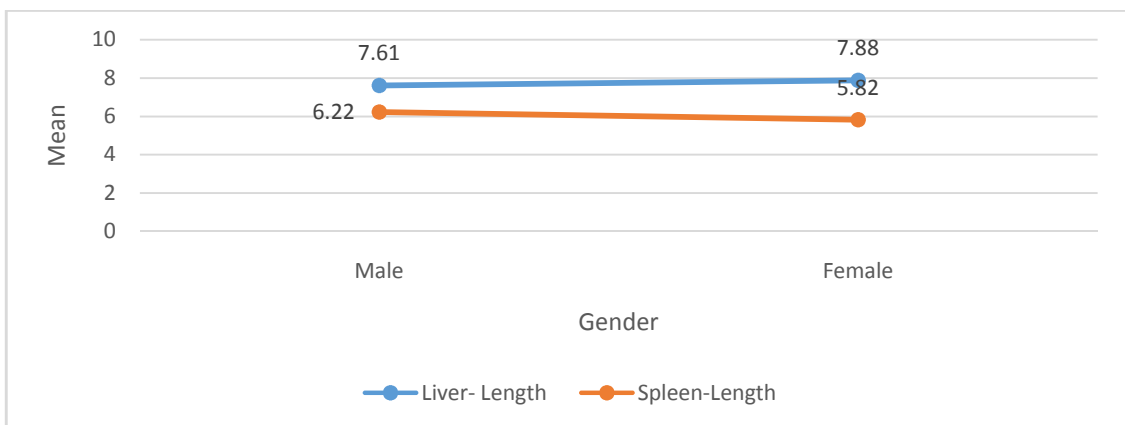
Graph6: Line chart for comparison of mean of liver- length and spleen - length of age group (1 month – <3 months) between gender(N=312)



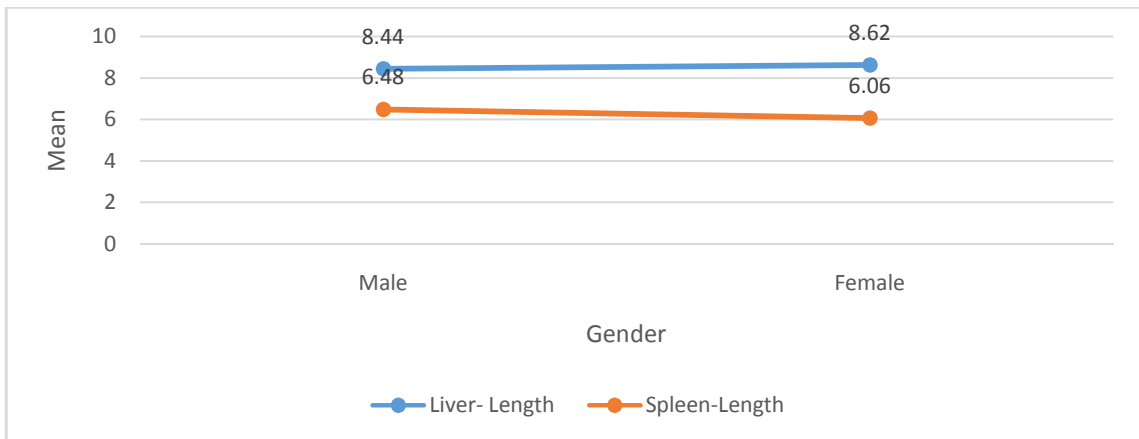
Graph 7: Line chart for comparison of mean of liver- length and spleen - length of age group (3 month – <6 months) between gender(N=312)



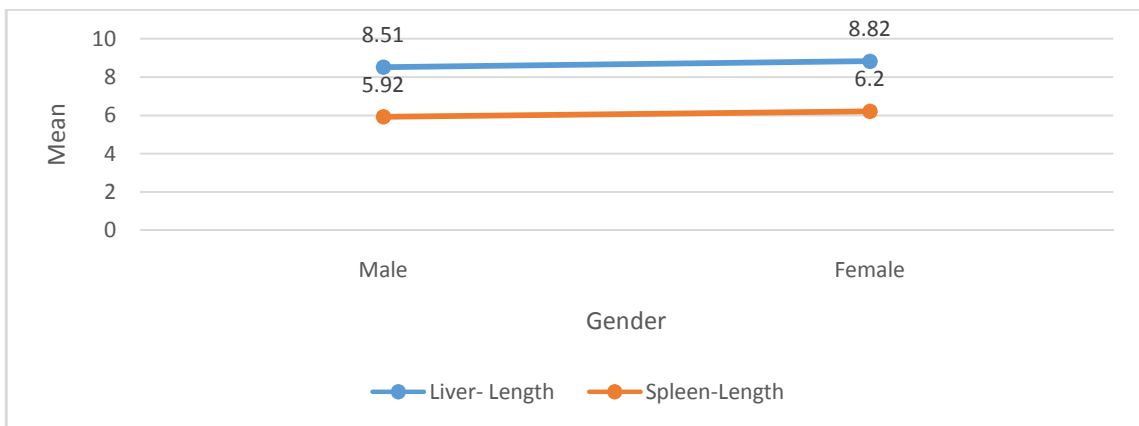
Graph8: Line chart for comparison of mean of liver- length and spleen - length of age group (6 month – <12 months) between gender(N=312)



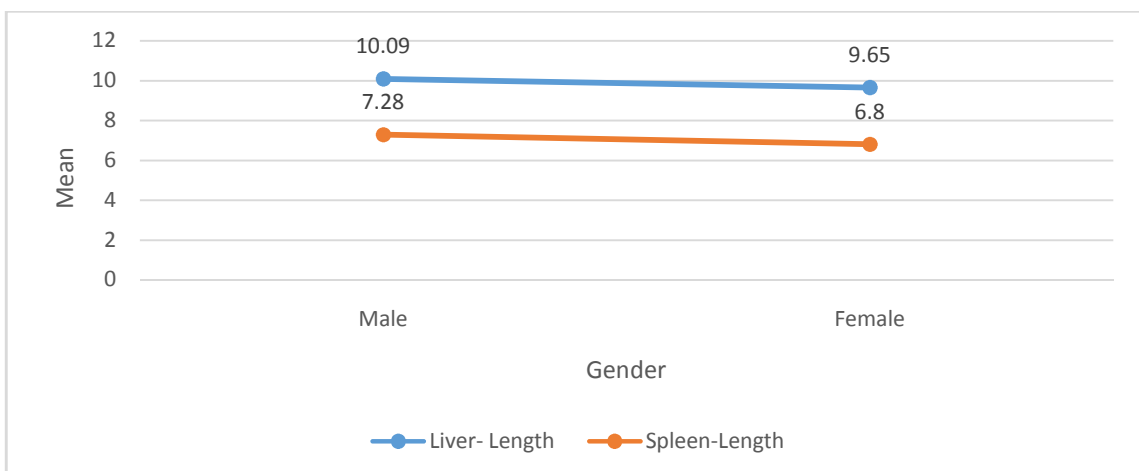
Graph9: Line chart for comparison of mean of liver- length and spleen - lengthof age group (1 year – <2years)between gender(N=312)



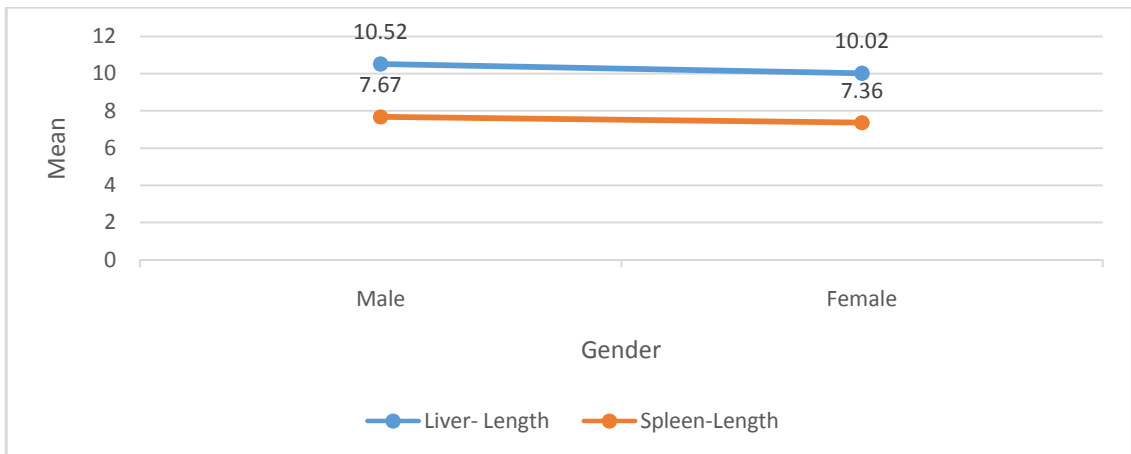
Graph10: Line chart for comparison of mean of liver- length and spleen - lengthof age group (2 years – <4years)between gender(N=312)



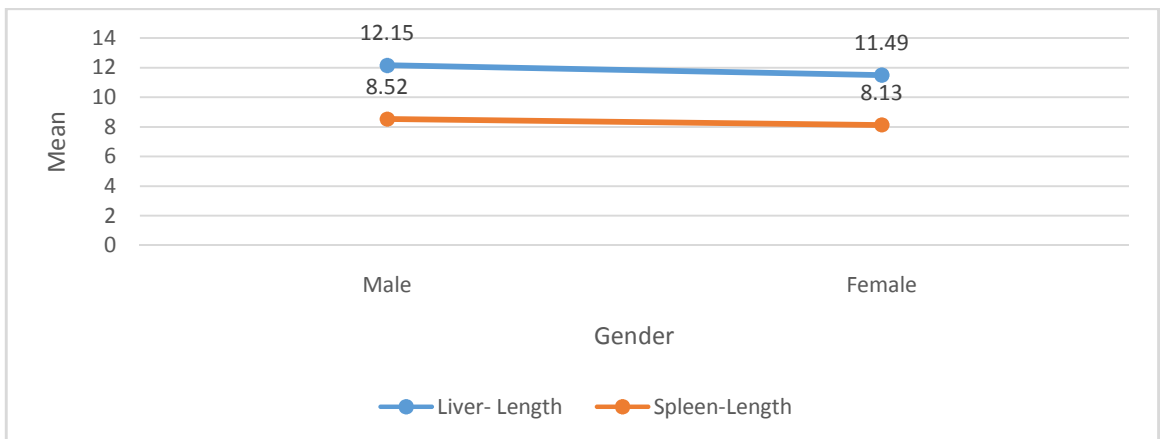
Graph 11: Line chart for comparison of mean of liver- length and spleen - lengthof age group (4 years – <6years)between gender(N=312)



Graph 12: Line chart for comparison of mean of liver- length and spleen - length of age group (6 years – <8years) between gender(N=312)



Graph 13: Line chart for comparison of mean of liver- length and spleen - length of age group (8 years – <10years) between gender(N=312)



Graph 14: Line chart for comparison of mean of liver- length and spleen - length of age group (10 years – <12years) between gender(N=312)

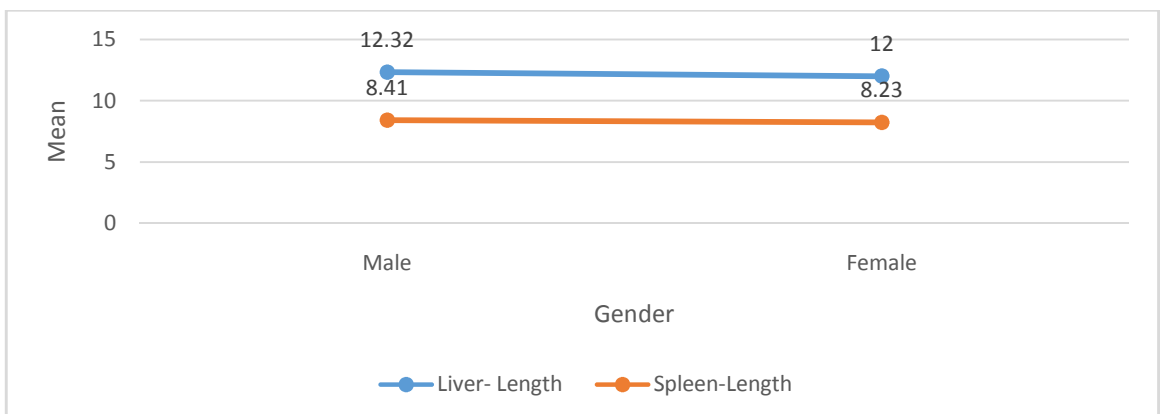


Table16: Simple linear regression between Liver length and age.

Dependant Variable: Liver Length.

Parameter	Coefficient	95% CI		P value
		Lower	Upper	
Age	0.481	6.833	7.262	<0.001
Intercept	7.049	0.444	0.518	<0.001

Simple linear regression showed a significant relationship for Age ($p < 0.001$). The intercept coefficient for Liver Length was 7.049. Liver Length increased by 0.481 (unit) length for per each year Age is increasing.

Regression line/Expected Liver length formula using Age

$$\text{Liver Length} = 7.04 + 0.48 * \text{Age (years)}$$

Table17: Simple linear regression between Spleen length and age.

Dependant Variable: Spleen Length.

Parameter	Coefficient	95% CI		P value
		Lower	Upper	
Age	5.340	5.133	5.547	<0.001
Intercept	0.297	0.261	0.332	<0.001

Simple linear regression showed a significant relationship for Age ($p < 0.001$). The intercept coefficient for Spleen Length was 5.34. Spleen Length increased by 0.297 (unit) length for per each year Age is increasing.

Regression line/Expected Spleen length formula using Age

$$\text{Spleen Length} = 5.34 + 0.297 * \text{Age (years)}$$

DISCUSSION

Any abnormality in the size of the liver or spleen may denote a pathological disease. But its assessment is challenging, with change in the size of the organs with age. The normative published values also vary according to the population and the methods used for estimation.¹ In cases like hepatomegaly, which is a relatively common clinical finding in children, it is necessary to identify the cause and treat at an earlier stage as it may be due to intrinsic liver diseases or due to hepatic steatosis or it could also be due to childhood obesity. Early detection is needed in critical cases to avoid premature liver failure. The size of the organ is critical in the interpretation of the disease. A physical examination may not be sufficient to detect the minor changes in the size of the organs like liver and spleen. Also interpreting the normative data is perplexing in children due to the effect of various anthropometric characteristics such as weight and height besides age, their body habitus and various known, unknown factors. But the literature on normal range of paediatric liver and spleen size by USG in north Karnataka is lacking. There are also no well-designed large scale studies in Karnataka to our knowledge in this regard.

BASELINE SOCIODEMOGRAPHIC VARIABLES:

This cross sectional study was conducted with the objective of estimating the normal values for liver and spleen size in children and to correlate it with age and sex of children. A total of 312 subjects were included in the final analysis aged between one month to 12 years. Similar to our study, Dhingra B et al³ did their study on 597 healthy Indian children and measured the length of the spleen and liver sonographically. Their study population included children between the age of one month to 12 years similar to our study. Calle-Toro JS et al¹ did a systematic review on

Liver, Spleen, and Kidney Size in Children as measured by ultrasound. Their study population included children from birth to 18 years. Rousan LA et al¹¹ did their study on 315 children to establish normal reference values for liver and spleen size in children similar to our study. Their study population included children between 0 to 14 years almost similar to our study. Konu OL et al⁶ did their study on 307 paediatric subjects aged between 5 days to 16 years. Rosenberg HK et al⁴ estimated the size of the spleen in 230 subjects aged between 0 to 20 years.

Table 18: Comparison of our study results with other studies:

Author	Sample size	Age group	Sex distribution (Male)	Association between age and liver size	Association between age and spleen size
Present study (2020)	312	one month to 12 years	55.77%	Statistically significant correlation Regression equation: Liver Length = 7.04 + 0.48 X age (years)	Statistically significant correlation Regression equation: Spleen Length = 5.34 + 0.297 X age (years)
Rousan LA et al ¹¹ (2019)	315	0 to 14 years	58.1%	Significant correlation	Significant correlation
Dhingra B et al ³ (2010)	597	one month to 12 years	45.1%	Statistically significant correlation (P<0.05) Age not significant predictor in multiple regression	Statistically significant correlation (P<0.05) Age not significant predictor in multiple regression
Konu OL et al ⁶ (2018)	307	5 days to 16 years	45%	Significant correlation	Significant correlation
Rosenberg HK et al ⁴ (1991)	230	0 to 20 years	38.7%	-	Significant correlation

GENDER DISTRIBUTION

With regards to gender distribution, male children contributed to 55.77% of the study population while female children constituted 44.23% of the study population. Our study population was similar to the study by Dhingra B et al³ with regards to gender wise distribution. 58.1% of the their study population were male children similar to the 55.77% observed in our study. In the study by Rousan LA et al¹¹, 54.9% of the study population were girls. Since there was no statistically significant difference gender wise with regards to size of spleen and liver, this was not a factor affecting the comparison of our study results with their study.

AGE DISTRIBUTION

There was an even distribution of study subjects across the age groups in our study. 25.3% of the children were aged between one month to one year. 17.95% were aged between two to four years while 14.42% were aged between one to two years. In the study by Dhingra B et al³, 17.9% of study subjects were aged between one month to one year. 22% of study subjects were aged between two to four years while 12.9% were aged between one to two years. Their median age was 48 months with a range of one to 156 months. The study subjects in their study were slightly older compared to our study as 50% of study subjects were aged 4 years and above in their study compared to only 42.3% in our study. There was also an equal distribution of study subjects, age group wise in the study by Rosenberg HK et al.⁴ In their study, out of the 230 subjects, 58 were aged less than one year, 36 subjects were aged between one to four years while 136 were aged between four to twenty years.

LIVER AND SPLEEN DIMENSIONS:

Normative dimensions of liver and as measured by ultrasound vary with age of the child. It is expected with the growth and development of the child. But in clinical practice, difference of a centimeter may lead to alarming diagnosis and an unnecessary biopsy. There can be differences in normal values considered in different regions of the world. Hence establishing normative values according to the region is crucial. There can be differences in the standard practices used to measure the length of the organs in various regions. Besides the innate factors of the human body, technical differences such as transducer placement, direction of measurement, way of measurement can also play a role in the differences seen.

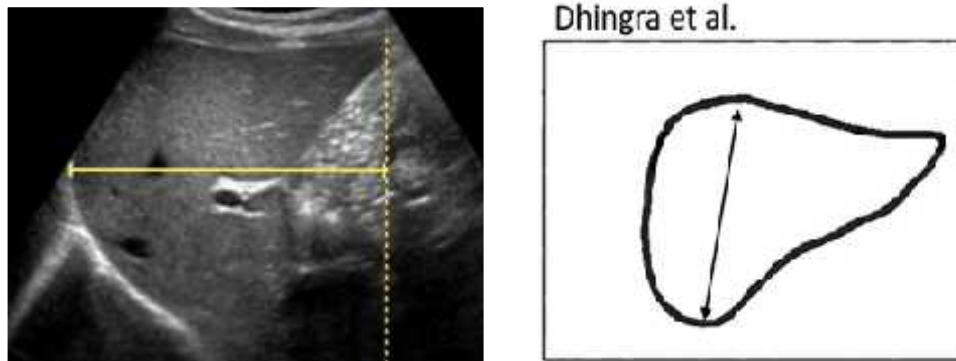
LIVER DIMENSIONS:

We measured the length of the liver sonographically. The results from our study provide a standard set of normative data age-wise and gender-wise.

LENGTH:

The mean Liver length was 9.2 ± 2.2 cm. The maximum length was 15 cm. The mean length of the liver was 9.59 ± 1.98 cm in the study by Dhingra B et al.³ It was similar to our study. They measured the liver length with the child in supine position along the MCL. They used Philips Envisor® Color Doppler system with a multi-frequency 3.5 to 5 MHz probe in their study. Usg machine G.E. VOLUSON P8 with a curved probe of 1.5 - 4.5 MHz (low frequency) and a linear probe of 4.5-13.0 MHz (high frequency) was used in our study. In our study also, the longitudinal axis in mid-clavicular plane was used. We also placed the subjects in supine position for measurement.

Figure 10: Comparison of liver length measurement by our study Vs Dhingra B et al³



Özdikici M et al²⁸ in their study observed the Midclavicular Line Longitudinal Diameter (MCLLD) in their study similar to our study. They also measured in the supine position with a 3.5 MHz convex transducer.

LENGTH VS AGE:

The mean liver length was 6.12 ± 1.12 cm in 1 month to <3 months age group in our study. There was a statistically significant difference between mean liver length at baseline compared to mean liver length at various age groups. There was a statistically significant increase in mean length of the liver with age. Dhingra B et al³ in their study also observed that there was a statistically significant increase in length of the liver with increase in age similar to our study ($P < 0.05$). Calle-Toro JS et al¹ in their systematic review also concluded that liver size increases constantly with growth of the child. Özdikici M et al²⁸ in their study also observed the same and also pointed out an accelerated growth rate in the first year of life. Calle-Toro JS et al¹ in their systematic review observed sagittal plane was used for measuring liver length longitudinally in most of the studies and it ranged from 7 cm to a maximum of 12.1 cm. In our study, the mean liver length similarly ranged from 6.12 cm in “one month to <three month age group” to “12.1 cm in 10 to <12 years age groups”.

LENGTH VS GENDER:

It was clear from our study results that sex was not a determining factor for organ dimensions in the pediatric age group. There was no statistically significant difference between male and female children with regards to mean length of the liver (p value = 0.815) in our study. There was also no statistically significant difference at various age groups between male and female children with regards to mean length of the liver. Özdikici M et al²⁸ in their study also observed that there was no significant difference between the sexes with regards to length at various age groups. Dhingra B et al³ in their study also observed there was no significant difference between the sexes with regards to mean length of liver across various age groups.

PREDICTION OF LIVER LENGTH FROM AGE:

Liver length increased by 0.481 cm for one year increase in age according to the regression equation “**Liver Length = 7.04 + 0.48 X age in years**” in our study. But Dhingra B et al³ in their study observed that in multiple regression analysis “only height (Beta coefficient 0.055, SE 0.007, P=0.0001) had significant independent positive association with liver length; no significant association could be seen with age (Beta coefficient 0.003, SE 0.004, P=0.39), bodyweight (Beta coefficient 0.214, SE 0.014, P=0.14) or body surface area (Beta coefficient -1.593, SE 1.97, P=0.42)”. Konu OL et al⁶ in their study observed that height was the one best correlated with the longitudinal dimension of liver followed by age, weight and BSA. Since we did not observe the correlation between various anthropometric variables and liver length, our study results cannot be compared with their studies.

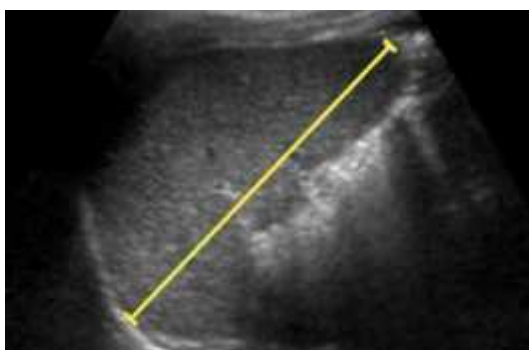
SPLEEN DIMENSIONS:

Clinical methods of splenic size can be very variable and inaccurate. USG provides a reliable method for estimating the size of the spleen. We established a normative data for size of the spleen in children from one month to 12 years.

LENGTH:

The mean Spleen length was 6.66 ± 1.63 cm. The maximum length was 11.5 cm. The mean length of the spleen was 6.99 ± 1.36 cm in the study by Dhingra B et al.³ It was similar to our study. In our study, right lateral decubitus position was used for measuring the spleen length longitudinally. In the study by Dhingra B et al.³, the longitudinal coronal view was used. In the systematic review by Calle-Toro JS et al.¹, the length of the spleen was measured in all studies in the sagittal plane longitudinally and ranged from 5.2 cm in younger patients, to a maximum of 12.5 cm in older patients

Figure 11: Comparison of spleen length measurement by our study Vs Konu OL et al⁶



LENGTH VS AGE:

The Mean spleen length was 4.88 ± 1.15 cm in 1 month to <3 months age group in our study. There was a statistically significant difference between mean spleen length at baseline compared to spleen length at various age groups except at 3 months to <6 months. There was a statistically significant increase in mean length of the spleen with age ($p < 0.001$) except at 3 months to <6 months age compared to baseline. Dhingra B et al³ in their study also observed that there was a statistically significant increase in length of the spleen with increase in age similar to our study. Calle-Toro JS et al¹ in their systematic review also concluded that spleen size increases constantly with growth of the child.

LENGTH VS GENDER:

Sex was not a determining factor for spleen dimension in our study. There was no statistically significant difference between male and female children with regards to mean length of the spleen (p value = 0.696). There was no statistically significant difference at various age groups between male and female children with regards to mean length of the spleen. Özdikici M et al²⁸ and Dhingra B et al³ in their study also observed there was no significant difference between the sexes with regards to mean length of spleen across various age groups.

PREDICTION OF SPLEEN LENGTH FROM AGE:

Spleen length increased by 0.297 cm for one year increase in age according to the regression equation “**Spleen Length = 5.34 + 0.297 X age in years**”. Dhingra B et al³ in their study observed that multiple regression analysis with spleen length as dependent variable showed that both height (Beta coefficient 0.038, SE 0.006, $P=0.0001$) and BSA (Beta coefficient 3.776, SE 1.68, $P=0.02$) had significant independent positive association with spleen length; no significant association could

be seen with age (Beta coefficient 0.0003, SE 0.003, $P=0.91$) or bodyweight (Beta coefficient 0.006, SE 0.012, $P=0.62$). Konu OL et al⁶ in their study observed that height was the one best correlated with the longitudinal dimension of spleen followed by age, weight and BSA. Since we did not observe the correlation between various anthropometric variables and spleen length, our study results cannot be compared with their studies.

Clinical methods of liver and spleen size can be very variable and inaccurate. USG provides a reliable and easy alternative method for estimating the size of the liver and spleen. In addition to size or length, there are several palpatory characteristics of the liver and spleen like the edges, nodularity, consistency etc. contributing to the bedside assessment of organomegaly. Hence clinical assessment also plays a role and imaging does not obviate the need of clinical assessment. But USG can provide a normative dataset for clinicians who are blindfolded with regards to normal size thus far and its variability with a age, to decide organomegaly depending on age on clinical examination. Besides diagnostic imaging provides vital information for further therapeutic management of the patient.

CONCLUSION

1. The size of the organ is critical in the interpretation of the disease.
2. A physical examination may not be sufficient to detect the minor changes in the size of the organs like liver and spleen.
3. This cross sectional study was conducted with the objective of estimating the normal values for liver and spleen size in children and to correlate it with age and sex of children.
4. A total of 312 subjects were included in the final analysis aged between one month to 12 years.
5. There was an even distribution of study subjects across the age groups.
6. Male children contributed to 55.77% of the study population.
7. The mean Liver length was 9.2 ± 2.2 cm. The maximum length was 15 cm.
8. There was a statistically significant difference between mean liver length at baseline compared to mean liver length at various age groups.
9. Sex is not a determining factor for organ dimensions in the pediatric age group. There was no statistically significant difference between male and female children with regards to mean length of the liver (p value = 0.815) and also across various age groups.
10. Liver length increased by 0.481 cm for one year increase in age
11. The mean Spleen length was 6.66 ± 1.63 cm. The maximum length was 11.5 cm.
12. There was a statistically significant difference between mean spleen length at baseline compared to spleen length at various age groups except at 3 months to <6 months.

13. There was no statistically significant difference between male and female children with regards to mean length of the spleen (p value = 0.696).
14. Spleen length increased by 0.297 cm for one year increase in age.

LIMITATIONS:

Our study was only a single center hospital based study. The sampling was done conveniently. Only the children referred by the treating consultant were included. The generalizability of our study results may not be valid. But our study is one of the kind in creating a database for normal values of liver and spleen from this part of the country. One limitation of USG is the inter observer variability, which was overcome by the same investigator performing all the procedures in our study. But new problems include enhanced visualization of various anatomic layers in the current scenario resulting from more advanced technology, leading to erroneous placement of measurement markers compared to previous studies.

RECOMMENDATIONS:

Large scale multi-centric community based studies incorporating larger sample sizes are the need of the hour especially in areas with endemic diseases such as malaria.

SUMMARY

The Liver and spleen are two of the most important intra-abdominal organs screened in paediatric population for any infection or any pathology. Ultrasound is usually the first-line imaging modality used for assessing the paediatric abdomen. Organ size is crucial to the image interpretation of disease: diseases of the liver and spleen can affect organ size and development, but a physical examination is not enough accurate to detect small increases in organ size. Normative data for organ size are challenging in the paediatric population because of changes that occur with growth and development and the effects of the body habitus, including height and weight in contrast to adults. Ultrasound may detect organ size abnormalities that indicate disease. But the literature on normal range of values of liver and spleen size by ultrasonography in children in north Karnataka is lacking. There are also no well-designed large scale studies in Karnataka to our knowledge in this regard. Hence this study was carried out with the objective of estimating the normal values for liver and spleen size in terms of length in children and to correlate it with age and sex of children.

A hospital based cross sectional study was conducted in the department of Radiodiagnosis at Jawaharlal Nehru Medical College, KAHER, Belagavi after getting ethical clearance. The study was done on 312 children aged between one month to 12 years who were advised USG abdomen as an investigation by the referring consultant to the Department of Radio-Diagnosis at KLE'S Dr. Prabhakar Kore hospital & MRC, Belagavi between 1st January 2019 to 31st December 2019. All the eligible subjects were recruited into the study consecutively by universal sampling till the sample size was reached. Non consenting patients and patients with any infective, inflammatory,

hematological, malignant, congestive or collagenous conditions that can affect the size of the liver and the spleen were excluded from the study. A detailed clinical history was taken using a proforma to exclude the presence of any infective, inflammatory, hematological, malignant, congestive or collagenous conditions that can affect the size of the liver and the spleen. Study was done using a USG machine G.E. VOLUSON P8. Liver measurements were performed in a supine position. The longitudinal axis was measured after clear visualization of the liver in the midclavicular plane. Spleen measurements were performed in a lateral decubitus position. The longitudinal measurement of the spleen was taken between the most supero-medial and the most infero-lateral margins. Liver- Length and Spleen-Length Were considered as primary outcome variables. Age, Gender were considered as other explanatory variable. P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis. Association between quantitative explanatory and outcome variables was assessed by Linear regression analysis. Regression coefficient, along with its 95% CI and p values were presented.

There was an even distribution of study subjects across the age groups. 25.3% of the children were aged between one month to one year. 17.95% were aged between two to four years while 14.42% were aged between one to two years. Male children contributed to 55.77% of the study population. The mean Liver length was 9.2 ± 2.2 cm. The maximum length was 15 cm. There was a statistically significant difference between mean liver length at baseline compared to mean liver length at various age groups. Sex was not a determining factor for organ dimensions in the pediatric age group. There was no statistically significant difference between male and female children with regards to mean length of the liver (p value = 0.815) and also across various age groups. Liver length increased by 0.481 cm for one year increase in age.

The Regression equation was “Liver Length = 7.04 + 0.48 X age (years)”.

The mean Spleen length was 6.66 ± 1.63 cm. The maximum length was 11.5 cm. There was a statistically significant difference between mean spleen length at baseline compared to spleen length at various age groups except at 3 months to <6 months. There was no statistically significant difference between male and female children with regards to mean length of the spleen (p value = 0.696). Spleen length increased by 0.297 cm for one year increase in age. **The Regression equation was “Spleen Length = 5.34 + 0.297 X age (years)”.**

Our study was only a single center hospital based study. The sampling was done conveniently. Only the children referred by the treating consultant were included. The generalizability of our study results may not be valid. But our study is one of the kind in creating a database for normal values of liver and spleen from this part of the country. Large scale multi-centric community based studies incorporating larger sample sizes are the need of the hour especially in areas with endemic diseases such as malaria.

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**ANNEXURE I –
INFORMED CONSENT**

TITLE OF THE STUDY: “NORMAL RANGE OF VALUES OF LIVER AND SPLEEN SIZE BY ULTRASONOGRAPHY IN CHILDREN IN BELAGAVI (NORTH KARNATAKA) – A ONE YEAR HOSPITAL BASED CROSS SECTIONAL STUDY”

PRINCIPAL INVESTIGATOR: REG. NO. BS0118002

INTRODUCTION AND PURPOSE:

The purpose of this study is to establish normal values for liver and spleen size in children and to correlate it with age and sex of children. This study will help to avoid misdiagnosis of those pathological conditions that can affect the size of liver and spleen.

PROCEDURE:

I request you to kindly participate in the study titled:“**NORMAL RANGE OF VALUES OF LIVER AND SPLEEN SIZE BY ULTRASONOGRAPHY IN CHILDREN IN BELAGAVI (NORTH KARNATAKA) – A ONE YEARHOSPITAL BASED CROSSSECTIONAL STUDY**” at Dr. Prabhakar Kore charitable hospital and Medical Research Centre,BelagaviisbeingconductedbyREG. NO. BS0118002postgraduateinRadiodiagnosisatJ. N. Medical College Belagavi, Karnataka, under the guidance of Dr. _____, Professor & HOD, Dept. of Radio diagnosis, J. N. Medical College, Belagavi.

We request you to participate in this study as you are eligible to be included. During the study you will be asked questions regarding your present and past medical history and you will be required to answer to the best of your knowledge. You will also be clinically examined as per the protocol drawn. If you agree to participate in the study, please furnish the details pertaining to the study.

BENEFITS:

- Noninvasive modality

COMPLICATIONS:

- No risk to the patient has been documented from USG imaging of the abdomen conducted earlier.

ALTERNATIVES:

If patient is not willing to take part in the study, his / her treatment or any other further investigations the patient wants to undergo, in future, in KLE will not be affected by his / her decision.

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. I may choose not to take part in this study, or if I decide to take part I can later change my mind and withdraw from the study. My decision will not change the present or future health care or other services that I receive. The study doctor or the sponsor may stop my participation in this study. I will tell if any important new findings that may change my willingness to continue to take part. If I choose not to take part in the study I will receive the standard treatment for patients with my condition.

COSTS:

NIL (The study is to be conducted on the participants who are advised USG abdomen as an investigation for any condition by the referring consultant and the participants will bear the charges for it.)

PAYMENT FOR PARTICIPATION: No incentive will be paid to you for participating in this study.

COMPENSATION:

In the event that I become injured as a result of taking part in this study, treatment whatever available at KLE charitable hospital, Belagavi, will be offered to me. No reimbursement, compensation or free medical care is given.

CONFIDENTIALITY:

All information collected about me during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify me in this research record. Information from this study may be published but my identity will be confidential in any publication.

QUESTION:

If any enquiries in the future or in case of research related injury illness, you may contact following person.

REG. NO. BS0118002	Dr. _____	Dr. Roopa.M.Bellad
Post-Graduate, Department of Radio- Diagnosis. J.N. Medical College, Belagavi	Guide , Professor & Head, Department of Radio- Diagnosis J.N. Medical College, Belagavi.	Professor and Unit Head Of Pediatics Chairman, Institutional Ethical Committee forHuman Subjects Research, J.N. Medical College, Belagavi. Ph. No: 0831- 2473777,Ext.1529

CONSENT TO PARTICIPATE IN RESEARCH STUDY:

1. I understand that I am participating in the study, which includes Ultrasonography of abdomen.
2. I confirm that I have read and understood the information in the patient information sheet. Procedure is explained to me in detail along with information about the advantages and disadvantages of taking part in the study. I have been given the opportunity to discuss all aspects of the study, to ask questions and hereby consent to participation in the trial outlined above.
3. I understand that the decision to take part in this study is completely voluntary and I am aware that I can choose to withdraw from the study at any point of time.
4. I consent to the photographing or recording of the procedure to be performed including appropriate portions of my body, for medical, scientific or educational purposes provided my identity is not revealed in the pictures or by the descriptive texts accompanying them.
5. I understand that there is no significant risk involved in the test that would be done in this study.
6. No guarantee or assurance has given by anyone as to the results that may be obtained.
7. My signature on this form signifies that I have willingly decided to participate after understanding the above information.

Participant's Name: _____

Parent or Guardian's name & Signature: _____




Name and signature of witness: _____

Name and signature of interviewer: _____

Date:

Place:

ANNEXURE II -ETHICAL CLEARANCE LETTER

	K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH (Deemed-to-be-University)
	Accredited 'A' Grade by NAAC (2 nd Cycle) Placed in Category 'A' by MHRD (Govt)
JAWAHARLAL NEHRU MEDICAL COLLEGE, NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)	
Website: http://www.jnmc.edu E-Mail: domc@jnmc.edu	Phone: (+91-0831) Office - 2472557 Principal - 2471701 Fax No. +91 (0)831 - 2470759
Ref: MDC/DOME/71	Date: 24/11/2018
To, REG. NO. BS0118002 PG student in Radio-Diagnosis, J.N.Medical College, BELAGAVI.	
Sub: Institutional Ethical Clearance for the study.	
With reference to the above, we wish to inform you that your proposed research project titled "NORMAL RANGE OF VALUES OF LIVER AND SPLEEN SIZE BY ULTRASONOGRAPHY IN CHILDREN IN BELAGAVI (NORTH KARNATAKA) -A ONE YEAR HOSPITAL BASED CROSS SECTIONAL STUDY", is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.	
 (Dr. Arathi Darshan) Member Secretary JNMC Institutional Ethics Committee on Human Subjects Research, J.N.Medical College, Belagavi.	 (Dr. Roopa M Bellad) Chairman, JNMC Institutional Ethics Committee on Human Subjects Research, J.N.Medical College, Belagavi.

ANNEXURE III-PROFORMA

NAME: _____

AGE & SEX: _____

OP/IP : _____

CHIEF COMPLAINTS:

HISTORY OF PRESENTING ILLNESS:

PAST HISTORY:

FAMILY HISTORY:

ULTRASONOGRAPHY FINDINGS;

1. LIVER LENGTH:

2. SPLEEN LENGTH:

ANNEXURE IV: FIGURES



Figure 12: GE VOLUSON P8 USG machine used for the study

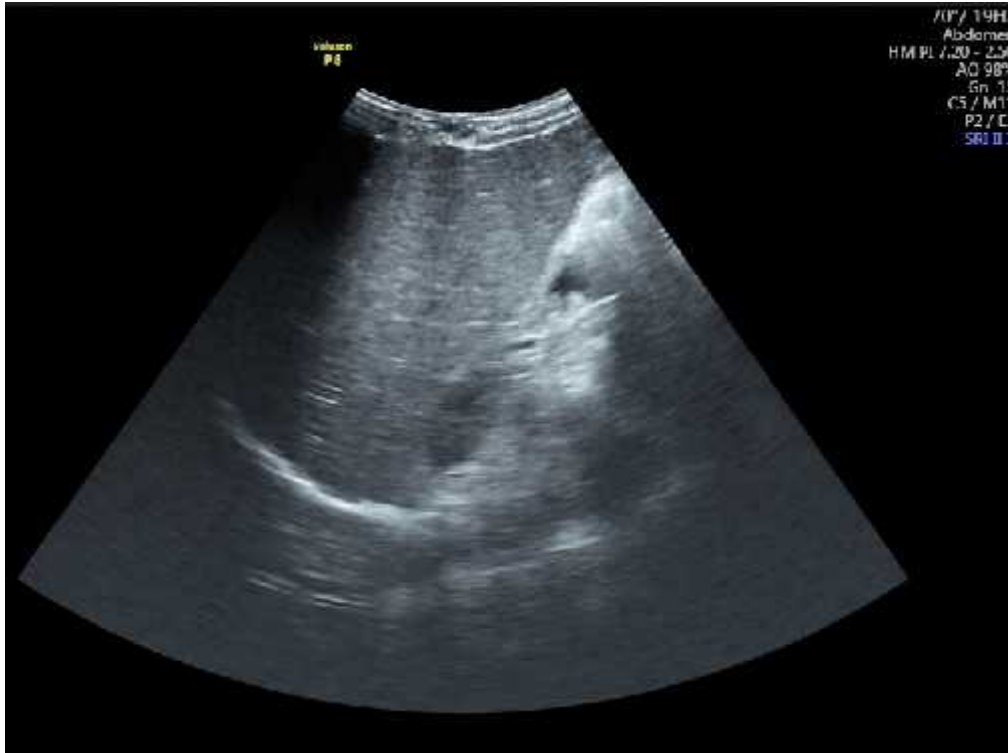


Figure 13: USG image of liver in the right midclavicular line

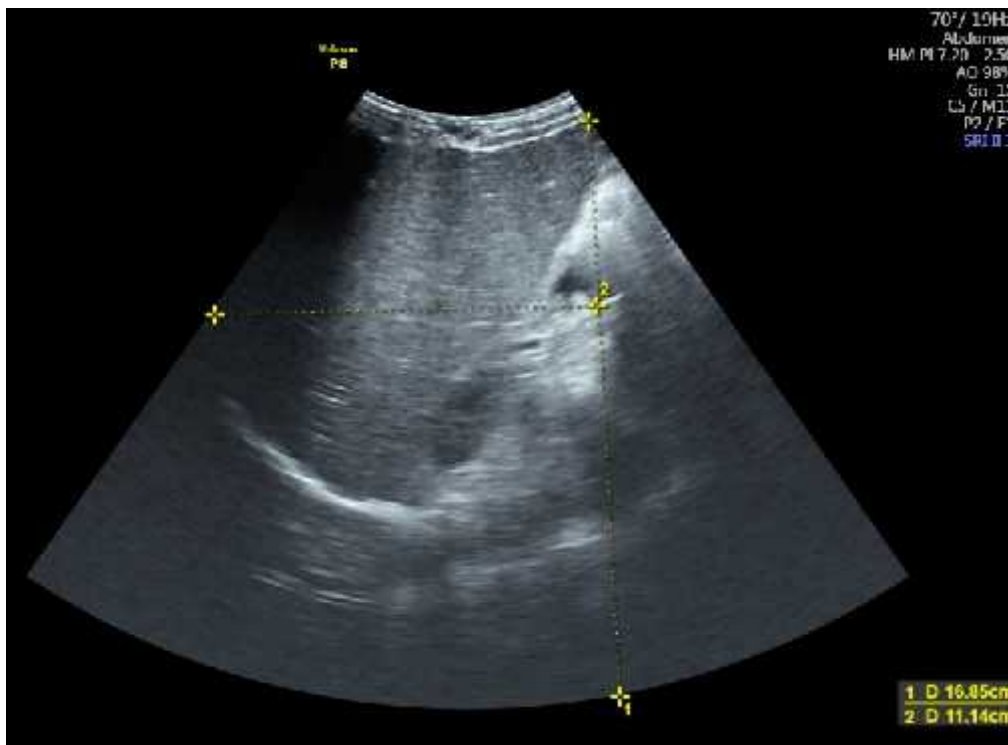


Figure14: USG image showing measurement of craniocaudal dimension of the liver in the midclavicular line



Figure 15: USG image of spleen, longitudinal view

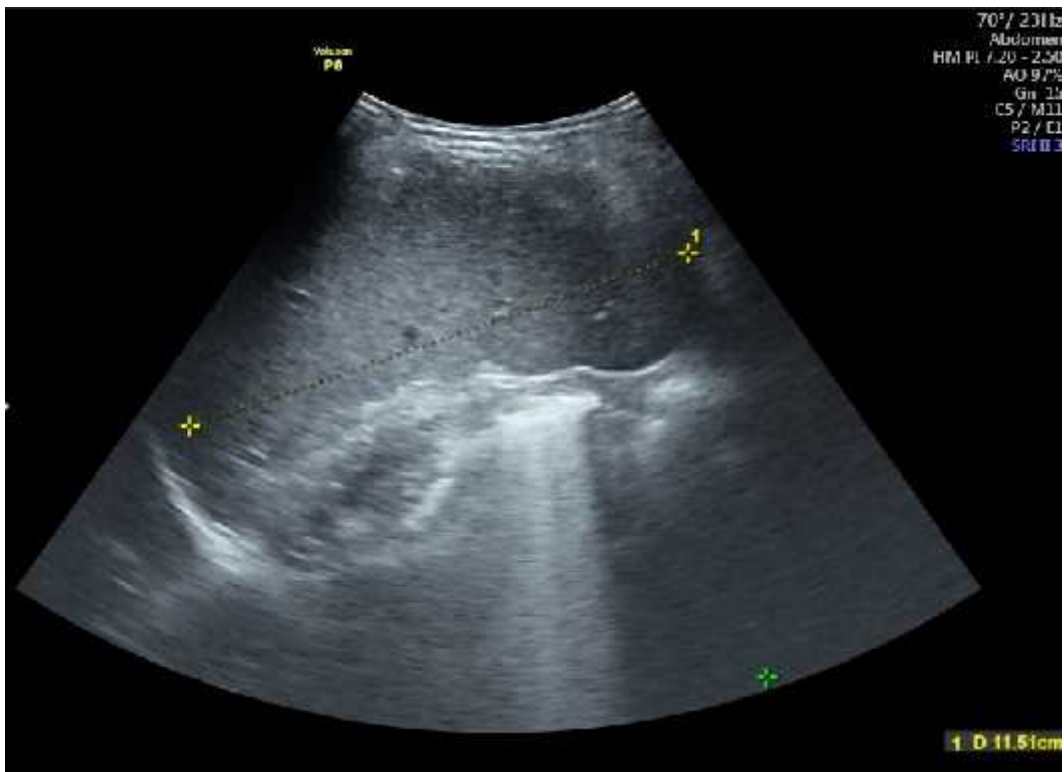


Figure 16: USG image showing measurement of spleen length between the most superomedial and the most inferolateral points

ANNEXURE V: KEY TO MASTERCHART

Sl. No	Serial number
USG - No	Ultrasonography number
cm	centimeters

ANNEXURE VI: MASTERCHART

SL. NO	USG-NO	AGE	SEX	LIVER-LENGTH (cm)	SPLEEN-LENGTH (cm)
1	19/647	1 month	M	4.5	3.5
2	19/2129	1 month	M	4.9	3.8
3	19/2447	1 month	M	5.1	3.6
4	19/5727	1 month	M	4.6	3.9
5	19/5581	2 month	M	5.4	4.2
6	19/766	2 month	M	5.7	4.1
7	19/11285	2 month	M	6.9	4.3
8	19/13861	2 month	M	6.7	4.5
9	19/14737	2 month	M	6.6	5
10	19/1556	2 month	M	6.8	4.6
11	19/2780	3 month	M	6.6	6.1
12	19/5184	3 month	M	7.4	5.9
13	19/5602	3 month	M	7.9	7.9
14	19/10538	3 month	M	8.3	7.1
15	19/1797	1 month	F	4.6	3.5
16	19/12857	1 month	F	4.8	3.9
17	19/6264	2 month	F	4.5	4.3
18	19/7050	2 month	F	5.4	4.5
19	19/7463	2 month	F	6.1	4
20	19/11883	2 month	F	5.8	5.2
21	19/11513	3 month	F	6.4	5.1
22	19/15976	3 month	F	7	5.2
23	19/678	3 month	F	6.8	5.3
24	19/7469	3 month	F	7	6
25	19/9293	3 month	F	7.2	6.4
26	19/1668	4 month	M	6	5.1
27	19/7601	4 month	M	6.1	5
28	19/8387	4 month	M	6	5.1
29	19/10702	4 month	M	6.3	5.1
30	19/12970	4 month	M	6.7	5.2
31	19/13362	4 month	M	6.5	5
32	19/1846	5 month	M	6.9	5
33	19/3651	5 month	M	7.7	5.3
34	19/8185	5 month	M	7.5	5.1
35	19/17850	5 month	M	7.4	5
36	19/6205	5 month	M	7.3	5.2
37	19/9724	5 month	M	7.7	5.3

38	19/10321	5 month	M	8	5.1
39	19/11758	5 month	M	7.8	5
40	19/15332	5 month	M	7.6	5.4
41	19/17605	5 month	M	8.6	5.9
42	19/2890	6 months	M	8.4	6.1
43	19/8268	6 months	M	8.8	6.8
44	19/8354	4 months	F	5.5	4.8
45	19/10558	4 months	F	5.9	5.2
46	19/8269	4 months	F	6.7	5.1
47	19/1730	4 months	F	6.8	5.5
48	19/4342	4 months	F	6.5	5
49	19/4467	4 months	F	7.3	5.4
50	19/10295	5 months	F	7.5	5.2
51	19/16294	5 months	F	6.9	6.3
52	19/5217	6 months	F	8.1	6
53	19/14981	6 months	F	8.6	6.4
54	19/659	7 months	M	6.4	4.1
55	19/2450	7 months	M	6.8	4.8
56	19/7920	7 months	M	6.6	4.9
57	19/12311	7 months	M	6.5	5.9
58	19/5346	8 months	M	6.9	4.9
59	19/12309	8 months	M	6.7	5.8
60	19/2492	8 months	M	6.8	5.9
61	19/17880	8 months	M	7	6.5
62	19/8388	9 months	M	7.3	5.9
63	19/16820	9 months	M	7.7	6.8
64	19/15145	9 months	M	7.8	5.8
65	19/13339	10 months	M	8.4	6.7
66	19/8354	10 months	M	8.6	6.4
67	19/6485	11 months	M	8.8	7.6
68	19/12344	11 months	M	9	7.9
69	19/14828	11 months	M	8.9	7.8
70	19/16765	11 months	M	9.2	8
71	19/12288	7 months	F	6.1	4.5
72	19/16263	7 months	F	6.5	4.9
73	19/16610	8 months	F	6.7	5.2
74	19/16892	8 months	F	7.5	5.5
75	19/11792	8 months	F	8.2	5.3
76	19/16795	9 months	F	8.8	6
77	19/15685	10 months	F	8.6	6.9
78	19/13185	11 months	F	9	7
79	19/16836	11 months	F	9.5	7.1

80	19/2679	1 year	M	7.1	4.5
81	19/1463	1 year	M	7.1	4.6
82	19/3602	1 year	M	7.6	4.5
83	19/6082	1 year	M	7.2	4.7
84	19/6284	1 year	M	7.1	5
85	19/6369	1 year	M	7	5.1
86	19/6755	1 year	M	7.8	5.3
87	19/6818	1 year	M	7.2	5.6
88	19/7233	1 year	M	7.2	5.7
89	19/7442	1 year	M	7.5	5.5
90	19/9033	1 year	M	7.8	5.3
91	19/10766	1 year	M	8.4	6.5
92	19/11194	1 year	M	8.2	6.1
93	19/11337	1 year	M	8.5	6.3
94	19/11965	1 year	M	8.3	6
95	19/15036	1 year	M	8.8	6.4
96	19/15228	1 year	M	8.9	6.2
97	19/15884	1 year	M	8.8	7.6
98	19/1522	2 year	M	9.3	7.4
99	19/2107	2 year	M	9.5	7.2
100	19/3148	2 year	M	9.3	7
101	19/3924	2 year	M	9.1	6.7
102	19/3970	2 year	M	9.9	8.1
103	19/2378	2 year	M	9.5	7.8
104	19/4288	2 year	M	9.4	8
105	19/2031	2 year	M	9.3	9.3
106	19/1166	2 year	M	10	9.5
107	19/4714	2 year	M	10.5	9.6
108	19/881	1 year	F	6.4	4.4
109	19/3744	1 year	F	6.8	4.6
110	19/4740	1 year	F	7.4	4.5
111	19/6411	1 year	F	7.7	4.8
112	19/7440	1 year	F	7.8	4.9
113	19/7564	1 year	F	7.6	5.5
114	19/8989	1 year	F	8.4	5.8
115	19/9407	1 year	F	8.5	6.1
116	19/9476	1 year	F	8.8	6.7
117	19/10766	1 year	F	8.7	6.3
118	19/3073	2 year	F	8.6	6
119	19/3603	2 year	F	8.9	6.7
120	19/16551	2 year	F	9.9	7
121	19/1039	2 year	F	9.8	6.8

122	19/13666	2 year	F	9.9	7.7
123	19/13044	2 year	F	10.5	7.5
124	19/12106	2 year	F	10.8	7.8
125	19/3019	3 years	M	7	3.9
126	19/3291	3 years	M	7.3	4.1
127	19/3769	3 years	M	7.5	4.3
128	19/15267	3 years	M	7.8	4.6
129	19/14813	3 years	M	7.3	4.4
130	19/2051	3 years	M	7.4	4.3
131	19/2070	3 years	M	7.5	4.5
132	19/2294	3 years	M	7.8	4.6
133	19/3841	3 years	M	8	4.7
134	19/14390	3 years	M	8.1	5
135	19/12223	3 years	M	8.4	4.9
136	19/4972	4 years	M	8.5	5.1
137	19/15749	4 years	M	8.2	5.3
138	19/15836	4 years	M	8.4	5.9
139	19/15838	4 years	M	8.5	5.8
140	19/2109	4 years	M	8.3	5.7
141	19/16474	4 years	M	8.4	5.8
142	19/1243	4 years	M	8.6	5.9
143	19/1847	4 years	M	8.5	6.4
144	19/6602	4 years	M	8.8	6.8
145	19/1198	4 years	M	9.3	6.5
146	19/10681	4 years	M	9.1	6.2
147	19/891	4 years	M	9.5	7.4
148	19/1559	4 years	M	9.2	7.6
149	19/1601	4 years	M	9.1	7.1
150	19/2292	4 years	M	9.5	7.8
151	19/1269	4 years	M	10	8.8
152	19/1668	4 years	M	10.1	8.9
153	19/10220	4 years	M	10.8	9.4
154	19/1671	3 years	F	6.5	5.1
155	19/2871	3 years	F	6.4	5.3
156	19/2930	3 years	F	6.7	5.5
157	19/1012	3 years	F	7.4	5.2
158	19/3491	3 years	F	7.9	5.6
159	19/1536	3 years	F	7.8	5.4
160	19/3980	3 years	F	8.2	5.5
161	19/5977	3 years	F	8.6	5.3
162	19/6001	3 years	F	8.8	5.7
163	19/15682	3 years	F	8.6	5.6

164	19/15074	3 years	F	8.5	5.9
165	19/14757	3 years	F	8.9	5.7
166	19/11896	3 years	F	8.4	5.5
167	19/15682	3 years	F	8.8	5.6
168	19/4336	4 years	F	8.6	6
169	19/4615	4 years	F	8.9	6.4
170	19/10685	4 years	F	9.8	6.3
171	19/10982	4 years	F	9.4	6.5
172	19/11715	4 years	F	9.8	6.2
173	19/12231	4 years	F	9.9	6.9
174	19/12633	4 years	F	9.4	6.4
175	19/14509	4 years	F	9.8	7.3
176	19/15219	4 years	F	9.9	7.8
177	19/15734	4 years	F	10.1	7.6
178	19/17324	4 years	F	10.4	7.4
179	19/17516	4 years	F	10.2	7.7
180	19/17535	4 years	F	10.4	8
181	19/3058	5 years	M	7.1	5.2
182	19/3651	5 years	M	7.3	5.4
183	19/2489	5 years	M	7.4	5.6
184	19/1796	5 years	M	7.8	5.8
185	19/1367	5 years	M	7.9	5.6
186	19/812	5 years	M	8.4	6.3
187	19/1864	5 years	M	8.6	6.1
188	19/2307	5 years	M	9.8	7.3
189	19/5211	5 years	M	9.3	7.1
190	19/17325	5 years	M	10.4	7.2
191	19/2581	6 years	M	11.5	8.5
192	19/2728	6 years	M	12.5	8.4
193	19/3018	6 years	M	12.6	9
194	19/3258	6 years	M	12.4	9.2
195	19/3554	6 years	M	13.6	9.4
196	19/2567	6 years	M	14.8	10.3
197	19/2631	5 years	F	6.3	5
198	19/3402	5 years	F	6.6	5.6
199	19/2543	5 years	F	6.7	5.4
200	19/1391	5 years	F	7.5	5.5
201	19/3402	5 years	F	7.8	5.7
202	19/3539	6 years	F	8.9	5.3
203	19/3565	6 years	F	8.7	6.3
204	19/7994	6 years	F	8.9	6
205	19/6615	6 years	F	9.5	6.6

206	19/5217	6 years	F	9.7	6.2
207	19/2344	6 years	F	9.5	6.5
208	19/14384	6 years	F	9.9	6.8
209	19/16427	6 years	F	10.5	7.4
210	19/15969	6 years	F	10.6	7.5
211	19/15301	6 years	F	11.1	8.2
212	19/14817	6 years	F	10.8	8
213	19/1007	6 years	F	11.9	8.4
214	19/11097	6 years	F	12.2	8.3
215	19/12320	6 years	F	12.8	8.2
216	19/16945	6 years	F	13	9
217	19/4935	7 years	M	8.8	6.2
218	19/12975	7 years	M	9.4	6.4
219	19/12103	7 years	M	9.5	6.8
220	19/1912	7 years	M	9.8	7
221	19/1379	7 years	M	9.6	7.3
222	19/1125	7 years	M	10.4	7.1
223	19/780	7 years	M	10.2	7.2
224	19/7615	7 years	M	10.6	7.1
225	19/6448	7 years	M	10.8	7.2
226	19/6175	7 years	M	10.5	6.9
227	19/5715	7 years	M	10.6	7.6
228	19/15792	7 years	M	10.9	8.2
229	19/11792	7 years	M	10.7	8.1
230	19/782	7 years	M	10.9	8
231	19/3236	8 years	M	11.2	8.9
232	19/5181	8 years	M	10.8	8.6
233	19/5769	8 years	M	11.6	8.5
234	19/5871	8 years	M	11.5	9.1
235	19/7508	8 years	M	12	9.5
236	19/3477	7 years	F	8	5.2
237	19/2344	7 years	F	8.6	5.6
238	19/4783	7 years	F	8.5	5.5
239	19/17262	7 years	F	8.4	5.9
240	19/2240	7 years	F	9.1	5.6
241	19/2246	7 years	F	9.8	6.6
242	19/17691	7 years	F	9.5	6.7
243	19/15176	7 years	F	10.1	6.8
244	19/2895	8 years	F	10.5	7.8
245	19/3718	8 years	F	10.8	7.8
246	19/17683	8 years	F	10.5	8.1
247	19/17372	8 years	F	10.3	8.5

248	19/2132	8 years	F	10.9	8.5
249	19/14522	8 years	F	11	9.2
250	19/14297	8 years	F	11.5	9.5
251	19/14294	8 years	F	12.8	10.4
252	19/5032	9 years	M	9.9	6.9
253	19/14123	9 years	M	10.2	7.5
254	19/12238	9 years	M	10.9	7.4
255	19/11492	9 years	M	10.8	7.8
256	19/1312	9 years	M	11.2	7.5
257	19/15699	9 years	M	11.3	7.8
258	19/16286	9 years	M	10.9	7.3
259	19/3005	10 years	M	10.6	8.2
260	19/9940	10 years	M	11.3	7.8
261	19/10892	10 years	M	11.8	8.5
262	19/12343	10 years	M	12.6	8.6
263	19/12511	10 years	M	12.5	8.2
264	19/12990	10 years	M	12.9	8.8
265	19/13641	10 years	M	13.2	8.6
266	19/813	10 years	M	13.4	9.3
267	19/16287	10 years	M	13.5	9.4
268	19/16529	10 years	M	13.1	9.5
269	19/16555	10 years	M	12.9	9.8
270	19/17364	10 years	M	13.8	9.7
271	19/17397	10 years	M	14	9.9
272	19/18032	10 years	M	14.4	10.5
273	19/3544	9 years	F	9.1	6.1
274	19/3710	9 years	F	9.8	6.8
275	19/3903	9 years	F	10.5	6.6
276	19/4671	9 years	F	10.2	6.6
277	19/5664	9 years	F	10.9	7.5
278	19/1654	9 years	F	11.2	7.6
279	19/4180	10 years	F	11.9	8.3
280	19/2093	10 years	F	11.6	8.7
281	19/1652	10 years	F	12.3	8.9
282	19/4603	10 years	F	12.4	9.3
283	19/5036	10 years	F	13	9.5
284	19/16555	10 years	F	13	9.8
285	19/13787	10 years	F	13.5	10
286	19/2710	11 years	M	10.8	6.5
287	19/2799	11 years	M	11.2	6.7
288	19/2410	11 years	M	11.5	6.6
289	19/1413	11 years	M	11.6	7

290	19/2047	11 years	M	11.9	8.3
291	19/2366	11 years	M	12.5	7.5
292	19/2404	11 years	M	12.4	8.4
293	19/694	12 years	M	12.1	9
294	19/1676	12 years	M	11.9	9.4
295	19/2580	12 years	M	12.6	9.6
296	19/2274	12 years	M	14.3	10.4
297	19/615	12 years	M	15	11.5
298	19/3383	11 years	F	9.3	6.4
299	19/4737	11 years	F	10.6	6.9
300	19/4856	11 years	F	10.8	7
301	19/16158	11 years	F	10.9	7.1
302	19/2357	11 years	F	11.2	7.3
303	19/16893	11 years	F	10.8	7.2
304	19/2208	11 years	F	11.9	7.9
305	19/2831	12 years	F	11.5	8
306	19/2159	12 years	F	12.8	8.3
307	19/2985	12 years	F	12.7	8.5
308	19/3177	12 years	F	12.9	8.7
309	19/5793	12 years	F	12.8	9.1
310	19/5960	12 years	F	13.9	9.6
311	19/967	12 years	F	13.6	10.5
312	19/1268	12 years	F	14.3	11