"ROLE OF COLOR DOPPLER ULTRASONOGRAPHY IN DIFFERENTIATING BENIGN AND MALIGNANT CERVICAL LYMPHADENOPATHY – ONE YEAR HOSPITAL BASED CROSS SECTIONAL STUDY."

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Dr. Ashwin S. Patil MD,
Professor and Head,
Department of Radio Diagnosis,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date:
Place: Belagavi

Dr. N. S. Mahantshetti MD
Principal,
J. N. Medical College,
Nehru Nagar,
Belagavi – 10

Date:
Place: Belagavi

ACCEPTANCE LETTER

KLE
JAWAHARLAL NEHRU MEDICAL COLLEGE
(Recognized by Medical Council of India, New Delhi)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi- 590 010, Karnataka, INDIA
0831 – 2471350 0831 – 2470759 www.jnmc.edu principal@jnmc.edu

Ref No: MDC/PG/ Date: 25-11-2021.

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Dr. (Mrs.) N.S. Mahantashetti.
Chairperson-Antiplagiarism Committee &
Principal,
J. N. Medical College, Belagavi.

To,
Reg. No. BS0119012.
Postgraduate Student,
2019-20 Batch,
Department of Radiodiagnosis,
J. N. Medical College, Belagavi.

LIST OF ABBREVATIONS USED:

LN	LYMPHNODES
SCM	STERNOCLEIDO MASTOID
SAN	SPINAL ACCESSORY NERVE
IJV	INTERNAL JUGULAR VEIN
SCC	SQUAMOUS CELL CARCINOMA
NHL	NON HODGKINS LYMPHOMA
HL	HODGKINS LYMPHOMA
TB	TUBERCULOSIS
HIV	HUMAN IMMUNO DEFICIENCY VIRUS
H&N	HEAD AND NECK
SN	SENSITIVITY
FNAC	FINE NEEDLE ASPIRATION CYTOLOGY
SP	SPECIFICITY
USG	ULTRASONOGRAPHY
BMUS	B-MODE ULTRASOUND
CDUS	COLOR DOPPLER ULTRASOUND
S/L RATIO	SHORT AXIS TO LONG AXIS RATIO
SAD	SHORT AXIS DIAMETER
RI	RESISTIVITY INDEX
PDUG	POWER DOPPLER ULTRASONOGRAPHY
HPE	HISTOPATHOLOGICAL EXAMINATION REPORTS
ROC	RECEIVER OPERATING CHARACTERISTIC CURVE
HPR	HISTOPATHOLOGICAL REPORT
L/S RATIO	LONG AXIS TO SHORT AXIS RATIO
LT RATIO	LONGITUDINAL TRANVERSE RATIO
VS	VERY SIGNIFICANT
HS	HIGHLY SIGNIFICANT

ABSTRACT

TITLE:

"ROLE OF COLOR DOPPLER ULTRASONOGRAPHY IN DIFFERENTIATING BENIGN AND MALIGNANT CERVICAL LYMPHADENOPATHY – ONE YEAR HOSPITAL BASED CROSS SECTIONAL STUDY."

Background & objectives

"Lymphadenopathy" is defined as an abnormality in size and / or alteration in consistency of the lymph nodes. Lymph nodes are frequently enlarged in various regional and systemic diseases and sometimes may be the only clinical finding or one of the several nonspecific findings. Cervical region as the major site involved with Tuberculosis being the most prevalent of all (45%) followed by reactive lymphadenitis 27%, non specific lymphadenitis 16% and metastatic 9%.

Ultrasound is a useful imaging tool for the initial evaluation of cervical lymph nodes because it has high sensitivity (98%) and specificity (95%), particularly when combined with fine needle aspiration cytology. It will characterize the lymph nodes in accordance with the morphologic criteria like size, shape, margins, discrete or matted, presence of fatty hilum.

Ultrasound with color Doppler can help in differentiation of benign and malignant lymph nodes have been well described in literature. Differentiation of benign and malignant lymph nodes without Fine Needle Aspiration Cytology (FNAC)/ biopsy is difficult, but crucial for patient management. Therefore, non-invasive imaging tools that can facilitate in differentiation of benign and malignant nodes are required. It will characterize the lymph nodes in accordance with the central**,** peripheral or mixed vascularity and resistive index.

This study mainly focuses on role of Ultrasound with color Doppler in differentiation of benign and malignant lymph nodes to minimize patients going for discomforting invasive procedures like FNAC/Biopsy.

Materials and methods

This is a hospital based cross sectional study, conducted from 1st January 2020 to 31st December 2020 for a period of 1 year in patients referred to radiology department of KLE'S Dr Prabhakar Kore Hospital for ultrasonography of the neck.

A total of 30 patients referred to the department of Radio-diagnosis for evaluation of the cervical lymphadenopathy with ultrasonography were included of all age groups. After obtaining informed consent patients were subjected to ultrasonography of lymph nodes on GE VOLUSON 7 or GE VOLUSON 8 machine equipped with a 7.5–12 MHz high frequency linear array transducer.

The findings of B-Mode and color Doppler ultrasound were assessed, analysed and later followed up with their histopathological / FNAC results.

Data was analyzed using IBM SPSS Version 22 for Windows.

Descriptive analysis was carried out for all the quantitative data.

Data was represented using appropriate diagrams like a bar chart.

Results

On evaluation of the pathological reports, out of total 30 patients, 17(56.7%) turned out to be benign and 13 (43.3%) malignant. On sonography correlation using B-Mode and color Doppler findings, out of the 10 nodes which were categorized as malignant, 9 (90%) were malignant and 1 (10%) were benign and out of 20 (66.7%) which were categorized as benign 16 (80%) were benign and 4 (20%) were malignant. This study proved to be significant with a "p value" of 0.0001. The variables taken into consideration for characterization of nodes are size, shape, margins, echotexture, presence of fatty hilum, distribution of vessels as central, peripheral or mixed and resistivity Index (RI)

Conclusion

The sensitivity, specificity, positive & negative predictive value and accuracy of 76.92%, 94.12%, 90.91%, 84.21%, and 86.67% respectively of B-Mode &color Doppler findings in differentiation of the nodes into benign and malignant categories. Thus, color Doppler

ultrasonography parameters like vascular pattern and resistive index along with the B-mode ultrasound can be used for differentiation of lymph nodes into benign and malignant.

Color Doppler ultrasonography is simple and easily applicable in evaluation of the cervical lymph nodes in daily practice.

Color Doppler features like mixed or peripheral vascular pattern and RI cutoff of greater that 0.67 are associated with malignancy and features like central vascularity and RI less than 0.57 are associated with benign lymph nodes.

Keywords

Cervical lymphadenopathy, vascularity and Resistive index (RI).

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INTRODUCTION

"Lymphadenopathy" is defined as an abnormality in size and / or alteration in consistency of the lymph nodes.

Lymph nodes are frequently enlarged in various regional and systemic diseases and sometimes may be the only clinical finding or one of the several nonspecific findings. Tuberculous lymphadenitis was noted as the most prevalent etiology, cervical region as the major site involved with prevalence of 45% followed by reactive lymphadenitis 27%, non-specific lymphadenitis 16% and metastatic 9%.

Ultrasound is a useful imaging tool for the initial evaluation of cervical lymph nodes because it has high sensitivity (98%) and specificity (95%), particularly when combined with fine needle aspiration cytology. It will characterize the lymph nodes in accordance with the morphologic criteria like size, shape, margins, discrete or matted, presence of fatty hilum.

Ultrasound with color Doppler can help in differentiation of benign and malignant lymph nodes have been well described in literature. Differentiation of benign and malignant lymph nodes without Fine Needle Aspiration Cytology (FNAC)/ biopsy is difficult, but crucial for patient management. Therefore, non-invasive imaging tools that can facilitate in differentiation of benign and malignant nodes are required. It will characterize the lymph nodes in accordance with the central**,** peripheral or mixed vascularity and resistive index.

This study mainly focuses on role of Ultrasound with color Doppler in differentiation of benign and malignant lymph nodes to avoid patients going for discomforting invasive procedures like FNAC/Biopsy.

AIM & OBJECTIVES

AIM:

1. Role of color doppler ultrasonography in differentiating benign and malignant cervical lymphadenopathy.

OBJECTIVE:

1. To compare the findings of color doppler ultrasonography of cervical lymph nodes to that of FNAC/ histopathological reports.

REVIEW OF LITERATURE

A HISTORICAL REVIEW

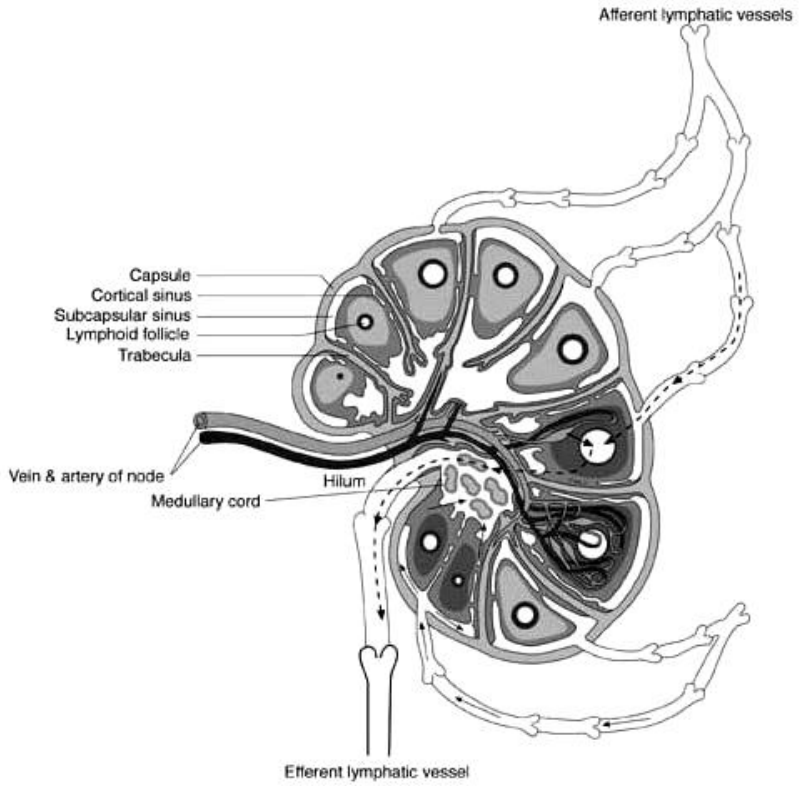
The lymphatic system is an element of the immune system of our bodies. It consists of a system of lymph vessels and lymphoid organs mainly lymph nodes [1].

The mystery of how lymph produced remained unsolved until Carl Ludwig proposed lymph as a blood filtrate in mid-nineteenth century.

Donald Morton devised the sentinel nodal biopsy technique, which was extremely useful in appropriately staging melanomas and preventing unnecessary nodal dissection. As a result, physicians and surgeons began to believe that local care of carcinomas should be complemented with treatment of regional lymphatic anatomical structures to improvise the rate of cure. Hence, the nodal dissection on the table became an essential element of oncology management [2].

ANATOMY [3]

Figure 1: Structure and histology of lymph node



The nodes in the region of neck are small bean-shaped structures. A noticeable depression is seen in the midline on one side termed hilum, from where the blood vasculature enters (afferent) and leaves the node (efferent). It has an outer cortex, middle paracortex, and inner medulla. The cortex is deficient at the hilum. The efferent vessels directly originate from the inner medulla while the afferent vessels have drainage into the outer cortex.

The capsule made up of "collagen fibers" and some "elastic fibers", forms the external cover. The paracortex acts as a transitional area for the lymphocytes to reach back to their parent system from the vascular anatomy. Lymphoid follicles from the cortex. The central medulla contains the trabeculae, cords, and sinuses

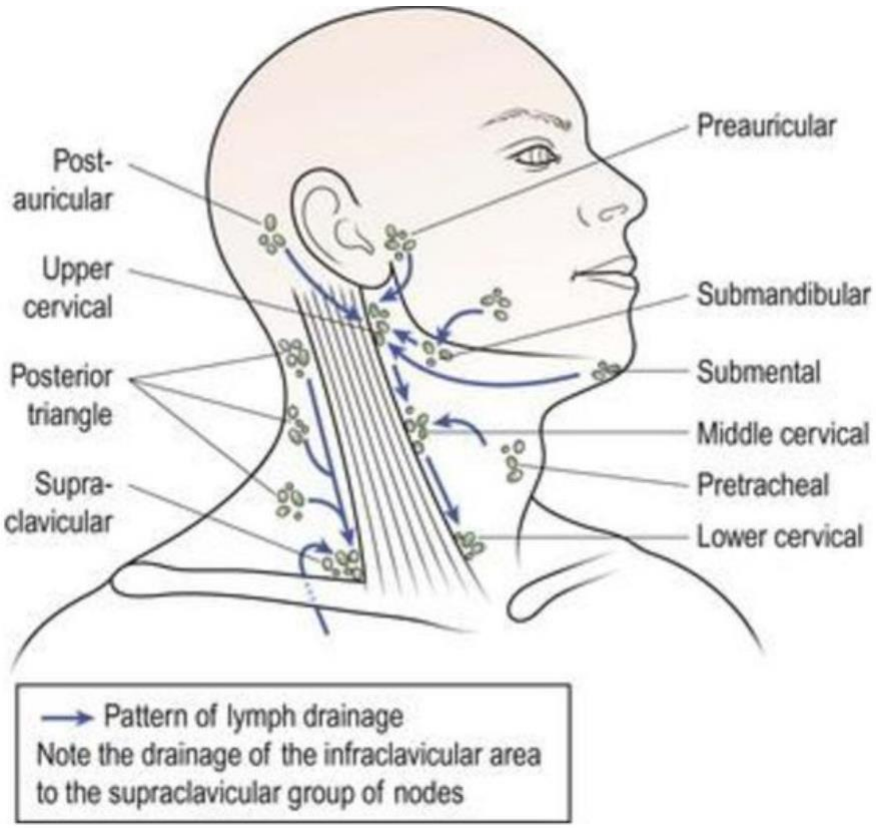
Arterial system:

The major artery enters the hilum and separates into several branches. Arterioles branch into capillaries in the outer cortical area and terminate in lymphoid follicles. Few arterioles go along the trabeculae up to the cortex in the central medullary region, but some end up supplying the capillaries.

Venous system:

The venous and arterial systems both pass via the hilum in a similar manner. The number of venules in the cortex converge to form a tiny vein, which then converges further to form the major vein in the medulla. The hilum is where the major draining vein exits.

Figure 2: Location of lymph nodes with its lymphatic drainage



NECK ANATOMY:

The cervical region contains an extensive lymphatic network bound by aponeuroses, a fibrous structure that helps in binding them to the adjacent muscles, vasculature, and peripheral nerves. The chains of lymphatic flow are strictly lateralized and usually do not mix with the contralateral system without any evidence of a pathologic process.

They should either drain directly into arteries through the left jugular-subclavian vein confluence or into the left thoracic lymphatic duct. On the opposite side, the flow comes to a halt in the lymphatic duct. Except for the midline tissues, which comprise the laryngeal, nasopharyngeal, and pharyngeal structures, and the tongue base, the majority flow into an ipsilateral chain.

The LNs' borders are determined by placing the patient in a supine posture with his or her head in a "neutral" position.

Classification:

Rouviere divided the cervical nodes into two groups: anterior and posterolateral, and the nodes around upper respiratory and gastrointestinal systems. He appropriately located and described the node's anatomical sites and drainage zones. Because anatomically based terminologies for neck node dissection were troublesome for surgeons, nodal classification changed over time into more simplified classification.

Based on clinical and pathologic knowledge gathered over the next few years, Shah et al in New York in 1981 pushed a noticeable simpler numerical classification (Table 1).

Figure 3: Cervical lymph node classification

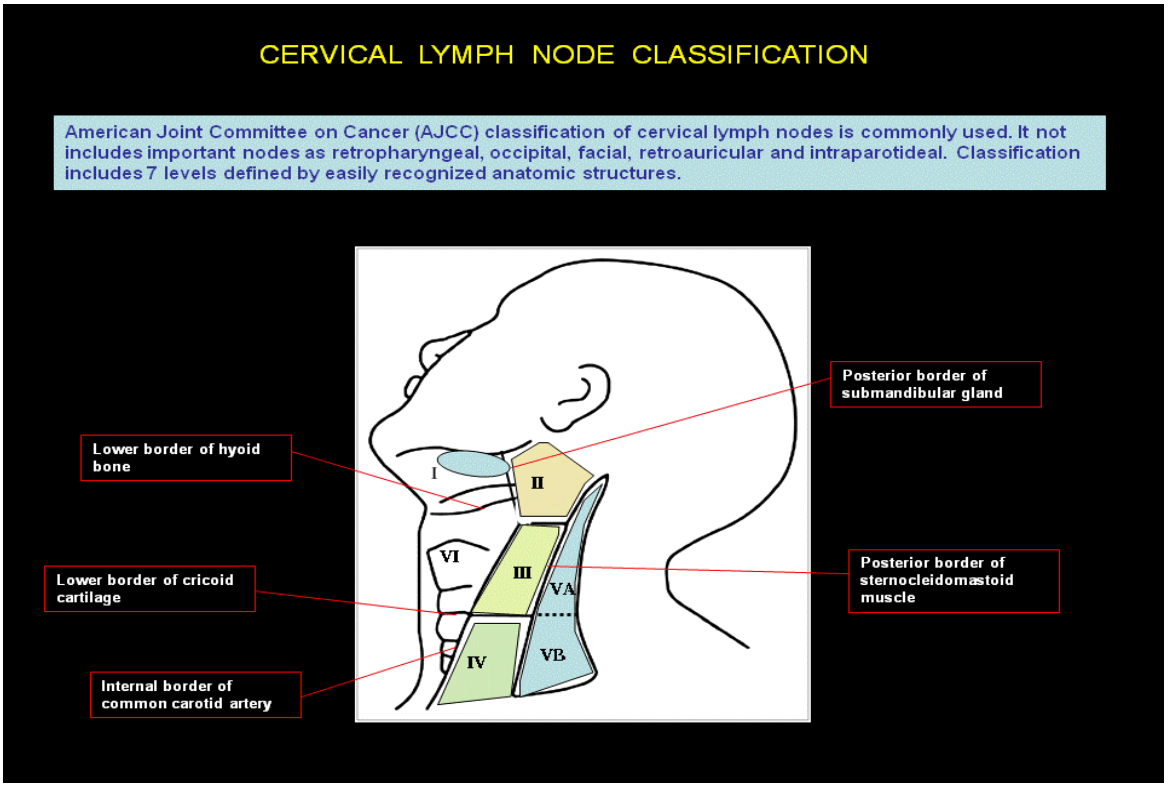
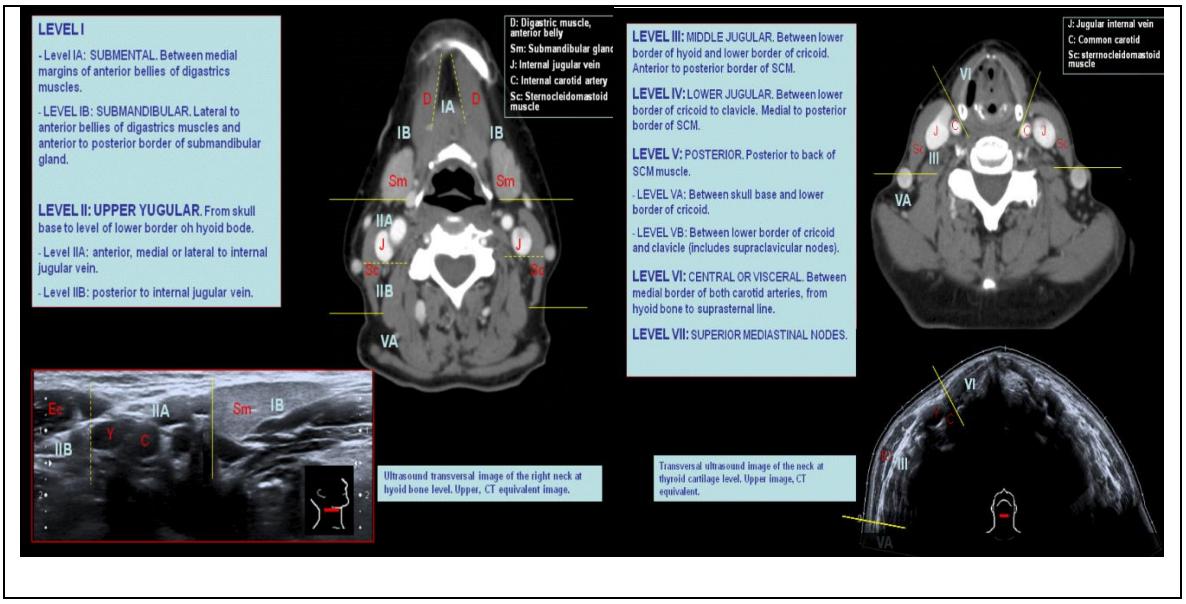


Figure 4: Ultrasound of cervical lymph nodes



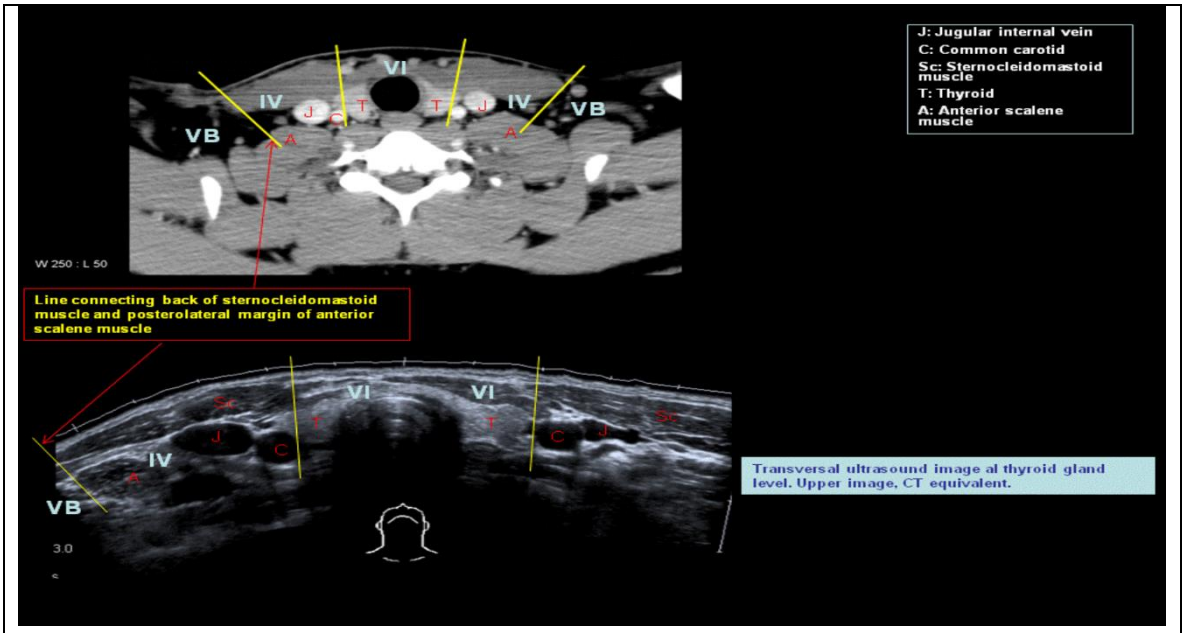

J: Jugular internal vein
C: Common carotid
Sc: Sternocleidomastoid muscle
T: Thyroid
A: Anterior scalene muscle
VI
IV
VB
W 250 : L 50
Line connecting back of sternocleidomastoid muscle and posterolateral margin of anterior scalene muscle
Transversal ultrasound image al thyroid gland level. Upper image, CT equivalent.

TABLE 1

Level	Location
IA	Submental lymph nodes
IB	Submandibular lymph nodes
II	Internal jugular (deep cervical) chain from the base of the skull to the Inferior border of the hyoid bone
III	Internal jugular (deep cervical) chain from the hyoid bone to the inferior Border of the cricoid arch
IV	Internal jugular (deep cervical) chain between the inferior border of the Cricoid arch and the supraclavicular fossa
V	Posterior triangle or spinal accessory nodes
VI	Central compartment nodes from the hyoid bone to the suprasternal notch
VII	Nodes inferior to the supra sternal notch in the upper mediastinum

Level I

Level I-a is located in midline between anterior bellies of bilateral digastrics, called submental nodes. They drain the skin over the chin, the mid part of the inferior lip, anterior aspect of the floor of mouth, and tongue (only tip). Hence are most vulnerable to metastases from primaries of these locations.

I-b are submandibular group of nodes. The lateral boundary is the mandible bone and the medialis the digastric. The space extends from symphysis menti reaching up to the submandibular salivary glands. They receive flow from the nasal cavity (lower aspect) and both hard &soft palate, two alveolar ridges (upper maxillary and lower mandibular), cheek region, and anterior 2/3rd of the tongue. These nodes have metastases from primaries of nasal & oral cavities, mid-face & salivary glands of submandibular space.

Level II, III, IV

These are called the upper, mid, and lower jugular nodes forming a chain along with the superior, middle, and inferior1/3rd of the XIth cranial nerve (SAN) and IJV. Their lateral extent is up to SCM and medial extent up to scalenus muscle and medial margin of ICA. The Upper 1/3rd of the jugular group is seen to extend from the first cervical vertebra to the hyoid. The middle jugular from the inferior margin of upper jugular group to cricoid ring cartilage & the lower ones extends up to an arbitrary line drawn 2 cm above the joint formed by sternum and clavicle. The jugular vein divides the "II group" of nodes into II-a&II-b. Level II receives lymph draining from the subcutaneous and muscular plane of the face, retropharyngeal nodes, and the three pairs of salivary glands (major glands), nose, pharyngeal & larynx tissues, middle ear &external ear meatus, and hence harbour secondaries from these primaries. Mid jugular, retropharyngeal, Waldeyer ring system, the base of tongue, and thyroid glands drain into middle jugular nodes.

Level IV-a and IV-b are subdivided by SCM. They have secondary deposits from epicenters which include laryngopharyngeal tissue, thyroid gland, naso-oropharynx, and pharyngeal tonsils. IV-b are the medial supraclavicular nodes.

Level V (Va, Vb, and Vc)

Va and Vb groups are located in the posterior triangle demarcated by the cricoids cartilaginous structure for oncologic dissections. Vc is lateral supraclavicular nodes. The anterior boundary is the transverse cervical vasculature &SCM and the posterior is trapezius. Superior extent is a plane that passes along the superior margin of themid-portion of hyoid and the inferior extent iscervical transverse artery. Lateral limits extend up toepidermis and underlying superficial platysma muscle. The medial extent is the muscle of the back (levator scapulae) cranially and posterior scalenus caudally.

Level V is seen to drain the posterior scalp region (parieto-occipital regions), the skin over the shoulders, and naso& oropharynx. These should be looked at with a great degree of suspicion in case of primaries of midline anatomic structures like the thyroid & pharynx.

Level Vc

They are called the lateral group of supraclavicular nodes which share a common boundary with level IVa, the inferior margin of level IVa marks the superior extent of Vc. Anterior extent reaching up to the epidermis and posterolaterally the trapezius. Medially, reaching up to the lateral margin of SCM. Commonly involved in nasopharyngeal carcinomas.

Level VIa and VIb

VIa and IVb groups lie in between the bilateral SCMs and common carotid arteries respectively.

The first group comprises the anterior compartment nodes located in front of the airways in visceral space and shares a common boundary with level Ib nodes- the superior extent of VIa is hyoid and inferior being glands located in submandibular space. The boundaries, anteriorly, being platysma &posteriorly, strap muscles. Nodal involvement must be suspected in cases of carcinomas of buccal mucosa of gingivo-mandibular sulcus and lips.

The second group rests on membrane joining the thyroid & hyoid and receives lymphatic flow from the tongue (tip), lip (lower), and structures below the mylohyoid muscle and thus are at risk of having metastatic deposits from these regions. The lower boundary is the manubrium of the sternum and upper is the cartilaginous tissue covering the thyroid, the medial is the trachea &esophagus and the lateral is the common carotid on either side. They receive afferents from the vocal cords and subglottis, adjacent pyriform sinuses, esophagus (cervical portion), and oral cavity structures.

Level VIIa and VIIb

These are the retropharyngeal and retro-styloid nodes respectively.

The first group lies in the retropharyngeal space extending from the atlas vertebrae to the hyoid bone with lateral extension up to the internal carotids. Ventrally it extends up to the intrinsic pharyngeal musculature – the superior constrictor and dorsally up to the longus group of muscles. Their involvement should be suspected in neoplastic etiologies of the waldeyer's ring tissues and internal auditory canal.

The second group is the proximal extension of II group nodes, situated in the carotid and prestyloid portion of parapharyngeal spaces with posterior extension being body of the first vertebra of the vertebral column and inferiorly up to the jugular foramen. They are vulnerable to the primaries of the nasopahrynx and are proven to have retrograde flow

from extensive level II involvement and thus should be noticed carefully with a high grade of suspicion in cases with massive lesions of neck regions.

CERVICAL LYMPHADENOPATHY

The process of identifying and classifying the causes of lymphadenopathy in the neck requires a meticulous approach. There are multiple conditions that present with cervical region lymphadenopathy, most commonly seen are the infectious causes and metastatic deposits.

Table 2: CAUSES OF CERVICAL LYMPHADENOPATHY
Infections Gram stain - negative and positive bacteria Tick borne disease- Borreliosis Cytomegalovirus infection Glandular fever/ kissing disease German measels Teeny's disease Toxoplasmosis AIDS
Granulomatous disease Typical /atypical mycobacterial infection Besnier-Boeck-Schaumann disease – sarcoid granulomas Hand–Schuller–Christian disease

Neoplasms Metastases from SCC of oropharynx, Thyroid Carcinoma (most commonly -Papillary Carcinoma of thyroid), lung, Esophagus, Renal carcinomas NHL& HL Kaposi's sarcoma
Miscellaneous (rare) Castleman's or Kikuchi's or Kimura's disease Immunoblastic lymphadenopathy Histiocytoid hemangioma Post radiation changes

Cervical lymphadenopathy can be a localised condition affecting only the cervical nodes, or it can be a component of a generalized lymphadenopathy.

The viral, bacterial, or protozoal infections most commonly cause lymph node enlargement in children. Reactive hyperplasia of the lymph nodes is caused by the viral process.Tuberculosis is the most prevalent infectious cause of death, accounting for a significant portion of cases. Tuberculosis is India's most common disease, afflicting over 40% of the population.

Lymphadenitis is the most common extrapulmonary sign of tuberculosis, with 63 percent of cases occurring in the cervical lymph nodes [7]. It primarily affects children and young people aged 11 to 30 years old, with a minor gender bias.

HIV, which is associated with extrapulmonary nodal TB, is another cause of lymphadenopathy. Other common causes include dental caries, tonsillitis, submandibular adenitis, oral ulcers, and other infections of the head and neck.

Adults are more likely than children to develop cancer. It might be either primary or secondary in nature. Head and neck tumours frequently cause secondary metastases. Lymphoma is the most common primary lymphadenopathy we see.

In 80% of instances of Head&Neck cancers, particularly the mucosal cancers of aerodigestive tract spread to cervical nodes. Lymphadenopathy in cervical region may be first evidence of metastasis in event of cancer. In terms of staging, therapy, and prognosis, its existence is crucial. When these patients have ipsilateral cervical lymphadenopathy, their 5-year survival rate drops to 50%[8,9]. Patients having lymphadenopathy on both sides of neck had a 5-year survival rate of about 25% [9,10]. When nodal metastases expand outside the capsule, it is further reduced by half [10]. As a result, examining such nodes is important as it determines the patient's prognosis and treatment options.

Rosai-Dorfman disease, is the benign proliferation of sinusoidal histiocytes, & is another unusual cause of cervical lymphadenopathy. Necrotizing lymphadenitis, arthralgia, and hepatosplenomegaly are symptoms of Kikuchi-Fujimoto disease, a benign lymphadenopathy. Kimura disease is an eosinophilic hyperplastic lymphogranuloma which causes painless cervical lymphadenopathy.

Table 3: Site of primaries and the commonly involved metastatic nodes

PRIMARIES	COMMONLY INVOLVED NODES IN METASTASES
Oropharynx, hypopharynx,larynx carcinomas	Level II, III and IV
Oral cavity and tongue carcinomas	Level Ib and II
Papillary carcinoma of the Thyroid	Level II, III and IV
Nasopharyngeal carcinoma	Level II and V
Non-head and neck carcinoma	Level Va and Vb

IMAGING MODALITIES:

B-mode ultrasonography is the most often used test for evaluating cervical lymphadenopathy and is considered the first line of investigation. This, in combination with Doppler study, is helpful for assessing and characterising lymph nodes.

Ultrasound has SN of 73 percent in assessing cervical lymph nodes and when combined with FNAC the SN rises to 92 percent& the SP rises to 93 percent [13].

USG is a non-invasive, quick, & generally low-cost method for nodal evaluation. Size, form, boundaries, & the presence or absence of the hilum, short axis - long axis ratio, cortical hilar ratio echogenicity, and homogeneity of internal structures are all B-mode USG features for evaluating lymph nodes [14,15].

With the exception of submandibular and parotid lymph nodes, normal lymph nodes have an oval form with hypoechoic cortex & fatty hilum compared to adjacent muscle and a short- long axis ratio of less than 0.5. On greyscale sonography, reactive lymph nodes seem to be normal lymph nodes [16]. Due to intranodal cystic necrosis and soft tissue edema, tuberculous lymph nodes appear as spherical, hypoechoic, and matted nodes with loss of fatty hilum [17].

On the other hand, metastatic nodes are hypoechoic, rounded entities with no echogeniic hilum &varying degrees of necrosis[14]. Necrosis is prevalent in squamous cell carcinoma metastases and indicates the malignant character of the nodes[14]. Coagulative necrosis is prevalent in the node, producing a clearly defined echogenic centre[14]. When tumoral infiltration is localised, it might result in focal cortical hypertrophy. Extracapsular spread is associated with ill-defined borders, which lowers the patient's prognosis [14]. Papillary carcinoma metastasis, on the other hand, appears spherical and hyperechoic to

neighbouring muscle with punctate calcification[17]. Addition to malignant node, lymphomas have intranodal reticulation[18].

Color Doppler sonography is utilised to accurately differentiate between benign and malignant cervical nodes. It accurately distinguishes between benign and malignant nodes based on histology evidence (sensitivity: 83-89 percent and specificity: 76-98 percent) [22,23]. Hilar vascularity or apparent avascularity can be found in both normal and reactive lymph nodes[22,23]. The conservation of normal vascular patterns implies the likeness of reactive lymph nodes to normal nodes[22,23]. Due to enhanced vascular dimension and blood flow, reactive nodes show significant hilar vascularity [20].

Malignant lymph nodes have hilar and peripheral vascular pattern which has been linked to tumour neo angiogenesis and related capsular vessel recruitment [22,23]. Tuberculous nodes mimic both benign and malignant node vascular patterns [23]. They depict hilar vessel displacement due to localised necrotic regions, separating it from the usual category [23].

The change in vascular resistance is another concept that Doppler sonography is founded on. The vascular resistance of inflammatory nodes decreases, while the resistance of malignant nodes increases [16]. Tumor cells proliferate, disseminate, and usurp a major section of the node in metastatic nodes, resulting in constriction of intranodal blood arteries and increase in vascular resistance[14]. The vascular resistance of tuberculous nodes was lower than that of malignant nodes[23]. Because Doppler results of benign reactive, tuberculous, and metastatic nodes are so similar, a conclusive diagnosis requires

histological investigation[21]. As a result, the most particular or valuable characteristics remain unknown.

Despite the fact that all of the aforementioned metrics provide a valuable and rapid diagnosing references with adequate sensitivity and specificity, one of the most crucial considerations to make before using them as universal criterion is subjectivity. As a result, a process that is easy, non-invasive, efficient, and cost-effective that produces consistent outcomes is required to differentiate benign and malignant cervical lymph nodes.

In a tertiary medical institution in South India, Kamat Rohan [(23)] conducted a two-year cross-sectional analytical inquiry, which was published in 2020.

Total, he had 166 patients in his research.

To evaluate the nodes, he employed BMUS and colour Doppler ultrasound (CDUS).

According to the final histology results, 87 (52%) of the 166 patients were benign, whereas 79 (48%) were malignant. He arrived at a cut-off point for the S/L ratio of 0.595, with a SN of 75%, SP of 81 percent, and accuracy of 79%. Absence of echogenic hilum is recognised with a SN of 95.4 percent and an accuracy of 79.5 percent. There were many more malignant nodes with ill-defined margins than benign nodes with fine demarcated margins. The malignant nodes exhibited significantly more ill-defined margins, with a p-value of 0.001. Malignant nodes exhibited peripheral and mixed vascularity, with a p-value of 0.001.

In comparison to benign nodes, he found that malignant nodes have much more SAD, more S/L ratio, lack of echogenic hilus, ill-defined borders, and peripheral/mixed vascularity. BMUS and CDUS help guide FNAC/BIOPSY and identify cancerous nodes.

Maj Somali Pattanayak[24], who published his findings in 2017, did a cross-sectional descriptive analysis in tertiary care teaching hospital in south India from September 2012 to August 2014.

He used both B-mode and CDUS to investigate the nodes.

He looked at 100 people who had clinically palpable neck nodes. The results of the B-mode and CDUS scans were compared to the cytological and histological findings.

With sensitivity of 88 percent and specificity of 97.3 percent, B-mode US successfully detected 22/25 (88 percent) of the reactive lymph nodes in 100 patients. With sensitivity of 92 percent and a specificity of 97.3 percent, CDUS identified 23/25 (92 percent) reactive lymph nodes.

As a result, he discovered that using specific B-mode characteristics alone was inefficient in identifying benign from malignant lymph nodes. On the other hand, combined BMUS and CDUS aid in the detection of reactive lymph nodes and can be used as a trustworthy diagnostic tool. They can't be used to diagnose metastatic or tuberculous nodes, though, and cyto/histopathology is still the gold standard in these circumstances.

A cross-sectional prospective study was undertaken in a private hospital in India by DeepankarMisra [25], which was published in 2016.

He included 80 cervical lymph nodes from 25 patients who had clinical signs of cervical lymphadenopathy but had not been treated. They had a clinical evaluation of lymph nodes, as well as CDUS and FNAC histological examinations.

Out of 59 CDUS certified benign nodes, 56 lymph nodes were confirmed to be histopathologically benign and three as malignant (false positive +3), while 21 CDUS

suspected malignant nodes were proved to be histopathologically malignant and one as benign (false positive +3).

As a result, he concluded that CDUS evaluation was more significant, with high SN and SP over clinical assessment (SN 98.25 percent and SP 86.96 percent for benign nodes and SN 72.22 percent and SP 94.29 percent for malignant nodes), CDUS accuracy 95.00 percent, and a p-value of P0.001, suggesting that biopsy/FNAC in reactive nodes could be avoided.

Maria C. Chammas[26], who published her findings in 2016, did a cross-sectional analytical investigation on patients who were referred for a cervical ultrasonography test in a Brazilian institution between December 2009 and January 2013.

A total of 91 individuals were examined. The greyscale, PDUS, spectra doppler analysis, and FNAC were used to analyse all nodes.

Out of 97 lymph nodes, he examined FNAC results revealed 59 (60.8%) are malignant lymph nodes& 38 (39.2%) are benign lymph nodes. The most common malignancies are papillary thyroid carcinomas & squamous cell carcinomas.

62 (61.8 percent) lymph nodes revealed aberrant vascularization on colour doppler imaging, including 8 benign and 54 malignant lymph nodes. Alternate vascularization had an SN of 91.5 percent, an SP of 79.9%, and anaccuracy of 86.6 percent for malignant nodes (p-0.001).

Benign nodes shows RI of 0.64 +/- 0.13, while malignant nodes shows RI of 0.74 +/- 0.13. (p0.001). RI's cutoffof 0.77, had a SN of 44.7 percent, a SP of 88.9 percent, and an overall accuracy of 38.1 percent (p0.001). The strongest sonographic indications of lymph node malignancy are altered vascular pattern, short-axis more than 0.9 cm, an irregular hilus, & a heterogenous echotexture, in that order.

A retrospective research at Korea University was undertaken by Inseon Ryoo[27] in 2016. In this study, he evaluated microvascular USG for discriminating metastatic lymphadenitis from TB lymphadenitis in 61 patients with pathologically established metastatic lymphadenopathy (n=34).

Microvascular USG was carried out to visualise extreme low-velocity flow and he concluded that microvascular ultrasonography can identify tiny arteries in lymph nodes with sluggish flow that are not visible on standard PDUG. The vascular pattern significantly differ between metastatic and TB lymph nodes (p0.002).

METHODOLOGY

Materials and methods:

Study Design: This was a cross sectional study.

Study site: This study was conducted in the Department of Radio Diagnosis at Jawaharlal Nehru Medical College, Belagavi, Karnataka.

Study duration: The data collection for the study was done from 1st January 2020 to 31st December 2020 for a period of 1 year.

Inclusion Criteria:

1. Patients with clinically suspected cervical lymphadenopathy.
2. Patients with suspected or proven head and neck malignancies or benign etiologies.
3. Operated cases of head and neck malignancies with suspected metastasis in cervical lymph nodes.
4. Patients with cervical lymph node secondary infections of unknown origin.
5. Patients with tuberculosis in the lungs or extrapulmonary lymph nodes.

Exclusion criteria:

1. Patients who would not get FNAC/BIOPSY done.
2. Patients lost to follow-up.

Sample size:

The prevalence rate of cervical lymphadenopathy is estimated to be 38% to 45% in children[30], where as in adults no specific prevalence rate of cervical lymphadenopathy found in the literature, but in the Kathmandu study, he reported prevalence rate of 54%, 33% and 11.1% for tuberculous lymphadenitis, reactive hyperplasia and metastatic lymph nodes respectively.

Considering varying percentages in the prevalence of cervical lymphadenopathy in children and adults depending on the etiology, we obtained a sample size of 30 between 1st January 2020 to 31st December 2020.

Statistical Methods:

Age, size, short axial dimension, shape, margins, evaluation of fatty hilum, necrosis, vascularity pattern and RI were the variable evaluated.

Mean and standard deviation were calculated for continuous quantitative variables. The data was divided into two groups for the purpose of comparison with respect to certain qualitative characteristic, the continuous variables were compared using suitable tools of statistics like unpaired student's 't' test. The study diagnosis was compared to the final diagnosis and the outcome was given using Chi-square test.

For all the tests the value of "p" less than 5% (0.05) was considered significant.

Study Duration: 1st January 2020 to 31st December 2020 for a period of 1 year.

Ethical considerations**:** This research was accepted by institutional human ethics committee. All research participants received informed written consent and only those participants willing to sign the informed consent were included in the research. Before obtaining the consent, participants were clarified the risks and benefits involved in the research and the voluntary nature of participation. Confidentiality of the participants in this research was preserved.

All study participants were evaluated with a full clinical history and physical examination of the swellings after receiving informed written consent. Demographic details of the patient, chief complaints, past & family history of any malignancy and treatment history were collected.

METHODOLOGY:

An informed written consent was received from all the subjects.

A pre-structured proforma was used to gather clinical data.

A comprehensive history including demographic details, chief complaints, past history of any malignancy, treatment history, associated risk factors (past history of TB, radiation exposure, generalized lymphadenopathy) and physical examination of the swellings was done.

The above-mentioned study population who met the inclusion criteria were subjected to ultrasonography of lymph nodes on GE VOLUSON 7 or GE VOLUSON 8 machine equipped with a 7.5–12 MHz high frequency linear array transducer. The patients were examined on real-time two-dimensional gray-scale, color Doppler with spectral waveform analysis and the images were saved on a portable drive.

Then FNAC/biopsy was done and the comparison of sonological findings with cytopathological/ histopathological (HPE) reports. In cases of multiple lymph nodes, the nodes which had the most suspicious sonographic findings for malignancy or the largest short axis diameter were selected for fine needle aspiration.

Techniques for imaging:

The patients were instructed to lie supine with their necks slightly extended and a pillow placed behind neck and chest for comfort. The patients were told not to swallow during the process since it would obstruct the examination. A conventional B-Mode Ultrasonogram was performed with a 7.5–12 MHz high frequency linear array transducer on a GE VOLUSON 7 or GE VOLUSON 8 Ultrasonogram equipment. To generate reproducible nodal levels, a consistent scanning procedure was used, starting axially from the sub-mental region and swiping down laterally along one side with the patient

moving to the opposite side. The swipe continued down to the supraclavicular nodes, including the submandibular region and the jugular chain, including the upper, middle, and lower cervical nodes. The posterior triangle was then examined. On the other side, the identical procedure was followed. For all patients, the following characteristics of each node were recorded.

The following parameters was assessed in the nodes by the grey scale and color doppler:

1. Grey scale B-Mode morphologic features like size, shape, margins, presence of fatty hilum.
2. Distribution of vessels on color Doppler: central, peripheral, mixed or avascular
3. Vascular resistance of lymph node vessels - Resistivity Index (RI)
4. The data gathered was analyzed and presented in the form of tables, charts, graphs and figures.

RESULTS

A total of 30 patients referred to the department of Radio-diagnosis for evaluation of the cervical lymphadenopathy with ultrasonography were included of all age groups. These patients were later followed up with their histopathological / FNAC results. On evaluation of the pathological reports, 17(56.7%) turned out to be benign and 13 (43.3%) malignant. On sonography correlation using B-Mode and color Doppler findings, out of the 10 nodes which were categorised as malignant, 9 (90%) were malignant and 1 (10%) were benign and out of 20 (66.7%) which were categorised as benign 16 (80%) were benign and 4 (20%) were malignant. This study proved to be significant with a “p value” of 0.0001. The in-detail results of the other variables taken into consideration for characterization of nodes is tabulated below.

Table 4: Categorization of the benign and malignant lymph nodes by gender groups

GENDER	BENIGN	%	MALIGNANT	%
FEMALE	12	70.59	4	30.77
MALE	5	29.41	9	69.23
TOTAL	17	100.00	13	100.00

In the current study number of male patients (53.3%) are more or less same as compared to the female patients (46.7%).

Graph 1: Bar chart depicting categorization of the benign and malignant lymph nodes by gender groups

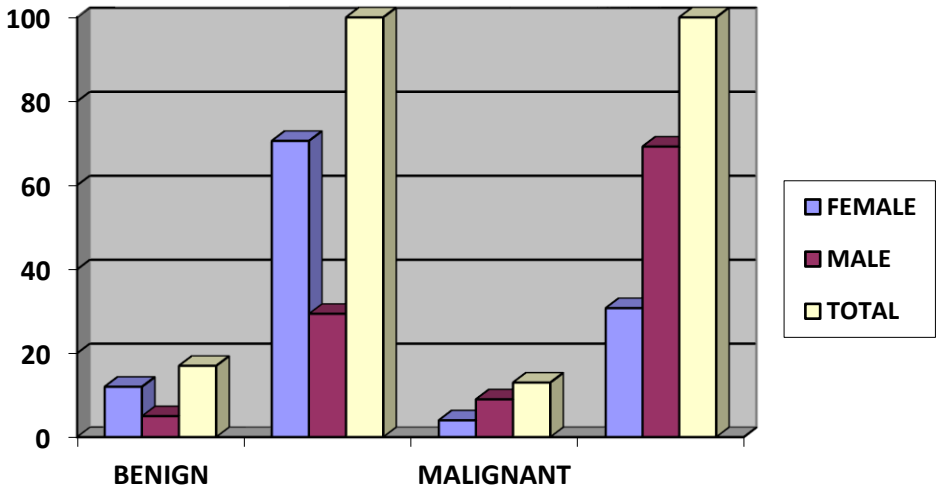


Table 5: Categorization of the benign and malignant lymph nodes by age groups

AGE in yrs	BENIGN	%	MALIGNANT	%
< 20	2	11.55	0	0.00
20 - 29	2	11.76	0	0.00
30 - 39	6	35.29	2	15.38
40 -49	3	17.65	5	38.46
≥ 50	4	23.53	6	46.15
TOTAL	17	100.00	13	100.00

The current study included maximum number of patients of benign etiology range between 30 – 49 yrs and maximum number of patients of malignant etiology >40 yrs

Graph 2: Bar chart depicting categorization of the benign and malignant lymph nodes by age groups

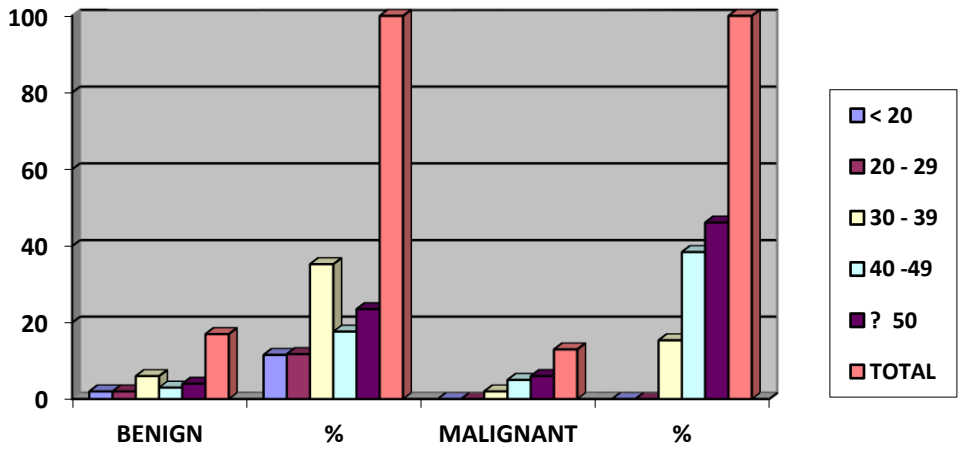


Table 6: Benign and malignant lymph nodes characterization by largest level

Largest level	Benign	%	Malignant	%	Total	%
Right Ib	2	6.6	0	0	2	6.6
Right II	3	10	3	10	6	20
Right III	1	3.3	0	0	1	3.3
Right IV	2	6.6	1	3.3	3	9.9
Left II	5	16.6	6	20	11	36.6
Left III	2	6.6	0	0	2	6.6
Left IV	1	3.3	2	6.6	3	9.9
Left V	1	3.3	1	3.3	2	6.6
Total	17	56.6	13	43.4	30	100

In the current study, both right and left level II cervical group of lymph nodes (17) 56.7% are involved in various benign and malignant etiologies.

Graph 3: Bar chart depicting level wise distribution of the lymph nodes into benign and malignant categories

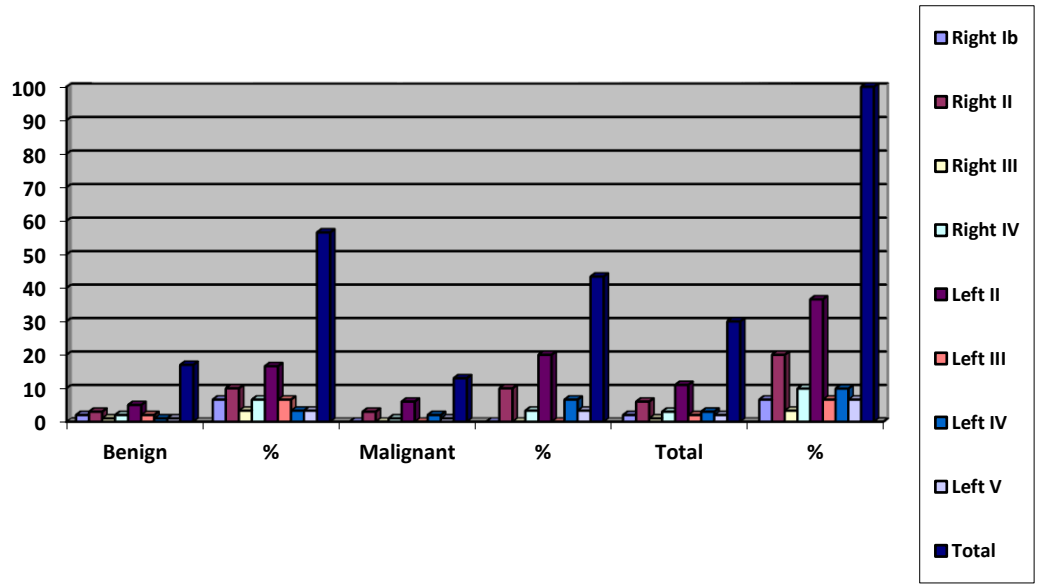


Table 7: Comparison of final diagnosis (Benign and malignant) with mean short axis by student's unpaired 't test'

	BENIGN				MALIGNANT					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
SHORT AXIS	0.81	0.45	0.5	2.3	1.33	0.48	0.5	2.2	0.0043	VS

In the current study, the mean short axis of benign lymph nodes is 0.81 +/- 0.45, whereas the mean short axis for malignant lymph nodes 1.33 +/- 0.48 with significant P value of 0.004.

Graph 4: Bar graph showing categorization of the nodes depending on the mean short axis diameter (cm)

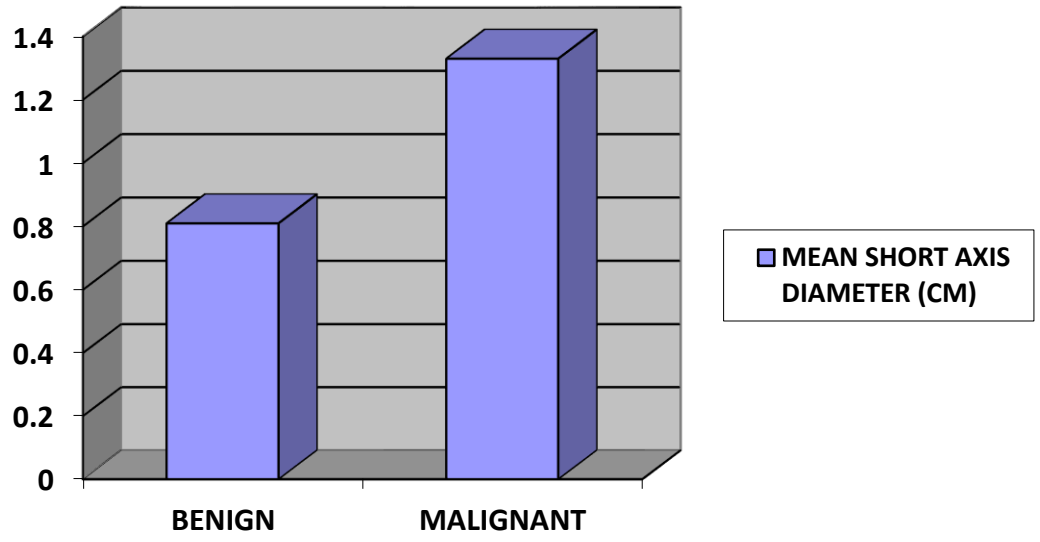


Table 8: Comparison of final diagnosis (Benign and malignant) with mean L/S ratio by student's unpaired 't test'

	BENIGN				MALIGNANT					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
L/S RATIO	2.29	0.76	1.1	3.7	1.47	0.31	1	2.1	0.0011	VS

In the current study, the mean L/S ratio of benign lymph nodes is 2.3 +/- 0.76 where as the mean L/S ratio for malignant lymph nodes 1.47 with significant P value of 0.001.

Graph 5: Area chart showing Benign and malignant lymph nodes categorization with mean L/S ratio

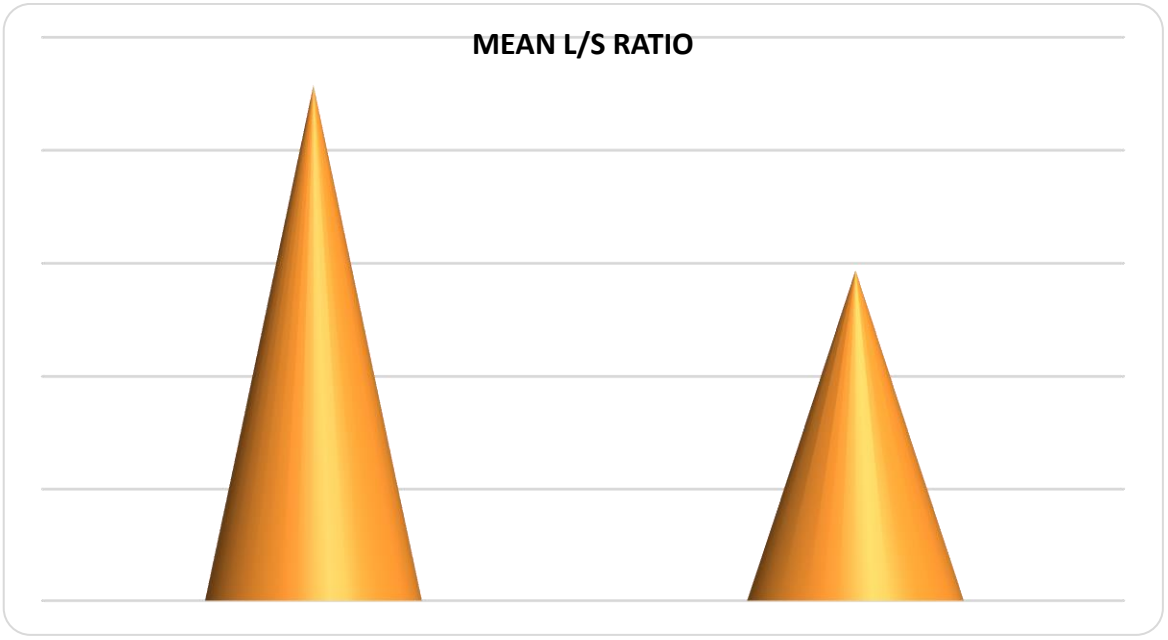


Table 9: Comparison of the final diagnosis with shape of the nodes

SHAPE	BENIGN	%	MALIGNANT	%	p VALUE	INFERENCE
ROUND	6	35.29	12	92.31	0.0016	VS
OVAL	11	64.71	1	7.69		
TOTAL	17	100.00	13	100.00		

In the current study, majority of benign patients 11(64.7%) had oval shape, where as majority of malignant patients 12(92.31%) had round shape with significant P value of 0.001.

Graph 6: Bar graph depicting the shape wise distribution of nodes

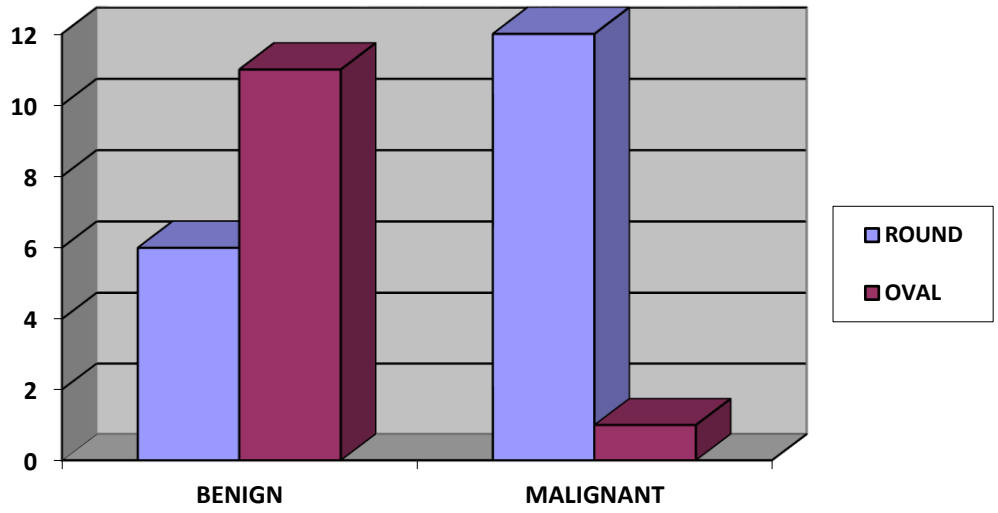


Table 10: Comparison of the final diagnosis with the margins of the nodes

MARGINS	BENIGN	%	MALIGNANT	%	p VALUE	INFERENCE
ILD	0	0.00	5	38.46	0.0051	VS
WD	17	100.00	8	61.54		
TOTAL	17	100.00	13	100.00		

In the current study, 100 % of benign patients (17) had well defined margins, where as majority of malignant patients 8(61.54%) had ill-defined margins with significant P value of 0.005.

Graph 7: Bar graph showing characterization of the nodes depending on the margins

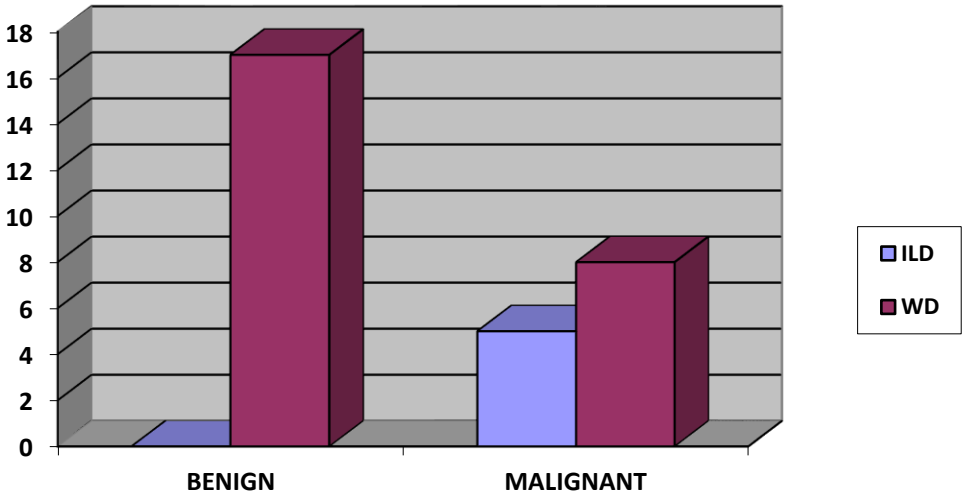


Table 11: Comparison of the final diagnosis with the status of fatty hilum of the nodes

FATTY HILUM	BENIGN	%	MALIGNANT	%	p VALUE	INFERENCE
0	2	11.76	8	61.54	0.0042	VS
1	15	88.24	5	38.46		
TOTAL	17	100.00	13	100.00		

In the current study, majority of benign patients 15/17 had well maintained fatty hilum, where as majority of malignant patients 8/13(61.54%) had loss of fatty hilum with significant P value of 0.004.

Graph 8: Bar graph showing categorization of the nodes depending on the preservation or loss of fatty hilum of the nodes

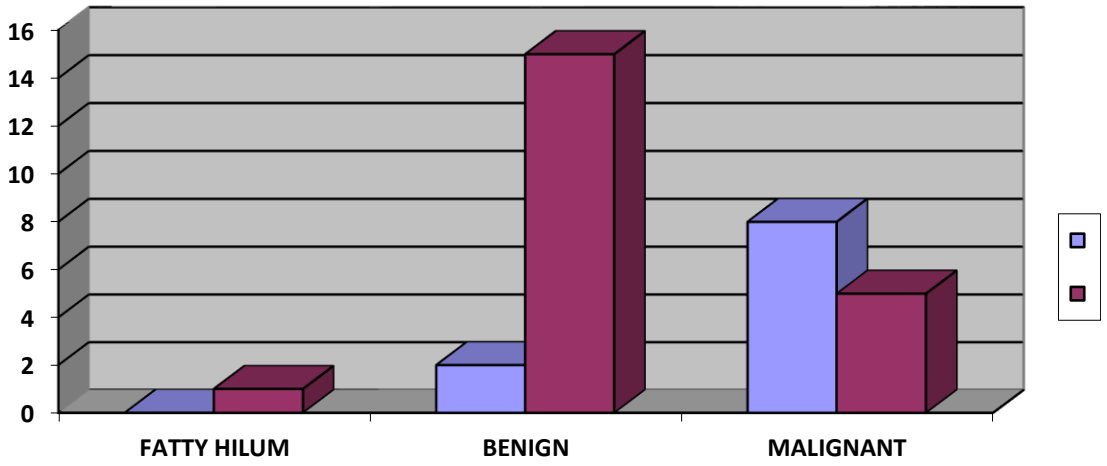


Table 12: Comparison of the final diagnosis with the vascular pattern of the nodes

VASCULAR PATTERN	BENIGN	%	MALIGNANT	%	p VALUE	INFERENCE
CENTRAL	15	88.24	2	15.38	0.0002	HS
MIXED	0	0.00	7	53.85		
PERIPHERAL	2	11.76	4	30.77		
TOTAL	17	100.00	13	100.00		

In the current study, majority of benign patients 15/17 (88.2%) had central vascularity, where as majority of malignant patients 7/13(53.85%) had mixed vascular pattern with significant P value of 0.0002.

Graph 9: Bar graph showing categorization of the nodes depending on the vascular pattern

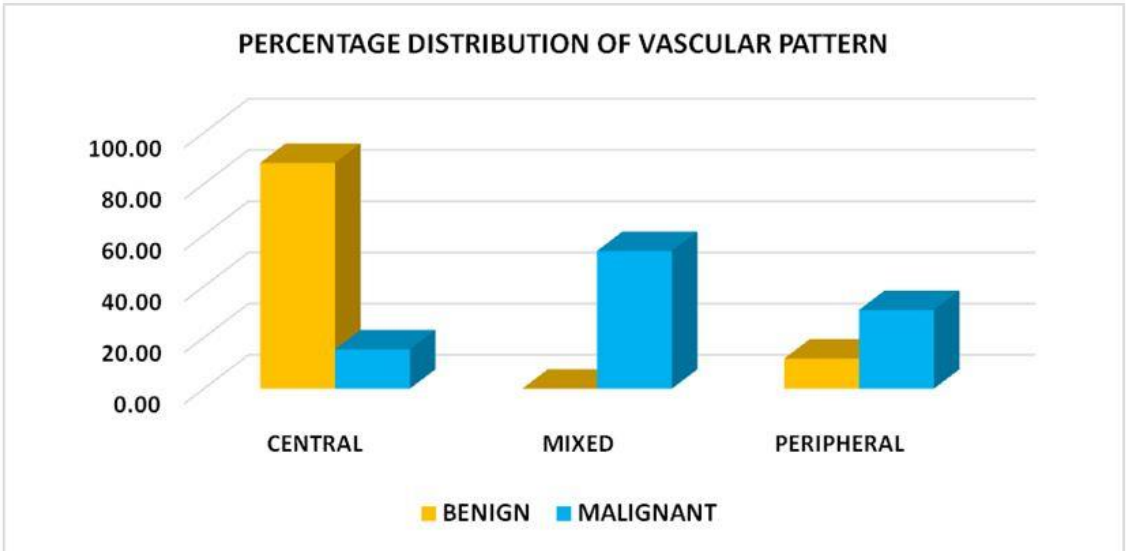


Table 13: Comparison of final diagnosis (Benign and malignant) with mean of RI using student's unpaired 't test'.

	BENIGN				MALIGNANT					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
RI	0.57	0.06	0.47	0.65	0.67	0.11	0.43	0.85	0.0029	VS

In the current study, the mean RI for benign nodes is 0.57, whereas mean of malignant nodes is 0.67 with significant P value of 0.0002.

Graph 10: Bar graph showing categorization of the nodes depending on the vascular resistance (RI).

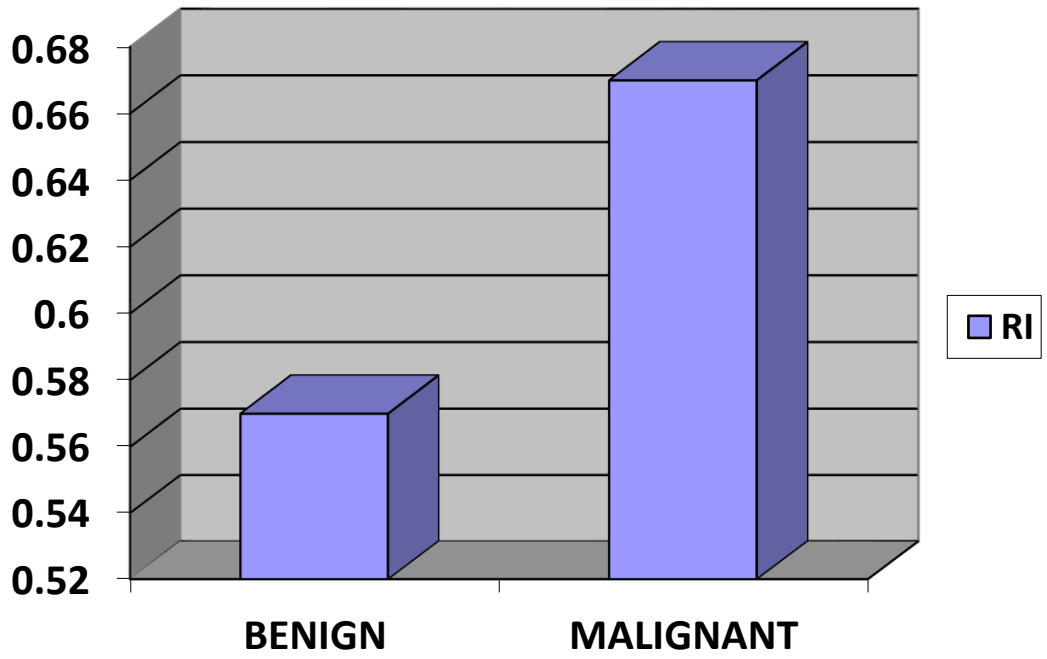
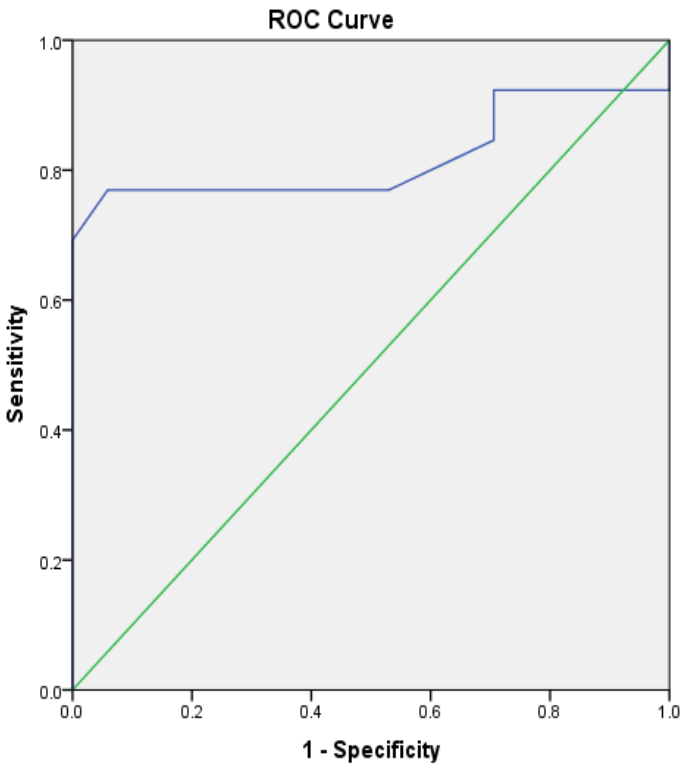


Table 11: Sensitivity, specificity, PPV, NPV and Accuracy of B-Mode & color Doppler findings in differentiation of the nodes into benign and malignant categories

Statistic	Value	95% CI
Sensitivity	76.92%	46.19% to 94.96%
Specificity	94.12%	71.31% to 99.85%
Positive Predictive Value	90.91%	59.34% to 98.56%
Negative Predictive Value	84.21%	66.25% to 93.54%
Accuracy	86.67%	69.28% to 96.24%

Graph 11: Receiver operating characteristic (ROC) curve of the RI values used for differentiating benign from malignant lymph nodes.

ROC CURVE FOR RI
AREA UNDER THE CURVE = 0.8188



DISCUSSION

The study was conducted in the Department of Radiodiagnosis, Jawaharlal Nehru Medical College, Belagavi, with 30 cervical lymphadenopathy patients who met the inclusion and exclusion criteria.

The aim of our study is to differentiate the cervical LNs into benign and malignant etiology based on the color Doppler ultrasonography and to correlate it with the FNAC/ histopatological diagnosis.

The most common finding in patients presenting to hospital with history of neck swelling or head and neck pathologies is cervical lymphadenopathy. The common causes being infectious and metastatic, hence it is necessary to differentiate the nodes for planning of further management.

B-mode ultrasonography is the most often used test for evaluating cervical lymphadenopathy and is considered the first line of investigation. This, in combination with Doppler imaging, is a valuable imaging tool for assessing and characterizing nodal shape and vascular pattern.

In the assessment of cervical lymph nodes, ultrasound has a sensitivity of 73 percent, and when combined with USG guided fine needle aspiration cytology, the sensitivity is enhanced to 92 percent and the specificity to 93 percent.

In our study, 30 patients with suspected enlargement of the neck nodes underwent color Doppler ultrasonography before biopsy or FNAC for deciding the treatment plan. Patients lost to follow-up and those who was not undergone FNAC/BIOPSY were excluded from this study. The categorical variables considered in our study are: age, gender, level, size, shape, margins, preservation of fatty hilum, vascularity, resistive index (RI) and final diagnosis. Final diagnosis was by histopathology / FNAC results.

Taking into consideration the histopathological/ FNAC results as the final diagnosis, 13 (43.3 %) patients had malignant nodes and 17 (56.7%) had benign nodes. Out of 13 malignant patients, 10(76.92%) patients included in this study group had head &neck carcinomas with metastatic LNs, out of which 3 from Squamous cell carcinoma of tongue, 1 from carcinoma right buccal mucosa, 1 from left aryepiglottic fold carcinoma, 1 from poorly differentiated carcinoma of unknown origin, 2 from follicular carcinoma of thyroid, 1 from carcinoma lung & in remaining 3 patients, 2(15.38%) patients presented with Non- Hodgkin Lymphoma, 1(7.69%) with nodular sclerosis Hodgkin Lymphoma and out of 17 patients(56.7%) with benign nodes, , 12(70.59%) with reactive lymphadenitis, 3(17.65%) necrotic lymph nodes, 1(5.88%) with non-caseating granulomatous lymphadenitis and 1(5.88%) with tuberculous lymphadenitis.

Out of 30 patients 17(56.7%) turned out to be benign and 13 (43.3%) malignant. On sonography correlation using B-Mode and color Doppler findings, out of the 10 nodes which were categorised as malignant, 9 (90%) were malignant and 1 (10%) were benign and out of 20 (66.7%) which were categorised as benign 16 (80%) were benign and 4 (20%) were malignant. This study proved to be significant with a “p value” of 0.0001.

The association of RI with type of LNs were assessed using a chi-squared test. The mean RI values between were compared using a unpaired student t-test. ROC was plotted of the RI numerical values and accuracy was calculated.

AGE WISE DISTRIBUTION:

Patients of all ages were included in the study and the patients were categorized depending on the final diagnosis which was given by the histopathological diagnosis.

In the current study number of female patients 16 (53.3%) are more or less same as compared to the male patients 14(46.7%).

LEVEL WISE DISTRIBUTION OF THE LARGEST LN:

The levels of the largest lymph nodes taken into consideration for its correlation with FNAC/ HPR reports

In the current study, majority of the lymph nodes involved are both right and left level II cervical group of lympnodes (17) 56.7% in various benign and malignant etiologies.

Dr. Choure A and Essing reported level II group of cervical lymphnodes are common site for metastasis in oral cavity cancers.[31,32]

SIZE:

SHORT AXIS:

In the current study, the mean short axis of benign lymph nodes is 0.81 +/- 0.45 cm, whereas the mean short axis for malignant lymph nodes 1.33 +/- 0.48 with significant P value of 0.004.

Because reactive lymph nodes can be as large as or larger than malignant lymph nodes, and malignancy can be observed in subcentimeter lymph nodes, size alone is a poor discriminant (because of micrometastasis).

Normal cervical lymph nodes have a maximum short axis axial diameter of 8 mm or less, according to Bruneton et al.[33] and Ying et al.[34].

SHAPE WISE DISTRIBUTION:

In the current study, majority of benign patients 11(64.7%) had oval shape, whereas majority of malignant patients 12(92.31%) had round shape with significant P value of 0.001.

Findings are correlated with Ying[15] and Ahuja[16] study which showed benign reactive lymph nodes are oval in shape and malignant lymph nodes are round in shape.

L/S RATIO:

In the current study, the mean L/S ratio of benign lymph nodes is 2.3 +/- 0.76, whereas the mean L/S ratio for malignant lymph nodes is 1.47 with significant P value of 0.001.

This study showed a significant correlation with a p value of 0.004 to differentiate the nodes depending on the L/S ratio.

In the study conducted by Poanta[36], with L/S ratio cut off value of 2 shows very high sensitivity and very low specificity to differentiate benign and malignant lymph nodes. He mentioned that it is already accepted in the literature that nodes with LT ratio ≥2 are classified as benign, while nodes with LT ratio <2 are malignant.

MARGINS:

In the current study, 100 % of benign patients (17) had well defined margins, whereas majority of malignant patients 8(61.54%) had ill-defined margins with significant P value of 0.005, suggesting that all the benign nodes have well defined margins and the malignant nodes with irregular margins.

This was compared to the study done by Dr. Choure A A et al[31] which showed 90.2 % benign nodes had smooth margins and 4% crenulated margins and 83.3% malignant nodes had irregular margins and 9.8% had regular margins.

FATTY HILUM:

In the current study, majority of benign patients 15/17(88.2%) had well maintained fatty hilum, whereas majority of malignant patients 8/13(61.54%) had loss of fatty hilum with significant P value of 0.004.

This was compared to the Dr. Choure A A et al study[31] which showed preserved hilum in 87.8 % benign nodes & alteration in 12.2% and preserved hilum in 6.7% of the malignant nodes and alteration in 93.3%.

VASCULAR PATTERN:

In the current study, majority of benign patients 15/17 (88.2%) had central vascularity, whereas majority of malignant patients 7/13(53.85%) had mixed vascular pattern (both central and peripheral) with significant P value of 0.0002.

This is in consistent with Ying& Ahuja studies[15,16], Ying reported that normal and benign nodes have hilar(central) vascular flow and no peripheral vascularity.

Ahuja[16] reported that lymphomatous and metastatic lymph nodes shows mixed or peripheral vascularity.

RESISTIVE INDEX(RI):

In the current study, the mean RI for benign nodes is 0.57 standard deviation of 0.06, whereas mean of malignant nodes is 0.67 standard deviation of 0.11 with significant P value of 0.0002.

In the study conducted by Kanika Gupta[38] he reported the Resistive Index (RI) values in benign lymph nodes ranged from 0.40 to 0.82 with a mean of 0.60 $\pm$ 0.10

Ahuja[40] reported that a resistive index value of greater than 0.7 had a sensitivity of 86% and specificity of 70% for the detection of malignant lymph nodes.

In study conducted by S Pattanayak[26], RI cut-off > 0.7 for lymphomatous nodes showed high specificity.

Adibelli et al[42]. found that there was no significant difference in RI between benign and malignant nodes.

It's well written in the literature that vessels in malignant nodes have a high peripheral resistance (i.e, high intravascular resistance index (RI)) due to compression by tumor

cells, whereas reactive lymph node vessels have low peripheral resistance (low RI) due to vasodilation because of inflammation.

Due to displacement of vessels by tumor cells and angiogenesis factors malignant lymph nodes tend to have either peripheral or mixed vascular pattern[41].

Using Grey-scale and color Doppler findings (vascular pattern & RI) lymph nodes can be differentiated into benign and malignant ones.

In the current study, the sensitivity, specificity, positive & negative predictive value and accuracy of 76.92%, 94.12%, 90.91%, 84.21%, and 86.67% respectively of B-Mode & color Doppler findings in differentiation of the nodes into benign and malignant categories.

ROC curve was plotted to calculate the RI threshold with an area under the curve of 0.818 and was found to be 0.67

CONCLUSION

- Color Doppler ultrasonography is non-invasive, cost effective imaging modality with no risks of radiation which makes the safest and first line investigation for evaluation of cervical lymphadenopathy
- The present study demonstrated the cervical LNs can be characterized into benign and malignant depending on the color Doppler features like vascular pattern and resistive index along with grey scale B-Mode features like size, shape, short axis diameter, long -short axis ratio, margins and presence or absence of fatty hilum.
- The morphologic features like oval shape, L/S ratio of 2.29 +/- 0.76, well circumscribed margins, short axis diameter of 8.1 +/- 4.5 mm, maintained fatty hilum, , central vascularity and RI < 0.57 are suggestive of benignity. Whereas round shape, L/S ratio of 1.47 +/- 0.31, ill defined margins, short axis diameter of 1.3 +/- 4.8 mm, loss of fatty hilum, mixed vascularity or peripheral vascularity, RI > 0.67 are suggestive of malignancy.
- The sensitivity, specificity, positive & negative predictive value and accuracy of 76.92%, 94.12%, 90.91%, 84.21%, and 86.67% respectively of B-Mode &color Doppler ultrasonography in differentiation of the nodes into benign and malignant categories.

SUMMARY

- Lymph nodes are frequently enlarged in various regional and systemic diseases and sometimes may be the only clinical finding or one of the several nonspecific findings. Differentiation of benign and malignant lymph nodes without Fine Needle Aspiration Cytology (FNAC)/ biopsy is crucial for patient management. Ultrasound is a useful imaging tool for the initial evaluation of cervical lymph nodes because it has high sensitivity (98%) and specificity (95%) [44].
- This is a hospital based cross sectional study, conducted from 1st January 2020 to 31st December 2020 for a period of 1 year in patients referred to radiology department of KLE'S Dr Prabhakar Kore Hospital for ultrasonography of the neck.
- This study is mainly to assess the ability of the color doppler ultrasonography in differentiating benign and malignant lymph nodes in comparison with pathological reports.
- Color Doppler features like vascular pattern and resistive index can be effective in characterizing the nodes into benign and malignant etiology in conjunction with grey scale B-mode features like size, shape, short axis diameter, long-short axis ratio, margins and presence or absence of fatty hilum.
- In my study majority of benign patients 15/17 (88.2%) had central vascularity, whereas majority of malignant patients 7/13(53.85%) had mixed vascular pattern (both central and peripheral) with significant P value of 0.0002. The mean RI for benign nodes is 0.57 standard deviation of 0.06, whereas mean of malignant nodes is 0.67 standard deviation of 0.11 with significant P value of 0.0002.
- The morphologic features like oval shape, L/S ratio of 2.29 +/- 0.76, well circumscribed margins, short axis diameter of 8.1 +/- 4.5 mm, maintained fatty

hilum, central vascularity and RI < 0.57 are suggestive of benignity. Whereas round shape, L/S ratio of 1.47 +/- 0.31, ill-defined margins, short axis diameter of 13.0 +/- 4.8 mm, loss of fatty hilum, mixed vascularity or peripheral vascularity, RI > 0.67 are suggestive of malignancy.

- The sensitivity, specificity, positive & negative predictive value and accuracy of 76.92%, 94.12%, 90.91%, 84.21%, and 86.67% respectively of B-Mode & color Doppler ultrasonography in differentiation of the lymph nodes into benign and malignant categories

LIMITATIONS:

The sample size is limited.

Inter-observer variance could not be assessed because the colour Doppler ultrasonography was operator dependent and the investigation was conducted by a single radiologist.

Only one lymph node was studied in patients who had several lymph nodes.

RECOMMENDATIONS:

From our study, we recommend that color Doppler ultrasonography parameters like vascular pattern and resistive index along with the B-mode ultrasound can be used for differentiation of lymph nodes into benign and malignant.

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ANNEXURE I – INFORMED CONSENT

TITLE OF THE STUDY: "ROLE OF COLOR DOPPLER ULTRASONOGRAPHY IN DIFFERENTIATING BENIGN AND MALIGNANT CERVICAL LYMPHADENOPATHY - ONE YEAR HOSPITAL BESED CROSS SECTIONAL STUDY."

PRINCIPAL INVESTIGATOR:

INTRODUCTION AND PURPOSE:

Cervical lymphadenopathy is a common presenting symptom and sign for a variety of diseases ranging from subtle infections to life threatening head and neck malignancies. Ultrasound with color Doppler can help in differentiation of benign and malignant lymph nodes have been well described in literature. Differentiation of benign and malignant lymph nodes without Fine Needle Aspiration Cytology (FNAC)/biopsy is difficult, but crucial for patient management. Therefore, non-invasive imaging tools that can facilitate in differentiation of benign and malignant nodes are required. So this study mainly focuses on role of Ultrasound with color Doppler in differentiation of benign and malignant lymph nodes.

PROCEDURE:

I request you to kindly participate in the study titled study "ROLE OF COLOR DOPPLER ULTRASONOGRAPHY IN DIFFERENTIATING BENIGN AND MALIGNANT CERVICAL LYMPHADENOPATHY - ONE YEAR HOSPITAL BESED CROSS SECTIONAL STUDY." at Dr. Prabhakar Kore charitable hospital and

Medical Research Centre, Belagavi" postgraduate in Radio-diagnosis at J. N. Medical College Belgaum, Karnataka,

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. U 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:

- Results will help in differentiating benign and malignant lymph nodes to minimize the need for invasive FNAC/BIOPSY study
- Noninvasive, cost effective modality

COMPLICATIONS:

- No risk to the patient has been documented from COLOR DOPPLER ULTRASONOGRAPHY earlier.

ALTERNATIVES:

If you are not willing to take part in the study, your treatment or any other further investigations the patient wants to undergo, in future, in KLE will not be affected by your decision.

VOLUNTARYPARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. You may choose not to take part in this study, or if you decide to take part you can later change my mind and withdraw from the study. Your decision will not change the present or future health care or other services that you receive. The study doctor or the sponsor may stop my participation in this study. You will tell if any important new findings that may change my willingness to continue to take part. If you choose not to take part in the study you 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 as a investigation for neck swellings 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 you become injured as a result of taking part in this study, treatment whatever available at KLE Charitable Hospital, Belagavi, will be offered to you. No reimbursement, compensation or free medical care is given.

CONFIDENTIALITY:

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

QUESTION:

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

Ph.0831-2473777, Ext. 1163 Mob- 7353100959	Ph. No. 0831-2473777, Ext. 1163	Ph. No: 0831-2473777,Ext. 1529

CONSENT TO PARTICIPATE IN RESEARCH STUDY:

1. I understand that I am participating in the study, which includes color Doppler ultrasonography of cervical lymph nodes
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 trial, 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/ legally authorized _____

Representative

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 (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ **Date: 24/12/2019**

To,

BS01119012
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 **"ROLE OF COLOR DOPPLER ULTRASONOGRAPHY IN DIFFERENTIATING BENIGN AND MALIGNANT CERVICAL LYMPHADENOPATHY – 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. Anita Dalal)
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 FOR DATA COLLECTION

NAME OF THE PATIENT: _____

AGE: _____ SEX: _____ OP/IP NO: _____

MOBILE NO: _____

ADDRESS: _____

USG NUMBER_____

CHIEF COMPLAINTS: _____

HISTORY OF PRESENTING ILLNESS: _____

PAST HISTORY: _____

CLINICAL EXAMINATION: _____

CLINICAL DIAGNOSIS: _____

USG FINDINGS:

- LOCATION _____
- SIZE _____
- SHAPE _____
- FATTY HILUM _____

USG DOPPLER FINDINGS

- VASCULAR PATTERN _____
- RESISTIVE INDEX _____

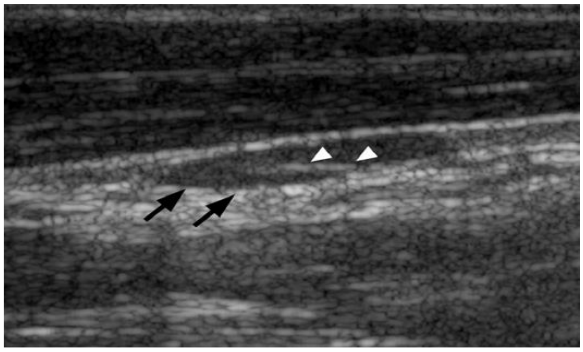
HISTOPATHOLOGY REPORT: _____

ANNEXURE IV: FIGURES

a

Fig 5: GE VOLUSON USG machine used for the study

Fig 6: High frequency linear array transducer used for the study



Arrowheads indicate echogenic hilus that is continuous with adjacent soft tissues

Fig 7: USG image showing normal anatomy of lymph node

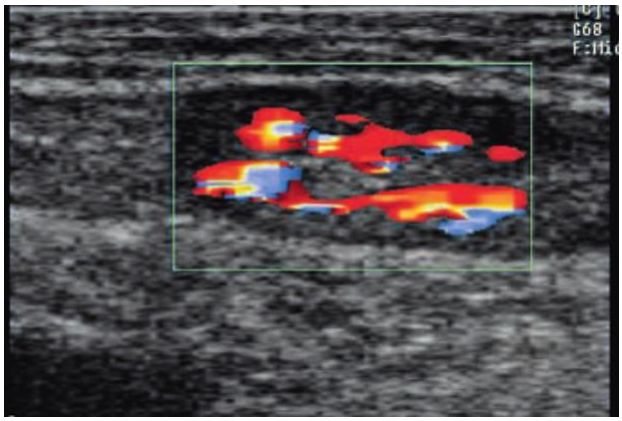


Fig 8: Doppler waveform of normal lymphnode

1. **A 66 year old male K/C/O carcinoma left tongue. USG revealed a enlarged left level II lymphnode. The lymphndoe had following features –** Round in shape, ill-defined margins, peripheral vascularity and RI 0.72. Categorized as malignant etiology B. FNAC showed it to be metastatic squamous cell carcinoma.

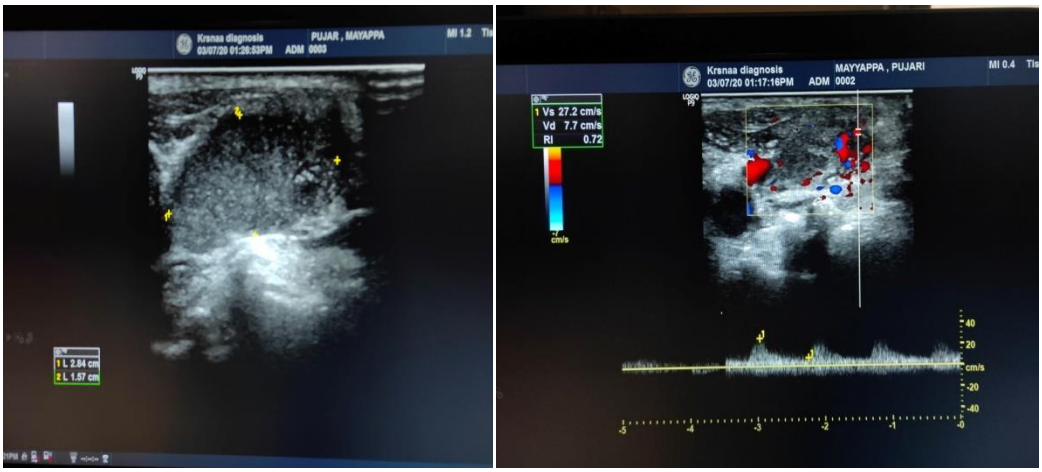


Fig 9: Ultrasound image of metastatic squamous cell carcinoma lymphnode

2. **A 12 year old presented with right sided neck swelling & fatigue. USG revealed a enlarged right level IV lymphnode. The lymphndoe had following features –** Oval in shape, well-defined margins, central vascularity and RI 0.53. Categorized as benign etiology B. FNAC showed it to be nodular sclerosis Hodgkins lymphoma

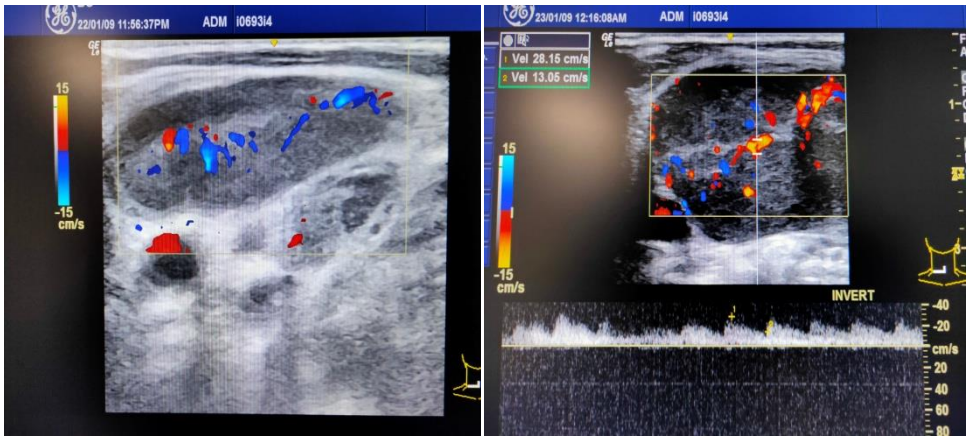


Fig 10: Ultrasound image of nodular sclerosis Hodgkins lymphoma lymphnode

3. **A 28 year old female came with history of swelling & pain in the neck. USG revealed a enlarged right II lymphnode. The lymphndoe had following features –** round in shape, well-defined margins, peripheral vascularity and RI 0.63. Categorized as benign etiology B. FNAC showed it to be TB lymphadenitis

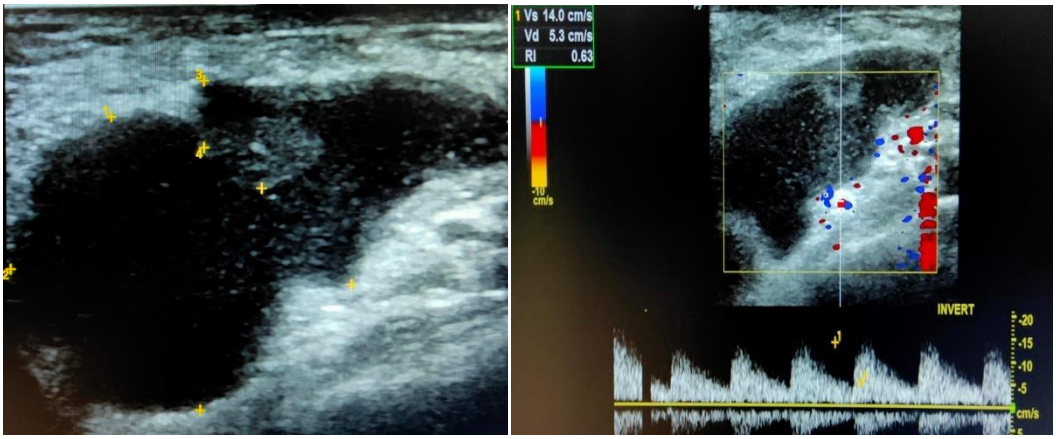


Fig 11: Ultrasound image of TB lymphadenitis lymph node

4. **A 36 year old female known case of follicular cell carcinoma of thyroid. USG revealed an enlarged right II lymphnode. The lymphndoe had following features –** Oval in shape(L/S ratio 3.2), well-defined margins, central vascularity and RI 0.54. Categorized as benign etiology B. FNAC showed it to be suspicious for metastatic lymph node

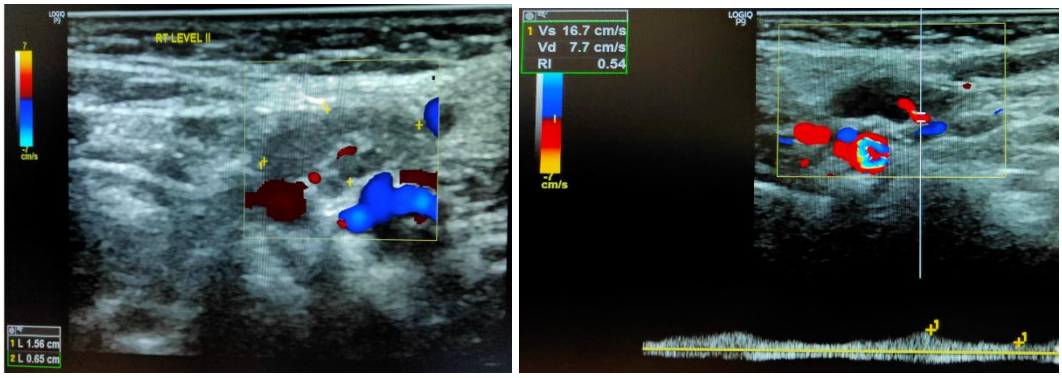


Fig 12: Ultrasound image of suspicious for metastatic lymphnode

5. **A 26 year old male came with history of swelling & pain in the back of neck. USG revealed an enlarged left V lymphnode. The lymphndoe had following features –** oval in shape, well-defined margins, central vascularity and RI 0.65. Categorized as benign etiology B. FNAC showed it to be reactive lymphnode (inflammatory cells)

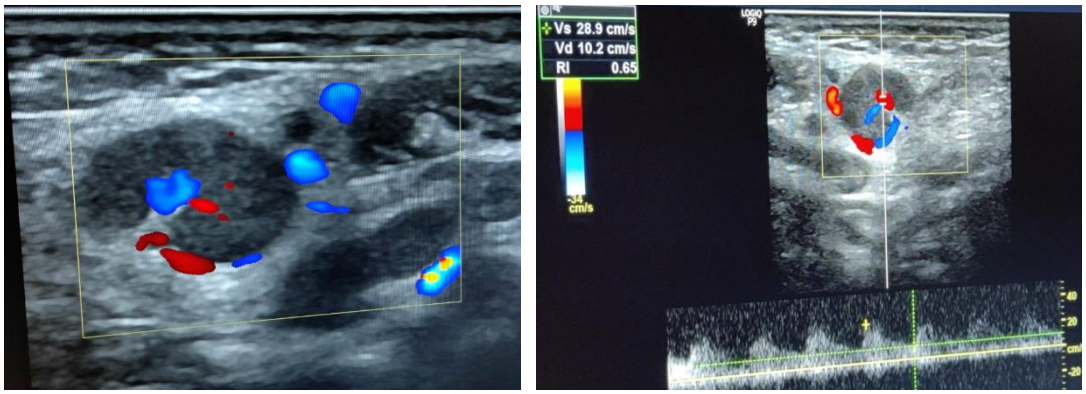


Fig 13: Ultrasound image of reactive lymphnode

ANNEXURE V: KEY TO MASTERCHART

Variable	**Code**	
	RI	Resistive index
	L/S ratio	Long axis/short axis diameter
Margins	WD	Well defined
	ID	Ill defined
Fatty hilum	0	Loss of fatty hilum
	1	Maintained
Study diagnosis	0	Benign
	1	Malignant
FNAC/histopathology diagnosis	0	Benign
	1	Malignant

SR NO	USG NO	AGE in YRS	SEX	PRESENTING ILLNESS		FEATURES OF SUSPICIOUS CERVICAL LYMPH NODES								FNAC/BIOPSY REPORTS OF LYMPH NODES			
					LEVEL	SIZE IN CM	SHAPE	MARGINS	FATTY HILUM	SHORT AXIS	L/S RATIO	VASCULAR PATTEN	RI		Study diagnosis	inal diagnosis	
1	905777	26	MALE	NECK SWELLING /PAIN	LEFT V	1.7 X 0.5	OVAL	WD	1	0.5	3.4	CENTRAL	0.65	INFLAMMATORY CELLS	0	0	
2	5632682	8	MALE	BILATERAL PALPABLE SWELLINGS	LEFT II	3.0 X 1.4	OVAL	WD	1	1.4	2.1	CENTRAL	0.54	REACTIVE HYPERPLASIA OF LN	0	0	
3	2999213	34	FEMALE	FEVER, NECK SWEELING	RIGHT III	1.1 X 0.7	ROUND	WD	1	0.7	1.6	CENTRAL	0.56	REACTIVE LYMPHNODE	0	0	
4	5627085	47	FEMALE	LEFT NECK SWELLING	LEFT IV	1.4 X 0.9	ROUND	WD	0	0.9	1.5	PERIPHERAL	0.63	TB LYMPHADENITIS	0	0	
5	1001935	63	FEMALE	FEVER/SORETHROAT	RIGHT II	1.3 X 0.6	OVAL	WD	1	0.6	2.1	CENTRAL	0.63	REACTIVE LYMPHADENITIS	0	0	
6	992180	42	FEMALE	K/C/O METASTATIC POORLY DIFFERENTIATED CARCINOMA	LEFT V	1.7 X 1.0	ROUND	WD	1	1	1.7	CENTRAL	0.7	ETASTATIC POORLY DIFFERENTIATED CARCINOM	1	1	
7	5753381	58	MALE	BILATERAL PALPABLE SWELLINGS	LEFT II	2.4 X 2.2	ROUND	ILD	0	2.2	1	MIXED	0.75	METASTATIC SQUAMOUS CELL CARCINOMA	1	1	
8	15338	49	MALE	SWELLING LT SIDE OF NECK	LEFT IV	2.5 X 1.7	ROUND	ILD	0	1.7	1.4	MIXED	0.74	METASTATIC LYMPHNODE	1	1	
9	4893492	39	MALE	OP/C/O CA LEFT BUCCAL MUCOSA	LEFT II	1.4 X 0.9	ROUND	WD	1	0.9	1.5	CENTRAL	0.51	LYMPH NODE WITH ABSCESS	0	0	
10	5743144	66	MALE	K/C/O CA LEFT TONGUE	LEFT II	2.8 X 1.5	ROUND	ILD	0	1.5	1.8	PERIPHERAL	0.72	METASTATIC SQUAMOUS CELL CARCINOMA	1	1	
11	14584	55	MALE	K/C/O CA LT ARYEPIGLOTTIC FOLD	LEFT II	1.4 X 1..0	ROUND	WD	1	1	1.4	MIXED	0.67	ASTATIC LYMPHNODE from CA LT ARYEPIGLOTTIC	1	1	
12	5984187	47	FEMALE	OP/C/O CA RT BUCCAL MUCOSA	LEFT II	2.2 X 2.0	ROUND	ILD	0	2	1.1	MIXED	0.85	METASTATIC LYMPHNODES	1	1	
13	1045803	45	MALE	FEVER/NECK PAIN	LEFT II	2.5 X 0.9	OVAL	WD	1	0.9	2.7	CENTRAL	0.64	INFLAMMATORY CELLS	0	0	
14	1028916	57	FEMALE	SWELLING RT SIDE OF NECK	RIGHT II	2.0 X 0.7	OVAL	WD	1	0.7	2.8	CENTRAL	0.52	LYMPHOCYTES WITH NECROTIC MATERIAL	0	0	
15	796895	44	FEMALE	NECK PAIN/SWELLING	RIGHT IB	2.6 X 0.7	OVAL	WD	1	0.7	3.7	CENTRAL	0.59	REACTIVE LYMPHNODE	0	0	
16	6289199	60	FEMALE	K/C/O MULTINODULAR GOITRE	LEFT III	1.4 X 0.7	OVAL	WD	1	0.7	2	CENTRAL	0.62	INFLAMMATORY CELLS	0	0	
17	372420	63	MALE	NECK SWELLING	LEFT IV	1.7 X 1.2	ROUND	WD	0	1.2	1.4	MIXED	0.72	METASTATIC	1	1	
18	5960406	53	MALE	K/C/O GENERALIZED LYMPHADENOPATHY	LEFT II	1.7 X 1.3	ROUND	WD	1	1.3	1.3	MIXED	0.67	LYMPHOMA	1	1	
19	8783816	57	MALE	NECK SWELLING	LEFT II	1.2 X 0.9	ROUND	WD	0	0.9	1.3	PERIPHERAL	0.65	METASTATIC LYMPHNODE	1	1	
20	6041686	38	FEMALE	FEVER/ WEAKNESS	RIGHT II	1.7 X 1.0	ROUND	WD	1	1	1.7	PERIPHERAL	0.43	LYMPHOMA	0	1	
21	325540	51	FEMALE	K/C/O SARCOIDOSIS	RIGHT IV	1.2 X 0.7	ROUND	WD	1	0.7	1.7	CENTRAL	0.54	ON CASEATING GRANULOMATOUS LYMPHADENIT	0	0	
22	307170	30	FEMALE	THYROID SWELLING	LEFT III	1.2 X 0.5	OVAL	WD	1	0.5	2.4	CENTRAL	0.52	REACTIVE LYMPHNODE	0	0	
23	285700	44	FEMALE	FEVER/COUGH	RIGHT IB	1.5 X 0.5	OVAL	WD	1	0.5	3	CENTRAL	0.54	REACTIVE LYMPHNODE	0	0	
24	9335694	31	FEMALE	RT SIDE NECK SWELLING	RIGHT V	1.0 X 0.6	ROUND	WD	1	0.6	1.6	CENTRAL	0.48	REACTIVE LYMPHNODE	0	0	
25	1068921	35	FEMALE	NECK SWELLING	LEFT II	2.0 X 0.6	OVAL	WD	1	0.6	3.3	CENTRAL	0.58	REACTIVE LYMPHNODE	0	0	
26	4354194	36	FEMALE	K/C/O FOLLICULAR CA THYROID	RIGHT II	1.6 X 0.6	OVAL	WD	0	0.5	3.2	CENTRAL	0.54	SUSPICIOUS FOR METASTASIS	0	1	
27	1056976	37	MALE	FEVER, NECK SWELLING	LEFT II	1.2 X 0.5	OVAL	WD	1	0.5	2.4	CENTRAL	0.47	FEW LYMPHOCYTES	0	0	
28	6230684	48	MALE	K/C/O CA TONGUE	RIGHT II	2.3 X 1.3	ROUND	ILD	0	1.3	1.7	MIXED	0.74	RESIDUAL/RECURRENT CA tongue metastatic	1	1	
29	1069314	12	MALE	NECK SWEELLING. FATIGUE	RIGHT IV	3.7 X 1.7	OVAL	WD	1	1.7	2.1	CENTRAL	0.53	NODULAR SCLEROSIS HODGKINS LYMPHOMA	0	1	
30	5801982	28	FEMALE	PAIN/NECK SWELLING	RIGHT II	2.7 X 2.3	ROUND	WD	0	2.3	1.1	PERIPEHRAL	0.63	NECROTIC LYMPHNODE	1	0	