Thesis Protocol

Proposed title:

Role of Color Doppler Ultrasound in Evaluation of Testicular Mass

Presented by

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Introduction

Color Doppler ultrasound (CDUS) is the combination of grey scale / B-mode ultrasonography (US) and color Doppler imaging. Color Doppler ultrasound is an important tool for diagnosis of testicular diseases because of its ability to depict anatomy and perfusion in real time. It is not only useful in detecting broad-spectrum grey scale changes but also helps in evaluation of blood flow in testicular vessels as well (Weatherspoon, Polansky & Catanzano, 2017).

Testicular masses are detected in 1.74% of patients undergoing ultrasound (US) examination. Most of the patients often locate a scrotal 'lump' or experience non-localizing pain. Frequently, episodes of mild trauma bring the patient's attention to the scrotum, palpating a mass that had been there previously but had not been appreciated. Occasionally, testicular masses present as acute pain or as a hydrocele. Some testicular masses are discovered incidentally in patients undergoing US evaluation for infertility or other non-related problems (Morse & Whitmore, 2015; Daniel et al., 2022).

High-resolution gray-scale US has long been the standard of reference for the imaging evaluation of testicular masses. The principal role of ultrasound examination is to distinguish testicular from extratesticular lesions, because the majority of intratesticular masses are considered malignant until proven otherwise. Computed tomography and magnetic resonance imaging offer little additional information in imaging of primary testicular masses, but has excellent role in tumor staging (Ulbright & Roth, 1999; Parenti et al., 2018).

Testicular tumors represent 1-2% of all tumors in males and the most common malignancy of 15-35 years male individuals. Nearly 90–95% of these are primary germ cell tumors (GCT). They are broadly divided into seminomatous and non-seminomatous types. Non-germ cell tumors represent the remainder of primary and secondary testicular tumours, and includes sex cord stromal tumors (Leydig or Sertoli cell tumors), lymphoma and metastasis (Gorman et al., 2005, Siegel et al., 2011; Huang & Sidhu, 2012).

Seminoma is the most common pure GCT. It accounts for 35–50% of all GCTs. It occurs in an older population, in comparison with NSGCTs, with an average patient age of 40.5 years. On B-mode ultrasound, a seminoma is usually homogeneous and uniformly hypoechoic. Larger tumors may be more heterogeneous. They vary in size from small incidental nodules to large infiltrative masses replacing the entire testicular parenchyma. On color Doppler, there is demonstrable increased vascularity within the lesion (Woodward et al., 2002; Lung & Sidhu, 2011).

NSGCTs account for 60% of the GCT usually found in combination as mixed germ cell tumors. Embryonal carcinoma is the most common component, and is often combined with one or more components of teratoma, seminoma and yolk sac tumour. B-mode features tend to be much more heterogeneous in nature, with mixed reflectivity, areas of necrosis, hemorrhage and calcification. In common with all malignant testicular tumors, the tumor will display an increase in color Doppler flow (Woodward et al., 2002; Lung & Sidhu, 2011).

Non-primary tumours such as lymphoma, leukaemia and metastasis can all manifest as an indeterminate testicular mass. Testicular lymphoma is the most common testicular neoplasm in males over 60 years of age. Primary leukaemia of the testis is rare; secondary testicular involvement is more common. Sonographic findings in both lymphoma and leukaemia may be represented by focal or multifocal hypoechoic lesions, and may be indistinguishable from GCTs (Lung & Sidhu, 2011).

Benign testicular masses are rare, but recognition is important to avoid unnecessary biopsy, or worse orchiectomy. Almost all intratesticular cystic lesions are benign and include cysts of the tunica albuginea, simple cysts, epidermoid cyst, tubular ectasia of rete testis, and intratesticular spermatocele. Epidermoid cyst is the most common benign testicular neoplasm, sometimes can mimic testicular malignancy on B-mode US. CDUS helps in confirming the benign nature of these since no blood flow will be seen within. Ninety percent of the sex cord stromal tumors are benign (Dogra, Gottlieb & Rubens, 2001).

Focal intratesticular lesions that may mimic solid malignancy include dermoid cysts, focal orchitis/abscess, hematoma, infarction and granuloma. All these entities share the lack of internal vascular flow on color Doppler. However, these cases need to be followed up closely to document involution and exclude malignancy. Testicular adrenal rest are rare benign masses with imaging features otherwise similar to testicular cancer except bilaterality (Allan, Baxter & Weston, 2011; Hodler, Wibmer & Vargas, 2018).

Testicular torsion usually present as painful scrotal swelling and in US shows enlarged heterogeneous testis with no color Doppler flow. A retrospective study by Uguz et al. conducted on 32 patients revealed an association between testicular torsion and testicular cancer of 6.4% (2015).

Varsamidis et al. found that follow-up CDUS is of value in patients with acute scrotal pain for differentiation between orchitis and testicular tumor. A total of 18 patients were evaluated, 11 found to have testicular tumors and 7 testicular inflammation (2001).

Testicular tumors appear hypoechoic than normal testes in 83% of cases. Color Doppler help to identify tumors that are relatively isoechoic with testicular parenchyma. Nearly 95% of primary testicular tumors larger than 1.5 cm in diameter show increased vascularity. The distribution of blood vessels within the tumor is usually disorganized with irregular, chaotic branching patterns (Horstman et al., 1992; Luker & Siegel, 1994; Dogra et al., 2004).

The symptomatic (mass containing) side may show a decreased RI or increased PSV with the same RI. Elevated PSV of >10 cm/sec (normal, 5-10 cm/sec) has been noted and RI ranges from 0.47 to 1.0 (mean, 0.70). An asymmetric increase in EDV of >5cm/sec (normal, 3-5 cm/sec) is due to the low-resistance tumor vascular beds (Coursey et al., 2015; Singh et al., 2016).

Despite the diagnostic challenge presented by intratesticular masses, the combination of B-mode ultrasound and color Doppler commonly provides sufficient information to differentiate between benign and malignant disease. It is the detection of vascularity with color Doppler that helps to differentiate benign (invariably avascular) from malignant (increase in vascularity and changes in the pattern of vascularity) condition (Lung & Sidhu, 2011).

A retrospective study by Song et al. on 325 patients with testicular masses found an increased malignant probability with the increase of vascularity and identified as an important indicator to distinguish benign from malignant. They concluded that, for the superficial organs such as the testes, vascular conditions can be accurately evaluated by CDUS (2019).

One study observed US to be 90% sensitive and 55% specific in detection of testicular neoplasm (Derouet et al., 1993), whereas another study reported that CDUS had a sensitivity of 87.5% and specificity of 66.7% in detection of testicular neoplasm (Gallardo et al., 1996). Rizvi et al. found 87.5% sensitivity and 66.7% specificity in diagnosis of testicular tumors by CDUS (2011). Another study by Fazal et al. revealed CDUS had sensitivity of 88.8%, specificity of 78.1% and diagnostic accuracy of 83.6% in diagnosis of testicular malignancy (2022).

Therefore, solid testicular masses with internal vascular flow must prompt a high level of suspicion for testicular malignancy, unless unequivocal imaging findings suggest a benign diagnosis. An accurate non-invasive analysis of the testicular mass is critical for facilitating adequate therapy and for preventing unnecessary surgical intervention (Schwarze et al., 2020).

Rationale

CDUS is a cost effective, easily accessible, less time consuming, lack of ionizing radiation modality having high resolution and excellent safety profile. Testicular masses include both benign and malignant lesions. Differentiation between benign and malignant lesions is a precondition of management plan. CDUS can play an important role in this differentiation. These modalities aid the clinician in developing an appropriate differential diagnosis and treatment plan. Although no ultrasound appearances are entirely diagnostic, features demonstrated with these technologies can help in early detection and better characterization of testicular masses, and will help in minimizing the delay in treatment, improving prognosis and significant reduction of mortality and morbidity. Till date, there are limited studies in this regard. Therefore, the current study has been designed to determine the role of CDUS as a primary investigational modality in evaluation of testicular masses comparing with histopathological examination as gold standard.

Research Question

What is the role of color Doppler ultrasound (CDUS) in evaluation of testicular masses?

Hypothesis

Color Doppler ultrasound (CDUS) has significant role in evaluation of testicular masses.

Objectives

General objectives:

- To assess the role of color Doppler ultrasound (CDUS) in evaluation of different testicular masses.

Specific objectives:

- To assess the findings of CDUS of different testicular masses eg. location, size, nature, echotexture, and vascularity (grades, pattern, PSV, EDV and RI).
- To assess the final diagnoses based on histopathological examination results.
- To find out the sensitivity, specificity, accuracy, positive predictive value and negative predictive value of CDUS in evaluation of different testicular masses comparing it with the histopathological examination results.

Methodology

Study design:

This will be a cross sectional study.

Place of study:

Department of Radiology and Imaging in collaboration with Department of Surgery, Department of Urology and Department of Pathology, Sylhet MAG Osmani Medical College Hospital, Sylhet

Period of study:

March, 2023 to February, 2025

Study population:

All patients with testicular swelling referred to the Department of Radiology and Imaging, Sylhet MAG Osmani Medical College Hospital, Sylhet within this study periods will be the study population.

Sample:

Among the study population who will fulfill the selection criteria.

Sampling method:

Purposive sampling.

Sample size (n):

According to a study, the testicular masses were present among 1.74% patients on US (Daniel et al., 2022). For this study, sample size will be calculated with 95% confidence interval and 5% error. Following formula will be used for calculating sample size-

For 1.74% P=0.0174, and for 95% confidence level Z = 1.96 and for 5% error (d) = 0.05

q= (1-p) = (1- 0.0174) =0.982

$n = (1.96^2 \times 0.0174 \times 0.982)/(0.05)^2$

n = 26.2

Therefore, for this study total 30 patients will be included.

Selection Criteria

Inclusion criteria:

- Patients with clinically suspected testicular masses referred to the Department of Radiology and Imaging, Sylhet MAG Osmani Medical College Hospital, Sylhet.

Exclusion criteria:

- All postoperative patients of scrotal surgeries
- Post radiotherapy patients
- Inguino-scrotal hernia

Variables

A) Sonographic and Doppler variables:

- Type of testicular lesion (focal or diffuse)
- Size of the lesion
- Echogenicity of the lesion
- Grades of vascularity
- Pattern of vascularity
- PSV (Peak systolic velocity)
- EDV (End diastolic velocity)
- RI (Resistivity Index)

B) Histopathological variables:

- Histopathological type
- Histopathological grade

C) Demographic and clinical variables:

- Age
- Testicular pain
- Testicular swelling
- Temperature
- H/O Trauma

Data Collection Technique

This cross-sectional study will be carried out in the Department of Radiology and Imaging, Sylhet MAG Osmani Medical College Hospital, Sylhet after approval by the local ethical committee. According to selection criteria, study population will be selected. An informed written consent will be taken from each patient or his legal guardian. Detailed history taking, relevant clinical examination, reviews of other investigations will be done carefully. All the patients will undergo high resolution B-mode ultrasonography of scrotum at first and then color Doppler imaging. An expert radiologist will perform the examinations. Philips Affiniti 30 Ultrasound System equipped with L-12-4 multi-frequency linear probe will be used. Linear probe will be chosen for scrotal sonography and color Doppler imaging. Scrotum will be palpated prior to scanning. This will ensure that special attention given to the area of palpable abnormality. The patient will be examined in supine position with a towel placed between his legs, and the penis will be over the abdomen with the help of patient's left hand. Copious gel will be used to ensure adequate contact. At B-mode ultrasound imaging, sagittal and transverse images, additional views in coronal and oblique planes will be obtained. A transverse scan incorporating both testes in the same field of view will be used in every case to compare parenchymal echogenicity. Size, location, nature, margin and echotexture of the space occupying lesion (mass) will be noted. Adjacent extra-testicular structures will be assessed for presence or absence of sonographic invasion. At color Doppler imaging, the Doppler controls will be optimized to detect low flow. The scale of pulse repetition frequency (PRF) will be set as low as possible, wall filters set low or removed and the color Doppler gate set as wide as possible. The color gain will be set high and then adjusted until background "noise" just disappears. In pulsed Doppler spectral analysis, the angle of insonation beam will be minimal and without steering. When examining with color Doppler, vascularity of space occupying lesion (mass) in terms of grades, patterns, PSV, EDV and RI will be recorded. Histopathology reports will be acquired later contacting with the patients or their local guardians. CDUS findings of all the patients will be compared with final diagnoses based on histopathological examination results. A pre-designed data collection sheet will be used to collect all data.

Data Collection Tools

- A pre-formed structured questionnaire
- Informed written consent in Bangla
- Informed written consent in English

Doppler Imaging Technique

A number of techniques have been developed which exploit the shift in frequency of ultrasound when it is reflected from moving blood. This frequency shift is known as the 'Doppler effect'. Motion of the reflector (eg. red blood cells) towards the transducer produces higher ultrasonic frequency, whereas motion away gives a lower frequency than that transmitted. Hence the system electronics extract information on the direction of motion relative to the transducer. There are three types of imaging used with Doppler techniques. The **first**, known as 'duplex Doppler', uses a real-time B-scanner to locate the site of blood flow then a Doppler beam interrogates that site showing graphical representations of flow velocity over time i.e. spectral Doppler. The **second** type creates a color-coded image based on average velocity and direction of blood flow known as 'color Doppler'. It is also normally combined with a conventional real-time B-scan. It allows the visualization of flow direction and velocity within a user defined area. The **third** type of Doppler imaging is similar to color Doppler but generates an image of the power of the Doppler signal from pixel locations throughout the field of view and is known as 'power Doppler'. A power Doppler image depicts the amount of blood moving in each region, i.e. an image of the detected blood pool (Rumack et al., 2011; Allan et al., 2011; Carroll et al. 2019).

Statistical Analysis

Following data collection, the collected data will be assessed for completeness, accuracy and consistency before the commencement of analysis. Data will be processed and analyzed with the help of Statistical package for social sciences (SPSS) software, version 25.0. Quantitative data will be analyzed by mean (standard deviation [SD]). Qualitative data will be analyzed by frequency (percentage [%]). Sensitivity, specificity, accuracy, positive predictive value and negative predictive value of CDUS in evaluation of testicular masses will be calculated taking in account histopathological examination results as gold standard.

Ethical Consideration

Prior to the commencement of this study, an approval of the research protocol will be obtained from the "Ethical Review Committee" of Sylhet MAG Osmani Medical College, Sylhet. The aims and objective of the study along with its procedure, alternative diagnostic methods, risk and benefits will be explained to the patients in easily understandable local language and then informed consent will be taken from each patient. It will be assured that all records would be kept confidential and the procedure would be helpful for both the physician and patients in making rational approach regarding management of the case. Non-participation will not hamper their treatment. Proper permission will be taken from the respective departments and institution concerned with this study.

Observation and Result

Observation and result will be presented by different tables, graphs, charts, diagrams etc.

Discussion

Discussion will be made after obtaining the results of the study according to the objectives with references and cross-reference.

Conclusion

Will be done on the basis of findings.

Recommendation

Will be done on the basis of findings.

Operational Definitions

Testicular mass: Any palpable lump or swelling of the testis which is found by the patient or physician on routine examination.

Color Doppler ultrasound (CDUS): It is a non-invasive imaging technology that utilizes combination of grey scale ultrasound and Doppler imaging. Conventional real-time B-scan along with variable combination of color Doppler, spectral Doppler or power Doppler are utilized.

Peak systolic velocity (PSV): It is an index measured in spectral Doppler corresponding to each tall "peak" in the a Doppler waveform. PSV ranges from 4.0 to 19.1 cm/sec (mean, 9.7 cm/sec) in intratesticular arteries, 5.0 to 23.4 cm/sec (mean, 19.0 cm/sec) in capsular arteries.

End-diastolic velocity (EDV): It is an index measured in spectral Doppler corresponding to the point marked at the end of the cardiac cycle (just prior to the systolic peak). EDV ranges from 1.6 to 6.9 cm/sec (mean, 3.6 cm/sec) in intratesticular arteries, 1.8 to 9.2 cm/sec (mean, 4.0 cm/sec) in capsular arteries.

Resistive index (RI): It is a calculated flow parameter in ultrasound, derived from the maximum, minimum, and mean Doppler frequency shifts during a defined cardiac cycle. It is typically used to assess the resistance in a pulsatile vascular system. RI ranges from 0.5 to 0.7 (mean, 0.6) in intratesticular arteries.

Grades of vascularity in color Doppler: Subjective assessment to describe the amount of flow.

Grade 0 (Absent)	: No Doppler signals in the ROI
Grade 1 (Minimal)	: Punctate Doppler signals in the ROI (<2 vascular signals per 10 mm)
Grade 2 (Moderate)	: Scattered Doppler signals in the ROI
Grade 3 (Marked)	: Continuous flow in the ROI (vascular signal >25mm in length).

* ROI (region of interest)

Sensitivity: Percentage of disease positives who are test positive [TP/TP+FN x 100 or, a/a+c x 100].

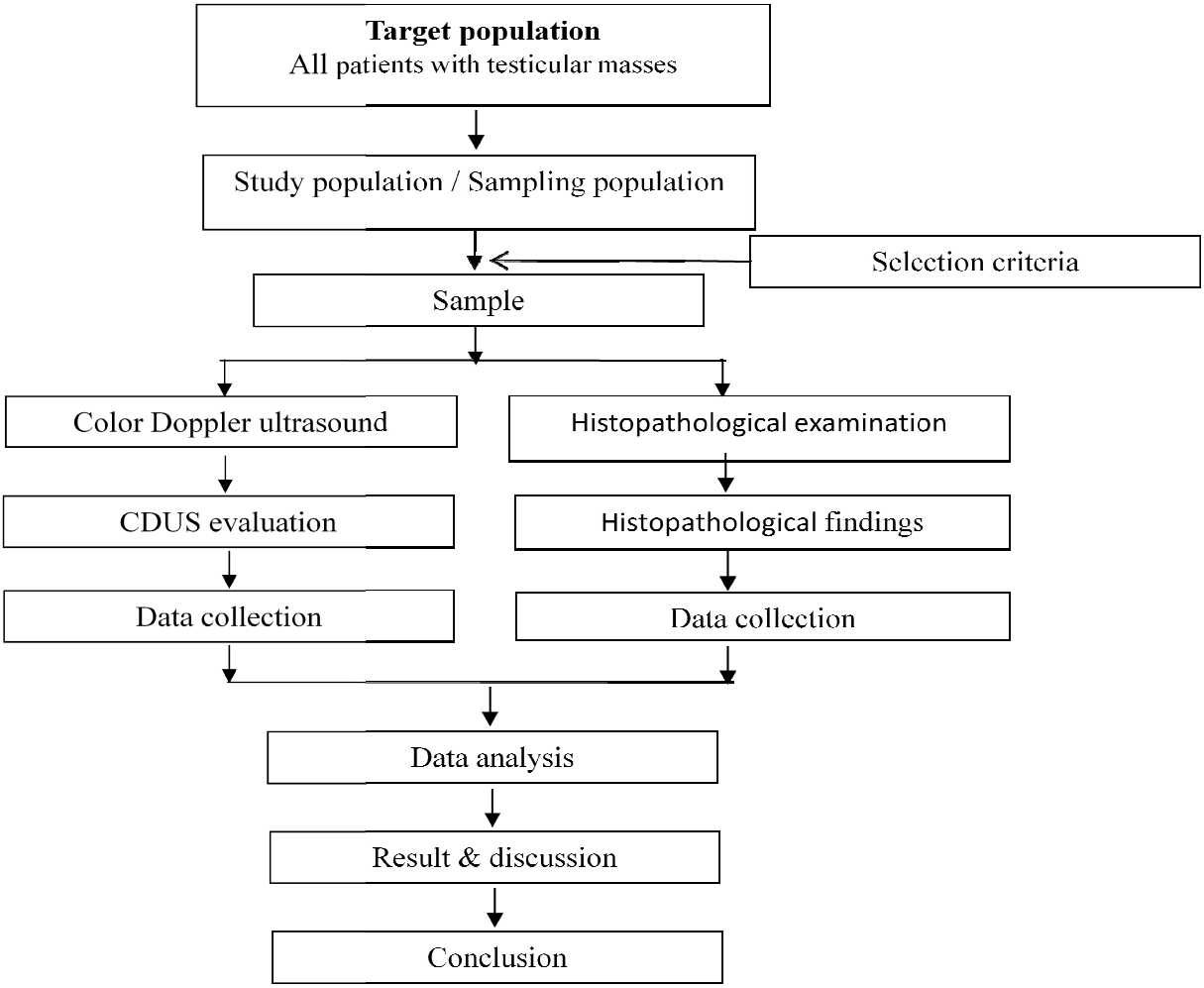
Specificity: Percentage of disease negatives which are test negative [TN/TN+FP x 100 or, d/b+d x 100].

Positive predictive value: Percentage of test positive who are truly disease positive [TP/TP+FP x 100 or, a/a+b x 100].

Negative predictive value: Percentage of test negative who are truly disease negative [TN/TN+FN x 100 or, d/c+d x 100].

Diagnostic accuracy: Percentage of all test results (positive and negative) that are correct [TP+TN/Total population x 100 or, a+d/N x 100].

Study Flow Chart



Study Time Schedule

(24 months from March, 2023 to February, 2025)

Activities	March 23	April 23	May 2 3	June 23 to November 24	Decem ber 24	January 25 to February 25
Literature review						
Title selection						
Study design						
Pretesting and finalizing of instrument						
Data Collection						
Data analysis						
Report writing, binding and Submission						

Total Budget

A) Total		1,20,000 Tk
B) Details:		
i)	Investigation Cost	50,000 Tk
ii)	Office – Stationary	5,000 Tk
iii)	Photo Copy	5,000 Tk
iv)	Data Analysis	10,000 Tk
v)	Contractual Service	1,000 Tk
vi)	Report Printing Compose & Analysis	10,000 Tk
vii)	Publication	25,000 Tk
viii)	Others	5,000 Tk

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Abbreviations

- CDUS: Color Doppler Ultrasound
- CT: Computed Tomography
- EDV: End Diastolic Velocity
- MRI: Magnetic resonance Imaging
- NPV: Negative Predictive Value
- PPV: Positive Predictive Value
- PSV: Peak Systolic Velocity
- RI: Resistivity Index
- SPSS: Statistical Package for Social Sciences
- US: Ultrasonography

Appendix-I

Data Collection Sheet

Title: Role of Color Doppler Ultrasound in Evaluation of Testicular Mass

1. Case no. Date: **2. Reg. no.**

3. Particulars of the patients:

Name:

Age: ☐ years Marrital status : ☐ 1= Married 2= Unmarried

Present address:

Contact no: Occupation :

4. Clinical Presentation:

i) Pain	☐	1. Yes	2. No
ii) Testicular swelling	☐	1. Yes	2. No
iii) Fever	☐	1. Yes	2. No
iv) H/O trauma	☐	1. Yes	2. No
v) History of previous surgery	☐	1. Yes	2. No

5. Physical examination:

i) Pulse	☐	1. Normal	2. Raised
ii) Temperature	☐	1. Normal	2. Raised
iii) Tenderness	☐	1. Yes	2. No

6. Gray scale features of the lesion:

i. Site of the lesion ☐ 1. Testicular 2. Extra-testicular

ii. Type of lesion ☐ 1. Focal 2. Diffuse

iii. Echogenecity of the lesion ☐

1. Normal echotexture
2. Hypoechoic
3. Mixed echogenic
4. Hyperechoic

7. CDUS features of the lesion:

a. Grades of vascularity ☐

i. Grade 0
ii. Grade 1
iii. Grade 2
iv. Grade 3

b. Pattern of vascularity ☐

i. Regular
ii. Irregular

c. PSV (Peak systolic velocity) ☐

i. Normal
ii. Increased
iii. Decreased

d. EDV (End diastolic velocity) ☐

i. Normal
ii. Increased
iii. Decreased

e. RI (Resistivity Index) ☐

i. Normal
ii. Increased
iii. Decreased

8. Color Doppler Ultrasound diagnosis …….
9. Histopathological diagnosis ……
10. Final clinical diagnosis ……..

Signature of the investigator Date:

Appendix-II

Informed Consent Form

I, Mr/Mrs ……., hereby giving informed consent willingly to participate in the study '**Role of Color Doppler Ultrasound in Evaluation of Testicular Mass'** to be conducted by **Dr. Muhammad Sirazul Munir,** without any prejudice. I am fully convinced that during study I will not suffer from any serious physical or psychological problems. I am also informed that this study was carried out in the developed countries safely and my participation will bring fruitful result that will be beneficial for most patients in our country. I have right to withdraw myself from this study at any time. I will not receive any financial benefit. I have understood that the personal information, medical records & laboratory tests results of mine will be kept strictly confidential & will be used for research purpose only.

Signature/Thumb impression of participant

Date: ……

Name: ……..

Address:……..

Signature of witness

Date:

Name of witness:

Signature of Researcher

Date:

সম্মতিপত্র

আমি ..... সানন্দে স্বতঃপ্রবৃত্ত হয়ে ডাঃ মোহাম্মদ সিরাজুল মুনির এর গবেষণা কর্ম "Role of Color Doppler Ultrasound in Evaluation of Testicular Mass"-এ অংশগ্রহণে সম্মত আছি। আমি পূর্ণ দৃঢ়তার সাথে বিশ্বাস করি যে, উক্ত কাজে কোন গুরুতর শারীরিক ও মানসিক ক্ষতির সম্মুখীন হব না। আমি আরও অবগত আছি যে, উন্নত দেশে এই গবেষণা কর্মটি নিরাপদে সম্পন্ন হয়েছে। আমার এই অংশগ্রহণ যে সুফল বয়ে আনবে তাতে আমাদের দেশের রোগীরা উপকৃত হবে। এই গবেষণা কর্ম থেকে যে কোন সময়ে নিজেকে প্রত্যাহারের পূর্ণ স্বাধীনতা আছে। আমি কোন প্রকার আর্থিক সুবিধা নিব না। আমি বিশ্বাস করি যে, আমার ব্যক্তিগত তথ্য, স্বাস্থ্যগত রেকর্ড ও ল্যাবরেটরি পরীক্ষার ফলাফল সমূহ কঠোরভাবে গোপন রাখা হবে এবং একমাত্র গবেষণা কর্মেই ব্যবহৃত হবে।

স্বাক্ষর/বৃদ্ধাঙ্গুলির ছাপ

তারিখ :

স্বেচ্ছাসেবকের নাম :

ঠিকানা :