

**STANDARD TREATMENT
GUIDELINES
INTERVENTIONAL
RADIOLOGY**

**Ministry of Health & Family Welfare
Govt. of India**

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BRONCHIAL ARTERY EMBOLIZATION IN MASSIVE HAEMOPTYSIS

I. WHEN TO SUSPECT/ RECOGNIZE?

a) Introduction:

Massive haemoptysis constitutes a significant and often life-threatening respiratory emergency and carries a poor prognosis when treated conservatively, with mortality rates ranging from 50% to 80% (1). The cause of death is usually asphyxiation, not exsanguination (2). Bronchial artery embolisation (BAE) as well as embolisation of a few relevant systemic arteries have become the established procedure in the management of massive and recurrent haemoptysis since 1973 (3). The efficacy, safety, and utility of BAE in controlling massive haemoptysis have been well documented in many subsequent reports (4-11). Moreover, because of poor pulmonary reserve and other medical co-morbid conditions, most patients with massive haemoptysis are not surgical candidates (1,2) The reported mortality rates for surgery performed for massive haemoptysis range from 7.1% to 18.2% (12). However, the mortality rate increases significantly, up to about 40%, when the surgery is undertaken as an emergency procedure (12). BAE is effective in an elective surgery (12). However, surgery is indicated in massive haemoptysis due to hydatid cyst, thoracic vascular injury, bronchial adenoma, and aspergilloma which are resistant to other therapies.

Case definition: For both situations of care (mentioned below*)

Massive haemoptysis has been described as the expectoration of an amount of blood ranging from 100 ml to more than 1,000 ml over a period of 24 hours, and the most widely used criterion is the production of 300-600 ml per day (1,2,12,13). A life-threatening condition may be caused by even a rather small amount of hemorrhage depending on the ability of the patient to maintain a patent airway. Thus, interventional management should be undertaken whenever the amount of hemorrhage has the potential to cause a life-threatening condition (13,14)

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY

Pulmonary tuberculosis has been the commonest cause of haemoptysis in India for more than four decades (15). It had been shown to be present in 79.2% of haemoptysis cases in the year 2009 (16).

III. DIFFERENTIAL DIAGNOSIS

After confirming the presence of blood, an initial task is to differentiate between haemoptysis, pseudo haemoptysis (i.e., the spitting of blood that does not come from the lungs or bronchial tubes), and haematemesis (i.e., the vomiting of blood).

In the non-Western world, pulmonary tuberculosis and tubercular bronchiectasis, are the most common underlying causes of massive haemoptysis(17-20) whereas bronchogenic carcinoma and chronic inflammatory lung diseases due to bronchiectasis, cystic fibrosis, or aspergillosis are the more prevalent causes of haemoptysis in Western countries (1,2,13). Other relatively common causes include lung abscess, pneumonia, chronic bronchitis, pulmonary interstitial fibrosis, pneumoconiosis, congenital cardiac or pulmonary vascular anomalies such as arterio-venous malformation, pulmonary embolism, elevated pulmonary venous pressure (mitral stenosis), systemic coagulopathy, use of anticoagulants or thrombolytic agents

IV. PREVENTION AND COUNSELING

Since pulmonary tuberculosis, bronchiectasis and malignancy are common etiologic causes in our country, creating awareness about importance of their early detection and seeking early medical attention(for cough more than 3 weeks, unexplained fever, weight loss, chronic purulent sputum, haemotysis) at appropriate medical facility is an effective preventive strategy.

Proper counseling of the patient should be done by explaining various treatment options including non-surgical treatments such as bronchoscopy guided interventions and bronchial artery embolization and their outcome. The importance of cessation of smoking to reduce risk of haemoptysis due to chronic bronchitis should also be duly emphasized.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA

***Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited**

a) Clinical Diagnosis:

After establishing true haemoptysis, the rate and volume of blood loss should be assessed. Historical evaluation must include important risk factors such as history of fever, weight loss, smoking, chronic obstructive pulmonary disease, exposure to asbestos, arsenic, chromium, nickel and certain ethers, anticoagulant use, heart disease, known malignancy elsewhere in the body, nausea, vomiting, malena, alcoholism, chronic use of non steroidal anti-inflammatory drugs, history of chronic purulent sputum production and frequent pneumonias including past history of pulmonary tuberculosis.

Physical Examination

General Physical examination: Recording of vital signs, pulse oximetry levels, fever, tachycardia, tachypnea, weight changes and hypoxia. Constitutional signs such as cachexia and level of patient distress, cyanosis, pallor, clubbing, ecchymoses, telangiectasia, gingivitis, evidence of bleeding from the oral or nasal mucosa, lymph node enlargement in neck, supraclavicular region, and axillae.

Examination of chest and lungs for signs of consolidation, wheezing, rales and trauma. Cardiovascular examination includes evaluation for jugular venous distention, abnormal heart sounds and edema.

b) Investigations:

Haematological & Biochemical

Haemoglobin & haematocrit

Total & differential blood count

Platelet count

Erythrocyte sedimentation rate

Prothrombin time, International Normalized Ratio, partial thromboplastin time

Blood group and cross-matching

Sputum Gram stain, culture, acid-fast bacillus smear and culture

Human immunodeficiency virus test

Sputum cytology

Arterial Blood gases

Imaging work up

Chest radiograph

Chest radiography may provide the diagnosis in only 50% of cases (19) and could demonstrate lesions which suggest either a localized pneumonia, acute or chronic pulmonary tuberculosis, healed tuberculosis, bronchogenic cancer or lung abscess (21).

Chest computed tomography (CT)

The role of CT in the evaluation of patients with hemoptysis has been validated (20,21). CT has proved to be of considerable value in diagnosing bronchiectasis, bronchogenic carcinoma, and aspergilloma in patients with massive hemoptysis (19,22). CT may demonstrate lesions that may not be visible on conventional radiographs, and contrast material-enhanced CT may help detect vascular lesions that cause massive hemoptysis. CT findings can suggest a specific diagnosis in 50% of patients in whom CT can also help localize the site of bleeding in 63% to 100% of patients with haemoptysis (14,18).

c) Treatment:

Standard Operating procedure

a) In Patient-

The management of a patient with haemoptysis has three objectives ó cessation of bleeding, prevention of aspiration and treatment of the underlying cause. As with any potentially serious condition, the initial approach would involve evaluation of the airway, breathing, and circulation (ABC).

Massive haemoptysis warrants a more aggressive approach, sometimes requiring intensive care and early consultation with a pulmonologist. Reassurance and reduction of anxiety are beneficial. In cases of massive or life threatening haemoptysis, diagnosis and therapy must occur simultaneously. Maintenance of the airway is vital because the primary mechanism of death is asphyxiation, not exsanguination (2).

Other measures include -supplemental oxygen, fluid resuscitation, hypotensive agents in adults if significantly hypertensive, blood transfusion, correction of coagulopathy, if necessary and intravenous antibiotics.

b) Out Patient- This is not applicable as all patients with massive haemoptysis should be admitted

c) Day Care- This is not applicable as all patients with massive haemoptysis should be admitted

d) Referral criteria:

If facilities for bronchial artery embolization or bronchoscopic intervention are not available, patient must referred to a hospital where these facilities are available.

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

a) Clinical Diagnosis: same as above

b) Investigations:

Multidetector CT is the investigation of choice for stable patients to show whether there are any hypertrophied bronchial arteries suitable for embolization and should be arranged as soon as possible after admission in a patient with massive haemoptysis. If hypertrophied bronchial arteries are (> 2mm in adults, significant chances are that these are responsible for haemoptysis. Multidetector CT allows rapid scanning, making timely examination feasible in critically ill patients. In addition, hypertrophied non bronchial systemic feeder vessels can be detected which contribute to the recurrence of haemoptysis after successful embolization of bronchial arteries(23).

CT versus Bronchoscopy

The overall diagnostic accuracy of fiberoptic bronchoscopy (FOB) in evaluating patients with haemoptysis is reported to be 10%–43% (18, 21). Bronchoscopy is unnecessary in patients with hemoptysis of known cause if the site of bleeding can be determined on conventional radiographs(21). Bronchoscopy may have disadvantage in massive, active haemoptysis as it is difficult to localize the bleeding site if there is excessive blood in the bronchi. bronchial therapies are not effective in most cases of massive haemoptysis (13). Bronchoscopy guided interventions are not effective in most cases of massive haemoptysis (13). Other disadvantages of bronchoscopy include possible airway compromise due to sedation, delay in treatment, hypoxemia and extra cost. CT should be performed prior to bronchoscopy in all patients with haemoptysis (13,20,21,24).

c) Treatment:

Standard Operating procedure

a. In Patient-

Initial management.

Nurse upright

Humidified Oxygen

A review of the patient's previous medical records and value of the forced expiratory volume (FEV1) may help in determining the feasibility of surgery. The interventional radiologist and the thoracic surgeon should be informed about admission of patient with severe haemoptysis.

Further management.

Appropriate antibiotics

IV Tranexamic Acid - 10mg/kg/td. Daily for 7 days if repeated bleeding occurs over a short period. If more than 100ml haemoptysis occurs on the third day, addition of intravenous Terlipressin (2mg bolus, followed by 1mg to 2mg every 4-6 hours (for a maximum duration of 72 hours) to control bleeding may be considered. However, this should not to be used in pregnancy.

Further investigations.

Bronchoscopic interventions are rarely useful in the acutely bleeding patient. In massive haemoptysis, rigid bronchoscopy, though technically difficult, may sometimes allow clot removal (with the additional risk of precipitating further bleeding), temporary tamponade of bleeding site using a Fogarty catheter or achieving haemostasis with thrombin glue or cold saline/ vasoconstrictor lavage.

Selective bronchial angiography and embolisation

In unstable patients, bronchial artery and embolization may be performed following chest radiograph, haematological & coagulation profile and renal function tests.

Rationale

The source of massive haemoptysis is usually the bronchial circulation (90% of cases) rather than the pulmonary circulation (5%) (25,26). In a minority of cases (5%), massive haemoptysis may originate from non bronchial systemic arterial supply to the lungs (27,28,29). In many acute and chronic lung diseases, the pulmonary circulation is reduced or occluded at the level of the pulmonary arterioles because of hypoxic vasoconstriction, intravascular thrombosis, and vasculitis (30). As a result, bronchial arteries proliferate and enlarge to replace the pulmonary circulation. The enlarged bronchial vessels, which exist in an area of active or chronic inflammation, may be ruptured due to erosion by a bacterial agent or due to elevated regional blood pressure. The arterial blood under systemic arterial pressure subsequently extravasates into the respiratory tree, resulting in massive haemoptysis (30).

Results

Previous studies have shown that BAE is very effective in controlling acute massive haemoptysis with initial non-recurrence rates reported to be 73%–98% (5-11,33,34).

Recurrence of bleeding may be caused by recanalization of embolized vessels, incomplete embolization, revascularization by the collateral circulation, inadequate treatment of the underlying disease, progression of basic lung disease, or non bronchial systemic arterial supply (1,2,31,37). Recurrent bleeding is more common in patients with chronic tuberculosis, aspergilloma, or neoplasm.

Long-term recurrence rates have been reported to be 10%–52% (1,2). However, the long-term success rate can be improved with repeat BAE. Haemoptysis may recur after successful BAE if the disease process is not controlled with drug therapy or surgery because embolization treats the symptom but not the underlying disease.

Complications

Chest pain is the most common complication, with a reported prevalence of 24%–91% (10,35,36). Chest pain is likely related to an ischemic phenomenon caused by

embolization and is usually transient. Transient dysphagia due to embolization of esophageal branches may be seen sometimes with a prevalence of 0.7% to 18.2% (10, 35). The most serious complication of BAE is spinal cord ischemia due to the inadvertent occlusion of spinal arteries. The prevalence of spinal cord ischemia after BAE is reported to be 1.4% to 6.5% (11, 32, 35, 37).

The visualization of radicular branches on bronchial or intercostal angiograms is not an absolute contraindication for BAE. However, when the anterior medullary artery (artery of Adamkiewicz) is visualized at angiography, embolization should not be performed.

Other rare complications include aortic and bronchial necrosis, bronchoesophageal fistula, non-target organ embolization (eg, ischemic colitis), pulmonary infarction, referred pain to the ipsilateral forehead or orbit, and transient cortical blindness (38-43).

Non bronchial Systemic Arterial Supply

Non bronchial systemic arteries can be a significant source of massive haemoptysis especially in patients with pleural involvement caused by an underlying disease. In the presence of pleural thickening, non bronchial systemic feeder vessels that originate from various arteries, for example, intercostal artery, branches of the subclavian and axillary arteries, internal mammary artery, inferior phrenic artery (2,8, 32,44) may develop along the pleural surface and become enlarged as a result of the inflammatory process. Use of CT to predict the presence of non bronchial systemic vessels that supply a parenchymal lesion is important prior to BAE because it helps in localizing the site of bleeding and in selecting systemic vessels for the interventional approach.

- a. **Out Patient-** This is not applicable as all patients with massive haemoptysis should be admitted for management.
 - b. **Day Care** – This is not applicable as all patients with massive haemoptysis should be admitted for management.
- b) **Referral criteria:** In case, haemoptysis is not controlled, repeat embolization may be performed. However, in case of no significant clinical improvement, option of Surgery in the form of resection of diseased part of the lobe or lung may be considered by thoracic surgeon.

VI. WHO DOES WHAT? and TIMELINES

- a. **Doctor - Supportive management by physician/pulmonologist** immediately Bronchial Artery Embolization (BAE) by interventional radiologist as early as feasible

- b. **Nurse** – Assisting during the procedure as well as before and after interventional treatment.
- a. **Technician**- Performing the CT scan and assisting in the BAE procedure.

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RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs and consumables and equipment. Quantity to also be specified)

Situation	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT
1	Physician -1 Radiologists-1 Anaesthetist -1 Radiographer Technicians ó2 Nurses ó 2 Orderly / Ward Boy ó 2	1. Routine blood examination Hb, TLC, DLC , ESR etc. 2. Sputum for AFB, malignant cells 3. Serum HIV 4. Renal function tests 5. Blood sugar 6. Chest Radiograph 7. CT Chest	1. Local anaesthetic & sedatives 2. Mist cough Linctus. Oxygen cylinder with masks Capsules and Injection of Tranexamic acid Life saving drugs	Pulse oxymeter/ non invasive monitor Crash cart containing laryngoscope and endotracheal tube
2	Doctors ó 2 (Radiologists-2(at least one interventional radiologist) Anaesthetist -1 Physician (preferably pulmonologist)-1) Technicians ó2 Nurses ó 2 Orderly / Ward Boy ó 2	same as above 2. CT Angiography of chest 3. BAE	Same as mentioned above Angiographic catheters, arterial sheath, guide wires, microcatheter, embolic material, puncture needles, X ray Documentation- films/CD/DVD Dressing material	Digital Subtraction Angiography equipment and Anaesthesia equipment

Fallopian Tube Recanalization in Infertility Due to Proximal Tubal Obstruction

VII. WHEN TO SUSPECT/ RECOGNIZE?

Infertility is defined as the inability to conceive after 1 year of contraceptive-free intercourse. Since the reasons for infertility may be due to multiple factors, a systematic approach is required diagnosis and management. It may be due to factors relating to fallopian tubes in 30-40%, mucus hostile to sperms in 15-20% and factors relating to males in 40% (1).

a) Introduction:

A large number of pathologic conditions can affect the proximal fallopian tube . Infection and subsequent inflammation or fibrosis is leading causes of proximal tubal obstruction. These are frequently consequent to chlamydial or gonococcal salpingitis or postpartum endometritis. About half of patients with bilateral proximal tubal obstruction (PTO) have very localized disease with no pelvic adhesions (2,3), making them ideal candidates for an attempt at tubal catheterization for establishing patency. Moreover, PTO often occurs because of the accumulation of mucus or debris, which forms an impacted plug in the interstitial or proximal isthmic portion of the tube . fallopian tube recanalization (FTR) is a minimally invasive procedure used to recanalize blocked fallopian tubes in patients with a history of infertility and confirmed proximal tubal obstruction.

b) Case definition: For both situations of care (*mentioned below)**

Proximal tubal obstruction is defined as obstruction in either the intramural segment or the uterotubal junction, diagnosed as cornual block on hysterosalpingogram with normal fallopian tubes on , hysteroscopy or laparoscopy during work up of female infertility.

INCIDENCE OF THE CONDITION IN OUR COUNTRY

The exact incidence of female infertility due to proximal tubal disease in our country is not known. The incidence in United states has been reported to be 15-20%. In India, proximal tubal obstruction due to tubal spasm or transient occlusion by mucus plugs or debris has been reported in 10-40% of women in 2009(4,5).

DIFFERENTIAL DIAGNOSIS

Proximal, distal and peritubal damage can be caused by a number of disease processes, such as inflammation, endometriosis and surgical trauma . Bacteriological examination of tubal fluid detects pathologic micro flora in the oviducts of 36.6% women with PTO. Most common cause of fallopian tube obstruction is infection such as pelvic inflammatory disease (PID). The tubal infertility has been reported to be around 12% after one, 23% after two, and 53% after three episodes of PID (6). Inflammatory etiology seems to be important in isthmic tubal occlusion, especially due to chlamydial infection which causes muscular hypertrophy leading to salpingitis isthmica nodosa. Other factors such as uterine curettage, pelvic inflammatory disease, endometritis, infections after childbirth or abortions and_intraabdominal infections including appendicitis and peritonitis and intrauterine devices may all influence PTO infertility .

VIII. PREVENTION AND COUNSELING

(a) **Awareness about sexually transmitted infections and its early treatment.**

Since tubal infertility may be the consequence of chronic pelvic inflammatory disease (PID), which can lead to tubal scarring. The latter can be prevented by early detection and treatment of sexually transmitted infections particularly Chlamydia infection (7).

(b) **Avoidance of tobacco , smoking and obesity.** These lifestyle factors can cause fertility impairment during the reproductive years (8). Tobacco products not only cause infertility but also interfere with its treatment (8). Hence tobacco screening and cessation is an important component of infertility care (9). Obesity may be associated with ovulatory and menstrual dysfunction and subsequent infertility, increased risk of miscarriage, and decreased effectiveness of Assisted Reproductive Therapy (10).

(c) **Regular treatment.** Proper & regular of the metabolic disorder associated with the polycystic ovary syndrome due to the link between overeating, insulin resistance, and the endocrine changes that reduce fertility in women with polycystic ovary syndrome (11).

(d) **Avoidance of excessive and repeated exposure to radiation**

(e) **Proper diet and exercise.** Optimal reproductive functioning requires both proper diet and appropriate levels of exercise. Women who are significantly overweight or underweight may have difficulty in becoming pregnant.

(f) **Assisted reproductive therapy (ART)**- In cases, where tubal recanalization is not possible in spite of various techniques, couples should be advised for Assisted reproductive therapy (ART)

IX. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA

*Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited

a) **Clinical Diagnosis:** Women with unilateral or bilateral proximal tube obstruction confirmed by hysterosalpingography (HSG) or laparoscopy are candidates for fallopian tube recanalization. Proper historical evaluation, general physical and gynaecological examination and exclusion of infective etiology should precede (HSG)

b) **Investigations:**

Sonography

Sonography should be performed for evaluation of uterus and adnexae to exclude uterine abnormalities, hydrosalpinx, polycystic ovaries, endometriosis and fluid in Pouch of Douglas.

Hysterosalpingography (HSG)

Hysterosalpingography (HSG) should be performed to demonstrate endometrial cavity, uterine abnormalities, fallopian tubes with peritoneal spill, level of blockage (proximal, mid or distal) in case of blocked fallopian tubes, presence or absence of hydrosalpinx. About 10% of patients with apparent bilateral blocked fallopian tubes on HSG become pregnant without further therapy

and may demonstrate patent tubes on repeat HSG. However, HSG is contraindicated in acute pelvic inflammatory disease, active uterine bleeding, recent curettage and intrauterine adhesions.

Diagnostic criteria of PTO

Hysterosalpingography shows persistent unilateral or bilateral tubal occlusion in spite of administration of anticholinergic drugs or spasmolytics.

c) **Treatment:**

Standard Operating procedure

- a. **In Patient-** This is not applicable as admission is not required for these investigations
- b. **Out Patient-** Sonography and HSG are performed as OPD procedures
- c. **Day Care** – This is not applicable as admission is not required for these investigations

d) **Referral criteria:**

Infertile women with detection of persistent unilateral or bilateral proximal tubal obstruction within the first 0-4 cm of the fallopian tube on HSG should be referred to a tertiary care centre having interventional and Assisted Reproductive Treatment (ART) facility.

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

- c) **Clinical Diagnosis:** Women with unilateral or bilateral proximal tube obstruction confirmed by hysterosalpingography (HSG) or laparoscopy are candidates for fallopian tube recanalization. Proper historical evaluation, general physical and gynaecological examination and exclusion of infective etiology should precede (HSG)

d) **Investigations:**

Hysterosalpingography (HSG)

A repeat study may be performed if not performed earlier or earlier study was not satisfactory.

Hysteroscopy or Laparoscopy

Hysteroscopy or laparoscopy can be considered depending on the availability and local expertise in the referred tertiary centre.

Combined Hysteroscopy and Laparoscopy Procedure

Patients with previous history of pelvic inflammatory disease, proximal tubal obstruction may be evaluated by combined hysteroscopy & laparoscopy especially if laparoscopy had not been performed previously. Moreover in patients with uterine mass, hysteroscopically guided removal may be preferred over fallopian tube recanalization

e) **Treatment:**

Fallopian catheterization

The procedure may be best carried out with use of fluoroscopic guidance if patient has had prior laparoscopy that showed either no or minimal pelvic disease. Small tapered catheters and wires can be easily advanced fluoroscopically if the obstruction is in the isthmic part of the tube, 3-5 cm from the tubal ostium.

Diagnostic Selective Salpingography and Therapeutic fallopian Tube Recanalization

It should be performed in case of non filling of fallopian tubes to differentiate technically inadequate hysterosalpingography or spasm from true obstruction or tubal disorder such as salpingitis isthmica nodosa (SIN). The other indications include discordance between HSG and laparoscopy, prior to recanalization of PTO and persistent hypofertility after surgical tubocornual anastomosis.

Tubal cannulation can be used effectively to restore tubal patency in sub fertility due to isolated PTO, thus helps to avoid expensive assisted reproductive techniques. Tubal cannulation also eliminates or postpone the need for laparoscopic or hysteroscopic interventions by identifying patients with proximal and distal occlusion (bipolar tubal occlusion) and differentiating between true and false diagnoses of PTO. This procedure is reported to be successful in 62% to 90% of patients.

Recanalization is possible but potentially less successful in women who have occluded tubes after surgical anastomosis for reversal of tubal ligation. The success rates depend upon postoperative scarring at the anastomosis and range from 44% (12) to 77% (13). In patients with fallopian tube occlusion related to salpingitis isthmica nodosa, recanalization is successful in 77% to 82% of tubes (14, 15).

The average pregnancy rates are reported to be about 30% following the procedure (16-19).

Alternative Therapies

Alternative therapies such as microsurgical tubocornual anastomosis, hysteroscopic tube cannulation or falloscopic tube cannulation and in vitro fertilization should be reserved for failed fluoroscopic transcervical fallopian tube recanalization.

Standard Operating procedure

- a. **In Patient-** This is not applicable as fallopian tube recanalization procedure is carried out as day care procedure.

- b. **Out Patient-** Follow up in OPD
- c. **Day Care-** Fluoroscopic transcervical procedure is carried out as day care procedure

f) **Referral criteria:** Not applicable

X. WHO DOES WHAT? and TIMELINES

- a. **Doctor-** mentioned below
- b. **Nurse-** -do-
- c. **Technician-** - do-

Designation	Responsibility
Gynaecologist	Clinical Evaluation & diagnostic work up
Diagnostic Radiologist	Perform Sonography, HSG , MRI(if required)
Gynaecologist trained in laparoscopy & hysteroscopy	Performs laparoscopy or hysteroscopy or both
Interventional Radiologist	IR Procedures óDiagnostic selective salpingography and fluoroscopic transcervical fallopian tube recanalization
Nursing Staff	Assist in managing the patient
Radiographer Technician	Assist in imaging of patient and during interventional procedure
Lab Technician (Haematologist & Biochemist)	Haematological & biochemical evaluation

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RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs and consumables and equipment. Quantity to also be specified)

SITUATION	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT(S)
1.	Doctors ó Gynaecologist ó 1, Diagnostic Radiologist -1 X ray Technicians ó1, Lab technician -1 Nurses - 2	Hemoglobin, Random Blood Sugar, total & differential blood count, platelet count, ESR , HIV, urine analysis, vaginal smear, chest radiograph,	1. Drugs: Injection Buscopan, Atropine Diazepam/ Midazolam Doxycycline capsules, Non ionic radiographic contrast,	Color Doppler Ultrasound (1) X ray machine with image intensifier (1) Vaginal speculum, introducer catheter/canula for HSG
2.	Gynaecologist trained in laparoscopy & hysteroscopy-1 Interventional radiologist -1 X ray Technicians ó 1 Lab technician -1 Nurses - 2	Hemoglobin, Random Blood Sugar, total & differential blood count, platelet count, ESR , HIV, urine analysis, vaginal smear, Chest radiograph,	Drugs: Injection Buscopan, Atropine Diazepam/ Midazolam Doxycycline capsules, Recanalization set (Cook) or 5 French and 3 French catheters. 0.018 inch and 0.035 inch hydrophilic guidewire Non ionic radiographic contrast,	Color Doppler Ultrasound (1) X ray machine with image intensifier (1) Vaginal speculum, introducer catheter/ canula for HSG

INTRACRANIAL ANEURYSM

When to suspect or recognize?

Intracranial aneurysms are focal outpouching from intracranial arteries with weak walls as compared to normal arteries and therefore have propensity to present with intracranial bleed, usually subarachnoid hemorrhage (SAH). Clinically, these cases present with sudden severe headache (≠thunderclap headache) in case of bleed (1-6). Occasionally, these lesions may grow to significant size without bleeding and manifest clinically because of compression of adjoining brain parenchyma or cranial nerves (2-4).

a) Introduction

The word aneurysm comes from the Latin word *aneurysma* which means dilatation. Aneurysm is an abnormal focal dilatation in the wall of a blood vessel, usually an artery, due to a defect, disease, or injury (5,6).

Aneurysms can be true or false. A false aneurysm is a cavity lined by blood clot. The 3 major types of intracranial aneurysms are saccular, fusiform, and dissecting (1,6).

b) Case definition

Any patient presenting with or suspected to have non traumatic subarachnoid hemorrhage (SAH) or uncommonly, focal neurological deficit with demonstration of aneurysm on Imaging should be suspected of harboring an aneurysm (3-6).

I. Incidence of the condition in our country

It is underdiagnosed, undertreated, and much more common than previously thought. Incidence of the condition in our country is not exactly known due to lack of organized data. International literature suggests incidence between 1-6% in general population.

Differential Diagnosis

Clinically, other causes of ≠thunderclap headache merit consideration (1-6). These include cerebral venous thrombosis, cervical dissection, migraine, pituitary bleed, reversible cerebral vasoconstriction (Call Flemming syndrome). Radiologically, other causes of subarachnoid hemorrhage need consideration which are trauma, brain arteriovenous malformations (AVMs), bleeding disorders and other rare causes.

II. Prevention and Counselling

At this time, a routine screening test to discover brain may not be required without clinical symptoms. However, certain modifiable risk factors as follows should be adequately controlled to prevent bleed:

- i. Cigarette smoking ó increases the risk of an aneurysm rupture. Smokers are three times more likely to have an SAH than non-smokers.

- ii. Alcohol & drugs use - It is unclear if alcohol use increases the risk of developing an aneurysm, but moderate to heavy drinking is considered a risk factor for the rupture of an aneurysm if present. Similarly, drug use, particularly cocaine, may increase the risk of rupture.
- iii. High Blood Pressure ó several studies found that having high blood pressure increases the risk for developing an aneurysm and for rupture of existing aneurysms (7).

III. Optimal Diagnostic Criteria, Investigations, Treatment & Referral Criteria -

Diagnostic Criteria

Aneurysm should be considered in the following clinical setting (1,5,6) :

- i) Sudden severe headache (thunderclap headache) in the absence of obvious head injury
- ii) Presence of SAH on imaging (CT/MRI)
- iii) Demonstration of aneurysm on imaging during evaluation for any neurologic problem.

Investigations

i) CT Scan

CT scan should be sought on any patient with non-traumatic SAH. Large Aneurysms or their wall calcification may also be at times seen on NCCT.

ii) CT Angiogram (CTA)

Conventional angiography like images of the cerebral vasculature can be obtained using rapid contrast infusion and thin-section dynamic CT scanning (CTA). Various 3-dimensional display techniques, including shaded surface display, volume rendering, and maximum intensity projection, are used to complement the conventional transaxial images. It has very high diagnostic accuracy with sensitivity and specificity of >95% (8-10).

iii) MR Angiogram (MRA)

MRA should be usually performed only if there is some contraindication to CTA or CT cannot be easily performed. The sensitivity and specificity is lower as compared to CTA (11).

iv) Digital Subtraction Angiogram (DSA)

It remains the gold standard for diagnosis, particularly in delineating small aneurysms. DSA is usually always required in case any endovascular or surgical treatment is planned (6,8).

Treatment

Two major strategies for treatment are:

- (1) To closely follow up in case of incidentally detected asymptomatic aneurysms by clinical and radiological re assessment periodically.
- (2) In symptomatic group, treatment options include endovascular coiling of the sac or surgical clipping of the aneurysm neck

Referral Criteria

*Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited:

1. Clinical diagnosis

- I. Subarachnoid hemorrhage:** The most common presentation of intracranial aneurysm is subarachnoid hemorrhage (SAH) in non traumatic background. On presentation, patients typically report experiencing the worst headache of their lives (thunderclap headache). The association of meningeal signs should increase suspicion of SAH.
- II. Mass effect:** The so-called giant aneurysms (diameter >2.5 cm) are more often symptomatic because of their mass effect. Some intracranial aneurysms produce cranial neuropathies. A common example is the third nerve palsy that is secondary to posterior communicating artery aneurysm or III/IV/VI nerve palsy seen in giant cavernous ICA aneurysms. Rarely, even visual loss caused by an ophthalmic artery aneurysm that compresses the optic nerve has been reported.
- III. Other symptoms:** Other, less common, symptoms include seizures, headaches, and transient ischemic attacks or cerebral infarction secondary to emboli (usually associated with large or giant partially thrombosed aneurysms).

Severe **vasospasm** associated with SAH is often the leading cause of death.

2. Investigations

- i) CT ó to confirm SAH or to look for diagnostic possibility of aneurysm as a cause for focal neurologic deficit
- ii) CTA/MRA ó if available, to confirm the diagnosis before referring to higher center.

3. Treatment

Based on the available literature, the management of aneurysm differs in ruptured and unruptured patients (1, 5,6, 12,13).

Ruptured aneurysms should be treated urgently (within 72 h of hemorrhage) to prevent rebleeding and to permit aggressive Management of vasospasm.

Unruptured aneurysms are generally treated electively and may even be followed up if small (<7mm) and incidentally detected.

- i) Initial management for Ruptured Aneurysms :
 - a. Administer calcium channel blockers (nimodipine for 21 d) to all patients; this has been shown to improve outcome (6,14).
 - b. Anticonvulsant use is controversial, but is generally given (levetiracetam or phenytoin), particularly for patients undergoing craniotomy or those with focal cerebral hematomas in addition to the SAH.
- ii) Ventricular drainage: Blood in the subarachnoid space obliterates the arachnoidal villi / ventricular foramina, causing acute hydrocephalus. In life threatening state, a ventriculostomy catheter should be emergently placed (6).

iii) Definite Management: Endovascular coiling or Surgical Clipping - To be done at higher center

with expertise and infrastructure.

i. Referral criteria

A diagnosed or suspected case of aneurysm which warrants urgent or early intervention due to presentation (SAH or neurological deficits) should be referred to tertiary care center with facilities for endovascular treatment or neurosurgery as early as possible.

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

b. Case Definition (tertiary care)

1. Clinical diagnosis:

i) **Subarachnoid hemorrhage:** The most common presentation of intracranial aneurysm is subarachnoid hemorrhage (SAH) in non traumatic background. On presentation, patients typically report experiencing the worst headache of their lives (thunderclap headache). The association of meningeal signs should increase suspicion of SAH.

ii) **Mass effect:** The so-called giant aneurysms (diameter >2.5 cm) are more often symptomatic because of their mass effect. Some intracranial aneurysms produce cranial neuropathies. A common example is the third nerve palsy that is secondary to posterior communicating artery aneurysm or III/IV/VI nerve palsy seen in giant cavernous ICA aneurysms. Rarely, even visual loss caused by an ophthalmic artery aneurysm that compresses the optic nerve has been reported.

iii) **Other symptoms:** Other, less common, symptoms include seizures, headaches, and transient ischemic attacks or cerebral infarction secondary to emboli (usually associated with large or giant partially thrombosed aneurysms).

Severe **vasospasm** associated with SAH is often the leading cause of death.

2. Investigations:

i) CT Scan - to confirm SAH or to look for diagnostic possibility of aneurysm as a cause for focal neurologic deficit Large Aneurysms or their wall calcification may also be at times seen on NCCT.

ii) CT Angiogram (CTA) ó Angiography like images of the cerebral vasculature can be obtained using rapid contrast infusion and thin-section dynamic CT scanning (CTA). Various 3-dimensional display techniques, including shaded surface display, volume rendering, and maximal intensity projection, are used to complement the conventional transaxial images (8-10).

iii) MR Angiogram (MRA)- MRA should be usually performed only if there is some contraindication to CTA or CT cannot be easily performed (6,11).

iv) Digital Subtraction Angiogram (DSA)- It remains the gold standard for diagnosis, particularly small aneurysms. DSA is usually always required in case any endovascular or surgical treatment is planned (1,5,6).

3. Treatment

i) Initial treatment and evaluation:

As outlined above. If not already started, supportive treatment should be started immediately.

ii) Definite Management: *Endovascular coiling or Surgical Clipping*

Obliteration of an aneurysm can be done by either putting metallic (usually titanium) clips at the aneurysm neck (=clipping) or by packing the aneurysm sac from inside by using platinum coils (=coiling) through endovascular (transarterial) route. While clipping is a major surgical procedure, coiling is a minimally invasive technique and therefore appears more attractive. However, the choice of procedure depends on various other factors and needs to be decided carefully. Recent evidence suggests that coiling is highly effective and in certain conditions (eg posterior circulation aneurysms) much more favored option (13,17-20).

ii. Referral criteria

A diagnosed or suspected case of aneurysm which warrants urgent or early intervention due to presentation (SAH or neurodeficits) should be referred to tertiary care center with facilities for endovascular treatment or neurosurgery.

Who does what? And Timelines

Designation	Clinical Role	Timeline
Physician (Internist)	Clinical Evaluation	Screening on presentation to OP
General Surgeon (GS)	Clinical Evaluation & supervising vascular evaluation	Specialist Consultant who becomes the primary care Physician once diagnosis is established
	Performs Vascular Surgery	When indicated or when IR procedures fail.
Biochemist	Biochemical evaluation	After evaluation by and on the request of GS
Diagnostic Radiologist	Evaluate NCCT, CTA or MRA	After evaluation by and on the request of GS
Neurosurgeon	Neurologic evaluation	After consultation by and on the request of GS
	Management of SAH and surgical clipping	If necessary, following GS consult and on the request of GS
Interventional	IR Procedures – Endovascular coiling,	Referring Specialist for IR

Radiologist	parent artery occlusion if safe, endovascular bypass device (flow diverters)	procedures on the request of GS/ NS
Nursing Staff	Assist in managing the patient	In-patient or Day Care in Vascular Surgery facility, Dialysis facility and Interventional Radiology facility
Technician	Assist in Imaging the patient	In CT,MR and Interventional Radiology facility after Radiology & IR consultation

RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs & consumables and equipment. Quantity to also be specified)

SITUATION	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT(S)
1.	Doctors – (Internist – 1, General Surgeon – 1, Diagnostic Radiologist -1, Technician(s) – 3, Nursing - 2	Hemoglobin, Random Blood Sugar, PT, APTT or INR, Platelet Count, Se. Creatinine, HBsAg, HIV	1. Drugs: Nimodipine, Heparin	MDCT or MRI with facility for Vascular Imaging
2.	Doctors – (Internist – 1, Vascular Surgeon with – 1, Diagnostic Radiologist -1, Interventional Radiologist – 1, Anaesthetist -1) Technician(s) – 3 to 4 Nurses – 3 to 4 for all the units	Hemoglobin, Random Blood Sugar, PT, APTT or INR, Platelet Count, Se. Creatinine, HBsAg, HIV	1. Drugs: Nimodipine, Heparin, Non Ionic radiographic contrast media 2. Consumables: Arterial access device, Diagnostic Catheter, Guiding catheter, balloon or self expanding Stent, GDC platinum coils	Vascular Doppler(1) Operation Theatre (1) Color Doppler Ultrasound (1) MDCT or MRI with Vascular Imaging (1) Digital Subtraction Angiography System (1) Sterile Suite Multichannel

				invasive monitor (1) Resuscitation equipment (1) Crash Trolley (1)
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Extra Cranial Carotid Stenosis

I. WHEN TO SUSPECT / RECOGNIZE?

a) **Introduction:** This is a common condition, predominantly affecting the elderly, as atherosclerosis is the commonest etiology. Most common site affected are carotid bifurcation and origins of carotid and vertebral arteries. It can also occur following radiation / trauma and can also be seen in connective tissue disorders and arteritis. It causes focal or diffuse narrowing of the carotid artery depending on etiology. It often presents with transient / permanent neurological deficits. Transient Ischemic Attack, Cerebral stroke, local bruit, amaurosis fugax, previous history of neck surgery or radiation therapy are some of the clues to clinical diagnosis.

b) Case definition :

The diagnosis is established by vascular imaging such as color Doppler / CT angiography / MR angiography / catheter angiography. Doppler is the first screening tool. However, catheter angiography remains the gold standard in this situation. The degree of stenosis is defined in comparison with the normal distal artery diameter (NASCET Criteria / ECST CRITERIA). Symptomatic Stenosis or stenosis more than 60% is of clinical significance.

II. **INCIDENCE OF THE CONDITION IN OUR COUNTRY:** Cerebral ischemic stroke is the third leading cause of death, and carotid artery stenosis is the commonest cause of cerebral ischemic stroke. The incidence of intracranial carotid disease is also on the rise in our country and high index of suspicion and proper imaging is often helpful in detecting the disease burden.

III. DIFFERENTIAL DIAGNOSIS:

The carotid stenosis may be caused by:

- Atherosclerosis
- Fibro muscular dysplasia
- Arteritis
- Radiation
- Trauma
- Dissection
- Secondary to involvement in malignant tumour in the neck

IV. PREVENTION AND COUNSELLING

Preventive measures as advised for atherosclerosis should be followed. These include:

- Avoidance of smoking
- Low fat diet
- Regular exercise

Control of blood pressure

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA:

Diagnostic criteria / investigations ó

Stenosis greater than 60% by NASCET criteria in symptomatic individuals and greater than 70% in asymptomatic individuals are presently considered as indications for interventional treatment.

The imaging modalities used are

1. Color Doppler
2. CT Angiography
3. MR Angiography
4. Catheter angiography

Treatment - It can be treated by endovascular stenting or surgical endarterectomy. Both modalities have shown similar results. However in non atherosclerotic etiology / difficult surgical access / high risk cases for surgery, stenting is of choice. Recent cerebral infarction is a relative contraindication. The procedure may need to be deferred for 3 weeks in such cases.

Follow up –

Color Doppler is the preferred imaging modality for follow up.

* **Situation 1: At Secondary Hospital / Non-Metro situation: Optimal Standards of Treatment in situations where technology and resources are limited.**

- a) **Clinical Diagnosis:** Transient Ischemic Attack, Cerebral stroke, local bruit, amaurosis fugax, previous history of neck surgery or radiation therapy are some of the clues to clinical diagnosis.
- b) **Investigations:** Hemoglobin, Total and Differential Leucocyte counts, ESR, Blood Sugar, INR, Platelet count, Serum Creatinine,

Imaging : Diagnostic criteria / investigations ó

Stenosis greater than 60% by NASCET criteria in symptomatic individuals and greater than 70% in asymptomatic individuals are presently considered as indications for interventional treatment.

The imaging modalities used are

1. Color Doppler
2. CT Angiography
3. MR Angiography
4. Catheter angiography

- c) **Treatment** : It can be treated by endovascular stenting or surgical endarterectomy. Both modalities have shown similar results. However in non

atherosclerotic etiology / difficult surgical access / high risk cases for surgery, stenting is of choice. Recent cerebral infarction is a relative contraindication. The procedure may need to be deferred for 3 weeks in such cases.

Standard operating procedure

- a. **In Patient** - All cases should be treated as in patients
- b. **Out Patient** - Not applicable
- c. **Day Care** - Not applicable
- d. **Referral criteria :**
Stenosis greater than 60% by NASCET criteria in symptomatic individuals and greater than 70% in asymptomatic individuals are presently considered as indications for interventional treatment.

If facilities for standard treatment are not available, patient is referred to super specialty hospital where these facilities are available.

* **Situation 2 : At super specialty facility in metro location where higher-end technology is available.**

- a) **Clinical Diagnosis:** Transient Ischemic Attack, Cerebral stroke, local bruit, amaurosis fugax, previous history of neck surgery or radiation therapy are some of the clues to clinical diagnosis
- b) **Investigations:** Hemoglobin, Total and Differential Leucocyte counts, ESR, Blood Sugar, INR, Platelet count, Serum Creatinine,

Imaging : Diagnostic criteria / investigations ó

Stenosis greater than 60% by NASCET criteria in symptomatic individuals and greater than 70% in asymptomatic individuals are presently considered as indications for interventional treatment.

The imaging modalities used are

- 5. Color Doppler
- 6. CT Angiography
- 7. MR Angiography
- 8. Catheter angiography

- c) **Treatment :** It can be treated by endovascular stenting or surgical endarterectomy. Both modalities have shown similar results. However in non atherosclerotic etiology / difficult surgical access / high risk cases for surgery, stenting is of choice. Recent cerebral infarction is a relative contraindication. The procedure may need to be deferred for 3 weeks in such cases.

Standard operating procedure

- a. **In Patient** - All cases are to be treated as in patients. They should be treated in centers equipped with Digital Subtraction Angiography equipment (DSA) with roadmap facility, facility of ICU care.
- b. **Out Patient** - Not applicable
- c. **Day Care** - Not applicable
- d. **Referral criteria** : Stenosis greater than 60% by NASCET criteria in symptomatic individuals and greater than 70% in asymptomatic individuals are presently considered as indications for interventional treatment.

VI. WHO DOES WHAT ? and TIMELINES

- a. **Doctor:** Diagnosis & interventional treatment.
- b. **Nurse:** Assistance in pre, during & post interventional clinical care.
- c. **Technician:** Assistance in pre, during & post interventional imaging.

VII. FURTHER READING / REFERENCES

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3. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guidelines on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease: Executive Summary A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery Developed in Collaboration With the American Academy of Neurology and Society of Cardiovascular Computed Tomography . Brott et al JACC Vol. 57, No. XX, 2011.

RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs and consumables and equipment. Quantity to also be specified)

Situation	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT
1.	Doctors ó 3 (Radiologists (specialist trained in Neuro - interventional procedures-1, Anaesthetist -1, Neurologist for clinical management ó 1) Technicians ó1 Nurses ó 1	Hemoglobin, Total and Differential Leucocyte counts, ESR, Blood Sugar, INR, Platelets, Serum Creatinine	1. Drugs: Aspirin, Clopidogrel, Nitroglycerine, Nimodipine, Heparin, Non-Ionic Iodinated contrast media 2. Consumables: Arterial access sheath, 90 cm long sheath, Guiding catheter, Self expanding carotid stent, Pre and post dilatation angioplasty balloon catheter, diagnostic angiography catheter, appropriate 0.014ö & 0.035ö guidewires, exchange length 0.035ö guidewire, Tuhoy SBorst Y connector, Indeflator, saline Pressure flush bag, distal (or proximal) protection device	Digital subtraction angiography system (DSA) Colour Doppler Ultrasound Multiparameter patient monitor Resuscitation equipment

2.	Minimum as mentioned above. In addition, Intensivist 1(desirable)	Same as mentioned above	Same as mentioned above	Same as mentioned above. In addition ACT machine (for activated clotting time determination) is desirable.
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Acute Cerebral Ischemic Stroke Due to a Major Vessel Occlusion

I. WHEN TO SUSPECT / RECOGNIZE?

a) Introduction:

Cerebral Stroke is a sudden onset neurological deficit due to neurovascular pathological conditions. Ischemic stroke due to a major vessel occlusion forms an important group in cerebral stroke. This is a common condition, predominantly affecting the elderly, as atherosclerosis with/without thrombo-embolism is the commonest etiology. It can also occur due to embolism from cardiac or neck vessel source, vasculitis and arteritis, traumatic or spontaneous dissection and other causes. It usually presents with stroke leading to transient / permanent neurological deficits.

c) Case definition:

The diagnosis is established by CT, MRI supplemented with vascular imaging such as CT angiography / MR angiography / catheter angiography. CT Perfusion or MR perfusion may be necessary. Cerebral ischemic stroke cases due to acute occlusion of a major intracranial vessel like ICA, A1/Proximal A2, M1/Proximal M2 and Basilar artery presenting in the recommended therapeutic time window period are suitable for intra arterial therapeutic recanalization procedures. Stroke due to a small vessel involvement as seen in atherosclerosis or vasculitis leading to lacunar infarction are not considered for intra arterial recanalization procedures.

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY:

Cerebral ischemic stroke is one of the important causes of death/disability in the elderly population.

III. DIFFERENTIAL DIAGNOSIS:

Cerebral ischemic stroke involving a major intracranial vessel may be caused by:

- Atherothrombosis
- Embolism
- Dissection
- Trauma

Clinically however stroke like picture may be due to a variety of causes including small vessel involvement as in atherosclerosis or vasculitis, and tumors, infection, demyelination etc.

IV. PREVENTION AND COUNSELLING

Preventive measures as advised for atherosclerosis should be followed. These include ó

- Avoidance of smoking
- Low fat diet
- Regular exercise
- Control of blood pressure and diabetes

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA:

Diagnostic criteria / investigations –

Cerebral ischemic stroke due to acute occlusion of a major intracranial vessel like ICA, A1/Proximal A2, M1/Proximal M2 and Basilar artery presenting in the recommended therapeutic time window period are suitable for intra-arterial therapeutic recanalization procedures. For anterior circulation upto 6-8 hrs from the onset of occlusion of vessel is the recommended therapeutic time window. A longer window period is available for posterior circulation and central retinal artery occlusion. Similarly further deferred therapeutic window period is available for cerebral venous sinus recanalization.

Intracranial hemorrhage, hypertension, deranged clotting parameters, low platelet counts, CT demonstrable infarction occupying more than a third of the hemispheric territory are some of the absolute and relative contraindications.

The imaging modalities used are

5. CT and/or MRI
6. CT Angiography
7. MR Angiography
8. Catheter angiography
9. CT or MR Perfusion imaging
10. Transcranial Doppler

Treatment - It can be treated by endovascular intra arterial thrombolysis and/or clot retrieval/aspiration. Adjuvant intracranial angioplasty/stenting may be required.

Follow up –

CT, MRI and non-invasive angiographic techniques are generally used for follow up and monitoring.

***Situation 1: At Secondary Hospital / Non-Metro situation: Optimal Standards of Treatment in situations where technology and resources are limited.**

- a) **Clinical Diagnosis:** Cerebral Stroke is a sudden onset neurological deficit due to neurovascular pathological conditions. Lacunar ischemic stroke and hemorrhagic strokes conditions need to be excluded. After clinical evaluation suitable imaging will be required to establish correct diagnosis.
- b) **Investigations:**
Hemoglobin, Total and Differential Leucocyte counts, ESR, Blood Sugar, INR, Platelets, Serum Creatinine,
Imaging as mentioned in diagnostic criteria
- c) **Treatment:** It can be treated by endovascular intra arterial thrombolysis and/or clot retrieval/aspiration. Adjuvant intracranial angioplasty/stenting may be required.

Standard operating procedure

- e. **In Patient** - All cases should be treated as in patients
- f. **Out Patient** - Not applicable
- g. **Day Care** - Not applicable
- h. **Referral criteria :**
Cerebral ischemic stroke cases due to acute occlusion of a major intracranial vessel like ICA, A1/Proximal A2, M1/Proximal M2 and Basilar artery presenting in the recommended therapeutic time window period are suitable for therapeutic recanalization procedures.

If facilities for standard treatment are not available, patient is referred to super specialty hospital where these facilities are available.

- * **Situation 2 : At super specialty facility in metro location where higher-end technology is available.**

- a) **Clinical Diagnosis:** Cerebral Stroke is a sudden onset neurological deficit due to neurovascular pathological conditions. Lacunar ischemic stroke and hemorrhagic strokes conditions need to be excluded. After clinical evaluation suitable imaging will be required to establish correct diagnosis.

- b) **Investigations:** Hemoglobin, Total and Differential Leucocyte counts, ESR, Blood Sugar, INR, Platelets, Serum Creatinine,

Cerebral ischemic stroke due to acute occlusion of a major intracranial vessel like ICA, A1/Proximal A2, M1/Proximal M2 and Basilar artery presenting in the recommended therapeutic time window period are suitable for intra-arterial therapeutic recanalization procedures. For anterior circulation up to 6-8 hrs from the onset of occlusion of vessel is the recommended therapeutic time window. A longer window period is available for posterior circulation and central retinal artery occlusion. Similarly further deferred therapeutic window period is available for cerebral venous sinus recanalization.

Intracranial hemorrhage, hypertension, deranged clotting parameters, low platelet counts, CT demonstrable infarction occupying more than a third of the hemispheric territory are some of the absolute and relative contraindications.

The imaging modalities used are

11. CT and/or MRI
12. CT Angiography
13. MR Angiography
14. Catheter angiography
15. CT or MR Perfusion imaging
16. Trans cranial Doppler

- c) **Treatment** : It can be treated by endovascular intra arterial thrombolysis and/or clot retrieval/aspiration. Adjuvant intracranial angioplasty/stenting may be required.

Standard operating procedure

- e. **In Patient** - All cases are to be treated as in-patients. They should be treated in centers equipped with DSA, with roadmap facility and facility of ICU care.
- f. **Out Patient** - Not applicable
- g. **Day Care** - Not applicable
- h. **Referral criteria:** Cerebral ischemic stroke cases due to acute occlusion of a major intracranial vessel like ICA, A1/Proximal A2, M1/Proximal M2

and Basilar artery presenting in the recommended therapeutic time window period are suitable for therapeutic recanalization procedures.

If facilities for standard treatment are not available, patient is referred to super specialty hospital where these facilities are available.

VI. WHO DOES WHAT? and TIMELINES

- d. **Doctor:** Diagnosis & Interventional treatment.
- e. **Nurse:** Assistance in pre, during & post interventional clinical care.
- f. **Technician:** Assistance in pre, during & post interventional imaging.

RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs and consumables and equipment. Quantity to also be specified)

SITUATION	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT
1.	Doctors ó 3 (Radiologists/specialist trained in neurointerventional procedures.-1, Anaesthetist -1, Neurologist - 1) Technicians ó1 Nurses ó 1	Hemoglobin, Total and Differential Leucocyte counts, ESR, Blood Sugar, INR, Platelets, Serum Creatinine	1. Drugs: Aspirin, Clopidogrel, Nitroglycerine, Nimodipine, Heparin, Non Ionic Iodinated contrast media, Urokinase/rTPA 2. Consumables: Arterial access sheath, Guiding catheter, diagnostic angiography catheter, appropriate guidewires, microcatheter/ microwire, infusion pump, clot removal devices like Merci, Penumbra, Solitaire AB stent device, intracranial angioplasty balloon and balloon mounted stent	Digital subtraction angiography system Multiparameter patient monitor Resuscitation equipment Transcranial Doppler preferable.
2.	Minimum Same as mentioned above. In addition, Intensivist ó	Same as mentioned above	Same as mentioned above	Same as mentioned above. In addition ACT machine

	1(desirable)			(for activated clotting time determination) is desirable.
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FURTHER READING / REFERENCES

1. Handbook of Interventional Radiologic Procedures. Authors: David Kumpe Edited by: Krishna Kandarpa, John E. Aruny, Publishers: Wolters Kluwer/ Lippincott, Williams & Wilkins
2. Guidelines for the Early Management of Patients With Ischemic Stroke
A Scientific Statement From the Stroke Council of the American Stroke Association
Harold P. Adams Jr, MD et al
3. Guidelines for the Early Management of Adults With Ischemic Stroke: A Guideline From the American Heart Association/American Stroke Association Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups: The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists. Circulation. 2007;115:e478-e534
4. Imaging-Guided Acute Ischemic Stroke Therapy: From "Time Is Brain" to "Physiology Is Brain" R.G. González, American Journal of Neuroradiology 27:728-735, April 2006

UTERINE FIBROID EMBOLISATION

I. WHEN TO SUSPECT/ RECOGNIZE?

Whenever a woman of child bearing age presents with menorrhagia (excessive bleeding during menstruation), dysmenorrhea (painful menses), or recurrent abortion.

1a Introduction: Uterine fibroid is a common benign tumour smooth muscle cells and fibrous connective tissue that develop within the walls of the uterus. It generally affects the middle-aged women and present with menorrhagia and pressure effects on the urinary bladder and or the rectum. Women with fibroids may also have dysmenorrhea. When occurring in the child bearing age, these fibroids may interfere with pregnancy and the lady is either unable to conceive or unable to carry the pregnancy till completion. Uterine fibroid embolisation (UFE) is a minimally invasive, percutaneous, endovascular (interventional radiological) therapy to treat the fibroids, by blocking the arteries supplying the fibroid.

1b Indications:

It is indicated for treatment of symptomatic uterine fibroids, causing menorrhagia /dysmenorrhea / pressure effects on rectum or urinary bladder.

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY: Fibroids is a common ailment of the middle aged women, occurring in up to 20%.

III. DIFFERENTIAL DIAGNOSIS: Other causes of uterine masses could be cancer cervix, endometrial cancer. Occasionally ovarian cancer may mimic a uterine fibroid. Imaging with Ultrasound / MRI and histopathological studies can give the correct diagnosis.

IV. PREVENTION AND COUNSELING: Menorrhagia / lower abdominal masses should be evaluated by imaging and histopathology, to arrive at the correct diagnosis, and early appropriate treatment should be implemented. The middle aged women should be always evaluated with a PAP smear to rule out any malignancy of uterine cervix.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA / FOLLOW UP

Diagnostic Criteria:

- Ultrasound: Reveals a spherical mass with heterogeneous middle level echoes. Most fibroids are intramural. Occasionally they may be pedunculated

and apparently detached from the uterus or they could be subendometrial. There is always an accompanied displacement of the endometrial echo, which also serves as an indirect indicator for the isoechoic fibroids.

- MRI: Reveals a uterine mass that is heterogeneously hyperintense on T2 and isointense on T1 images. There is hypertrophy of the uterine arteries.

Investigations:

- Ultrasound Pelvis
- MRI Pelvis
- PAP smear from Cervix
- Endometrial biopsy, if there is suspicion of endometrial Ca
- Blood - Hb, TLC, DLC, ESR
- Blood – Platelets count
- Blood – PT(INR) and APTT
- Blood Creatinine

Treatment:

Uterine fibroid embolisation – The uterine artery is accessed endovascularly and the tip of the catheter / microcatheter is placed distal to the ovarian / cystic / cervical branch, and embolised with Poly Vinyl alcohol particles, till the flow becomes very sluggish.

Referral criteria:

Patients meeting the criteria for UFE should be referred to centers equipped with capability to perform UFE.

Follow up:

Patient would be admitted a day prior to the embolisation and managed as inpatient till 2-3 days till the pain and nausea gets tolerable. Thereafter Clinical follow up is done at 2 weeks, 6 weeks, 3 months and 6 months. During these follow up ultrasounds could be done to assess the size of the fibroid.

***Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited**

b) **Clinical Diagnosis:** As above

c) **Investigations:** As above

d) **Treatment:**

Standard Operating procedure: Patient would be assessed and evaluated by the primary gynecologist to rule out any other gynecological problems. Thereafter patient will be assessed by the interventional radiologist for the feasibility of embolisation. Most of the times the procedure would be done under local anesthesia and if required the anesthesiologist's consultation can be taken. The patient's uterine artery would then be accessed by endovascular

approach; the catheter tip will be placed beyond the branches to the ovary, urinary bladder and uterine cervix. Then polyvinyl alcohol particle would be injected for embolisation of the artery till the flow becomes sluggish.

- a. **In Patient:** UFE is to be done as inpatient.
 - b. **Out Patient:** no.
 - c. **Day Care:** no
- e) **Referral criteria:** As above

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

- g) **Clinical Diagnosis:** As above
- h) **Investigations:** As above
- i) **Treatment:** As above

Standard Operating procedure: As above.

- a. **In Patient** – The procedure will be done as an inpatient therapy
 - b. **Out Patient** – No
 - c. **Day Care** - No
- j) **Referral criteria:** As above.

VI. WHO DOES WHAT? and TIMELINES

Designation	Clinical Role	Timeline
Gynecologist	Clinical Evaluation and assessment of the gynecologic status of the patient. To rule out any other malignancy by PAP smear. Pharmacological control of bleeding and symptomatic management of pain till the embolisation is done. Patient to be informed about option of UFE and referred to interventional radiologist. Following this the patient should decide between hysterectomy / myomectomy / UFE	Screening on presentation to OP till the embolisation is performed. Post embolisation, to be followed up by gynecologist and interventional radiologist
Pathologist	To assess the PAP smear or any other	As soon as possible

	histopathology examination	
Diagnostic Radiologist	Imaging of the uterine pathology by USG or MRI	As soon as possible.
Interventional Radiologist	Assessment for feasibility for uterine fibroid embolisation	As soon as possible.
Biochemist	Biochemical evaluation	As soon as possible
Cardiologist	Cardiac evaluation	After consultation by and on the request of interventional radiologist for patients who are high risk for cardiac status
Interventional Radiologist	Performs the uterine fibroid embolisation	After the patient is declared fit for the procedure by the above timelines
Nursing Staff	Assist in managing the patient as In-patient in ward and in Interventional Radiology Suite	NA
Technician	Assist in Imaging the patient, assist the IR specialist in the IR suite, and manage the DSA images also.	NA

VII. FURTHER READING / REFERENCES

1. Quality improvement guidelines for uterine artery embolisation for symptomatic leiomyomata. DM Hovesejian, GP Siskin, J Bonn et al. CIRSE website.
2. Leiomyomata treated with uterine artery embolisation Factors Associate with successful symptom and Imaging outcome. JB Spies, AR Roth, BS Reena C Jha, Jackeline Gomez-Jorge, EB Levy, TC Chang, SA Ascher. Radiology 2002; 222:45-52.
3. Embolic Agents Used for Uterine Fibroid Embolization. GP Siskin, Meridith Englander, BF Stainken, JAhn, K Dowling, EG Dolen. AJR:175, Sept 2000, 767-773
4. Limited uterine artery embolisation with Trisacryl Gelatin Microspheres for Uterine fibroids. JP Pelage, O Le Dref, JP Beregi, M Nonent, Y Robert, M cosson, D Jacob, JB Turc. JVIR 2003; 14: 15-20
5. A multi-centre retrospective cohort study comparing the efficacy, safety and cost-effectiveness of hysterectomy and uterine artery embolisation for the treatment of symptomatic uterine fibroids. The HOPEFUL study. A Hirst, S Dutton, O Wu, A Briggs, C Edwards, L Waldenmaier, M Maresh, A Nicholson and K McPherson. Health Technology Assessment 2008; Vol. 12: No. 5

RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs and consumables and equipment. Quantity to also be specified)

SITUATION	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT(S)
1.	Doctors – (Gynaecologist– 1, Interventional Radiologist – 1, Diagnostic Radiologist -1, Technician(s) – 1, Nursing - 1	Hemoglobin, Random Blood Sugar, PT, APTT or INR, Platelet Count, Se. Creatinine, HBsAg, HIV	1. Drugs: MRI contrast media, Lignocaine, Nitroglycerine, , Heparin, Non Ionic radiographic contrast media 2. Consumables: Angiographic catheters – pigtail - 1, Cobra / sim2/uterine -1, Guidewire 0.035”– 1 Vascular sheath – 1 PVA particles – 2 vials	Ultrasound (1) MRI Digital Subtraction Angiography
2.	Doctors – (Gynaecologist– 1, Interventional Radiologist – 1, Diagnostic Radiologist -1, Technician(s) – 1, Nursing - 1	Hemoglobin, Random Blood Sugar, PT, APTT or INR, Platelet Count, Se. Creatinine, HBsAg, HIV	1. Drugs: Lignocaine, Nitroglycerine, , Heparin, Non Ionic radiographic contrast media 2. Consumables: Angiographic catheters – pigtail - 1, Cobra / sim2/uterine -1, Guidewire 0.035”– 1 Vascular sheath – 1 Microcatheter and guidewire – 1 each, PVA particles – 2 vials	Ultrasound (1) MRI Digital Subtraction Angiography System (1) Sterile Suite Multichannel invasive monitor (1) Resuscitation equipment (1) Crash Trolley (1)

Chemoembolization for unresectable hepatocellular carcinoma(HCC)

I. WHEN TO SUSPECT / RECOGNIZE ?

a) **Introduction** : The treatment of choice for HCC remains surgical resection or liver transplantation, however, in a non-surgical case a variety of percutaneous therapeutic interventional palliative treatment techniques such as transcatheter arterial chemoembolization (TACE), transcatheter arterial radio- embolization (TART) and percutaneous ablative therapies like radiofrequency ablation (RFA) are available (1-3).

d) **Case definition :**
For both situations of care (mentioned below*)

A clinically or radiologically suspected, biopsy or laboratory proved case of hepatocellular carcinoma.

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY : HCC is one of the common cancer and the cause of cancer related death in the world. Its incidence in India is also increasing due to increase in incidence of cirrhosis and hepatitis B&C.

III. DIFFERENTIAL DIAGNOSIS: Liver metastasis, benign hepatic lesion.

IV. PREVENTION AND COUNSELLING: Since HBV is the most common etiologic agent in our country, the vaccination against hepatitis B may be an effective preventive strategy.

The other cause such as alcohol induced cirrhosis may be avoided by avoidance of alcohol.

Proper counseling of patient by explaining him various non-surgical interventional treatment options and their outcome should be explained to every patient.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA :

Diagnostic criteria / investigations –

17. Clinical - features of cirrhosis & palpable mass.
18. Biochemical ó Serum alpha fetoprotein (AFP), viral markers (HBV & HCV)
19. Radiological ó Imaging features on US, CT & MR.
20. Histological ó Fine needle aspiration cytology or biopsy as & when required.

**Treatment - Chemoembolization for unresectable tumour with
child's class A & B.**

1. Tumour size > 5 cm in diameter.
2. Tumour size > 3 cm in diameter and 2 or 3 in number.
3. Treatable size tumour with ipsilateral portal vein invasion.

Referral criteria –

Patient fit for chemoembolization is treated with angiographic treatment. If angiographic facility is not available at the hospital, patient is referred to the hospital with such treatment facilities.

*** Situation 1 : At Secondary Hospital / Non-Metro situation : Optimal Standards of Treatment in situations where technology and resources are limited.**

- a) **Clinical Diagnosis:** Clinical features of cirrhosis &/or palpable mass.
- b) **Investigations :**
Biochemical ó Serum alpha fetoprotein (AFP), viral markers (HBV & HCV)
Radiological ó Imaging features on US, CT & MR.
Histological ó Fine needle aspiration cytology or biopsy as & when required.
- c) **Treatment : chemoembolization for unresectable tumour with
Child's class A & B.**

Standard operating procedure

- i. **In Patient** - Chemoembolization is performed as indoor case
- j. **Out Patient** - Not applicable
- k. **Day Care** - Not applicable

l. Referral criteria :

If facilities for standard treatment are not available, patient is referred to super specialty hospital where these facilities are available.

*** Situation 2 : At super specialty facility in metro location where higher-end technology is available.**

- a) **Clinical Diagnosis :** Clinical features of cirrhosis &/or palpable mass. b)
- Investigations :**

Biochemical ó Serum alpha fetoprotein (AFP), viral markers (HBV & HCV)
Radiological ó Imaging features on US, CT & MR.
Histological ó Fine needle aspiration cytology or biopsy as & when required.

**c) Treatment : Chemoembolization for unresectable tumour with
Child's class A & B.**

Standard operating procedure

- i. In Patient** - Chemoembolization is performed as indoor case
- j. Out Patient** - Not applicable
- k. Day Care** - Not applicable

- l. Referral criteria** : Not applicable

VI. WHO DOES WHAT ? and TIMELINES

- g. Doctor** : Physician performs clinical management. Radiologist performs imaging and interventional radiologist performs the interventional treatment.
- h. Nurse** : Assists in clinical management, during & post interventional treatment.
- i. Technician** : **performs imaging and** assists during interventional treatment.

VII. FURTHER READING / REFERENCES

1. Gu YK, Luo RG, Huang JH et al. Transarterial embolization ablation of HCC with lipiodol ó ethanol mixture. World J. Gastroenterology 2010 ; 16 (45) : 5766 ó 72.
2. Srivastava DN, Thulkar S, Sharma S, et al. Therapeutic radiological interventional procedures in hepatocellular carcinoma. Indian J. Gastroenterology 2002 ; 21 : 96 ó 98.
3. Kumar R, Saraswat MK, Sharma BC et al. Characteristics of hepatocellular carcinoma in India : a retrospective analysis of 191 cases. Oxford J. Medicine 2008 ; 101 (6) : 479 ó 485.

RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs and consumables and equipment. Quantity to also be specified)

Situation	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT
1.	(Radiologists-2 Anaesthetist -1 Clinician - 1) Technicians 02 Nurses 02 Orderly / Ward Boy - 2	1. Routine blood examination Hb, TLC, DLC etc. 2. S. alfa fetoprotein 3. Serum HBV & HCV 4. Liver function tests 5. Blood sugar etc	1. Doxorubicin 50 ó 100 mg. 2. Other chemotherapeutic drugs as per case 3. Lipiodol 20 ml 4. Angiographic catheters (4 ó 5 F) 5. Microcatheter (3F) 6. Gel foam 7. PVA 3/4 vials	Digital subtraction angiography equipment with life saving devices and Ultrasound (colour Doppler) equipment
2.	Same as mentioned above	Same as mentioned above	Same as mentioned above	Same as mentioned above

Radiofrequency Ablation (RFA) in Hepatocellular carcinoma and liver metastases

I. WHEN TO SUSPECT / RECOGNIZE?

- a) **Introduction:** The best treatment for hepatocellular carcinoma (HCC) is either surgical resection of the tumour or transplantation of the liver. However, in a patient who is unsuitable for surgery, a variety of percutaneous interventional treatment options are available to treat HCC or liver metastases like transcatheter arterial chemoembolization (TACE), transcatheter arterial radio-embolization (TARE) and ablative therapies like radiofrequency ablation (RFA) (1,2).
- b) **Case definition:** A clinically suspected case of hepatocellular carcinoma or colorectal liver metastases which has been proven by imaging, biopsy and laboratory parameters.

II. INCIDENCE OF THE CONDITION IN OUR COUNTRY: HCC and metastases form the commonest group of malignancies involving the liver. These are the leading causes of deaths due to malignancy. Its incidence in India is increasing due to the increase in the prevalence of liver cirrhosis and liver infections caused by hepatitis viruses B and C (3).

III. DIFFERENTIAL DIAGNOSIS: Benign hepatic lesions. These can be differentiated in most cases by imaging findings.

IV. PREVENTION AND COUNSELLING: Since the Hepatitis B virus is a common cause of HCC in our country, an effective preventive strategy could be vaccinations against hepatitis B. Alcohol induced liver cirrhosis could be prevented by avoiding alcohol and de-addiction programs. Counseling of the patient by explaining various non-surgical interventional treatment options and their outcome would be beneficial.

V. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT AND REFERRAL CRITERIA:

Diagnostic criteria/investigations:

1. Clinical – Finding suggestive of liver cirrhosis and its complications. Sometimes a liver mass is palpable.
2. Biochemical – Serum alpha fetoprotein (AFP), viral markers (HBV & HCV)
3. Radiological – Imaging features on US, CT and MR.
4. Histological – Fine needle aspiration cytology or biopsy as required.

Treatment: Radiofrequency ablation of HCC and metastases (4,5)

1. A single tumour sized less than or equal to 5 cm in diameter.
2. Multiple tumours sized less than 3 cm in diameter and two to three in number.

Referral criteria: A patient found suitable for treatment with radiofrequency ablation is best treated with radiofrequency ablation (6). If this facility is not available at the hospital, patient should be referred to another hospital having such treatment facilities.

*** Situation 1 : At a secondary hospital or non-metro situation where technology and resources for optimal standards of treatment are limited.**

45. Clinical Diagnosis : Finding suggestive of liver cirrhosis and its complications. Sometimes a liver mass is palpable.

46. Investigations:

Biochemical – Serum alpha fetoprotein (AFP), viral markers (HBV & HCV) **Radiological** – Imaging features on US, CT and MR

Histological – Fine needle aspiration cytology or biopsy as required

47. Treatment: Radiofrequency ablation of HCC and Metastases

- A single tumour size less than or equal to 5 cm in diameter.
- Multiple tumours size less than 3 cm in diameter and two to three in number.

Standard operating procedures

- a. In patient- Radiofrequency ablation should be performed as indoor case..
- b. Out patient- not applicable
- c. Day care- not applicable.
- d. Referral criteria: If this facility for RFA is not available at the hospital, patient should be referred to another hospital having such treatment facilities.

*** Situation 2: At a super specialty facility in a metro location where high-end technology is available.**

1. Clinical Diagnosis : Finding suggestive of liver cirrhosis and its complications. Sometimes a liver mass is palpable.

2. Investigations:

Biochemical – Serum alpha fetoprotein (AFP), viral markers (HBV and HCV). **Radiological** – Imaging features on US, CT & MR.

Histological – Fine needle aspiration cytology or biopsy as required.

3. Treatment: Radiofrequency ablation of HCC and colorectal metastases to the liver

- A single tumour sized less than or equal to 5 cm in diameter.
- Multiple tumours sized less than 3 cm in diameter and two to three in number.

Standard operating procedures

- II.** In patient – Radiofrequency ablation should be performed as indoor case.
- III.** Out patient - Not applicable
- IV.** Day care - Not applicable
- V.** Referral criteria- Not applicable

VI. WHO DOES WHAT? and TIMELINES

- a. Doctor: Diagnosis and interventional treatment.

- b. Nurse: Assistance in patient care before, during and after interventional treatment.
- c. Radiography technologist: Assistance in imaging of the patient before, during and after interventional treatment.

RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 Kg)

Situation	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT
1.	Doctors – 4 (Clinician - 1 Anaesthetist -1 Radiologists-2 out of which at least one should be an interventional radiologist) Radiography technologists –2 Nurses – 2 Orderly/ward Boys – 2	1. Routine blood examination- Hb, TLC, DLC etc. 2. S. alfafetoprotein 3. Se HBV & HCV 4. Liver function tests 5. Blood sugar	Local anaesthetic and sedatives.	Radiofrequency equipment (1), Ultrasound scanning machine (1), Anesthesia and monitoring equipment (1), Resuscitation equipment with crash trolley (1)
2.	Same as mentioned above	Same as mentioned above	Same as mentioned above	Same as mentioned above

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NAME OF THE CONDITION: PERIPHERAL ARTERIAL DISEASE

IV. When to suspect or recognize?

Peripheral Arterial Disease should be suspected for adults 50 years and older who have atherosclerosis risk factors. Likewise for adults 70 years and older with complaints of fatigue, aching, numbness or pain in the lower extremity or any history of walking impairment (suggesting exertional limitation of the lower extremity muscles), pain at rest localized to the lower leg or foot and its association with the upright or recumbent positions and poorly healing or non-healing wounds of the legs or feet(1).

c) Introduction

The term "Peripheral Arterial Disease (PAD)" broadly encompasses the vascular diseases caused primarily by atherosclerosis and thromboembolic pathophysiological processes that alter the normal structure and function of the aorta, iliac and the arteries of the lower extremity. Patients with PAD have an increased risk of mortality, myocardial infarction, and cerebrovascular disease. They also suffer from significant functional limitations in their daily activities, and the most severely affected are at risk of limb loss.

d) Case definition

Peripheral arterial disease (PAD) is the preferred clinical term that should be used to denote stenotic and occlusive diseases of the aorta and its branch arteries, exclusive of the coronary arteries.

V. Incidence of the condition in our country

It is underdiagnosed, undertreated, and much more common than previously thought. Incidence of the condition in our country is not exactly known due to lack of organized data. A strong association exists between advancing age and the prevalence. Almost 20% of adults older than 70 years have PAD. An American survey of 2174 patients older than 40 years of age used the Ankle-Brachial Index (ABI) as a screening tool, and showed a PAD prevalence of 0.9% between the ages of 40 and 49 years, 2.5% between the ages of 50 and 59 years, 4.7% between the ages of 60 and 69 years, and 14.5% for the ages of 70 years and older(2).

Differential Diagnosis

Differential Diagnosis of Intermittent Claudication						
Condition	Location of Pain or Discomfort	Characteristic Discomfort	Onset Relative to Exercise	Effect of Rest	Effect of Body Position	Other Characteristics
Intermittent claudication	Buttock, thigh, or calf muscles and rarely the	Cramping, aching, fatigue, weakness, or frank pain	After same degree of exercise	Quickly relieved	None	Reproducibl e

	foot					
Nerve root compression (e.g., herniated disc)	Radiates down leg, usually posteriorly	Sharp lancinating pain	Soon, if not immediately after onset	Not quickly relieved (also often present at res)	Relief may be aided by adjusting back position	History of back problems
Spinal stenosis	Hip, thigh, buttocks (follows dermatome)	Motor weakness more prominent than pain	After walking or standing for variable lengths of time	Relieved by stopping only if position changed	Relief by lumbar spine flexion (sitting or stooping forward)	Frequent history of back problems, provoked by intra-abdominal pressure
Arthritic, inflammatory processes	Foot, arch	Aching pain	After variable degree of exercise	Not quickly relieved (and may be present at rest)	May be relieved by not bearing weight	Variable, may relate to activity level
Hip arthritis	Hip, thigh, buttocks	Aching discomfort, usually localized to hip and gluteal region	After variable degree of exercise	Not quickly relieved (and may be present at rest)	More comfortable sitting, weight taken off legs	Variable, may relate to activity level, weather changes
Symptomatic Baker's cyst	Behind knee, down calf	Swelling, soreness, tenderness	With exercise	Present at rest	None	Not intermittent
Venous claudication	Entire leg, but usually worse in thigh and groin	Tight, bursting pain	After walking	Subsides slowly	Relief speeded by elevation	History of iliofemoral deep vein thrombosis, signs of venous congestion, edema
Chronic compartment syndrome	Calf muscles	Tight, bursting pain	After much exercise (e.g., jogging)	Subsides very slowly	Relief speeded by elevation	Typically occurs in heavy muscled athletes

Adapted from J Vasc Surg, 31, Dormandy JA, Rutherford RB, for the TransAtlantic Inter-Society Consensus (TASC) Working Group, Management of peripheral arterial disease. (PAD), S16S296, Copyright 2000

VI. Prevention and Counselling

Individuals at risk for lower extremity disease should undergo a vascular review of symptoms to assess walking impairment, claudication, ischemic rest pain and/or the presence of non-healing wounds.

Aggressive lifestyle modification to reduce underlying risk factors (e.g. atherogenic diet, overweight or obesity, physical inactivity), to control risk factors such as diabetes, hypertension and hyperlipidemia are recommended for individuals with asymptomatic lower extremity PAD.

VII. Optimal Diagnostic Criteria, Investigations, Treatment & Referral Criteria -

Diagnostic Criteria

PAD is considered in the following clinical setting -

- iv) Adults 50 years and older who have atherosclerosis risk factors and
- v) Adults 70 years and older with the following symptoms -
 - Fatigue, aching, numbness or pain in the lower extremity or any history of walking impairment (suggesting exertional limitation of the lower extremity muscles)
 - Pain at rest localized to the lower leg or foot and its association with the upright or recumbent positions.
 - Poorly healing or non-healing wounds of the legs or feet.

Acute limb ischemia (ALI) - refers to a rapid decrease of perfusion in the affected extremity that requires urgent revascularization to preserve tissue viability. Complications include rhabdomyolysis and renal failure.

Chronic Limb Ischemia (CLI) - refers to a chronic, severely compromised arterial blood supply in the affected extremity that manifests as ischemic pain at rest, ulcers or gangrene in various combinations.

Investigations

1. Measurement of Ankle-Brachial Index (ABI)

2. Color Doppler evaluation –

Color flow and pulsed wave Doppler allows an estimation of the stenosis severity on the basis of Doppler-derived velocity criteria. It is an accurate method for determining the degree of stenosis or length of occlusion of the arteries supplying the lower extremity. It is also useful in the follow-up of patients who have undergone endovascular (percutaneous transluminal angioplasty/stent) or surgical revascularization.

3. Magnetic Resonance Angiography (MRA) -

Magnetic resonance angiography (MRA) of the aorta and peripheral vasculature can be performed rapidly with excellent image quality. Being noninvasive, it is virtually replacing invasive diagnostic angiography as the primary modality for vascular imaging. Determining the

type of intervention is feasible on a technically adequate MRA study. However, availability of the scanners with capability for peripheral vascular imaging and patients with relative contraindications to MR evaluation limits the utilization.

4. Computed Tomographic Angiography (CTA) -

Higher spatial resolution, absence of flow-related phenomena that may distort MRA images and the capacity to visualize calcification and metallic implants such as endovascular stents or stent grafts is an advantage with CTA when compared with MRA. Its advantages over invasive angiography include volumetric acquisition, improved visualization of soft tissues and other adjacent anatomic structures, less invasiveness and thus fewer potential complications. Exposure to ionizing radiation and the need for iodinated contrast medium limits its utilization as also availability of scanners with capability for peripheral vascular imaging.

5. Digital Subtraction Angiography (DSA) -

Vascular imaging with ultrasonography, CTA, and MRA has replaced catheter-based techniques in the initial diagnostic evaluation in most circumstances. The major advantage of DSA is the ability to selectively evaluate individual vessels, obtain physiologic information such as pressure gradients and as a platform for percutaneous intervention. Exposure to ionizing radiation, use of iodinated contrast agents, and risks related to vascular access and catheterization are limitations of this technique.

Treatment

Two major strategies for treatment are:

- (3) To improve symptoms and quality of life with medical therapy alone or with percutaneous / surgical revascularization and
- (4) To prevent cardiovascular events with a comprehensive program that includes smoking cessation, an exercise program, control of blood pressure, achievement of goal LDL-C, antiplatelet therapy, and control of diabetes.

Asymptomatic Lower Extremity PAD -

1. Smoking cessation, lipid lowering, diabetes and hypertension treatment.
2. Antiplatelet therapy - to reduce the risk of adverse cardiovascular ischemic events.
3. Angiotensin-converting enzyme (ACE) inhibition.

Symptomatic Lower extremity PAD –

Medical Management-

Best medical treatment is considered the main therapeutic pillar in patients with PAD. These patients are at increased risk for major adverse cardiovascular events (MACE) and cardiovascular death. Antithrombotic, antihypertensive and lipid lowering therapy has been

shown to reduce the relative risk by 25% each. Medication should only be used in combination with aggressive lifestyle modification to reduce underlying lifestyle risk factors as mentioned above.

Revascularization

Before offering revascularization, a predicted or observed lack of adequate response to exercise therapy and claudication pharmacotherapies must be considered. Three clear indications for revascularization in patients with PAD are ischemic rest pain, ischemic ulcers or gangrene, and claudication that interfere with the patient's lifestyle.

Revascularization by endovascular or surgical means, will be guided by the lesion morphology based on TASC II (Trans Atlantic Society Consensus) document criteria, where TASC A & B lesions are treated by endovascular approach and type D lesion are treated surgically. TASC C lesions can be attempted by endovascular approach and if the same fails, surgery is resorted to.

Endovascular procedures for revascularization depend upon whether the clinical presentation is acute or chronic and whether it is because of thrombotic occlusion or steno-occlusive lesion. Acute thrombotic occlusions are treated by Catheter directed thrombolysis, whereas chronic occlusions may require mechanical thrombectomy. Stenosis and short length occlusions (TASC A & B) are treated by Angioplasty & Stenting. Diffuse atheromatous plaques causing stenosis require Plaque Excisional Atherectomy. Long length occlusions in Iliac and SFA may yield to subintimal angioplasty followed by stent insertion if needed.

Referral Criteria

*Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited:

a) Clinical Diagnosis: Same diagnostic criteria as above.

b) Investigations: Following thorough clinical evaluation, following investigations are required -

- Measurement of Ankle-Brachial Index (ABI) & hand held vascular doppler
- Color Doppler Sonography
- Magnetic Resonance Angiography (MRA) or Computed Tomographic Angiography (CTA)

c) Treatment:

Asymptomatic Lower Extremity PAD - Smoking cessation, lipid lowering, diabetes and hypertension treatment. Antiplatelet therapy - to reduce the risk of adverse cardiovascular ischemic events (10, 11).

Symptomatic Lower extremity PAD ó Best medical treatment is considered the main therapeutic pillar in patients with PAD. These patients are at increased risk for major adverse cardiovascular events (MACE).

Symptomatic Lower extremity PAD:

- c) Modification of lifestyle to improve diet and physical activity and to control obesity, diabetes, hypertension and hyperlipidemia.
- d) Medical treatment with antithrombotic, antihypertensive and lipid lowering drugs.
- e) Revascularization, either endovascular or surgical (12).

Standard Operating Procedure

- a. Out Patient / Day Care – Asymptomatic and symptomatic patients with less severe symptoms are treated on an Outpatient or Day Care basis.
- ii) Referral criteria: Patients may be referred to higher medical facility based upon -
 - Worsening of symptoms despite adequate medical management including aggressive lifestyle modification or
 - Patient presents with acute limb ischemia (ALI) where immediate limb salvage is required.

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

Clinical Diagnosis: Same diagnostic criteria as above.

Investigations:

1. Measurement of Ankle-Brachial Index (ABI) & hand held vascular doppler
2. Color Doppler Sonography
3. Magnetic Resonance Angiography (MRA) or
4. Computed Tomographic Angiography (CTA)
5. Digital Subtraction Angiography (DSA)

Treatment:

Asymptomatic Lower Extremity PAD –

1. Smoking cessation, lipid lowering, diabetes and hypertension treatment.
2. Antiplatelet therapy - to reduce the risk of adverse cardiovascular ischemic events.

Symptomatic Lower extremity PAD –

1. Aggressive lifestyle modification to reduce underlying lifestyle risk factors (e.g. atherogenic diet, overweight/obesity, physical inactivity) to control risk factors such as diabetes, hypertension and hyperlipidemia.

2. Medical treatment with antithrombotic, antihypertensive and lipid lowering therapy is given to reduce the relative risk of adverse events.
3. Revascularization – endovascular or surgical

Standard Operating procedure

- a) Out Patient - Asymptomatic and symptomatic patients with less severe symptoms are treated on an Outpatient or Day Care basis.
- b) In Patient - Symptomatic patients requiring revascularization will need hospitalization for minimum duration depending upon endovascular or surgical approach, where the former approach requires shorter hospital stay. Similarly patients with major adverse cardiovascular events will need hospitalization to treat the adverse events.

Referral Criteria:

1. Worsening of symptoms despite adequate medical management including aggressive lifestyle modification or patient presents with acute limb ischemia where immediate limb salvage is required.

Who does what? And Timelines

Designation	Clinical Role	Timeline
Physician (Internist)	Clinical Evaluation	Screening on presentation to OP
Vascular Surgeon (VS)	Clinical Evaluation & supervising vascular evaluation	Specialist Consultant who becomes the primary care Physician once diagnosis is established
	Performs Vascular Surgery	When indicated or when IR procedures fail.
Biochemist	Biochemical evaluation	After evaluation by and on the request of VS
Diagnostic Radiologist	Perform Duplex Doppler Sonography, Evaluate CTA or MRA	After evaluation by and on the request of VS
Cardiologist	Cardiac evaluation	After consultation by and on the request of VS
	Management of MACE	If necessary, following VS consult and on the request of VS
Interventional Radiologist	IR Procedures – PTRAs & Stenting, Thrombolysis, Mechanical thrombectomy, Subintimal Angioplasty	Referring Specialist for IR procedures on the request of VS

	etc.	
Nursing Staff	Assist in managing the patient	In-patient or Day Care in Vascular Surgery facility, Dialysis facility and Interventional Radiology facility
Technician	Assist in Imaging the patient	In CT,MR and Interventional Radiology facility after Radiology & IR consultation

RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs & consumables and equipment. Quantity to also be specified)

SITUATION	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT(S)
1.	Doctors – (Internist – 1, Vascular Surgeon – 1, Diagnostic Radiologist -1, Technician(s) – 3, Nursing - 2	Hemoglobin, Random Blood Sugar, PT, APTT or INR, Platelet Count, Se. Creatinine, HBsAg, HIV	1. Drugs: Aspirin, Clopidogrel, Nitroglycerine, Nimodipine, Heparin	Vascular Doppler(1) Color Doppler Ultrasound (1) MDCT or MRI with facility for Vascular Imaging (1)
2.	Doctors – (Internist – 1, Vascular Surgeon with – 1, Diagnostic Radiologist -1, Interventional Radiologist – 1, Anaesthetist -1) Technician(s) – 3 to 4 Nurses – 3 to 4 for all the units	Hemoglobin, Random Blood Sugar, PT, APTT or INR, Platelet Count, Se. Creatinine, HBsAg, HIV	1. Drugs: Aspirin, Clopidogrel, Nitroglycerine, Nimodipine, Heparin, Non Ionic radiographic contrast media 2. Consumables: Arterial access device, Diagnostic Catheter, Guiding catheter, Self expanding or balloon expanding Stent, Pre and post dilatation angioplasty balloon(s), Compatible guidewire (s)	Vascular Doppler(1) Operation Theatre (1) Color Doppler Ultrasound (1) MDCT or MRI with Vascular Imaging (1) Digital Subtraction Angiography System (1) Sterile Suite Multichannel

				invasive monitor (1)
				Resuscitation equipment (1)
				Crash Trolley (1)

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NAME OF THE CONDITION: RENOVASCULAR HYPERTENSION

When to suspect or recognize?

Renovascular hypertension should be suspected or recognized whenever there is any of the following(1) -

- Onset of hypertension occurring in patients younger than 30 years without risk factors
- Abrupt onset of severe hypertension in patients older than 55 years
- Severe or resistant hypertension despite appropriate antihypertensive therapy
- Abrupt increase in blood pressure over previously stable baseline in patients with previously well-controlled essential hypertension as well as patients with known RAS
- Negative family history for hypertension
- History of smoking tobacco products
- Symptoms of atherosclerotic disease elsewhere in the presence of moderate-to-severe hypertension, particularly in patients older than 50 years
- Recurrent flash pulmonary edema in the setting of moderate-to-severe hypertension

Introduction:

Although hypertension is most often ðessentialö or idiopathic in origin, renovascular disease is an important and potentially remediable cause of both hypertension and progressive renal insufficiency. The coexistence of renal arterial vascular disease and hypertension defines this type of nonessential hypertension. Renal artery stenosis may be caused by a heterogeneous group of conditions, but > 90% of cases is accounted for by atherosclerotic renovascular disease or fibromuscular dysplasia of the renal artery. Takayasuø arteritis is a less common cause. Thrombosis, embolism and dissection of the renal artery are rare causes(2).

Case definition:

Renovascular hypertension (RVHT) is the hypertension secondary to renal artery stenosis. It denotes the causal relationship between anatomically evident arterial occlusive disease and elevated blood pressure. Hemodynamically significant RAS should be defined as either: 1) Severe (> 70%) angiographically confirmed stenosis, or 2) moderate (50-70%) stenoses as determined by angiography that are accompanied by hemodynamic evidence of renal ischemia documented by either a hyperemic systolic gradient > 20 mmHg, or renal fractional flow reserve of < 0.8.

Incidence of the condition in our country:

It is the most common type of secondary hypertension, accounting for 1-5% of cases in unselected populations and as many as 30% of cases in selected populations. The prevalence may be up to 60% in patients older than 70 years. In general, the prevalence of atherosclerotic RAS increases with age, particularly in patients with diabetes, aortoiliac occlusive disease, coronary artery disease or hypertension.

Differential Diagnosis:

Prevention and Counselling:

Preventing atherosclerosis may prevent the development of renal artery stenosis. Lifestyle changes may reduce risk of high blood pressure. Cessation of smoking, maintenance of healthy

weight, low cholesterol and lipid levels, regular exercise and diet with low protein, low sodium and high fiber content helps control blood pressure(3).

Optimal Diagnostic criteria, Investigations, Treatment & Referral Criteria -

Diagnostic Criteria:

Clinical presentation is protean. In addition to elevated systemic blood pressure, renovascular hypertension usually produces symptoms common to hypertensive states, such as headache, palpitations, tachycardia, anxiety, light-headedness, decreased tolerance of temperature extremes, retinopathy, and mental sluggishness. Significant complications include heart failure, myocardial infarction, stroke and, occasionally, renal failure.

A high index of clinical suspicion may help in picking-up such patients. In particular, hypertensive patients with extensive atherosclerotic disease in other areas are prime candidates. Hypokalaemia, an abdominal bruit, the absence of a family history of essential hypertension, duration of hypertension of less than one year, and the onset of hypertension before the age of 50 years are suggestive.

Investigations:

Investigations comprise tests to assess overall renal function, perfusion studies to assess differential renal blood flow, and imaging studies to identify renal artery stenosis. Imaging studies establish the diagnosis; assess the location and severity of the clinically suspected RAS.

Hematological Studies – To assess overall renal function, blood urea, serum creatinine, creatinine clearance and e GFR studies are needed.

Duplex renal artery sonography - following clinical and laboratory evaluation, Duplex Doppler Sonography is the first line of imaging. It helps direct visualization of the renal arteries with measurement of various hemodynamic changes in the main renal artery with Doppler, providing both structural and functional assessment of renovascular hypertension. Additional information regarding kidney size and presence of hydronephrosis can be obtained by ultrasound. Doppler for renal artery evaluation is limited by operator dependency, obesity and bowel gas artifacts.

Captopril Scintigraphy adds valuable information regarding revascularization. The study relies on the effect of captopril, an angiotensin-converting enzyme inhibitor, to reduce glomerular filtration in an ischemic kidney and increase it in the contralateral normal kidney. This difference can be imaged under a gamma camera. Asymmetry of flow or unilateral delayed isotope appearance but good bilateral renal concentration and excretion are strongly suggestive of large renal artery vascular occlusive disease that might be cured by revascularization. Test results may be falsely negative in the presence of bilateral disease.

Magnetic Resonance Angiography – Magnetic resonance angiography (MRA) is a noninvasive test for assessing renal artery stenosis, especially among patients with renal insufficiency at higher risk for contrast nephropathy. Evaluates not only the main renal arteries but also the accessory renal arteries and distal stenosis. The reliability of magnetic resonance angiography is not affected by the presence of bilateral renovascular disease unlike scintigraphy. MRA may overestimate the severity of stenosis relative to angiography.

Computed Tomographic Angiography – CT angiography (CTA) especially with MDCT is a valuable noninvasive study for assessing renal artery stenosis. If the patient has normal renal function, this probably represents the best screening test. It is much faster to perform than MRA, is less prone to false positive results, and has superior spatial resolution. It is not limited by flow related artifacts and presence of mural calcification. Evaluates not only the main renal artery but also the accessory renal arteries and distal stenosis. Subset of patients not suitable for MRA can be evaluated by CTA.

Digital Subtraction Angiography - remains the gold standard to determine the degree and location of renal artery stenosis. With the availability of noninvasive imaging, DSA is reserved to confirm the diagnosis, often as a prelude to percutaneous intervention. However, it is limited in providing information about the functional role and thus the clinical significance of the lesion. Use of Iodinated contrast and related nephropathy limit its use(4).

Treatment:

Management of RAS should ideally control hypertension, restore renal function (renal salvage) and ultimately reduce cardiovascular mortality in the long term. Revascularization of the ischemic kidney helps to preserve renal function as well as lower blood pressure. Once the lesion is found and proved to be functionally significant, three modalities of management are available:

1. Medical therapy
2. Angioplasty and stenting
3. Surgery

Relative merits of the different types of treatment depend on a variety of factors such as the age of the patient, the etiology and severity of the renal artery stenosis, and the presence or absence of concomitant disease(3).

Medical Management: ACE inhibitors are widely accepted as being superior to other antihypertensive drugs in controlling renovascular hypertension. Furthermore, ACE inhibitors have been associated with improved survival of these patients, many of whom carry a heavy burden of generalized atherosclerotic disease.

Endovascular Management: Percutaneous Transluminal Renal Angioplasty & Stenting (PTRA) - For patients with symptomatic, hemodynamically significant RAS, reperfusion by angioplasty and stent placement is the treatment of choice (4-10). Patients with significant RAS who benefit most are those with:

- 1) Poorly controlled hypertension on adequate medical therapy - with hemodynamically significant renal artery stenosis and accelerated hypertension, resistant hypertension, and malignant hypertension.
- 2) Ischemic nephropathy in a viable kidney with declining renal function - with renal artery stenosis and progressive chronic kidney disease with bilateral renal artery stenosis or a stenosis to a solitary functioning kidney.

- 3) Cardiac destabilization syndromes, *i.e.*, flash pulmonary edema, recurrent congestive heart failure or refractory unstable angina - with hemodynamically significant renal artery stenosis (*i.e.*, >70% stenosis on angiography) and recurrent, unexplained congestive heart failure or sudden, unexplained pulmonary edema.

Referral Criteria:

***Situation 1: At Secondary Hospital / Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited:**

Clinical Diagnosis:

Clinical presentation is protean. In addition to elevated systemic blood pressure, renovascular hypertension usually produces symptoms common to hypertensive states, such as headache, palpitations, tachycardia, anxiety, light-headedness, decreased tolerance of temperature extremes, retinopathy, and mental sluggishness. Significant complications include heart failure, myocardial infarction, stroke and, occasionally, renal failure.

A high index of clinical suspicion may help in picking-up such patients. In particular, hypertensive patients with extensive atherosclerotic disease in other areas are prime candidates. Hypokalaemia, an abdominal bruit, the absence of a family history of essential hypertension, duration of hypertension of less than one year, and the onset of hypertension before the age of 50 years are suggestive.

Investigations:

1. Biochemical studies to assess overall renal function.
2. Imaging studies to identify renal artery stenosis and to assess the location and severity of the clinically suspected RAS.

Hematological Studies – To assess overall renal function, blood urea, serum creatinine, creatinine clearance and e GFR studies are needed.

Duplex renal artery Sonography - First line of imaging following clinical and laboratory evaluation. It helps by direct visualization of the renal arteries with measurement of various hemodynamic changes in the main renal artery with Doppler, providing both a structural and a functional assessment.

Once suspected, the patient can be referred to tertiary care center for further evaluation and management.

Treatment:

Medical Management: ACE inhibitors are widely accepted as being superior to other antihypertensive drugs in controlling renovascular hypertension. Furthermore, ACE inhibitors have been associated with improved survival of these patients, many of whom carry a heavy burden of generalized atherosclerotic disease.

Standard Operating Procedure

Out Patient: Medical management for RVHT without complications can be done on an outpatient basis.

Day Care: If patient is on maintenance hemodialysis, day care is needed.

In Patient: To manage complications of RVHT such as heart failure, myocardial infarction, stroke and, occasionally, renal failure patients may require hospitalization.

Referral criteria:

Poorly controlled hypertension on adequate medical therapy, Ischemic nephropathy in a viable kidney with declining renal function, Cardiac destabilization syndromes, *i.e.*, flash pulmonary edema, recurrent congestive heart failure or refractory unstable angina are the indications for referring for further aggressive management.

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

Clinical Diagnosis: Criteria same as in Situation 1

Investigations: Required to establish the diagnosis, assess the location and severity of the clinically suspected RAS.

1. Studies to assess overall renal function
2. Physiological studies to assess the renin ó angiotensin system
3. Perfusion studies to assess differential renal blood flow and
4. Imaging studies to identify renal artery stenosis

Biochemical evaluation

Duplex Doppler Sonography of renal artery

Captopril Scintigraphy

Magnetic Resonance Angiography (MRA)

Computed Tomographic Angiography (CTA)

Digital Subtraction Angiography (DSA)

Treatment:

Medical Management: ACE inhibitors are widely accepted as being superior to other antihypertensive drugs in controlling renovascular hypertension.

Endovascular Management (Percutaneous Transluminal Renal Angioplasty & Stenting) - For patients with symptomatic, hemodynamically significant RAS, reperfusion by angioplasty and stent placement is the treatment of choice. Patients with significant RAS who have 1) poorly controlled hypertension despite adequate medical therapy, 2) Ischemic nephropathy in a viable kidney with declining renal function, 3) Cardiac destabilization syndromes, *i.e.*, flash pulmonary edema, recurrent congestive heart failure or refractory unstable angina are the subset who will benefit from revascularization.

Standard Operating procedure

In Patient: For revascularization procedures, such as Percutaneous Transluminal Renal Angioplasty & Stenting (PTRA), patient needs admission into the hospital for minimum three to four days. To manage complications of RVHT such as heart failure, myocardial infarction, stroke and occasionally, renal failure the duration of stay may be longer.

Day Care: If patient is on maintenance hemodialysis, day care is needed.

Out Patient: Medical management is done on an outpatient basis.

Referral criteria:

Poorly controlled hypertension on adequate medical therapy, Ischemic nephropathy in a viable kidney with declining renal function, Cardiac destabilization syndromes, *i.e.*, flash pulmonary edema, recurrent congestive heart failure or refractory unstable angina are the indications for referring for further aggressive management.

Who does what? And Timelines

Designation	Clinical Role	Timeline
Physician (Internist)	Clinical Evaluation	Screening on presentation to OP
Biochemist	Biochemical evaluation	Following evaluation by Physician
Nephrologist	Specific management including Dialysis, if needed	Specialist Consultant who becomes the primary care Physician once diagnosis is established
Diagnostic Radiologist	Perform Duplex Doppler Sonography, Evaluate CTA or MRA	Following evaluation by Nephrologist
Cardiologist	Management of Cardiac complications	When indicated
Interventional Radiologist	PTRA & IR management of vascular complications, if any	Referring Specialist for IR procedures on the request of Nephrologist
Nursing Staff	Assist in managing the patient	In-patient or Day Care in Nephrology or Dialysis facility and Interventional Radiology facility
Technician	Assist in Imaging the patient	In CT,MRI and Interventional Radiology facility after Radiology & IR consultation

CTA=CT Angiography, MRA=MR Angiography, PTRA=Percutaneous Transluminal Renal Angioplasty, IR = Interventional Radiology, CT=Computed Tomography, MR=Magnetic Resonance Imaging

RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs and consumables and equipment. Quantity to also be specified)

Situation	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT
1	Doctors - 6 (Physician, Biochemist, Nephrologist, Diagnostic Radiologist, Cardiologist, Interventional Radiologist) Nursing – 6 - 8 Technician – 4 - 6	Hematological Imaging -Duplex Doppler Sonography	-Antihypertensive drugs	- Hematological laboratory - Color Doppler Ultrasound (1)
2	Doctors - 4 Nursing - 4 Technician – 6	Hematological Imaging: - Duplex Doppler Sonography - Radionuclide Scintigraphy - CTA or MRA - DSA (PTRA with Stenting)	-Antihypertensive drugs -Anticoagulants -Vasodilators -Radioisotopes -Radiographic Contrast medium -Parenteral fluids etc. -Vascular access devices -Catheters for diagnostic angiography -Compatible guiding catheter -Compatible guidewire -Stent -Inflatable infusion bag(s)	-Hematological laboratory -Color Doppler Ultrasound (1) -SPECT (1) -CT or MRI Scanner (1) -DSA equipment (1)

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VERTEBROPLASTY

VIII. WHEN TO SUSPECT/ RECOGNIZE?

1a Introduction: Vertebroplasty is injection of bone cement into a diseased vertebra, Percutaneously, under image guidance. This is done to provide pain relief and to strengthen the diseased vertebra.

1b Indications:

It is indicated under the following conditions for near immediate pain relief / where prolonged bed rest is contraindicated / pain relief is inadequate with analgesics:

1. Painful osteoporotic collapse vertebra
2. Painful metastatic collapse vertebra
3. Painful Hemangioma of vertebra
4. Post traumatic painful partial collapse in a non osteoporotic vertebra without retropulsion causing cord compression

IX. INCIDENCE OF THE CONDITION IN OUR COUNTRY: Osteoporosis and malignancy have a world wide distribution. Cancer is the leading cause of death. Osteoporosis is inevitable with age.

X. DIFFERENTIAL DIAGNOSIS N/A

XI. PREVENTION AND COUNSELING: Early diagnosis of osteoporosis and malignancy and their appropriate treatment will reduce the incidence of osteoporotic collapse vertebrae and of metastases. This can reduce the incidence of vertebral collapse.

XII. OPTIMAL DIAGNOSTIC CRITERIA, INVESTIGATIONS, TREATMENT & REFERRAL CRITERIA / FOLLOW UP

Diagnostic Criteria:

- Vertebral tenderness
- Radiograph Spine – shows partial collapse of vertebral body that s tender

- MRI – shows marrow edema in the vertebral body
- Radiograph and MRI – Not suggestive of infective etiology
- Bone biopsy to be done along with vertebroplasty if MRI suggests metastatic possibility

Investigations:

- Radiograph of Spine – AP and Lateral views
- MRI Spine
- Blood - Hb, TLC, DLC
- Blood – Platelets count
- Blood – INR
- Blood Creatinine

Treatment:

Vertebroplasty

As required for etiology of partial collapse, such as for malignancy or Osteoporosis

Referral criteria:

Patients meeting the criteria for vertebroplasty should be referred to centers equipped with capability to perform vertebroplasty

Follow up:

Clinical after 1 week

Subsequent follow up should be if there is recurrence of symptoms.

***Situation 1: At Secondary Hospital/ Non-Metro situation: Optimal Standards of Treatment in Situations where technology and resources are limited**

- f) **Clinical Diagnosis:** Back ache with local tenderness on the spinous process of the vertebra.
- g) **Investigations:** i. Radiograph Spine AP and lateral views, ii. MRI Spine iii. Blood – Hb, TLC, DLC, ESR, Platelets, INR, Glucose fasting and post prandial, Creatinine
- h) **Treatment:**

Standard Operating procedure : Based on the clinical condition of the patient, the procedure can be done under Local anesthesia / Conscious sedation / General Anesthesia. The patient is positioned on a Fluoroscopy unit, in a prone position for

dorsal and lumbar vertebrae and supine for cervical vertebrae. A patient who cannot lie prone or supine may lie in a decubitus position. A biplane DSA unit is preferable. However the procedure can be done in a single plane fluoroscopy unit.

Appropriate anesthesia / sedation is given. The Needle approved for Vertebroplasty is positioned into the anterior half of the vertebral body Under Image guidance with Image intensifier. Opacified bone cement approved for Vertebroplasty is injected into the vertebral body under live fluoroscopy, so as to diffuse into the affected vertebral body. Care be taken to avoid cement passage out of the vertebral body. The needle is removed. The patient is on bed rest for a minimum period of 3 hours. Additional restrictions are as per the anesthesia.

- a. **In Patient:** If necessitated by the general condition of the patient.
- b. **Out Patient:** Can be treated as outpatient.
- c. **Day Care:** Can be treated as outpatient.

i) **Referral criteria:** As above

***Situation 2: At Super Specialty Facility in Metro location where higher-end technology is available**

k) **Clinical Diagnosis:** As above

l) **Investigations:** As above

m) **Treatment:** As above

Standard Operating procedure: As above

- a. **In Patient**
- b. **Out Patient**
- c. **Day Care**

n) **Referral criteria:** As above

XIII. WHO DOES WHAT? and TIMELINES

- a. ***Doctor – Patient evaluation, Informed Consent, Procedure***
- b. ***Nurse – Assists the Doctor***

c. Technician – Manages the C Arm

XIV. FURTHER READING / REFERENCES

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RESOURCES REQUIRED FOR ONE PATIENT / PROCEDURE (PATIENT WEIGHT 60 KGS)

(Units to be specified for human resources, investigations, drugs and consumables and equipment. Quantity to also be specified)

Situation	HUMAN RESOURCES	INVESTIGATIONS	DRUGS & CONSUMABLES	EQUIPMENT
1	Interventional Radiologist -1	Blood Hb, TLC, DLC	Vertebroplasty Set -1	C Arm. Preferably Biplane
	Nurse -1	Blood Platelet count	Local Anesthetic – 10ml	Muti parmeter monitor
	X Ray Technitian trained in C Arm - 1	Blood – INR	Sedative	Oxygen
	Anesthetist if required	Blood Creatinine	Analgesic	Defibrillator
				Suction Machine
2	Same as above	Same as above	Same as above	Same as above