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CONTENTS

Editorial

Health care in the era of innovations

In 1995, nearly two decades ago, Harvard Business School Professor Clayton Christensen coined the phrase "disruptive innovation" to describe new technologies that transform industries by bringing simplicity and affordability to products and processes that are complicated and high cost. The word has been used since then rather loosely to describe stumbling of a previously developed technology by a newer one. However, "Disruption" describes a process whereby a smaller company with fewer resources is able to successfully challenge established incumbent technology because of its simplicity, affordability and acceptability by the people. In fact, it focus on improving on some existing technology so that it also targets the overlooked segments at an economical price. Gradually it is being adopted by a larger segment of people and led to disruption of existing technology.

Healthcare is now at cusp of drastic changes fuelled by demand and emerging technologies. Biomedical engineers are working hard to take their model work from bench to bedside but are facing challenges. Scientists are unprepared and only focus on technology without a consideration for personal touch or interaction. This may prove to be disastrous as the efforts which have gone in designing the technology will not be acceptable by people and profession generally. Another challenge is the implementation which should stand by the regulatory hurdles. Here comes the quality. The regulatory bodies wish to ensure that the new product is safe, better, durable and comforms to survival of an individual to life time. That means that rigorous clinical trials are needed which judges the robustness of new technology to surpass the existing method.

It has now been felt by physicians and biomedical scientists that in order for an innovation to be successful it should have capability to empower patients. There is a need for harnessing technology for an end in human experimentation. For example, instead of doing a trial on animals and humans, we can design billions of simulations using computing and bioinformatics devices to reach same conclusion which are more fool proof. Moreover we can make use of artificial intelligence in research and biodesign.

Emergence of 3D printing technology has open a new gateway for faster technology development bypassing the time consuming mathematical calculations.

The drug development can have a handshake with genomics to enable personalized medicine individualised to the need of each person.

In this issue of Annals one can feel the impact of such innovations.

Dr Sanjeev Misra

Ann Natl Acad Med Sci (India), **52(1):** 1-10, 2016

Role of percutaneous nonvascular Interventional Radiology treatments in musculoskeletal lesions

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SUMMARY

Many new, minimally invasive interventional radiology procedures are now viable alternatives to traditional invasive therapy. These interventional radiological procedures can be performed in the outpatient setting and the overall cost to the patient may be less in the long run. Radiofrequency and Laser ablation techniques are now widely used and rapidly expanding technologies in the interventional radiology used in the treatment of tumours, varicose vein and lumbar disc treatment. Similarly percutaneous vertebroplasty (PVP) is used in the treatment of spinal lesions and osteoporotic vertebral collapse. The knowledge of these procedures is vital as medicine moves into minimally invasive procedures with targeted treatments as these procedures offer less risk, less pain and less recovery time compared to various surgical procedures.

In this presentation I would like to present my work related to percutaneous vertebroplasty (PVP) in spinal lesions, percutaneous Laser disc decompression (PLDD) in the treatment of chronic discogenic low back pain and percutaneous radiofrequency ablation (RFA) in musculoskeletal lesions. The technique, results and long term outcomes of these newer procedures will be discussed.

Key words : Interventional radiology, MSK, Vertebroplasty, PLDD, RFA, arthrography.

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ACHANTA LAKSHMIPATI ORATION delivered during NAMSCON 2015 at the All-India Institute of Medical Sciences, Patna.

INTRODUCTION

Interventional radiological techniques are useful in the diagnosis and treatment of some of the musculoskeletal pathologies. Among these are diagnostic and therapeutic treatments of back pain using discography, nerve root injections, percutaneous vertebroplasty (PVP) and percutaneous laser disc decompression (PLDD). Similarly arthrography in conjunction with a post arthrogram MRI is used in the diagnosis of joint pathologies.

Percutaneous technique like biopsy is used for diagnosis of musculoskeletal lesions and radiofrequency or laser ablation is used in the treatment of these lesions. These techniques are as follows:

Interventional spinal procedures :

Low back pain (LBP) represents the second cause for a medical consultation in primary care setting and a leading cause of disability worldwide (1). It is a disorder with many possible etiologies, occurring in every groups of the population, and with several definitions. Severe back pain can cause serious disability as it can impair mobility and affect quality of life.

In the elderly population, the common causes include osteoporotic collapse, metastatic vertebral lesions and multiple myeloma. Even younger patients can have significant back pain due to vertebral lesions such as haemangiomas, which may cause backache without reduction in the vertebral body height. Although involutional osteoporosis from ageing is the most common cause of osteoporosis and osteoporosis related fractures, certain medical conditions like cushing's syndrome, exogenous steroid administration, surgical procedures and drugs are associated with the development of osteoporosis in 20% of women and 40% of men (2).

Disc herniation is also an important cause of low back pain that generally affects elderly people and is now increasingly affecting younger people by virtue of misdirected kinetics (3). In recent years, several minimally invasive interventional radiology procedures under local anaesthesia have been developed for the treatment of low back pain due to various aforesaid causes. These include:

- Percutaneous vertebroplasty (PVP)
- Percutaneous treatment of disc herniation
  [laser disc decompression (PLDD) & ozone therapy]

Percutaneous Vertebroplasty (PVP) :

Percutaneous vertebroplasty is a well-accepted interventional procedure for the treatment of painful vertebral lesions. The technique first introduced in 1984 by Deramond *et al* (4) in a patient with haemangioma of a cervical vertebra not responding to conventional measures to obtain pain relief, have been subsequently used for the treatment of numerous lesions causing back pain associated with vertebral involvement like osteoporotic vertebral collapse, metastatic disease, multiple myeloma and symptomatic vertebral haemangiomas.

Technique :

The procedure consists of instilling acrylic bone cement into the affected vertebra through a bone biopsy needle by a percutaneous approach. The cement consists of polymethylmethacrylate (PMMA) is obtained by mixing liquid monomer to the powdered polymer, which is mixed just before injection. The cement is injected into the lesion after needle placement, under fluoroscopic control (5). The cement polymerises and subsequently sets, affording support to the vertebra (Fig. 1). The steps of the procedure are:

Fig. 1: 30 yr female with symptomatic D12 vertebral haemangioma, successfully treated with percutaneous vertebroplasty using polymethylmethacrylate (PMMA) bone cement. The vertebroplasty needle is seen in position with injected bone cement.

I. Patient is placed in prone position on angiography/fluoroscopy table.
II. The procedure is performed under sterile conditions. The skin over the centre of the pedicle is anaesthetised with local anaesthesia. A small skin incision is made and bone biopsy needle is positioned with its tip in the centre of the mid point of the pedicle.
III. The needle is advanced under AP and Lat fluoroscopy till the junction of the anterior and middle third of the vertebral body. Approximately 6 ml PMMA cement is injected.
IV. Patient is placed in supine position for few hours after the procedure and is discharged after 6 hours.

Results :

Vertebroplasty results in relief of pain with decrease in analgesic use. It provides strength so prevents further collapse and pain relief by coagulating the tissue. The relief is obtained irrespective of the cause of pain, and is long lasting (5).

It is a safe procedure with a high efficacy in pain relief, and improvement of quality of life in patients with diverse types of vertebral metastases from breast cancer (6). In a study it has also been used successfully as a first line treatment in patients with non-osteoporotic compression fractures and can decrease pain, increase mobility and decrease narcotic administration (7).

Complications :

The incidence of complications is

less though various complications associated with the procedure are as follows:

1. Cement leaks outside the vertebra are mostly inconsequential, but can cause local or radicular pain, neurological damage and pulmonary embolism. The major leaks of cement were seen into the spinal canal, intravasation into veins, neural foramens leak and leak into disc space. Acrylic cement of polymethylmethacrylate injected into the vertebral body can leak into the paravertebral venous system and reach the pulmonary artery via the azygos vein leading to a cement pulmonary embolism (8).
2. Inaccurate needle placement can injure nerve root or spinal cord.
3. Pain exacerbation may occur due to substantial cement leaks.
4. Rarely puncture site infection and bleeding may occur.

Laredo *et al* (9) reviewed the various complication rates from numerous studies and reported total complication rates for malignant cases 38% to 72.5% and in osteoporosis 30% to 65%.

Future Directions :

Although vertebroplasty can give considerable pain relief, it is not very useful in vertebral body height restoration. Another technique called kyphoplasty (10) involves the inflation of a bone tamp within the vertebral body to restore the height of the vertebra, and subsequently placing bone cement for augmentation of strength.

Gangi A (11) described a dedicated therapeutic vertebroplasty technique that uses newly designed instruments, acrylic cement, and dual guidance with ultrasonography and computed tomography for pain control in patients with bone failure. They performed PVP procedures in patients with severe osteoporosis, vertebral tumors, and symptomatic haemangiomas and satisfactory results were obtained in osteoporosis (78%) in vertebral tumors (83%) and in haemangiomas (73%).

Percutaneous vertebral augmentation remains a proven medically appropriate therapy for treatment of painful vertebral compression fractures refractory to non-operative medical therapy and for vertebrae weakened by neoplasia when performed for the medical indications outlined in the published standards (12).

Percutaneous Treatment of disc Herniation :

Treatment of herniated disc has evolved from open surgical techniques to minimally invasive or micro therapeutic procedures under local anaesthesia. The long term outcome, the complications and the suboptimal results that may accompany open disc surgery have led to the early development of other treatment techniques that would avoid a surgical approach through the spinal canal. These include percutaneous laser disc

decompression (PLDD), percutaneous ozone therapy and percutaneous/ endoscopic nucleotomy.

In PLDD, laser energy is delivered into nucleus pulposus by laser fibre, through a needle. The aim of PLDD is to vaporize a small portion of the nucleus pulposus. The ablation of this small volume results in reduction of intradiscal pressure, thus reducing the disc herniation (3) (Fig. 2).

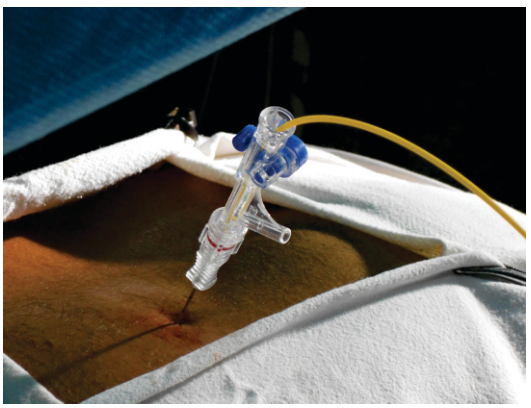

Fig. 2: Percutaneous laser treatment of herniated disc. A lumbar puncture needle is placed into the disc under fluoroscopy. After proper position of needle, optical fibre is advanced through the needle and laser energy is deposited.

In a recent study the feasibility, safety and efficacy of real time MR guidance and thermometry of PLDD was found to be feasible with complete remission of radicular pain in 21% of patients at six months follow-up assessment without any major complications (13).

The role of provocative discography prior to PLDD has been assessed and found to be useful. Discography is often carried out as the first step of an operative procedure such as chemonucleolysis, intradiscal radiofrequency or laser therapy or intradiscal injection of steroids or anaesthetics (14).

In percutaneous ozone treatment, mixture of ozone-oxygen gas is administered into nucleus pulposus through the needle. This mixture has a direct effect on the proteoglycans of the nucleus pulposus, resulting in release of water molecules and subsequent degeneration of matrix and reduction of volume (15) (Fig. 3).

Fig. 3: Percutaneous ozone treatment of herniated disc. A lumbar puncture needle is placed into the disc under fluoroscopy and ozone gas is injected after preparing it from ozone generator machine.

Both PLDD and percutaneous ozone therapy are not used for uncontained herniations or sequestered disc. In both the procedures, patient is positioned prone and using either fluoroscopy or CT guidance a proper lumbar puncture needle (18 – 21G) is inserted into the centre of disc. After proper position of the needle, for PLDD, an optical fibre is advanced through the needle and proper laser energy is given. For ozone treatment, approximately 4 ml of ozone-oxygen mixture is injected with an ozone concentration of 27 µg/ml (16).

Arthrography in conjunction with a post arthrogram MRI :

Conventional arthrography used to be the procedure of choice in the evaluation of joints, however it has been replaced with CT and MR arthrography as these can additionally show internal structures of joints. CT or MR arthrography is now frequently used in the diagnosis and treatment of various joint diseases like shoulder, elbow, wrist, hip, knee and ankle (17, 18, 19).

It is performed under fluoroscopic guidance using a 21 gauge lumbar puncture needle under aseptic precautions and after distending the joint with contrast, cross sectional imaging (CT or MR) is done (Fig. 4). It is useful in both adults and paediatric population (20).

Percutaneous ablation of bone tumours:

Percutaneous image guided tumor ablation with thermal energy source such as radiofrequency, laser or microwave energy is used in the treatment of both benign (osteoid osteoma, osteoblastoma, enchondroma etc.) and malignant (metastatic) lesions in place of surgery due to potentional benefits such as minimal invasiveness, reduced cost and morbidity (21, 22).

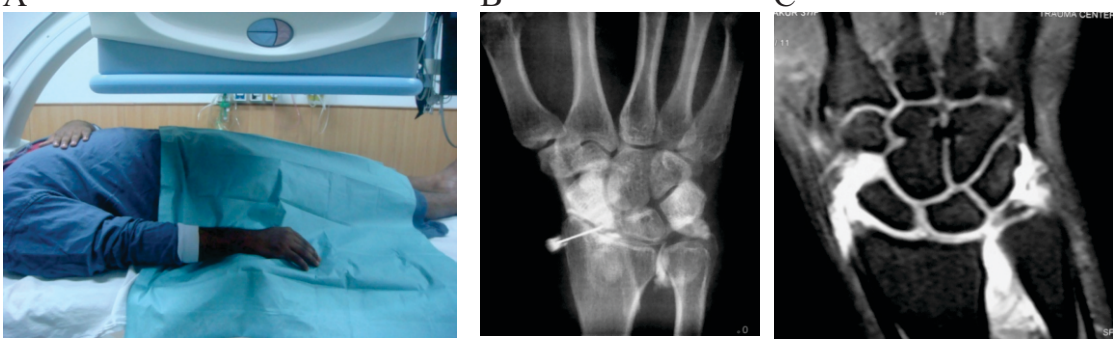

Fig. 4 A to C: Arthrography in conjunction with a post arthrogram MRI of wrist in evaluation of triangular fibrocartilage complex (TFCC) Tears. A needle is placed into the joint under fluoroscopy (A). After proper position of needle, the joint is distended with contrast (B) and MR arthrogram is done. Coronal fat suppressed T1W MR arthrogram (C) is showing TFCC tear.

A

B

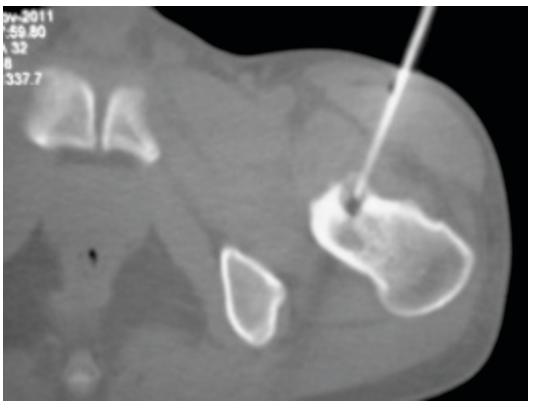

Fig. 5 A & B: Percutaneous RF ablation of osteoid osteoma. After placement of bone biopsy needle into the lesion under CT guidance the stylet was withdrawn and the RF probe was introduced (A). Axial CT image at the time of procedure (B) showing tip of the biopsy needle in the lesion.

Osteoid osteoma is a benign but painful bone tumour, usually found in lower extremities of children and young adults and ablation is done for control of pain.

The procedure is performed with CT guidance under either general anaesthesia or conscious sedation. A proper bone biopsy needle is placed into the lesion with the help of a hammer or a drill. Radiofrequency probe or laser fibre is introduced through the cannula and proper energy is delivered for ablation (Fig. 5).

Conclusion :

Interventional radiology offers minimally invasive image guided therapy for a growing range of nonvascular diseases. Percutaneous image guided peritendinous injections of various drugs including platelet rich plasma (PRP) that contains various growth factors & cytokines that stimulate healing of bone and soft tissues are now frequently used in sports related injuries (23, 24).

I believe that the future of musculoskeletal procedures is bright with promise. We will need to work hard and creatively to maintain collegial working relationships with other specialties. We must learn to address and satisfy the expectations that come with greater patient care responsibilities, and above all, we must support innovations that are in the best interest of our patients.

Acknowledgments :

The author thanks the students especially Dr. Muneer Essa and Dr. Vankatesh and clinical colleagues for their help, support and for many fruitful discussions.

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Non Coronary Interventions In Contemporary Cardiac Practice

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SUMMARY

Catheter based techniques, whether palliative or corrective, are now the accepted therapy for many congenital cardiac defects. The spectrum of transcatheter procedures has rapidly increased over the last three decades with improving technical skills of the operator combined with sound anatomic and hemodynamic understanding of the patient's condition and the choice of appropriate equipments. In today's pediatric cardiology practice many congenital defects can be treated with balloons used for dilatation of the stenotic valves or vessels combined with the use of various stents for prevention of recurrence of stenosis, some defects can be closed with various devices or coils. With rapidly growing concepts, innovative hardware improvements, development and expertise of interventionalists and surgeons, the application of catheter interventions and hybrid procedures are becoming standard practice. Some of these are practiced in India. Many of them at present are not being practiced in India due to non availability of hardware and the prohibitive cost.

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GLAXO ORATION delivered during NAMSCON 2012 at the Anna Centenary Library Convention Centre, Kotturpuram, Chennai.

Catheter based interventions in pediatric population are an accepted modality of treatment in certain lesions. Sir William Rashkind was the pioneer to start the concept of therapeutic use of cardiac catheterization as early as 1966 (1). He increased the size of interatrial communication in a baby of classical transposition by forcefully pulling a latex balloon inflated with contrast media across the interatrial septum. This procedure of balloon atrial septostomy has saved many babies with transposition. In the last few decades the role of catheter interventions in the therapeutic management of congenital heart diseases has tremendously expanded. With the availability of balloon catheters and other gadgets that can be passed through 3 or 4 French sheaths, the field has also expanded into the neonatal age group. This has completely revolutionized the role of pediatric cardiologists in the cardiac catheterization laboratory.

These procedures could be curative, palliative or adjunctive to surgery. The procedures can be grouped under following headings:

1. Enlarging or creating an interatrial communication
2. Dilating obstructing valves/channels
3. Occluding abnormal communications and channels
4. Unconventional.

Most pediatric catheter interventions are done in cardiac catheterization laboratory and require taking measurements of saturation, pressure and cine-angiograms. These procedures are done mostly under deep sedation or general anesthesia, appropriate equipment and manpower should be available for this in the cardiac catheterization laboratory. Before the procedure, a carefully done echocardiography study is essential for planning the interventional procedures. In some cases echocardiography imaging may also be needed during the procedure.

1. ENLARGING OR CREATING INTERATRIAL COMMUNICATION

A. Balloon atrial Septostomy (BAS) :

In 1966 Rashkind and Miller described this nonsurgical procedure to enlarge an atrial septal communication using a balloon catheter in a baby with classical transposition (Fig. 1). Since then its use has expanded for the initial management in many admixture lesions with restricted interatrial communication. Used primarily in babies under six weeks of age, balloon atrial septostomy has limitations in older infants, due to the increased thickness of the atrial septum. In these cases blade septostomy or static balloon dilation of the atrial septum are preferred to enlarge the interatrial communication (Fig. 2).

Although BAS is mostly a safe procedure, various complications have been reported in upto 11 % of procedures in some series. These consist of rhythm disturbances like premature ectopic beats, supraventricular tachycardia, atrial flutter and fibrillation, partial or complete heart

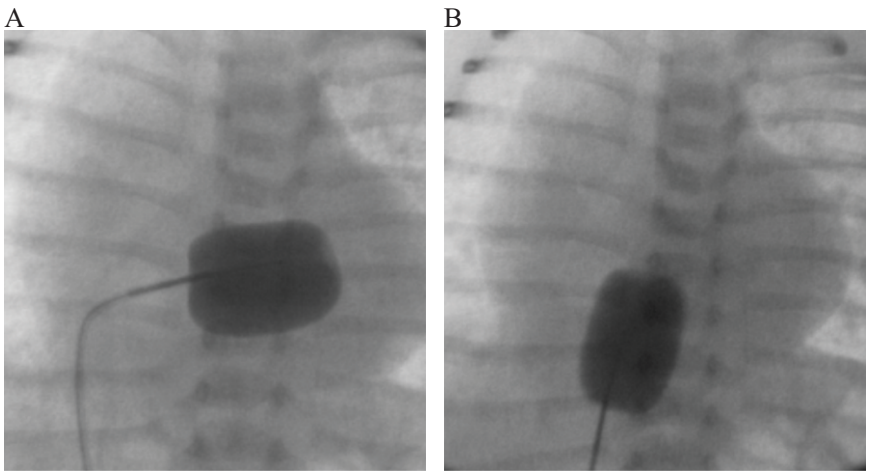

Fig. 1: Antero-posterior view
A.Balloon across the patient foramen ovale PFO into left atrium LA
B.Balloon pulled across the PFO fully inflated into RA

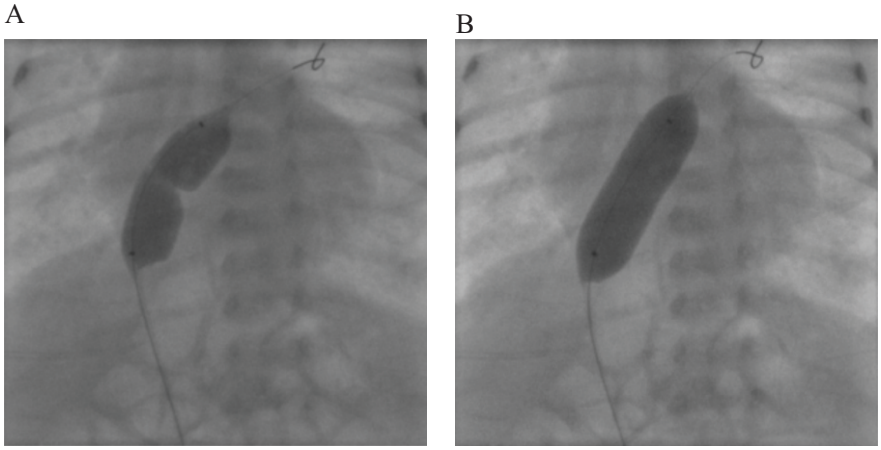

Fig. 2: Antero-posterior View
A.Static Balloon across the atrial septum
B.Fully inflated balloon

block, ventricular arrhythmias, perforation of the heart, balloon fragment embolization, laceration of atrioventricular valve, systemic or pulmonary veins and failure of balloon deflation.

B. Blade atrial septostomy :

In older infants above 6 weeks of age blade atrial septostomy with Park blade catheter (2) can be done for the same indications as for balloon atrial septostomy. Although this technique has

had good success rates, ranging from 70 % to 90 %, it can cause fatal complications especially when the left atrium is small (3) as such this technique is not routinely used.

C. Static Balloon Dilatation :

Balloon dilatation done after transseptal placement of a guidewire can be effective in enlarging an atrial septal communication. The resultant defect will be somewhat smaller than the balloon used for dilation so an oversized balloon is desirable to use. Balloons three to four times of the size of the interatrial communication are generally used for dilatation of the atrial septum (4, 5).

D. Radiofrequency Ablation (RFA) :

Rarely the atrial septum is imperforate and in these babies the initial opening is created by RFA at the site of patent foramen ovale and later it is dilated with a balloon.

II. DILATING OBSTRUCTED VALVES OR CHANNELS

A. Balloon dilatation of pulmonary valve:

Balloon dilatation of pulmonary valve using a noncompliant balloon was first reported by Kan et al in 1982 (6). The technique has been successfully used in patients of all age groups from the newborn period to adult life. With its excellent results and low rate of procedure related complications, maximum instantaneous systolic Doppler gradients of as little as 35 mmHg, when combined with evidence of right ventricular hypertrophy, should be considered for balloon pulmonary valvuloplasty (Fig. 3). The optimum balloon diameter should be between 1.2 and 1.3 times the size of the pulmonary valve annulus for single-balloon dilation (7, 8). Lower balloon-to-

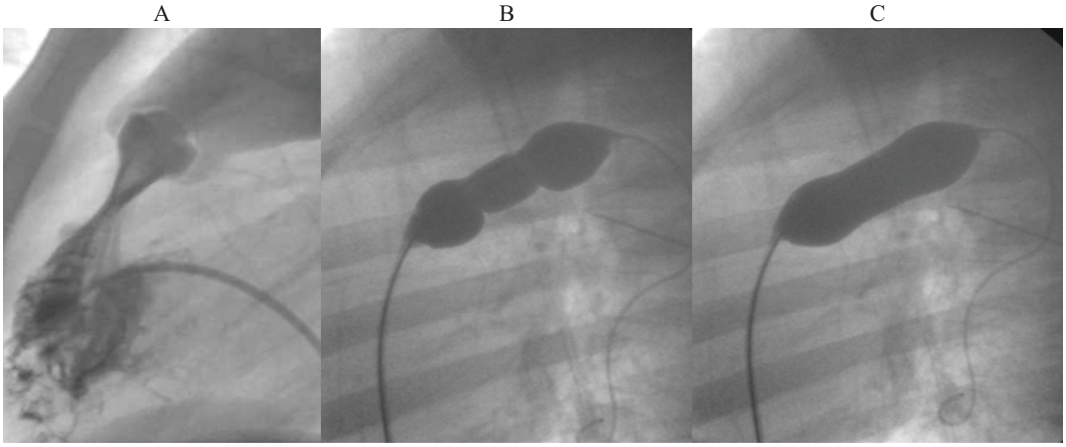

Fig. 3: Lateral view showing
A.RV angiogram showing severely stenosed pulmonary valve
B. Balloon across the pulmonary valve, C.Balloon fully inflated to relieve the obstruction

valve annulus ratios are associated with residual pulmonary valve stenosis and/or an increased risk of recurrence, whereas ratios of 1.4 or above are associated with an increased risk of clinically significant pulmonary insufficiency.

Balloon dilatation of pulmonary valve produces long term gratifying results, and re-stenosis rates are extremely low except in neonates. Restenosis rates of between 5 – 11 % have been reported on 10 years follow up (9, 10).

Balloon Dilatation of Neonatal Pulmonary Stenosis or Valvar Atresia

This is a special subset of patients with pulmonary stenosis. They are duct dependant and also require careful assessment of the right ventricle size by echocardiography in order to assess potential for normalization of ventricular size, which finally determines whether the patients will have a single or bi-ventricular repair. In critical pulmonary stenosis and valvar pulmonary atresia in neonates the right ventricular outflow tract is oriented posteriorly instead of superiorly. The right coronary catheter (4F or 5F) is better suited to cross the pulmonary valve. Some authors use a 5F coronary guiding catheter to achieve a stable position beneath the pulmonary valve. The advantage of this technique is that the initial balloon dilation of the valve can be done with the guiding catheter is position. The atretic valve in these cases has to be perforated by a radiofrequency catheter in order to gain access to the pulmonary artery (11).

B. Balloon dilation of Aortic Valve :

Balloon dilatation of stenotic aortic valve is now procedure of choice in most patients of aortic valvar stenosis in pediatric and adolescent age group (Fig. 4). In comparison to dilatation of pulmonary valve, balloon dilatation of aortic valve is more difficult and less gratifying. Aortic valvuloplasty is usually palliative and not infrequently aimed at

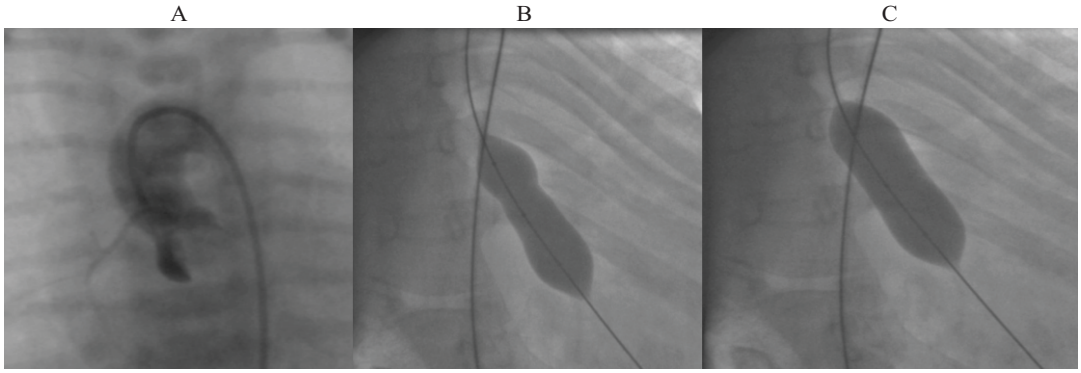

Fig. 4: Right anterior oblique view
A. Aortic root angio showing doming stenosed aortic valve
B. Partially inflated balloon across the aortic valve
C. Fully inflated balloon across the aortic valve

delaying an inevitable surgical procedure, be it valve replacement or a Ross procedure, until a time when the child has reached close-to-adult size.

Guidelines for the treatment of congenital aortic valve stenosis in children are where a peak-to-peak gradient > 60 mmHg and mean gradient is > 45 mmHg in asymptomatic patients in presence of normal left ventricular function. In presence of left ventricular dysfunction occurring as a result of aortic valve stenosis or symptoms, the gradients become irrelevant and balloon dilatation of aortic valve should be done even if the gradients are less. The balloon diameter used is 90 % of the aortic annulus. With dilation of the aortic valve, the gradient should be reduced by 60 % to 70 % or to a gradient < 30 to 40 mmHg. This usually can be accomplished without inducing significant aortic insufficiency, no more than that seen after surgical valvotomy. The long term results, like surgical valvotomy, will be palliative; however, the catheter balloon dilation procedure is accomplished without a sternotomy or cardiopulmonary bypass with their inherent risks and morbidity (12, 13).

C. Balloon dilation of Discrete Subvalvular Membrane (DSS) :

Thin membranous (1-3 mm) DSS can be effectively and safely dilated with Balloon percutaneously without production of significant aortic regurgitation. These patients remain intervention free in long term follow up. In case there is restenosis, they can be redilated with balloon (14).

D. Balloon dilation of Coarctation of Aorta :

Fierce controversy still rages on the best method to treat coarctation of aorta. This is because of the complex nature of the lesion and the varied presentation. The lesion can be classified as below:

1. Native coarctation
- Neonatal
- Older children
- Adolescent/Adult

2. Recurrent coarctation

Classifying according to age of presentation is useful because it may determine the type of therapy (15, 16).

1. Native Coarctation:

Neonatal and infantile coarctation

The role of balloon dilatation of native coarctation in infants remains controversial despite 20 years of experience. There is a high risk of restenosis in neonates and infants upto 6 months with the recurrence rates approaching 100 % within 6 months. It is desirable to refer such patients for surgical correction except in those patients who present with shock and severe ventricular dysfunction in whom an initial balloon dilatation may be offered due to high surgical risk.

Babies > 6 months

Though in this group of children recurrence is less common, residual gradients are an issue but they are similar to that after surgery. Aneurysm formation has been reported in 5 % of patients. In general, results of balloon dilatation are better if there is a localized coarctation, rather than long segment coarctation or associated arch hypoplasia. Children above 9 years could be considered for stenting of the coarctation.

Adolescent and Adults

In the majority of cases balloon dilatation with or without stent is offered as the first choice of treatment. Restenosis is comparable to surgery. Better abolition of gradients is seen with use of stents. Covered stents may have to be used if there is significant dissection or aneurysm formation in the post dilatation angiogram (17, 18, 19) (Fig. 5).

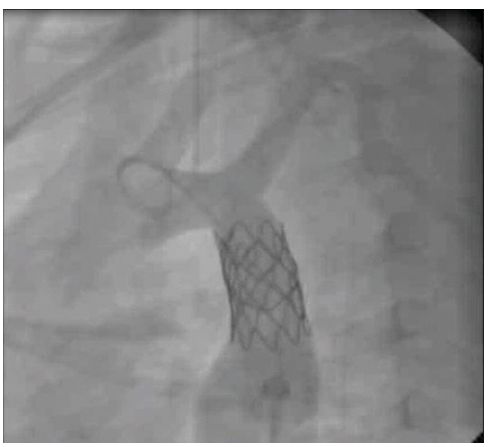

Fig. 5: Left lateral view showing stent placed in coarcted segment of aorta

2. Recurrent Coarctation :

There is a consensus that recurrent coarctation should be treated by balloon dilatation and stenting in the absence of significant arch hypoplasia.

E. Balloon dilation and stenting of pulmonary arteries :

Branch pulmonary artery stenosis is often seen as a residual or recurrent problem in patients with Fallot's tetralogy or pulmonary atresia having undergone total repair. It may also be seen as isolated lesion in certain group of patients such as William's syndrome, Allagile syndrome etc. These lesions, usually solitary (multiple in syndromic patients) are often difficult to dilate and require high-pressure balloons. There is also a risk of dissection at the time of dilatation. The lesions are often fibrotic and restenosis is quite common. Cutting balloons often give better outcome as compared to simple balloons. With standard balloon angioplasty few of the dilated vessels are maintained at a normal diameter. The true success rate of achieving a vessel of normal diameter with no gradient is < 20 %. At the same time, there is a definite morbidity and even mortality for the procedure. In view of these problems associated with balloon dilatation, stent implantation has been used to open up stenotic pulmonary arteries with 90 % success rate and low incidence of restenosis (20) (Fig. 6).

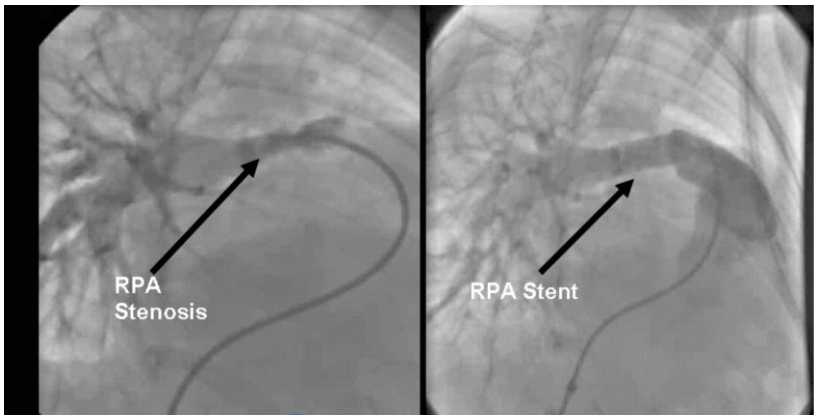

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Fig. 6: Antero-posterior view with cranial angulation
A.Showing stenosis at origin of right pulmonary artery (RPA)
B.Stent placed to open up the right pulmonary artery

III. CLOSURE OF CARDIAC DEFECTS AND CHANNELS

A. Closure of Patent Ductus Arteriosus (PDA):

Coil occlusion and device closure of patent arterial ducts are widely accepted practice.

Coil Closure of PDA

If the PDA size is less than 2.5 mm, the PDA can be successfully closed by placing Gianterco coils percutaneously with the help of bioptome (Fig. 7). The success rate of the procedure is 95 % with minimal complications. Before introduction of the Amplatzer duct occluder, many moderate to large sized PDAs were occluded using multiple coils (21, 22, 23).

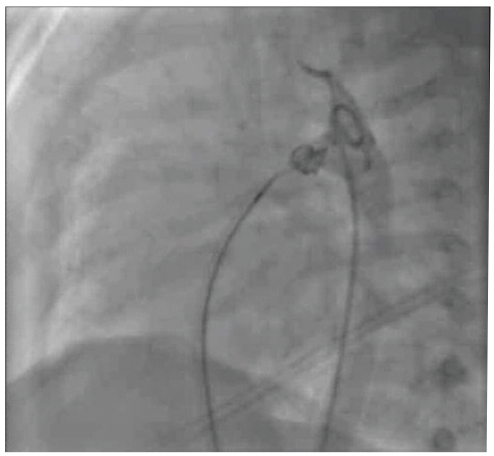

Fig. 7: Left lateral view Patent Ductus Arteriosus closed by Gianterco Coil placed with help of Bioptome

Device closure of PDA

If the PDA is bigger than 2.5 mm, it is better closed by Duct occluder (Fig. 8). The device is available in various sizes. The optimum device size is chosen after the standard aortogram in such a way that

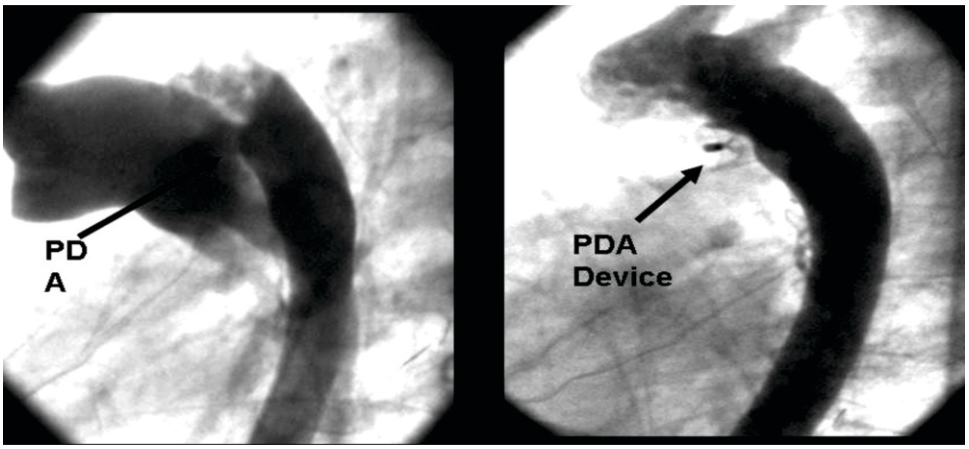

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Fig. 8: Left lateral view
A. Showing a large PDA
B. Closure of Patent Ductus Arteriosus done by PDA device

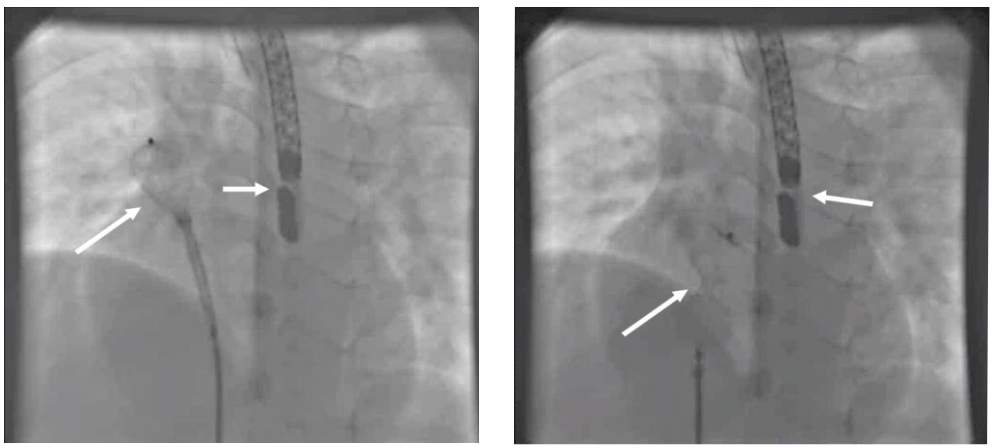
the pulmonary end is 2 mm larger than the narrowest duct diameter. For larger arterial ducts with reversible pulmonary hypertension, one may up-size the device to next available larger size. The device closure can be successfully done in babies > 5 kg. The results of device closure of PDA are excellent, 100 % closure by 3 months. The complication rates are less than 1% (24, 25).

B. Closure of Atrial Septal Defects (ASD) :

Surgical closure of ASD remains gold standard, however catheter based device closure is possible in selected patients, with fossa ovalis type of defects. A careful echo evaluation for the size and type of ASD done transthoracically or transesophageally in adolescent and adults or in patient with poor Echo windows helps in selecting a suitable patient. Single centrally placed defects with good margins all around (at least 5 mm) are considered most suitable for device closure. A variety of devices are available for the purpose, but Amplatzer septal occluder has been most widely used (26, 27) (Fig. 9). It is double disc device, made of Nitinol. The device is self-centering, and is available in a range of sizes. It has the potential to close ASD of anatomical sizes up to 38 mm. The intermediate and long term follow up (up to 10 years) show excellent closure rates (> 98 % closure rates) (28, 29, 30).

Complications of ASD device Closure

Complication rates for ASD device closure are less than 1%. Embolization of the device is the most common complication seen most often during attempts to close large ASD's. Embolization to right sided circulation, left atrium, left ventricle have all been reported. Retrieval of the device can be



A B

Fig. 9: Antero-posterior view
A.Showing ASD device with delivery cable in Left atrium antero-posterior (Large arrow). TEE probe (Small arrow). B.Left anterior oblique view showing deployment of the device (Large arrow) across the atrial septal defect. TEE probe (Small arrow).

done with snare but a large percentage of patients may have to undergo surgical retrieval.

Malposition of device across the atrial septum - this can be avoided by careful attention to details on TEE before release of device.

Erosion by device into adjacent structures - this is a rare complication. The commonest site reported is the aorta where the device straddles followed by roof of atria.

C. Closure of Ventricular septal defects (VSD):

Closure of the ventricular defect in the catheterization laboratory still remains a challenge. Most defects that need closure in pediatric age group are large, and need to be closed in early infancy. Hence surgery remains the of choice procedure.

Device closure can be done in selected group of patients with muscular ventricular septal defects (31, 32) and residual VSD after surgery. Device closure of perimembranous ventricular septal defects, though feasible, has resulted in heart block in some cases on follow-up hence remains controversial. A meta analysis of 1569 cases showed a complication rate of 11.73 % (33). Moderate size muscular defects either de-novo, residual or acquired after myocardial infarction are considered technically suitable for catheter based intervention (34, 35). Amplatzer devices

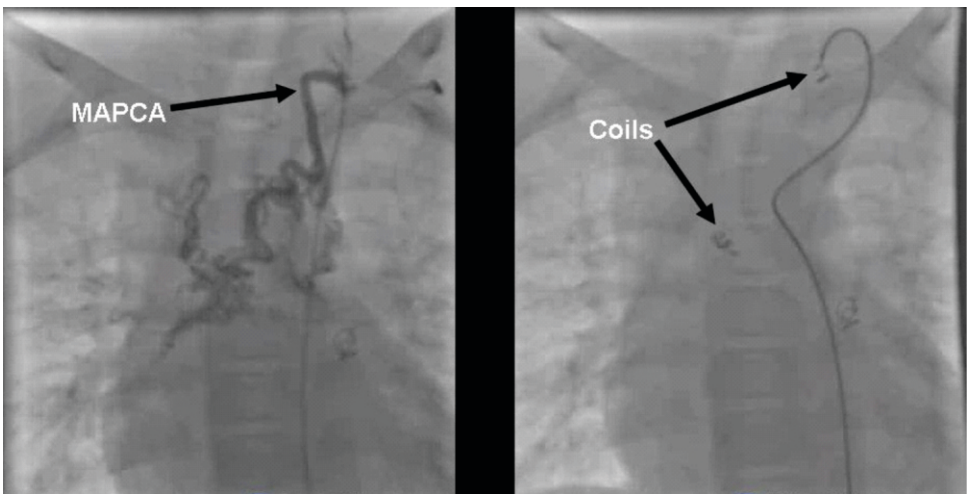


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Fig. 10: Antero-posterior view
A.Selective catheterization of one large aorto - pulmonary collateral (MAPCA)
B.Coil closure of the MAPCA

have been used widely for the purpose.

It is important that after positioning the device across the ASD/VSD, before its release, following are carefully evaluated - encroachment over adjacent structures such as SVC, IVC or pulmonary veins, mitral regurgitation, pericardial effusion, atrial or aortic leaks, clots, increase in pulmonary artery pressure. In event of any of these the device should not be released.

Difficult to approach muscular VSD are also now being closed by device during the surgery as hybrid procedures. The device is delivered periventricularly, through the RV free wall. The procedure is still in infancy and with installation of fluoroscopy in pediatric cardiac surgical suits, this will probably become the procedure of choice in many cases.

D. Closure of Aorto pulmonary collaterals:

In any busy congenital heart disease unit treating complex cyanotic congenital heart diseases, catheter closure of aorto - pulmonary collaterals forms a large percentage of interventional procedures being performed. The logic of closing these lesions is two fold:-

- To prevent excess return during cardio pulmonary bypass.
- It can be a source of intra pulmonary bleed during the postoperative phase (36).

These collaterals can be easily closed by using Gianterco coils with almost 100% success and very low complication rates (Fig. 10).

E. Closure of venovenous collaterals:

Patients with complex congenital heart disease having undergone the Glenn procedure may develop progressive desaturation. One important cause for this is enlargement of existing connecting venous channels between the superior vena cava and Inferior vena cava. Of these, the azygos or hemiazygos are the most common. These decompressing venous channels contribute to systemic desaturation. Conversion to the Fontan automatically "solves" this problem as finally all desaturated blood (upper and lower limb) reaches the pulmonary circulation. If however the hemodynamics and age of the patient do not permit conversion to Fontan, then closure of these channels may improve systemic saturation. This procedure is best performed non-surgically. The decompressing channel is easily accessed from the jugular or subclavian vein. After engaging these channels, coils, vascular occlusion device or combination can be used to occlude these channels (37) (Fig. 11).

F. Closure of Ruptured sinus of Valsalva :

Though the most definitive treatment of ruptured sinus of valsalva is surgical correction; in highly selected cases percutaneously delivered device have been used to occlude the ruptured aneurysm. The device used is Amplatzer septal occluder (38).

G. Pulmonary AV Fistula :

Coil/Septal Occluder/vascular occlusive devices have all been used to close pulmonary AV fistulas and are the

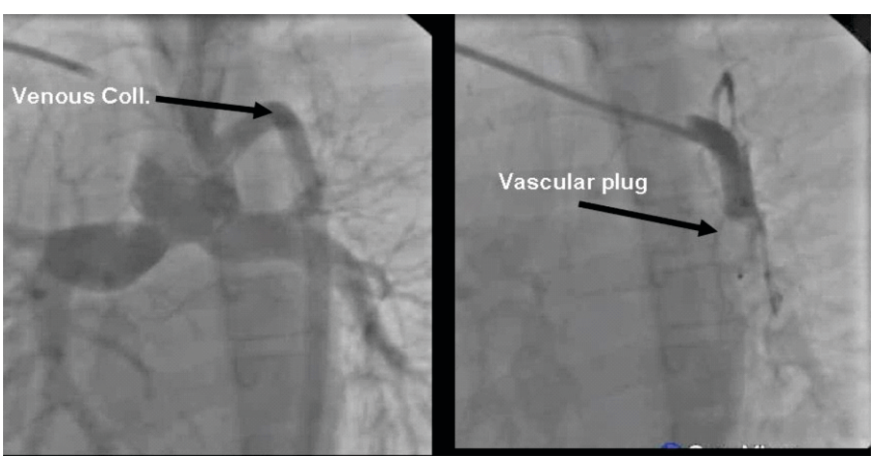

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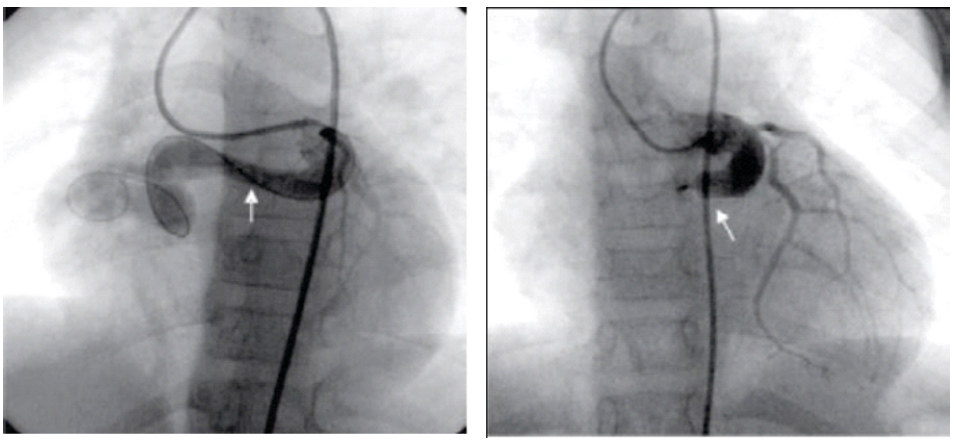
Fig. 11: Antero-posterior view
A.One large veno - venous collateral after Glenn shunt C
B.Closed by vascular plug



A B

Fig. 12: Antero - posterior view
A.Coronary - cameral fistula from left circumflex artery to right atrium (arrow)
B.Closure of the coronary-cameral fistula done by vascular plug (arrow)

treatment of choice in the localized (single or multiple) variety (39, 40). The results are judged by the immediate rise in saturations as the fistula is blocked.

H. Coronary AV Fistula :

Non surgical closure of coronary AV fistula is the treatment of choice. Depending on the size of communication, coils or devices (vascular occlusion device, PDA device) (Fig. 12) can be used to close the communication (41, 42).

Unconventional uses of Septal Devices :

At present closure of certain non septal defects with devices conventionally used for cardiac septal defects is being done successfully. Some of the devices are being used for closure of defects which were not originally meant to close those defects.

Aorto Pulmonary Window (AP window) :

Small AP windows can be closed by patent duct occluders. Care needs to be taken that after placing the device the right pulmonary artery flow and the left coronary artery flow is not compromised and the device does not interfere with the closure of aortic valve. Some series have shown that 10 % cases of AP windows could be suitable for device closure.

Amplatzer Duct Occluder II :

This is a modified duct occluder device for unusual duct anatomy particularly long tubular and angulated PDA. As it is more flexible, this device is being successfully used to close muscular VSDs and some of the perimembranous VSDs (43). In muscular VSDs, as it is more flexible, it conforms easily to the

unusual tracts of muscular VSDs. In small perimembranous VSDs because of its flexibility it is less likely to cause heart block which was a complication with Amplatzer VSD device used to close perimembranous VSDs and many centres including ours had abandoned its use. The initial results with ADO II are encouraging. However long term results are awaited.

PDA stenting in duct dependant lesions in new born and infants (44) :

In cyanotic babies with markedly reduced pulmonary blood flow, conventionally Blalock Taussing shunt is done to increase the pulmonary blood flow and reduce the cyanosis. Now a days in many centres including ours, stenting the patent ductus arteriosus to increase the pulmonary blood flow is being used.

Stenting of Right Ventricular outflow tract :

In infants and children with subvalvular right ventricular outflow obstruction stenting is being used to open the out flow tract.

Interventions in pipeline :

Interventions which are being done in USA and Europe but due to hardware non availability and cost, we are not yet doing these in India.

1. Percutaneous pulmonary valve implantation :

This technique is very useful in effectively treating right ventricular out flow tract conduit stenosis and free pulmonary regurgitation resulting in right ventricular dilatation in patient operated for TOF physiology. This avoids second open heart surgery. Medtronic Melody valve is most commonly used (45). Late restenosis in short term follow up is not significant. Complication in terms of coronary compression and stent fracture (treated by insertion of second stent) have been noted. However the durability has not been tested in humans due to lack of long term data. The cost remains prohibitive.

2. Fontan Completion by Catheter Intervention (46) :

In patients of univentricular physiology, Fontan completion surgery is done after the initial palliative Bidirectional Glenn (BD Glenn) Surgery. In some of these patients in early infancy, a Blalock Taussing Shunt or pulmonary artery banding is also needed. Presently in some centres, a lateral tunnel is created at time of BD Glenn. The atrial end of superior vena cava is closed by a patch. The aperture of lateral tunnel is kept larger than the Inferior vena cava diameter. At the time of Fontan completion, the SVC patch is perforated by a RF catheter and stent is placed at SVC – Atrial junction. The aperture is closed with atrial-septal occluder. This procedure results in less pleural effusions and arrhythmias – compared to surgical Fontan completion. Additionally there is a potential for successive dilation of Fontan pathway created percutaneously to accommodate for growth.

Hybrid Procedures :

Procedures in which the pediatric cardiac surgeon and the cardiologist work together in an area where the facilities of operation theatre and the angiocardiography are available in the same room. The Echocardiography and in some places the MRI equipment is also available in the same area. Thus it needs very highly specialized and costly infrastructure. Unusually located muscular VSDs can be closed by putting the Device perventricularly. The VSD closure and pulmonary artery stenting can be done simultaneously, larger size of stent can be placed irrespective of patient size, limited vascular access. Stent could also be placed for recurrent coarctation of aorta, across Fontan Fenestration, right ventricular out flow tract.

Fetal Cardiac Interventions (47) :

Since last two decades various centres in USA, UK, and Europe have been trying Fetal Cardiac Interventions. Limited success has been reported in few lesions – like severe aortic stenosis, pulmonary stenosis, restrictive foramen ovale, closing patent ductus arteriosus. However this procedure needs the collaboration of highly specialized team of pediatric cardiologist, obstetrician, anesthetist, Echocardiography consultant, nurses and technicians. Also it needs highly specialized equipment. The results do not seem to be so gratifying.

Summary:

Therapeutic cardiac catheterization represents significant advance in care of patients with congenital heart disease. There are many cardiac lesions, which can be either corrected or palliated without an incision or putting the patient on cardiopulmonary bypass by these percutaneous techniques. The short hospital stay and lower indirect cost of therapy have led to their wide acceptance. Recently therapeutic cardiac catheterization has advanced beyond the confines of catheterization laboratory and many hybrid procedures are done with cooperation between interventional cardiologist and cardiac surgeon.

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Vitiligo – An Indian Perspective

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SUMMARY

The prevalence of vitiligo in India is high. It affects DLQI. Exact aetiology is not clear. Melanocytorrhagy hypothesis is important. Classification into segmental and non segmental vitiligo is satisfactory from prognosis and treatment point of view. Onset of vitiligo after the age of 30 years is defined as late onset vitiligo: separate subset with strong genetic background and presence of precipitating environmental factors. Mucosal vitiligo is a distinct subset. Koebner type 2 A phenomenon needs redefining.

Oral minipulse and minocycline are effective in progressive unstable vitiligo. Narrowband UVB phototherapy is effective in both children and adults: it has an edge over PUVA. NCECS is the most common surgical technique used in treatment. Suspension in patient's serum gives better results. NCECS is better than SEBG. Camouflaging and depigmentation are required in some cases.

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INTRODUCTION :

Vitiligo is a common acquired chronic pigmentation disorder characterized by white patches. It affects 0.5 to 1 % of the world's population. India is amongst the countries with highest prevalence rates varying from 0.46 % in Calcutta to 2.16 % in Chandigarh. It is a disorder of great cosmetic significance and a source of considerable psychological distress and social isolation especially in dark races. It is associated with significant impairment in the quality of life. Patients suffer low self esteem and depression and they have difficulties in finding a job or getting married. Pandit Jawahar Lal Nehru, the first Prime Minister of India ranked vitiligo as one of the three major medical problems of India, the other two being leprosy and malaria.

Historical Background :

The word vitiligo is derived from Latin 'vitium' meaning blemish. In Atharveda from India, it is described as 'kilas' or white disease. In 'Charaka Samhita' it has been designated as 'svitra'.

Aetiopathogenesis :

The exact aetiopathogenesis of vitiligo is not clear. There are a number of theories and each has some contribution to its pathogenesis.

Genetic theory: Most cases of vitiligo occur sporadically; about 15-20% of patients have a positive family history. Familial aggregation takes a non-Mendelian pattern that is suggestive of polygenic, multifactorial inheritance. Increased prevalence of HLA-DR4, HLA-B13, HLA-DRW6, HLA-DRW52, HLA-DQW1, HLA-DQW3, HLA-CW6 and decreased prevalence of HLA-CL4AQO has been found to be associated with vitiligo.

Autoimmune hypothesis:

A number of clinical conditions alleged to be of autoimmune origin like thyroid dysfunction, Addison's disease and pernicious anemia have been shown to be associated with vitiligo. Auto-antibodies have been found against certain surface antigens of melanocytes and the titers of these antibodies correlate well with the extent of depigmentation and response to therapy. Antityrosinase antibodies have also been detected.

Neurogenic hypothesis:

This is based on the observations of autonomic dysfunction in the vitiliginous patches. Lesions may also exhibit increased levels of nor epinephrine and neuripeptide-Y (cytotoxic to the cells or indirectly by causing vasoconstriction).

Melanocyte self destructive hypothesis:

Melanocytes may be destroyed by the very factors that are responsible for melanogenesis (accumulation of some toxic metabolites like indoles, breakdown products of pterin homeostasis (such as 6-BH- 4 and 7-BH-4).

Oxidative stress hypothesis:

Lesional and nonlesional skin of vitiligo patients exhibits low levels of catalase levels which correlate with high levels of hydrogen peroxide.

Viral infections:

Cytomegalic virus infection has been implicated.

Growth factor defect hypothesis:

Basic fibroblast growth factor deficiency can be associated with vitiligo.

Melanocytorrhagy hypothesis:

This theory is getting important. Melanocytes are weakly anchored in skin. A minor friction can cause their detachment and produce depigmentation-Koebner's phenomenon. We carried out a study in which Perilesional skin melanocytes from patients with stable and unstable vitiligo were cultured and studied for morphological changes, adhesion to collagen type IV and caspase 3 expression.

Melanocytes from unstable vitiligo showed significantly low adhesion to collagen type IV compared with controls and stable vitiligo melanocytes. Caspase 3 and annexin staining was significantly greater in melanocytes cultured from unstable vitiligo as compared with the controls (1).These morphological and adhesion findings support the theory of melanocytorrhagy as the primary defect underlying melanocyte loss in unstable vitiligo.

Liver X receptor alpha has been implicated in proliferation, carcinogenesis, differentiation and permeability barrier function of skin. We observed that LXR-alpha mRNA expression was significantly higher in Perilesional skin as compared to uninvolved skin of non segmental vitiligo patients. This leads to decreased cell adhesion molecule and proliferation resulting in detachment of melanocytes from basement membrane (2).

Convergence Theory :

There are now probably too many hypotheses of vitiligo; all are not mutually exclusive. Combination of these mechanisms can contribute to vitiligo.

Classification of Vitiligo :

The vitiligo global issue conference classification divides vitiligo into two main types: Segmental and Non segmental. Among segmental vitiligo, it may be uni-, bi-, or pluri-segmental. The non segmental vitiligo includes Acrofacial, mucosal, generalized, universal and mixed.

Clinical Presentation :

Clinically the disease starts as focal patch and thereafter it may either stabilize leading to localized disease or spread explosively or more gradually into

generalized vitiligo. The most common sites involved are fingers, hands, face and other trauma prone areas of the body.

There is no sex predilection for vitiligo as such. Peak incidence of vitiligo is found in 10-30 years of age. Incidence of vitiligo decreases with increasing age.

Segmental vitiligo:

It affects young patients mainly before the age of 20 years with a relatively rapid course of a few months and then gets stabilized. Involvement of one side of body is usually observed. There is poor response to medical/phototherapy. High rates of repigmentation are achieved with surgical techniques.

Non segmental vitiligo:

It is a slowly developing condition with a tendency to progress throughout the years. In a small percentage of these individuals, arrest of the condition may occur.

We studied the effect of age at onset on disease characteristics in vitiligo (3). Of 1416 patients, 1211(85.5%) had an early onset of disease whereas 205 (14.5%) patients had late onset vitiligo. Patients with disease onset after 30 years (late onset) had a significantly higher association with precipitating factors such as trauma and stress; higher incidence of positive family history and a higher association with leucotrichia. Early onset non segmental vitiligo was associated with a higher incidence of photosensitivity and pruritus compared to early onset segmental vitiligo. Late onset vitiligo is defined as vitiligo occurring after the age of 30 years. It is a separate subset that manifests in patients with a strong genetic background and the presence of precipitating environmental factors. Hands are the most common initial sites to be involved and the disease onset may be preceded by a precipitating factor in a significant proportion of patients.

Few studies have suggested that mucosal involvement is associated with progression of the disease. We carried out a comprehensive review of 241 cases to find out if it is true (4). Of 241 cases, 70 had pure mucosal involvement, 35 had onset in mucosae and then spread to skin and 136 had onset in skin and then spread to mucosae. The mean age of patients with pure mucosal involvement was 31 years. Fifty five had involvement of lips. History of smoking was commoner as compared to other groups. Smoking probably acts as low grade thermal trauma to the lips thus precipitating vitiligo in genetically predisposed individuals. There was no difference in groups related to history of associated autoimmune disease, family history and sites of mucosal involvement. In our opinion no relation is there between involvement of mucosae and extent of skin involvement. We think that pure mucosal vitiligo is a distinct subset.

Koebner phenomenon in Vitiligo :

Koebner phenomenon (KP) has been reported as occurring in 21-62% of

patients with vitiligo. Patients showing KP have a significantly older age at onset of vitiligo. Presence of KP in a patient with segmental vitiligo may be an indicator of subsequent development of non segmental vitiligo. In a retrospective study of 1416 patients, we observed that 6.6% had KP. Patients with KP had significantly older age of onset and shorter duration of illness as shown in earlier studies (5). Recently the vitiligo European task force group has divided KP into three types:

Type 1: for which diagnosis of KP is based on history
Type 2A: for which depigmentation is present on areas of chronic friction
Type 2B: for which depigmentation is clearly induced by trauma
Type 3: which refers to experimentally induced KP.

Trauma to the dermis rather than superficial epidermis is required to induce KP.

We carried out a prospective study of Type 2A Koebner phenomenon in 202 patients. KP was present in 130 (64.4%) of patients. Type 2 A was the commonest type present in 116 (57.4%) patients (6). Since the predilection sites of vitiligo are located at areas of friction and pressure, we question the value of assessing Type 2A KP. We propose that the definition of Type 2A KP needs more clarification since it is different from other subtypes. Patients exhibiting KP have higher mean age and age at onset, more body surface area is involved and hence systemic therapies are required to control disease activity.

Treatment :

Multiple treatment options are available. A positive approach is recommended involving explaining the nature of disease process, the likely prognosis and the treatment options with their expected results to the patients.

Various therapies used for treatment of vitiligo are divided into TWO major groups-Medical and surgical. Choice of treatment also depends on the morphologic subtype and extent of vitiligo.

Corticosteroids :

Corticosteroids can be used both topically and systemically. Topical corticosteroids are first line therapy for localized vitiligo and are recommended for facial and/or small lesions and in children. Topical potent and ultrapotent corticosteroids though found to be most effective should be limited to 2-4 months. Systemic corticosteroids are indicated in vitiligo when it is progressive and unstable. A study was carried out to assess the efficacy of low dose dexamethasone oral mini pulse therapy 2.5 mg per day for two consecutive days in progressive unstable vitiligo. A total of 444 patients were analyzed (7). In 408(91.8%) patients, arrest of disease activity was achieved at a mean of 16.1 plus minus 5.9 weeks. In addition, some repigmentation of the lesions was seen in all patients after a mean of 16.1 plus minus 5.9 weeks. Fifty of 408 (12.25%) patients experienced one or two episodes of relapse in disease

activity and were treated with reinstitution of oral mini pulse therapy. The mean disease free survival until the first relapse was 55.7 plus minus 26.7 weeks. Adverse reactions such as weight gain, lethargy and acneiform eruptions were observed in 41 (9.2%) patients. Low dose OMP therapy with dexamethasone is a good therapeutic option to arrest the activity of progressive unstable vitiligo. Its effectiveness in controlling disease activity is comparable to that of other schedules in which systemic steroids are administered at a much higher dose, albeit with less adverse effects. However, it is not suitable alone for repigmentation of vitiligo lesions.

Minocycline has wide range of anti inflammatory, immunomodulatory and free radical scavenging actions. In 32 patients with gradually progressive vitiligo, 100 mg oral minocycline once a day was administered for 3 months. In 29 patients, the progression of the disease was arrested. In a comparative study of OMP and oral minocycline, a total of 50 patients with rapidly spreading vitiligo were randomized to revive either minocycline 100 mg a day or OMP 2.5 mg dexamethasone on two consecutive days in a week for 6 months (8). Both OMP and minocycline were observed to be effective drugs for managing the arrest of disease activity in vitiligo.

Tacrolimus:

Topical tacrolimus was first used for treatment of vitiligo by Grimes *et al* (9). It acts by suppression of autoantibody recognization of melanocyte antigen and inhibition of cytotoxic T cell proliferation.We carried out a study of topical treatment with tacrolimus 0.03% ointment in 25 children (10). Tacrolimus was applied twice daily for 12 weeks. 19 (86.4%) children showed some repigmentation at the end of three months and other 3 had no response. Of these 19 children, repigmentation was marked to complete in 11 (57.9%), moderate in five (26.3%) and mild in three (15.7%) children.

Phototherapy :

Ultraviolet B can induce T-regulatory (suppressor) cell activity. Releases IL 10 is important for differentiation and activation of T-regulatory cells which may suppress autoimmune conditions. UVB exposure increases the number of residual melanocytes most probably by enhancing melanocyte growth factors such as bFGF and endothelin-1(ET-1).

14 patients aged 12-56 years with generalized vitiligo were treated thrice weekly with NBUVB radiation therapy for a maximum period of 1 year. 10 patients (71.4%) had marked to complete repigmentation and 2 each (14.3%) had moderate or mild repigmentation. It was concluded that NBUVB therapy is effective and safe in Indian patients with vitiligo (11).

Twenty six children with generalized vitiligo manifesting a minimal extent of depigmentation of 5 %

of the body surface were recruited. Patients were treated with starting dose of 280 MJ/cm2 and treated for one year. Dose of NBUVB was increased by 20% on subsequent visits. Marked to complete repigmentation was observed in 15 (75%). Average of 34 plus minus 2 visits were required for 50 % repigmentation. It was concluded that NBUVB is effective and well tolerated modality for childhood vitiligo (12).

PUVA versus NBUVB:

Studies to evaluate PUVA versus NBUVB seem to depict some advantages in favour of NBUVB with higher repigmentation rates and better color matching. However, comparing with NBUVB with monochromatic excimer laser, 308-nm MEL was found to be more effective and faster than NBUVB. In an open prospective study comparing systemic PUVA and NBUVB in treatment of vitiligo, we observed that mean degree of repigmentation attained in the NBUVB group was 52.24% over a mean treatment period of 6.3 months whereas in the PUVA group it was 44.7% in a mean time of 5.6 months. Although repigmentation was better in the NBUVB group, the difference was not statistically significant (p=0.144).Color match was better and side effects minimal (13).

Surgical Treatment :

The aim of surgical induction of repigmentation is to replenish melanocytes in the depigmented lesions of vitiligo which either have no reservoir or fail to activate melanocytes in outer root sheath with known treatment modalities. Although surgical trauma induces proinflammatory cytokines which have an effect on melanogenesis and pigment cell migration, the presence of melanocytes in grafts is crucial for repigmentation.

Before carrying out the surgical treatment it is important that the vitiligo should be stable. The concept of stability in vitiligo is multifaceted and no consensus has yet been reached on defining the criteria for this so far. There are clinical, ultra-structural, serological and biochemical parameters to distinguish between stable and active disease. However these studies are cross sectional and hence do not shed light on the correlation of these parameters with the course and prognosis of the disease. The Indian Association of Dermatologists and Venereologists (IADVL) taskforce defines stability as: no reporting of new lesions; no progression of existing lesions and absence of Koebner phenomenon during the past one year.

Autologous non cultured epidermal cell suspension (NCECS) is the most common used method. This technique pioneered by Gauthier and Surleve-Bazeille (14) in 1992 has revolutionized the scenario of surgical therapy of vitiligo. Cold trypsinization was further modified by Olsson and Juhlin (15) thereby significantly reducing the duration of the procedure. NCECS yields cosmetically acceptable results in a short period of time.

The NCECS technique involves 3 steps: harvesting of donor skin; preparation of melanocyte rich basal layer cell suspension and dermabrasion followed by application of the cells over recipient area.

Acral vitiligo and lesions over the joints were treated with NCECS (16).

In total, 36 patients with 80 lesions over acral areas and joints were reviewed. Of 80 treated lesions, 51 had regained more than 75 percent repigmentation and 23 had regained 50-75% repigmentation. In another study (17) it was observed that suspending the melanocytes in the patient's own serum gives better repigmentation. Even repigmentation of leucotrichia was observed (18). In a comparative study between NCECS and suction blister epidermal grafting in stable vitiligo, it was observed that NCECS has an edge over SBEG in terms of extent of repigmentation, patient satisfaction and DLQI (19). Recently non cultured extracted hair follicle outer root sheath cell suspension has been shown to be effective in surgical treatment of vitiligo. Both these techniques were compared and their efficacy was similar (20).

Some patients would require camouflaging and in those patients with extensive vitiligo, mono benzyl ether of hydroquinone (MBEH) at a concentration of 20% is used to remove the residual melanocytes.

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Global Burden of Mental Disorders: Meeting the Challenge

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SUMMARY

Mental disorders are one of the major contributors to the global burden of disease, constituting about 14% of the burden. Both severe mental disorders (SMDs) as well as the common metal disorders (CMDs) contribute to the global burden of disease and are responsible, and need active intervention on the part of mental health experts and the health planners. Inadequate mental health resources and a large untreated population are important contributors to the burden. Thus the global burden of disease due to mental disorders imposes a major challenge. Possible solutions include enhancing the manpower resources, improving the mental health literacy, integration of mental health in general medical care and active community participation. Under the National Mental Health Programme of India, a number of such activities have been undertaken. The primary care doctors are also an important resource, since they provide care to a vast majority of the patients with CMDs. Strengthening primary care for the mental disorders, raising community awareness, mental health promotion, and control of alcohol and substance abuse could be important strategies in meeting the challenge. There is also need for creating services for enhancing welfare measures for the patients with disability due to mental disorders. Barriers to the mental health care and services also need to be tackled.

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INTRODUCTION

Neuropsychiatric disorders are a major contributor to the global burden of disease, responsible for around 14% of the disease burden (1). Depression, bipolar disorder, schizophrenia, and alcohol and substance-use disorders are the major contributors to this burden. The World Health Organization (WHO) estimates the life time prevalence of mental disorders at about 25%. About 20-25% of the patients attending various medical settings suffer from an underlying psychiatric disorder (2). The burden caused by mental disorders imposes a major challenge to the mental health professionals and the health planners, especially in the low resource countries like India. There is a need to develop well planned strategies to deal with this burden.

This presentation discusses the concept of global burden of disease, extent of problem due to mental disorders, characteristics of the burden caused by mental disorders, challenges imposed by it, barriers and strategies to meet the challenges.

Global Burden of Disease :

Historically, mental disorders were never a global health priority, especially when compared with communicable diseases and non-communicable diseases such as cancer or cardiovascular disease, because in health planning the focus was always on mortality statistics. With the publication of the World Development Report in 1993 by the World Bank, global attention was also directed to the relative burden associated with disease morbidity, rather than mortality alone. Mental and substance use disorders were identified as major contributors to the global burden of disease. The Harvard School of Public Health in collaboration with the World Bank and the WHO assessed the Global Burden of Disease (GBD) study in 1993. To estimate burden of disease, the GBD study used the concept of the disability adjusted life years (DALYs), besides assessing the mortality and morbidity statistics (3). DALY is a health gap measure, which combines the impact of premature death, and disability and other non-fatal health outcomes. One DALY can be thought of as one lost year of healthy life. DALYs for a disease are the sum of the years of life lost due to premature mortality (YLL) and the years lost due to disability (YLD).

The GBD 1990 showed that mental and neurological disorders accounted for 10.5% of the total DALYs (3). WHO reassessed the GBD for 2000 and estimated that the neuropsychiatric disorders (mental, neurological and substance use disorders) accounted for more than a quarter of all non-fatal burden, measured in years lived with disability (YLD). Depression was the most disabling disorder worldwide measured in YLDs, and the fourth leading cause of overall burden measured in disability adjusted life years (DALYs). Depression was associated with the largest amount of disability, accounting for almost 12% of the YLDs. The

contribution of mental and neurological disorders to the global burden increased to 12.3% in 2000 (2) and 14% in 2005 (1). In the GBD 2000 study, mental and neurological conditions accounted for 30.8% of all YLDs. Depression, alcohol use disorders, self-inflicted injuries, schizophrenia and bipolar disorder were amongst 10 leading causes of DALYs in the most productive age group of 15-44 years. Six neuropsychiatric conditions figured in the top twenty causes of YLDs in the world. These included unipolar depression, alcohol use disorders, schizophrenia, bipolar affective disorder, Alzheimer's and other dementias, and migraine (2).

In 2007, a new GBD study was launched and the results for the Global Burden of Diseases, Injuries and Risk Factors Study 2010 (GBD 2010) were reported in December 2010(4). GBD 2010 was a comprehensive reanalysis of burden for 291 causes, 20 age groups, both sexes, and 187 countries in 21 world regions for 1990 and 2010. The number of specific mental and substance use disorders was expanded to 20 disorders, consisting of all anxiety disorders (compared with three in the original study), eating disorders (anorexia nervosa and bulimia nervosa), childhood behavioural disorders (attention-deficit/hyperactivity disorder and conduct disorder), pervasive developmental disorders (autism and Asperger's syndrome), and idiopathic intellectual disability, a residual category capturing intellectual disability not attributed to any of the other diseases and injuries. Substance use disorders were expanded to include burden for alcohol use disorders (alcohol dependence and foetal alcohol syndrome) and illicit drug use disorders (opioid dependence, cannabis dependence, cocaine dependence, and amphetamine dependence).

Worldwide, mental and substance use disorders accounted for 183·9 million DALYs (95% UI 153·5 million– 216·7 million), or 7·4% (6·2–8·6) of total disease burden in 2010. Global burden caused by the mental disorders was higher than that due to HIV/AIDS and tuberculosis, and diabetes, urogenital, blood and endocrine diseases. Although the burden of mental and substance use disorders increased by 37·6% between 1990 and 2010, the change for mental disorders was almost entirely attributable to population growth and ageing. The group were the leading global cause of all non-fatal burden of disease (YLDs), and the fifth leading disorder category of global DALYs. It accounted for 175·3 million (95% UI 144·5 million– 207·8 million) YLDs, or 22·9% (18·6–27·2) of all non-fatal burden. The burden of mental and substance use disorders spanned all age groups. The highest proportion of DALYs occurred in adolescents and young to middle-aged adults (aged 10–29 years) (5). Cumulative global effect of mental disorders in terms of lost economic output has been estimated to the extent of US $16 trillion in the next 20 years, which is equivalent to 25% of global GDP in 2010 (6).

Burden due to mental disorders :

Broadly, from the public health point of view, the mental disorders can be divided into severe mental disorders (SMDs) and common mental disorders (CMDs). SMDs include schizophrenia, bipolar disorder, severe depression and other psychotic disorders, whereas CMDs mainly include anxiety disorders, depression, somatoform and other neurotic disorders. Both SMDs as well as CMDs contribute to global burden and disability (1, 3, 4, 5, 7-9). Burden imposed by the mental disorders is a major challenge to the public health, considering the high prevalence of the mental disorders, inadequate resources and a number of barriers to seeking care. There is a large untreated population of persons with mental disorders (2).

Burden due to the mental disorders is contributed by the effect of illness on the patient, the family and the society at large (2, 7, 9). Most mental disorders, both SMDs as well as the CMDs tend to last for a long time with duration varying from months to years to life long, and often have first onset at a young age. Hence, the illness affects the most productive period of the life. If the onset is during adolescence or early 20s, it affects the academic career and early professional growth, and if it occurs during the later period, it would affect the social, occupational and family functioning. The illness affects almost all spheres of life, personal, family, occupation and social. Persons with mental illness also face social stigma and discrimination from the society. Mental disorders can be disabling, and the sufferer may not be able to function to the full capacity, further adding to the burden. The patient also has difficulty in getting a job, since the prospective employers often don't want to employ a person with mental illness because of the associated stigma, and a notion that the person may not be able to perform to full capacity. Persons with mental illness many times are perceived as prone to violent or disorganised behaviour, and also portrayed in the media in such a manner. All these factors add to the financial problems of the patient and his or her family.

The patients and their family members often face social ostracism, with the friends, neighbours and relatives often avoiding them and not maintaining relations with them. The family members also have to face the violent and disorganised behaviour of their patients in periods of relapse (7). In our country, the families are main caregiver of the persons with mental illness, and hence face considerable stress and burden. The caregiving role also takes a lot of time of the family members, affecting their functioning in different areas. The caregivers also face financial problems since they have to take leave from their job affecting their income (10, 11). Costs of the treatment including periodic visits to the doctor further add to the financial burden.

Suicide rate is also high in persons with mental disorders, with nearly 10-

15% of patients suffering from schizophrenia, bipolar disorder, depression and alcohol dependence ending their life by suicide (12).

Persons with mental illness are also prone to develop different medical problems. Patients suffering from schizophrenia, bipolar affective disorder and other psychotic disorders are at a higher risk to develop nutritional deficiencies, cardiovascular and metabolic disorders, and infectious diseases. Due to their poor communication ability and the treating doctor focussing on psychiatric symptoms, physical problems tend to be missed till in advanced state. The life span of patients with schizophrenia, bipolar disorder, depression, and substance use disorders is often shortened due to the associated severe physical problems, and also deaths due to accidents and suicide (13).

All the above factors add to the global burden of disease due to mental disorders, affecting the patient, the family, the society and the nation.

Challenges :

Global burden of disease due to mental disorders is a major challenge to the mental health professionals and the health planners (2, 14). High prevalence of mental disorders, chronicity, inadequate mental health resources, a large untreated population and barriers to seeking treatment contribute to the burden.

Extent of problem :

As per the WHO, one in four persons is likely to develop a mental disorder during life time. Point prevalence of mental disorders is about 10%. India with current population of about 1.28 billion has huge numbers of persons with mental disorders (15). A number of epidemiological studies of mental disorders have been undertaken in India. Reddy & Chandrashekar's (16) in a meta-analysis of various Indian epidemiological studies estimated the prevalence of mental disorders at 70 per 1000. Thus by a rough estimate, India has 90.3 million persons with mental illness, out of which about 9 million suffer from severe psychiatric disorders like schizophrenia and other severe mental psychotic disorders. This is a huge number.

Resources in LAMI Countries:

Most of the low and middle income countries (LAMIC) have a gross deficiency of mental health care workers. Total number of mental health care workers in 58 countries from the LAMIC group were estimated at 362,000 in 2005, representing 22.3 workers per 100,000 in low income countries and 26.7 per 100,000 in the middle income countries, comprising 6% psychiatrists, 54% nurses and 41% psychosocial care providers. The figure adds up to a shortage of 1.18 million mental health workers in the 144 LAMIC countries (17). As per the WHO Mental Health Atlas of 2005, mental health resources in India consist of 0.25

psychiatric beds per 10,000 population, 0.2 psychiatrists, 0.03 clinical psychologists, 0.05 psychiatric nurses, 0.03 social workers per 100,000 of the population (18). Currently, by a rough estimate, India may be having currently about 5000 psychiatrists (about 0.4 psychiatrists per 100,000 of population). Relocation to the other countries like the USA, the UK, Australia and others has been an ongoing problem. There is a gross disparity between resources and needs. Figures for psychologists, psychiatric social workers and psychiatric nurses working in mental health care are equally inadequate.

Average national deficit of psychiatrists in India has been estimated at 77%. More than 1/3 population has >90% deficit of psychiatrists. Only the states /union territories of Chandigarh, Delhi, Goa and Puducherry have a surfeit of psychiatrists. Kerala and Maharashtra have less than 50% deficit, while all the other states have more than 50% deficit of psychiatrists (19).

There are 133 medical colleges and postgraduate institutes in India, which admit 327 MD degree students in psychiatry each year, besides which, 56 medical colleges, have training facilities for 125 DPM students. In addition, 50 to 60 postgraduates appear every year for examinations leading to the award of DNB in psychiatry by the National Board of Examinations (20). There has also been an increase in the training facilities in psychiatry, clinical psychology, psychiatric social work and psychiatric nursing in the newly established centres of excellence under the National Mental Health Programme (NMHP) of India. But still the required numbers are difficult to achieve in near future (21).

Barriers to seeking treatment and care:

Scarcity of available resources, inequities in their distribution and inefficiencies in their use have been identified as the three main obstacles to better mental health especially in LAMI countries (22). Stigma associated with mental disorders and poor community awareness about mental disorders are some other important barriers to seeking treatment and care for mental disorders. Due to inadequate mental health resources, a large section of the population suffering from mental disorders is unable to seek treatment for their problem.

Stigma associated with mental disorders further prevents patients with mental disorders from seeking treatment. Due to the fear of stigma, patients and their families don't access the treatment facilities because of the fear of being labelled as mentally ill. Lack of awareness about the mental health problems being an illness needing treatment, and about the treatment facilities often delays the treatment, further adding to the disability due to mental illnesses (23).

Mental health has always been at low priority in policy making and budget allocation despite a large uncovered population and inadequate manpower. Health budget has been one of the lowest

in India as compared to the developed as well as underdeveloped countries, and funding for mental health is abysmally low.

Strategies at Meeting the Challenges :

Key Strategies for meeting the challenges could include transforming health systems and policy responses, building human resource capacity, improving treatment and expanding access to care, prevention and implementation of the early interventions, and identifying the root causes, risks and protective factors (14).

Transforming health systems and policy responses :

Health systems need to be transformed in the direction of strengthening the mental health component by establishing and implementing minimum health-care standards for mental disorders around the world, and redesigned to integrate the care of mental disorders with the care of other chronic diseases. Investments in treatment, training, research and prevention in the mental health needs to be augmented (14).

A number of changes have taken place in the last 3-4 decades in the health system in India, many of which have been a part of the NMHP of India, which was launched in 1982 (24). Recently, India has declared its Mental Health Policy in October 2014 (25).

NMHP has the objectives of ensuring availability and accessibility of minimum mental healthcare for all in the foreseeable future, particularly to the most vulnerable and underprivileged sections of the population; encouraging the application of mental health knowledge in general healthcare and in social development; and promoting community participation in the mental health service development and to stimulate efforts towards self-help in the community (24). Since in the initial years there was a slow development, districts were taken up as the units to implement the programme under the District Mental Health Programme (DMHP).

The focus in DMHP has been on early detection and treatment, training of manpower and raising public awareness about the mental disorders. Mental health services have been developed at the district level and also at peripheries to make them easily accessible to the community. Training component has included imparting short term training to the medical officers in diagnosis and treatment of common mental illnesses with limited number of drugs, and training of the health workers in identifying persons with illness and raising community awareness. Public awareness programmes are undertaken periodically in form of information, education and communication (IEC) activities. The programme had covered 123 districts across the country till 2012, and is expected to cover most of the districts by the end of the current five year plan (21, 26).

India did not have a mental health policy till recently. The Government of India launched its Mental Health Policy on 10th October 2014. It aims at providing universal access to mental health care, increasing access to and utilisation of comprehensive mental health services, and reducing prevalence and impact of risk factors associated with mental health problems. The policy has a vision to promote mental health, prevent mental illness, enable recovery from mental illness, promote destigmatisation and desegregation, and ensure socioeconomic inclusion of persons with mental illness by providing accessible, affordable and quality health and social care to all persons through their life span, within a right based framework. There is emphasis on the principles of equity, justice, integrated care, evidence based care and quality, following a participatory and rights based approach in all training and teaching programmes. It also discusses the issues of inter sectoral collaboration, funding and research (25).

To cover the deficiency in the mental health resources, the WHO in 2008 launched the mental health Gap Action Programme (mhGAP) to address the lack of care for people suffering from mental, neurological, and substance use disorders, especially for the low- and middle-income countries (27). mhGAP asserts that with proper care, psychosocial assistance and medication, tens of millions could be treated for depression, schizophrenia, and epilepsy, prevented from suicide, and can begin to lead normal lives, even where the resources are scarce. mhGAP has prepared intervention guides for prevention and management for each of these priority conditions, which can be used in primary care settings.

There have been some more developments in the mental health sector in India in the area of welfare from the policy perspective. Mental illness was included in the list of illnesses eligible for disability benefits in the Rights of Persons with Disabilities Act, 1995. The intent was good, but it had a limited reach due to various procedural and legal limitations (28). The Rights of Persons with Disabilities Bill, 2012 has broadened the definition of mental illness for purpose of various disability benefits. Disability pension for various disabled persons with more than 40% disability has been introduced in some states of India. These are the beginnings, and the steps may bring some relief to the caregivers at reducing burden. In India, there is no insurance for persons with mental illness, though it exists in most of the developed world. Various insurance companies offering health insurance have put mental illness under 'general exclusions' (suicide, self-inflicted injury or illness, mental disorder, anxiety, stress or depression, use of alcohol or drugs are the categories excluded). An initiative has been taken in the proposed Mental Health Care Bill (MHCB), 2013 to rectify this deficiency. The MHCB has included a section which states that the Insurance Regulatory Development Authority established under the Insurance Regulatory Development Authority Act, 1999 shall endeavour to ensure that all insurers make provisions

for medical insurance for treatment of mental illness on the same basis as is available for treatment of physical illness (29).

Build human resource capacity :

Building human resource capacity is integral to meet the challenge of the global burden of disease including the mental disorders. Strategies could include creating regional centres for mental-health research, education, training and practice that incorporate the views and needs of local people, and develop sustainable models to train and increase the number of culturally and ethnically diverse lay and specialist providers to deliver evidence-based services. There is also a need to strengthen the mental health component in the training of all health care personnel (11).

Mental health resources are generally scarce across most of the low and middle income (LAMI) countries. Government spending on mental health in LAMI countries is far lower than required. Most care is institution based. There is an inequitable distribution between countries, between regions, and within communities. Populations with high rates of socioeconomic deprivation have the highest need for mental health care, but the lowest access to it (17).

India has taken a number of initiatives under the NMHP as well as independently. There has also been a focus on creating more manpower by developing new facilities and expanding the existing ones. Upgrading of the mental health services and training facilities in the state run medical colleges and general hospitals, and modernisation of the state mental hospitals has been done under the NMHP. To expand the training facilities in the field of mental health, centres of excellence in mental health have been opened in collaboration with the existing services, which have also started postgraduate training programmes in psychiatry, clinical psychology, psychiatric social work and psychiatric nursing all across the country. All these steps are likely to ease the burden associated with mental disorders by early detection and treatment of the mental health morbidity in the community (21, 26). Number of postgraduate training centres in psychiatry and allied disciplines in the country has shown a tremendous growth from about 10 in early 1970s to about 200 (20). However, relocation of the trained manpower to the western countries remains an ongoing problem. It is known fact that the number of psychiatrists of Indian origin in the Western countries is much more than those available in India.

Expansion of the mental health training facilities for the mental health professionals may not generate manpower sufficient to meet the demand. Thus the alternatives to the specialised care are to be explored, where the primary care physician remains an important resource, since most of the patients with mental health problems especially those with CMDs are seen in the primary care. Early research in community psychiatry in India had shown that most cases of common

mental illnesses can be effectively managed in the primary care settings (30, 31). Therefore the focus under DMHP has also been on strengthening mental health services in the primary care as discussed earlier. Task shifting has been an important strategy at creating alternate sources to provide mental health care, when there is a deficiency of the trained manpower (17).

Since most patients with mental health problems are seen in the primary care settings, NMHP has also undertaken periodic short term training programmes for the primary care doctors and para medical workers. Sensitising the primary care doctors in providing treatment for common mental problems occurring in primary care has been the objective of such programme (21, 32, 33). Different kinds of training modules varying from one day sensitisation to 2 weeks long programmes have been used (32).

Improve treatment and expand access to care :

Screening for mental disorders and basic mental health care can be integrated into routine primary health care. Cost effective treatment and medications need to be ensured in primary care settings as well as in secondary and tertiary care. Treatments which can be conveniently used by the non-specialists, including lay health workers with minimal training, need to be developed and introduced. Assessment of the functional impairment and disability due to the mental disorders should also be included at appropriate settings. There is also a need to provide effective and affordable community-based care and rehabilitation (34). Children with mental health problems also need to be attended to. The modern developments in the mobile and IT technologies (such as telemedicine) can be used to increase access to evidence-based care (11).

A delay is seeking treatment is an important contributor to the burden. Even in developed countries, treatment is often delayed by many years after the onset of illness (35). Establishing the community based mental health care facilities will reduce the distances travelled by the patients with mental illness and their caregivers to seek treatment. Making the mental health services easily accessible, available and affordable is essential to meet the challenge of the global burden of the mental disorders, and has also been one of the objectives of the NMHP of India. Attempts have been made under the DMHP to provide services at the district level by a psychiatrist and at peripheral hospitals by providing satellite services as well as by training the primary care doctors in short term sensitisation programmes in psychiatry (26, 35). Till recently only 123 districts had been covered under the DMHP. It is proposed to cover all the districts in the 12th Five Year Plan, which is good in intent but appears overambitious considering the available resources.

In the recent past, a number of new initiatives have taken place in our country both in voluntary sector as well as the

government sector. Efforts from the voluntary sector as well as from the mental health professionals have been successful in bringing law towards welfare of the mentally ill and their caregivers (36). A number of non-governmental organisations (NGOs) have been working in area of providing community support to the persons with mental illness and their caregivers. Some of these include Ashadeep (Assam), AMEND (Bangalore), Aasha (Chennai), SAA (Pune), NAMI India (Mumbai), Turning Point (Kolkata) and SCARF (Chennai) (37) .

Prevention and implementation of the early interventions :

An effective prevention programme in psychiatry needs to act at multiple levels like acting on risk and protective factors, developing strategies to reduce risk and improve quality of life, reducing stressors and enhancing resilience, and targeting directly the psychiatric disorders (38).

Both mental health promotion and early intervention are important components of a prevention programme in psychiatry. Healthy life style, regular physical exercise and staying away from drugs and alcohol are some of the important preventive interventions in the field of mental health (39). Steps need to be taken to reduce the duration of untreated illness by developing culturally-sensitive early interventions across settings. Interventions also need to be developed to reduce the long-term negative impact of low socioeconomic status on cognitive ability and mental health. Evidence based primary prevention interventions need to be developed for a range of mental and substance use disorders. Active measures need to be taken to act on risk factors like childhood abuse, alcohol and substance abuse, Child protection needs to be taken on priority. A number of steps have been taken in this direction in our country in the recent past (40).

In general, psychological distress is not considered as something requiring medical care or intervention. The modern medical care is considered as having only a limited expertise in the area. The mental health services have also only a limited availability in the public health services. Community awareness programmes need to focus on that mental disorders are like any other medical illness, and can be effectively treated and the patient can live a nearly normal life in the community. Media can play an important role in spreading the messages. An initiative has been taken by the NMHP in this direction by broadcasting and telecasting such messages on the audio-visual media. Similarly a number of such initiatives have taken place in the print media in the last 2-3 decades (21, 40, 41).

India has a tradition of giving importance to mental health, evidence of which can be found in Hindu philosophy. Yoga, meditation and spiritual ways of understanding adverse life situations have always been popular in the Indian culture since time immemorial. But there is also a

need to disseminate new knowledge on these practices and strengthen those that are helpful in order to benefit the persons in need (21, 41).

Mentally ill persons are also discriminated in the society. Finding a house on rent for a family with a mentally ill person often is major ordeal for the family. Often they may be forced to change the house frequently. It is not only with psychotic disorders. Even illnesses like obsessive compulsive disorder may become highly stigmatizing. In India, it is not uncommon for families to give a fictitious name while registering in the hospital, so that the case records may not be traced in future by the prospective spouse or his/her family or a prospective employer. The improved mentally ill person faces great difficulty in finding a suitable job in South East Asia, as part time jobs are often not available, and more so, no employer wants to employ a person with a mental illness (40). Raising community awareness about treatability of mental disorders and correcting misconceptions can go a long way in reducing stigma and increase support for persons with mental illness (23). The steps will also help integration of persons with mental illnesses in the society, and in turn reduce the stresses faced by the caregivers (41).

Long stay facilities are required for persons with mental illness, who don't have any family members to look after or the family members are not in a position to take care of them due to ill health or old age (42). There have been some initiatives in this area from the voluntary sector, but no such facilities exist in the Government sector (37).

Identifying the root causes, risks and protective factors :

There is a need to identify modifiable social and biological risk factors across the life course so as to prevent development of mental disorders, especially in the face of major stressors. Impact of poverty, violence, war, migration and disaster on mental disorders can be studied to identify the risk and protective factors. Research is also required to identify the biomarkers for mental disorders. Relationship between early developmental factors and mental disorders needs to be investigated. Studies need to be done to identify phenotypes and endophenotypes of mental disorders. Role of gene–environment interactions associated with the increased risk for mental disorders needs to be investigated (11).

Changing realities :

In India, most people suffering from psychiatric disorders do not receive any financial benefits from the state on account of their illness or unemployment. Those living in nuclear families are facing a new problem, because in the past families used to be bigger, and joint families provided human as well as material resources for the care of people with mental illness. In a nuclear household, it becomes an onerous duty for the already extremely busy family

members to look after the person with mental illness (7, 40).

The gradual breakdown of the joint families with urbanization and smaller nuclear families with both spouses working has introduced the new problem of increasing load on the family caregivers. Once a family member gets a chronic mental illness, there is a huge drain on the family resources. The caregiver may have to make considerable compromises on his or her job so as to extend constant care to the sick family member, and sometimes may even to have leave the job, further increasing the financial problems (10, 11, 41).

Sometimes, the family breaks down due to death or divorce and the role of caregiving may be taken by some other relative, such as parents or siblings. This creates a new crisis, which needs to be handled by the mental health professional. In many cases, the mental illness may itself be in the background of the marital breakdown. Sometimes, a female patient is deserted by her husband, and the mother extends all sorts of support to her ill daughter as well as to her grandchildren. Caregivers of women with schizophrenia and broken marriages are at a double disadvantage (43).

In this background, more and more families are looking up to the professionals for help. This further emphasizes the need for family based intervention programmes. Family caregivers who are in contact with treatment teams for a long time learn to develop healthy coping methods to deal with the burden of caring for relatives with severe mental illness by both experience and prolonged therapeutic contact with the treating doctors (11).

Use of Modern IT Technologies :

Using the recent developments in the field of information technology, it should be possible to create online peer support groups and introduce online family interventions like online psyhoeducation programmes in mental health. India has got high mobile penetration, and offers an excellent opportunity to introduce mobile apps for psychoeducation and introducing mental health promotion skills. Mobile apps can also be used for reminders for taking medications, appointment and for taking up activities as a part of therapeutic interventions. However, one also needs to be careful because the excessive use of mobile applications also carries the risk of increasing social isolation, exposing the participants to misinterpreting advice or reducing engagement with the health care providers.

Recently, for the first time in India, a mobile telepsychiatry unit commissioned by Schizophrenia Research Foundation (SCARF) and supported by the TATA Educational Trust has been initiated in 2011. The programme includes a bus with tele conferencing facilities, a computer for data storage and a large television fixed at its rear. This television is used for awareness programmes in the villages.

The bus moves from village to village accessing persons with mental illness. After the psychiatric consultation through linking with Chennai SCARF office, the medicines are given from the pharmacy located within the bus (44). There have also been developments in telepsychiatry based services at other places like the All-India Institute of Medical Sciences, New Delhi and the Postgraduate Institute of Medical Education and Research, Chandigarh. Feasibility studies have taken place of providing telepsychiatry services to distant places (45).

Conclusion :

Global Burden of mental disorders is a great challenge. Possible solutions include spreading community awareness, budget enhancement for mental health, early identification and treatment, improving treatment adherence, supporting the caregivers, manpower enhancement and integrating mental health component in primary care, and ensuring easy availability of psychotropics in primary care, and use of modern technology in mental health care.

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Simulation Based Skills Training in Neurosurgery and Contemporary Surgical Practices

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SUMMARY

Neurosurgery training is based on a time-bound apprenticeship model, resulting in mentor-dependent, non-uniform, anecdotal, slow skills acquisition, sometimes with morbid consequences. The complexity of neurosurgical procedures and constraints of present education have demands for alternative methods of training. The use of simulation in surgical skills training was pioneered by work in laparoscopy, which began only in the last 25 years. Existing neurosurgery training model should be supplemented with efficient skills training curricula.

The present study illustrates formulation, standardization, validation and evaluation of efficacy of neurosurgery skills training modules using formative and summative assessment. 160 regular residents and short-term trainees were trained over 3096 skills training sessions under formative assessment; 176 'graduate neurosurgeons' were trained with 12 skills training programs under summative assessment. Training involved skills development in micro-neurosurgery, high-speed drilling, neuro-endoscopy and spine-instrumentation by practice on structured low and high-fidelity simulation models. The effectiveness of content, course modules, and teaching faculty on skills development were assessed using spot and gap-based evaluation.

Seven basic, 7 intermediate and 14 advanced skills training modules have been developed. Trainees rated 71% of overall training sessions as excellent quality content with 69·8%, 70·1%, and 71% respectively for micro-suturing and high-speed drilling, neuro-endoscopy and spine-instrumentation modules. Faculty with higher ratings was included as program instructors. On gap-based evaluation, >80% of responded trainees

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GOLDEN JUBILEE COMMEMORATION AWARD LECTURE delivered during NAMSCON 2015 at the All-India Institute of Medical Sciences, Patna.

reported better orientation with high speed drilling followed by micro-neurosurgery and spine-instrumentation. Neuro-endoscopy training scored low assimilation into clinical practice.

We suggest structured modular validated skills training curriculum to supplement the existing neurosurgery training. This would help in improving learning curve outside operation-rooms, at convenience and individualized needs of trainees under supervision, and would thus help in skills translation without endangering patients.

Keywords : Competency, Curriculum, Modular, Neurosurgery Education, Residency, Simulation.

INTRODUCTION

Traditional residency training program has used the operation theatres to transfer the art and craft of surgery to residents. Till the end of last century, Halstedian training program had hardly any criticism; but in view of accelerating changes in health care system worldwide, apprenticeship model of training is being considered suboptimal (1). In this era of minimally invasive and robotic surgery, several forces are making it difficult for the operation theatres to be the predominant venue for the acquisition of primary technical skills (2). The reasons are manifold, as increasing financial and medicolegal constraints in the operating room are putting tremendous pressure on the residents and training faculty. Secondly, demand of maximum possible efficiency in surgical care because of patients being admitted with serious and complex surgical problems in the teaching institutes. There are several social and legal concerns about teaching basic skills on an already compromised human being. Last but not the least, is the increasing number of residents in surgical discipline and decreased work-hours leading to less and less opportunity to teach and supervise (3). All these problems are not exclusive to surgical discipline only but definitely surgery is the worst sufferer.

There is an ancient proverb, "The axe forgets, but the tree remembers". This concern becomes magnified in high-end branches like neurosurgery, as brain tissue is a non-forgiving structure. Intracranial structures have reluctance to minimal retraction forget about excision. As surgeons, our motto always remains, "First do no harm", but simultaneously we have a duty to pass on the expertise to the future generation. It is difficult to achieve this fine line of balance. Hence, there is a pressing need to develop methods of technical skills instructions that occur outside the operating rooms (4-8). The use of sporadic courses and workshops to teach basic skills is not a new concept.

But, surgical skill acquisition is an on going practice, which is learnt over a course of time under a watchful eye. The need of the hour is to incorporate simulation based training curriculum to supplement regular training program in surgery. This will help in the initial learning curve of a naïve resident with safety to our patients (9-11).

Neurosurgery Education and Training School (NETS) is an attempt to establish a skills training curriculum from neurosurgical perspective to fill learning gap. It involved formulation, standardization, validation and evaluation of efficacy of structured modular skills training program for short-term and long-term training using formative and summative assessment tools (12-18).

Methods :

Development of Neurosurgery Education and Training School

Infrastructure:

Simulation in neurosurgery in India has made a significant step in education and skills training of neurosurgery on an academic and translational platform. NETS was established in 2009 at All India Institute of Medical Sciences (AIIMS), New Delhi, India with intra-institutional collaboration between departments of Neurosurgery, Anatomy, Forensic Medicine; inter-institutional collaboration with Indian Institute of Technology Delhi (IIT-D) and international collaboration with

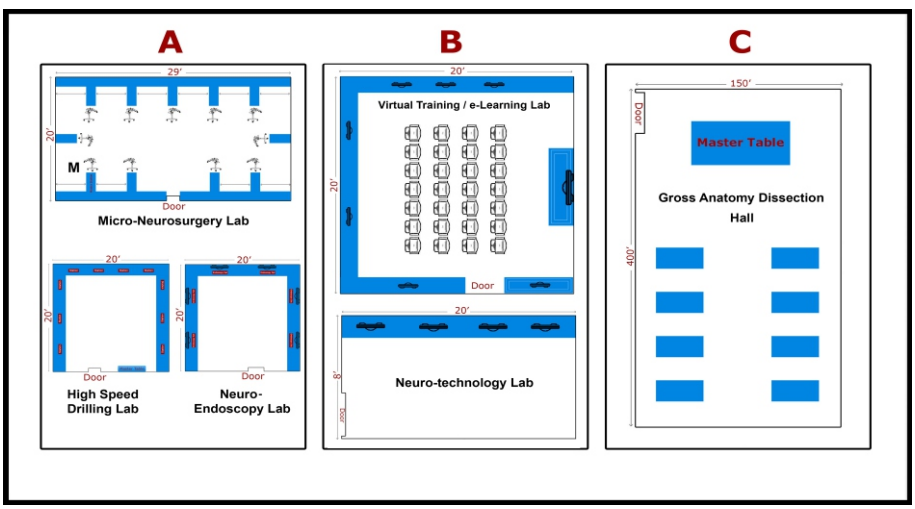


Fig. 1: Infrastructure of Neurosurgery Education and Training School (NETS).
A. Micro-neurosurgery Skills Training Laboratory, High Speed Drilling Skills Training Laboratory and Neuro-Endoscopy Skills Training Laboratory;
B. Virtual Training e-Learning Laboratory and Neuro-Technology Laboratory;
C. Gross Anatomy Dissection Hall for cadaver dissection.

department of Neurosurgery, Hospital Barmherzige Bruder, Trier and department of Anatomy, University of Mainz, Germany. The facility consists of well-equipped separate skills training laboratories (Fig. 1)(14, 15).

Assessing the educational needs, NETS has also established an open source, free access, global, interactive e-learning platform delivering customized educational content. The learning material includes neurosurgery seminars, modular courses, edited operation videos and 3D animation graphics content (14, 15).

At present, majority of neurosurgical procedures are performed under magnification. Under microscope, instruments move faster, field is several times magnified and tremors are more apparent (16). Transition from microscopic to neuro-endoscopy habitat is further challenging as one operates at a distance looking at a monitor with only 2 dimensions of vision and limited field of surgery. A neurosurgeon has to be more cautious and familiar not only with the changed view of the anatomy but also the changed habitat and their instruments (16).

Simulation helps in adapting the changed ergonomics of conventional microsurgery and neuro-endoscopy ORs. Neurosurgery Skills Training Facility comprise of well-established separate laboratories for micro neurosurgery, high speed drilling, neuro-endoscopy and gross cadaver anatomy laboratories. All laboratories are equipped with operating microscopes, endoscopes, microscopic and endoscopic instrument sets, pneumatic and electric drills, high definition cameras and monitors with recording and storage facilities. NETS comprise computer based and non-computer based simulation for neurosurgery education and skills training (14, 15).

Teaching Faculty at NETS :

NETS follows strict trainee and teaching faculty inclusion criteria formulated by 'Scientific Advisory Committee' (NETS-SAC) consisting of experienced neurosurgeons.

Selection criteria for trainees :

Trainees are categorized as regular trainees, short-term trainees, workshop trainees and senior research fellows (12-19).

- 'Regular-trainees' are postgraduate residents of institute designated “Senior Resident (SR)”, (1-6 as per training year of residency). This corresponds to PGY system of American Medical Schools.
- 'Short-term trainees' are residents or practicing neurosurgeons from all over India and abroad. They are trained for 2-4 weeks.
- Trainees in three days 'Neurosurgery Skills Training Workshops' are certified practicing neurosurgeons. This workshop is organized quarterly, at 35 USD enrolment cost only.
- Certified post-doctorate senior

research fellows/officers (SRO) are selected by the Indian Council of Medical Research (ICMR) for research on skills training and cadaver dissection.

Selection Criteria for Teaching Faculty:

The faculty should have keen interest and active involvement in practicing and teaching skill sets in neurosurgery for continuation as 'Curriculum Instructors' (CI). Trainees' feedback is taken into account to select faculty of maximum impact and identify faculty with CI potential.

Teacher of Teachers (TOT) :

TOTs are senior faculty members with more than 10 years experience of imparting skills training and evaluating other faculty members in the institutes. This helps in faculty up-gradation, with identification of potential faculty for skills training program.

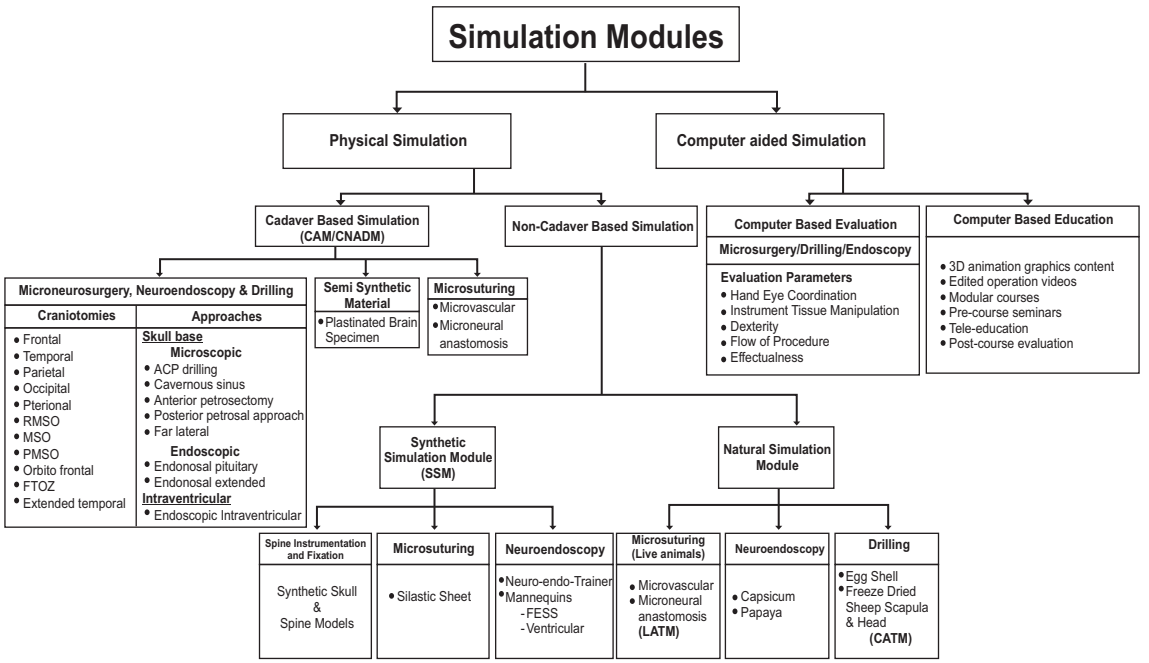


Fig. 2: Structured Simulation-based Skills Training Modules in Neurosurgery (ACP, Anterior Clinoid Process; CAM, Cadaver Anatomy Module; CATM, Cadaver Animal Tissue Module; CNADM, Cadaver Neuroanatomy Dissection Module; FESS, Functional Endoscopic Sinus Surgery; FTOZ, Fronto-Temporal-Orbito-Zygomatic; LATM, Live Animal Tissue Module; MSO, Midline Suboccipital; PMSO, Paramedian Suboccipital; RMSO, Retromastoid Suboccipital; SSM, Synthetic Simulation Module; VDM, Video Demo Module)

Table 1: Structured neurosurgery skills training modules for basic, intermediate and advanced stages of learning (CAM, Cadaver Anatomy Module; CATM, Cadaver Animal Tissue Module; CNADM, Cadaver Neuroanatomy Dissection Module; DNB, Diplomate of National Board; LATM, Live Animal Tissue Module; MCh, Magister Chirurgiae; SR, Senior Resident; SSM, Synthetic Simulation Module; VDM, Video Demo Module).

Skills	Basic	Intermediate	Advanced
Level	SR1 (3 Year MCh/DNB) SR3 (6 Year MCh/DNB)	SR2 (3 Yea r MCh/DNB) SR4 (6 Year MCh/DNB)	SR3 (3 Year MCh/DNB) SR5,6(6 Year MCh/DNB)
Micro-Neurosurgery Modules	Suturing on Synthetic models (4-0 to 7-0)	Suturing on Synthetic models (9-0 to 10-0) Cadaver vessel and nerve anastomosis	Sciatic Nerve Anastomosis Femoral Vessel Anastomosis (Live animal- rats/ guinea pigs)
	VDM, SSM	VDM, SSM, CATM	VDM, LATM
High Speed Drilling Modules	Flap Design, Burr Holes, Sheep Scapula drilling Sheep head drilling	Sheep head split calvarial graft, Egg shell drilling, Microscopic drilling(Sheep head/ Sheep scapula)	Microscopic cadaver drilling Anterior clinoid process, Petrous, Far lateral Endoscopic cadaver drilling Endo-nasal extended skull base
	VDM, CATM	VDM, CATM	CAM, VDM, CNADM
Neuro-Endoscopy Modules	Parts assembly, Hand eye coordination practice on capsicum, papaya (natural simulation)	Neuro-Endo-trainer	Ventricular and Skull base anatomy, ETV (Synthetic model) FESS model, Endo-nasal extended skull base (cadaver) Endoscopic spine (optional)
	VDM, NSM	VDM, SSM	CAM, VDM, CNADM
Spinal Instrumentation Modules	Entry points Laminoplasty	Anterior cervical plate fixation (Synthetic model)	Occipito-cervical fixation, Odontoid screw placement, C1-2 Trans-articular screw fixation, Dorsal/ Lumbar pedicle screw fixation, Inter-body Fusion
	VDM, SSM	VDM, SSM	VDM, SSM

Neurosurgery Skills Training Modules (Table 1, Fig. 2) :

Skills training modules consists of structured modular approaches for neuro-anatomy, micro-neurosurgery, neuro-endoscopy, high-speed drilling and spine instrumentation. Modules are categorized into task-based (TBSM) and procedure-based sub-modules (PBSM) for the purpose of standardization and validation. TBSM are designed as skills training experiments, where the trainees' activities could be evaluated with the help of formative assessment. These modules are competency based and every person is upgraded for higher-level only if found competent at earlier skills level (14, 15).

Standardization of TBSM (Fig. 3) :

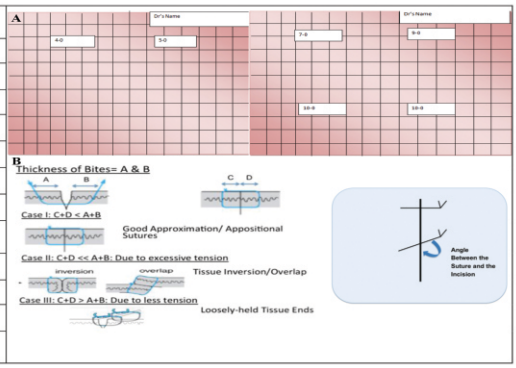
Micro-Neurosurgery Skills Training Module :

Micro-neurosurgery is practiced over sialistic sheet (marked in equal spaced squares of 1x1cm^2), under predefined fixed criteria of suturing material and magnification.

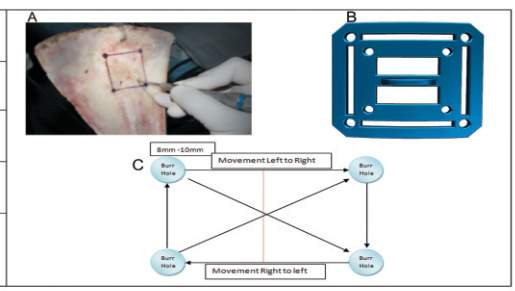
High Speed Drilling Skills Training Module :

High speed drilling is practiced under magnification on defined criteria over an area marked with stencil. Trainee is asked to fashion all four-burr holes

Basic Micro-suturing Training on Synthetic Material		
Suture	**Material**	**Magnification**
4-0	Silk	2·83 (0·4)
		4·25 (0·6)
5-0	Silk	2·83 (0·4)
		4·25 (0·6)
7-0	Monofilament	7·08 (1·0)
		11·33 (1·6)
Intermediate Micro-suturing Training on Synthetic Material		
9-0	Monofilament	11·33 (1·6)
		17·71 (2·5)
10-0	Monofilament	11·33 (1·6)
		17·71 (2·5)



Basic Drilling	
Bit-type	**Magnification**
3mm Cutting Match Head	4·25 (0·6)
Advanced Drilling	
3mm Diamond Match Head	7·08 (1·0)



Basic Neuro-endoscopy	
Particulars	**Dimension**
Forceps	160mm
Plate	Straight
Collars	20mm
Angle of scope	0 degree
Advanced Neuro-endoscopy	
Particulars	**Dimension**
Forceps	160mm
Plate	Tilted (Left and Right)
Collars	10mm
Angle of scope	30 degrees, 45 degrees

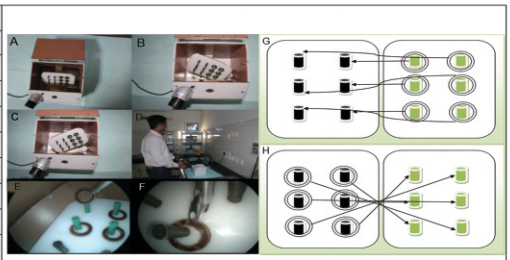


Fig.: 3 Standardization of Micro-suturing Skills Training Module
A, Synthetic material for micro-suturing training; B, Evaluation of effectualness of micro-suturing
Standardization of High Speed Drilling Skills Training Module
A, Drilling practice on sheep scapula on standardized markers for evaluation;
B, The stencil for marking on sheep scapula/ head;
C The drilling practice patterns on stencil marked area.
Standardization of Neuro-endoscopy Skills Training module.
A, NETS Neuro Endo Trainer showing black and green pegs with rings at its base, a burr hole sized hole at the anterior aspect of the box for endoscope and instrument, and auxiliary camera for independent observation; B and C, the acrylic base can be rotated in various directions for testing eye-hand co-ordination-perceptual switch; D, a trainee practicing on Endo-trainer with task based mechanism and viewing over the screen; E,F, pick and place with different angled 0, 30, 45 degrees endoscopes; G, H patterns for doing the experiment

Table 2: NETS criteria for neurosurgery skills evaluation.
(NETS, Neurosurgery Education and Training School)

S No.	Criteria	Evaluation Parameter	1	2	3	4
1	Eye hand coordination	-Handling of instruments (Needle holder, forceps, drill, endoscope, grasper) -Depth perception (under magnification)	Continuous struggle throughout the activity	Frequent loss of coordination	Grossly smooth coordination	Perfect coordination
2	Instrument tissue manipulation	-Tissue handling under magnification with various instruments -Appropriate pressure and force -Confrontation with neighboring objects (Repeated puncture)	Grossly unacceptable	Frequent difficulty	Smooth handling	Perfect manipulation
3	Dexterity	-Tremors/ jitteriness -Therblig (intraoperative elemental motion)	Irregular therblig/ tremors/ jitteriness throughout the activity	Frequent difficulty	Grossly smooth	Perfect dexterity
4	Flow of procedure	-Time management during activity -Total duration in task completion -Unnecessary delays in inter or intra therblig	Grossly unacceptable	Frequent lapses	Grossly smooth	Perfect flow
5	Effectualness	Evaluation of end result on predefined criteria* for -Micro-suturing or -High speed drilling or -Neuro-endosocpy	Grossly unacceptable	Partially acceptable	Grossly acceptable	Perfect end result

Criteria for effectualness*

A. Micro-suturing:
-Margins (Overlapped/ loose/apposed);
-Inter-sutural distance (equal/ unequal);
-Sutural distance on both sides of the incision (equal/unequal);
-Angulation between suture and knot (Near perpendicular- Yes/No)

B. High Speed Drilling:
-Drilled burr hole (cylindrical versus irregular shape viz. cone, serpiginous)
-Intactness of dura/ inner core of egg/ periosteum on other side of bone
-Drilling within stencil marked area
-Approximation of straight movement/ direction

C. Neuroendoscopy:
-Final position of rings
1. ≥3 rings slipped
2. 2 rings slipped
3. 1 ring slipped
4. All rings in place

followed by drilling along the path in predefined direction.

Neuro-endoscopy Skills Training module :

Neuroendoscopy skills training module is practiced on NETS Neuro Endo Trainer box for pick and place experiment.

Formative Assessment and Evaluation Parameters for Trainees :

All skills training activities are recorded for self and expert evaluation. These sessions help in the development of eye-hand coordination, instrument-tissue manipulation, dexterity, speed and effectualness translating into steep learning curve. Each student is evaluated on structured spot four-point NETS criteria for basic neurosurgical skills (Table 2).

Validation of Neurosurgery Skills Training Curriculum :

'Neurosurgery Skills Training Workshops' are organized thrice a year for three days. On an average, 13-18 trainees are enrolled. Each training module consists of an interactive cognitive training regarding a procedure, video demonstration followed by recapitulation of techniques for use of instruments, followed by hands-on practice. Practice sessions comprise micro-neurosurgery, neuro-endoscopy, high-speed drilling and

spine instrumentation. Teachers independently evaluate trainees on subjective and objective criteria. Such evaluation reduces the chances of observer bias. The best performers in each activity are awarded.

Summative assessment Criteria for Neurosurgery Skills Training Modules and Faculty Evaluation :

Trainees also evaluate scientific program and trainer efficiency on structured predefined criteria. For the matter of confidentiality, all evaluations and feedbacks are forwarded to NETS-SAC. This feedback helps in making necessary changes in training modules and faculty selection.

Gap-based Feedback :

Gap-based feedback is obtained by personal communication (email). It is required to assess the translational effect of training into improved surgical performance and patient outcome.

RESULTS :

Formulation of Structured Simulation-based Skills Training Program :

Simulation in neurosurgery has made a significant step in education and skills training on an academic and translational platform (Fig. 2) (14).

The structured simulation neurosurgery skills training program consisted of Basic, Intermediate and Advanced Modules. The modules were graded based on their difficulty and fidelity. The Basic and Intermediate Modules are predominantly low fidelity task-based modules to acquire eye-hand coordination, instrument and tissue handling, dexterity and smooth flow of procedure. The Advanced Modules are predominantly high fidelity cadaveric procedure-based modules for training in surgical approaches using the basic and intermediate skills. These were provided to the trainees of our institute based on their year and level of training.

Micro-Neurosurgery Skills Training Modules (Fig. 3) :

These module starts with instructions regarding handling of microscope and micro-instruments, and the micro-suturing techniques. Basic and Intermediate Modules are practiced over silastic sheet (marked with squares of 1 x 1cm^2 area) mounted on a fixation board. After making 1 cm straight incision on the silastic sheet, trainee practices tying interrupted knots with suture and magnification according to his level. In the ***Basic Module***, 4-0 Silk, 5-0 Silk and 7-0 monofilament sutures are used at lower magnifications / magnification factor (MF) (2.83/0.4, 4.25/0.6 and 7.08/1.0). In the ***Intermediate Module*** finer monofilament suture material like 9-0 and 10-0 Nylon are used at higher magnifications (11.33/1.6 and 17.71/2.5).

Advanced Micro-suturing Skills Training Module:

This module comprises of hands-on micro-suturing practice over high fidelity 'Live Animal Tissue Module'

(LATM). The rat or guinea pig is anesthetized using intra-peritoneal phenobarbital. The sciatic nerve is exposed under lower magnification. The nerve is sectioned and anastomosis is performed with fine monofilament sutures (Nylon 10-0) under high magnification (11.33/1.6 and 17.71/2.5). Following successful nerve anastomosis, the trainees perform micro-vascular anastomosis of rat femoral artery under high magnification with 10-0 Nylon. Following exposure of the target artery, the clamps are applied on either sides of site of incision. The cut edges are stained with Methylene Blue for vessel demarcation. The blood clots at the edges are flushed with heparinized saline. Heel and toe approximation sutures are placed at the two ends; three to four interrupted sutures are placed on one side and the vessel is turned over and similar fine sutures are placed on the other side. The patency is checked by release of the clamps.

High Speed Drill Skills Training Modules (Fig. 3) :

Basic Module consists of naked eye drilling over freeze-dried sheep head and scapula (Cadaver Animal Tissue Module - CATM). In the ***Intermediate Module***, trainee practices drilling under microscope on flat and curved bones (freeze dried sheep scapula and head) over an area marked with stencil (Neuro-Drill-Trainer-Stencil Patent application number: 2874/DEL/2014). The "Stencil" marks a square with predefined areas for burr-hole placement and interconnecting drill path in set directions. Initial drilling is done with cutting match-head drill bit followed by diamond match-head drill bit to preserve the inner membrane (periosteum or dura). Following elevation of the flap/calvarium, it is split with fine tapered drill bit. The eggshell drilling using fine diamond match-head drill bit without breaching the inner membrane is also a part of this module.

The ***Advanced Module*** is a 'Cadaveric Neuro-anatomy Dissection Module' (CNADM) incorporating planning, techniques and tips for usage of high-speed drills in cadaveric microscopic skull base approaches e.g. anterior clinoidectomy, anterior and posterior petrosal approaches, far lateral approaches. (3D Microscope: Sony Inc., Japan and Carl Zeiss, Germany). The Advanced Modules consist of anatomical demonstration, pathological and radiological discussions regarding lesions for which the approach is used, surgical operative videos, 3D cadaveric demostrations and hands-on cadaveric dissection.

Neuro-endoscopy Skills Training Modules (Fig. 3) :

In the ***Basic Module***, the trainee is familiarized with endoscope part assembly and eye-hand coordination practice. They practice on natural simulations like capsicum and papaya. Inner structures of capsicum and papaya simulate endonasal and ventricular anatomy respectively. Trainees practice biopsy, and pick and place in these

modules to develop dexterity and eye-hand coordination. It helps acclimatize to the changed anatomy (3-dimensional to 2-dimensional visualization) and ergonomics.

The ***Intermediate Module*** involves practice on a box trainer called Neuro-Endo-Trainer. (Patent application number: 2875/DEL/2014). It is a training box with 12 pegs on a rotatable base plate. There are 6 rubber rings around the pegs. Each session consists of picking and placing of the rings from the object area to the target area. The patterns for training are:

1) Pick and place the rings from object to target area in horizontal manner.
2) Pick and place the rings in diagonal manner, back to earlier arrangement.

The activity is recorded with endoscopic camera for evaluation. The trainees perform endoscopy practice with the base plate in three different positions namely, straight (0^0), left tilt ($+30^0$) and right tilt (-30^0) providing a perceptual switch. Initial practice is performed with 0 degree scope followed by 30 and 45 degrees scopes.

The ***Advanced Module*** has 'Synthetic Simulation Module' (SSM) and 'Cadaveric Neuro-anatomy Dissection Module' (CNADM) to detail the intricacies of skull base and ventricular neuro-endoscopy techniques. Skull base neuro-endoscopy sub-modules include endoscopic anatomy of sella and skull base, and endoscopic endonasal approach to pituitary and extended skull base. The skull base cadaveric demostrations are done with 3D endoscope for better anatomic orientation (3D Neuro-endoscope, Vision Sense Inc, USA). Ventricular neuro-endoscopy sub-modules comprise of endoscopic anatomy of ventricles, and its approaches e.g. Endoscopic Third Ventriculostomy (ETV) and endoscopic treatment of intraventricular cysts and lesions.

Spine Instrumentation Module :

Basic Spine Module familiarizes the trainee with spine anatomy and identification of landmarks and entry points for commonly practiced surgical approaches.

Intermediate and Advanced Spine Instrumentation Skills Training Modules: Training in these modules include detailed study of cervical, dorsal and lumbar spine instrumentation and hands-on practice on synthetic models (saw bones).

- Cervical spine: anterior cervical plate fixation, odontoid screw fixation, posterior occipito-cervical fixation and C1-C2 transarticular screw fixation.
- Dorsal and lumbar spine: pedicles screw fixation and anterior thoracolumbar fixation.

Summative assessment :

Content Evaluation (Summative Assessment) :

Till December 2013, 179 trainees attended 12 neurosurgery skills training workshops. Trainees consistently rate these workshops high (Fig. 4).

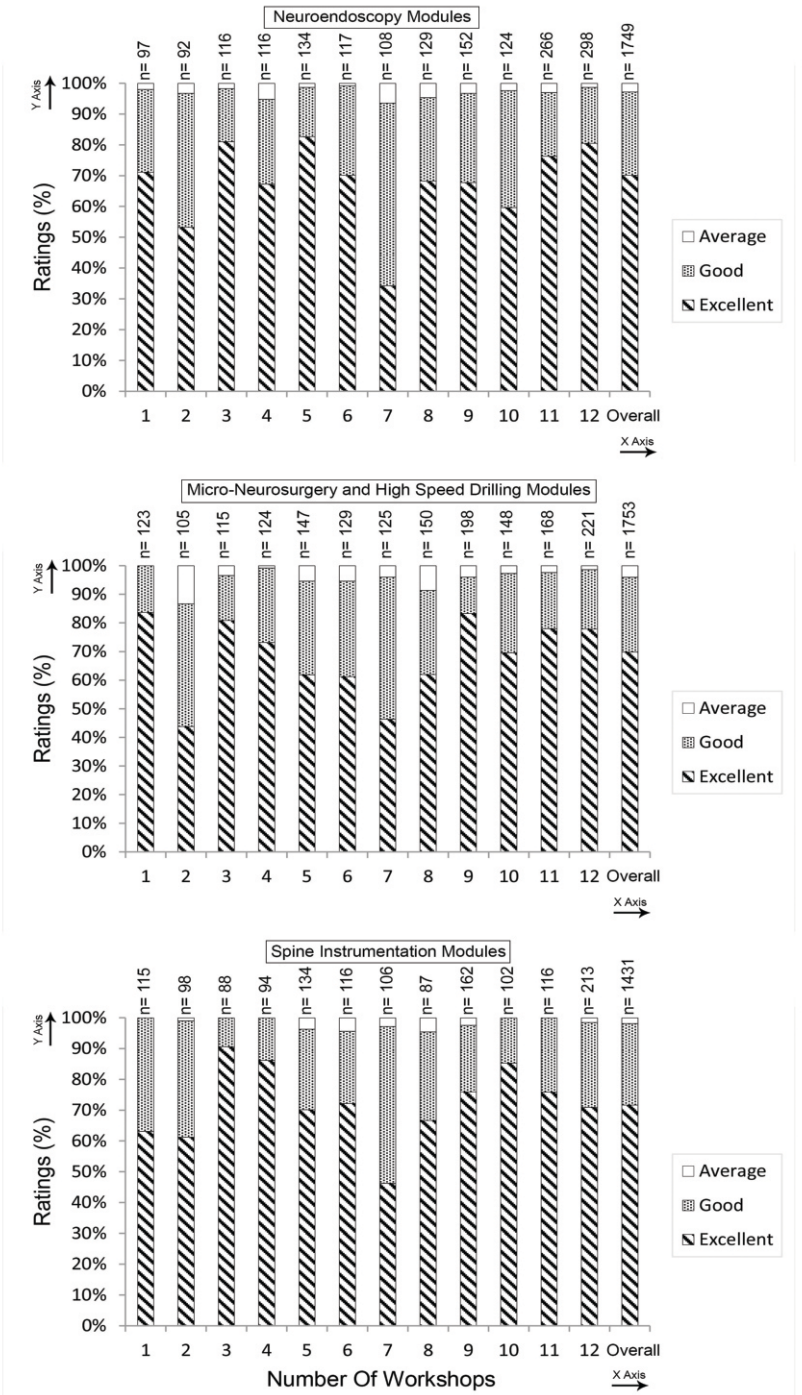


Fig. 4: Ratings of Neuroendoscopy, Micro-suturing, High Speed Drilling, and Spine Instrumentation Modules

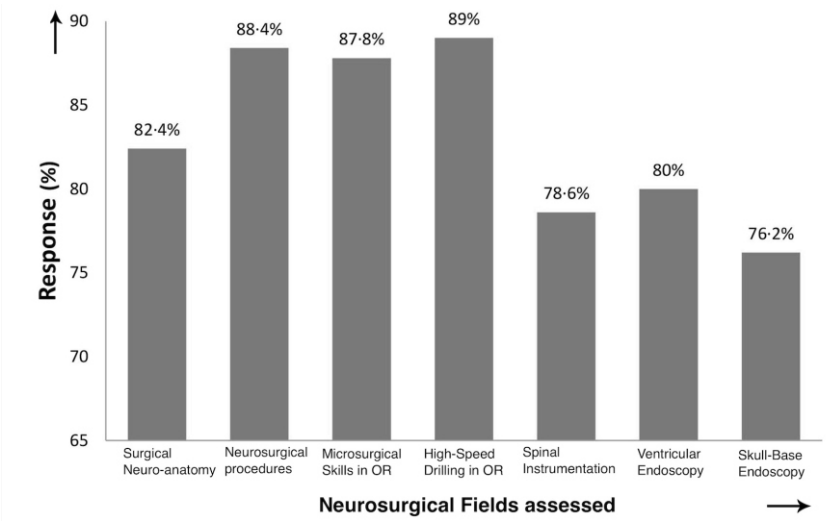


Fig. 5: Gap-based Evaluation

Faculty Evaluation (Summative Assessment):

Faculty evaluation is of prime importance to decide candidates with CI potential. For inter-faculty comparison, we have chosen only excellent markings. Only faculty with participation in ≥3 workshops, were included in comparative analysis (Fig. 4).

Gap-based Evaluation :

179 workshop trainees were contacted with emails for long-term feedback. Among these, 22 emails could not be delivered. 34/157 (21.7%) trainees responded back and the mean of component-based feedbacks is depicted in Fig. 5. Trainees were maximally benefitted in high-speed drilling followed by micro-neurosurgery. Most of the trainees were satisfied with content modules and teaching faculty, but 23.8% trainees were still not confident with skull-base endoscopy. This highlights the deficit of training in neuro-endoscopy in existing residency program, which needs a reform.

Discussion :

Skills training in a dynamic educational environment is an inevitable aspect in any field, especially when it involves nimbleness and dexterity. Achievement of surgical competence is a complex process that involves the attainment of knowledge, judgment, professionalism and surgical skills (20). In depth knowledge of the rules and legerdemains of any sport cannot increase the manoeuvrability of a naïveté, unless allowed to practically experiment with the respective equipment along with stringent training. For a neurosurgeon, it becomes furthermore imperative to manoeuvre the tactics of basic surgical skills to deal with

the demanding situations encountered almost daily in neurosurgery OR. Iatrogenic injuries are the eighth leading cause of death in America and occur in approximately 4% of hospitalizations (19-24). Council of State Neurosurgical Societies post-residency survey shows inadequate level of general neurosurgical training felt by 20% of board-certified neurosurgeons. This is later on reflected by large number of them (40%) taking part in different fellowships after completing residency program (5).

Surgical Skills Training Programs: Competency cum Period Based Training :

Surgical subspecialties emphasizing minimally invasive procedures (like obstetrics and gynaecology, laparoscopic surgery) have foreseen the need of laboratory training for capacity building. Reznick *et al* (24) have discussed the utilization of available 'low and high fidelity' laboratory models for surgical training, depending upon the degree to which they replicate surgical substrate. Bench models are cheap, reusable and low fidelity; useful for teaching novices, the basic skills such as suturing, knot tying and instrument manipulation. Live animals and cadavers are high fidelity models allowing a trainee with advanced procedural knowledge to practice and refine entire surgical procedures. Spectrum of these devices stretches from simple homemade cardboard boxes to the most advanced 3D surgical simulator incorporating haptic interfaces and advanced graphics. From observations on the performance of expert musicians, chess players and athletes, it has been shown that the level of expertise thus attained is dependent on the time devoted to deliberate practice. 'Deliberate practice' involves focusing on a particular step, identified by an expert instructor, with an aim to improve trainees overall performance for a given task. Following the same logic, breaking down surgical procedures into modules designed for lab practice is also expected to benefit a trainee in better utilization of his time (24).

Contemporary Training Programs in Neurosurgery :

It can be argued that neurosurgical operations are complex and its replication in a laboratory may not always be feasible. With limiting volume of exposure and decreased time in OR, opportunities to learn are getting less. An effective strategy for acquisition of expertise in such a scenario is a time honoured deliberate competency based practice (25, 26).

Imparting basic neurosurgical skills and simulation of common surgical procedures, outside the OR answers the need for a non-threatening environment, closely mimicking surgical settings, where a trainee can practice at comfortable pace. Most of the existing simulation models are low fidelity with non-structured criteria for skills evaluation. Only a few of these skills training programs are replicable to neurosurgical scenario. SNS bootcamp course has a promising impact in development of neurosurgery skills

training curriculum to be incorporated into routine residency program (27, 28).

Neurosurgery Skills Training Curriculum (NSTC) :

Curriculum design involves multidisciplinary consultation and research paying due attention to the needs of residents, work hour restriction and societal needs. This integrates opinions of residents, health professionals, administration officials, governmental policies, educationalists and industrial designers (28). Modular curriculum emphasizes the use of bench models for training basic task-based skills (28), which can further augment trainees' experience with cadavers and live animals for procedural skills. "Three stage theory of motor skill acquisition" explains that minutiae's of procedural skills can be grasped only after mastery at basic surgical skills (28). A surgeon incompetent at this basic step cannot learn the advanced stages of the field. A standardized simulation program incorporates the benefits of aforementioned low and high-fidelity training systems (Fig. 5). It allows supervision, self-instruction and practice of basic and advanced surgical techniques. Trainee attending short-term skills training program gradually improves by self and expert assessment (formative assessment). The workshops focus on trained certified neurosurgeons to revise, update and evaluate procedural skills on high-fidelity simulation models (summative assessment).

Skills Evaluation Criteria :

Skills evaluation criteria have been a matter of debate since the advent of simulation systems. Most of these criteria have been developed for general surgical skills evaluation and none for neurosurgery skills (microscopic and endoscopic). For objective skills evaluation, we have followed objective assessment criteria with neurosurgical perspective, namely "NETS criteria" (Table 2).

e-Learning Platform :

We believe that there should be no time, place or monetary constraints for any learner of any class or creed that could limit their potential because of unavailability of learning material. e-Learning platform provides learner's control over content, learning sequence, pace of learning and time, making it a "quick surf, find and extract" platform, allowing them to meet their individual learning objectives. Neurosurgeons can collaborate, discuss and contribute in the process of learning, and the educators become facilitators of the learning process rather than deliverers while students become participants rather than listeners (17).

Skills Transfer in OR :

80% of trials have suggested that there is significant improvement in NETS score in OR after simulation training (29, 30). Laboratory training methods may abbreviate only the initial part of the

learning curve associated with acquisition of basic procedural skills (31) . Nevertheless, the implementation of such methods will enable a trainee to be more efficient and productive with time. Gap-based evaluation indicates that workshop attendees feel more comfortable in OR after high-fidelity simulation training.

Suggested guidelines :

There is an earnest need for neurosurgery skills training curriculum reform in accordance with the existing educational and training demands. Good quality papers specifically on education written by neurosurgeons are sparse over the last 30 years (2). To fill gaps in education system, skills training curriculum should aim at:

- Supplementing existing system of Halstedian apprenticeship model of teaching.
- Shortening time required to learn basic skills of neurosurgery: acquisition of minimal level of competency.
- Training significant part of the learning curve outside OR, to enhance patient safety and to provide opportunity for focused practice.
- Encouragement of evaluation based improvement of skills acquisition.
- Open source, free access e-learning material, irrespective of geographical boundaries.
- Capacity Building: Encouragement of trained practicing neurosurgeons to play the role of faculty in future.
- Collaborative training by visiting consultants from various institutes.
- With the modular based studies, it is well evident that skills training cannot be imparted only with the help of workshops; rather should be as a part of the regular residency program. This will be in par with the technical advancements and provide sufficient time for skills acquisition. So, it becomes necessary to pay proper attention to incorporate such programs to maintain same level of skill and expertise among all neurosurgeons to protect and preserve quality neurosurgical education now and in future (32, 33).

Conclusion :

Technical evolution in surgery has created new skill sets and techniques that must be mastered by both practicing surgeons and trainees prior to clinical application. With modular training program, it is evident that skills training cannot be imparted only with help of workshops; rather should be part of regular residency program. This will be in par with technical advancements and provide sufficient time for skills acquisition.

We do not oppose time honoured years-in-place based training system but propose to substantiate it with competency-based training. Positive results of incorporation of skills training curriculum may be regarded as a value base for such programs in other branches of medical practice. This would help in achieving greater visibility in professionalism imperative for high-end

branches like neurosurgery and proven competency at the end of training program.

Acknowledgement :

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