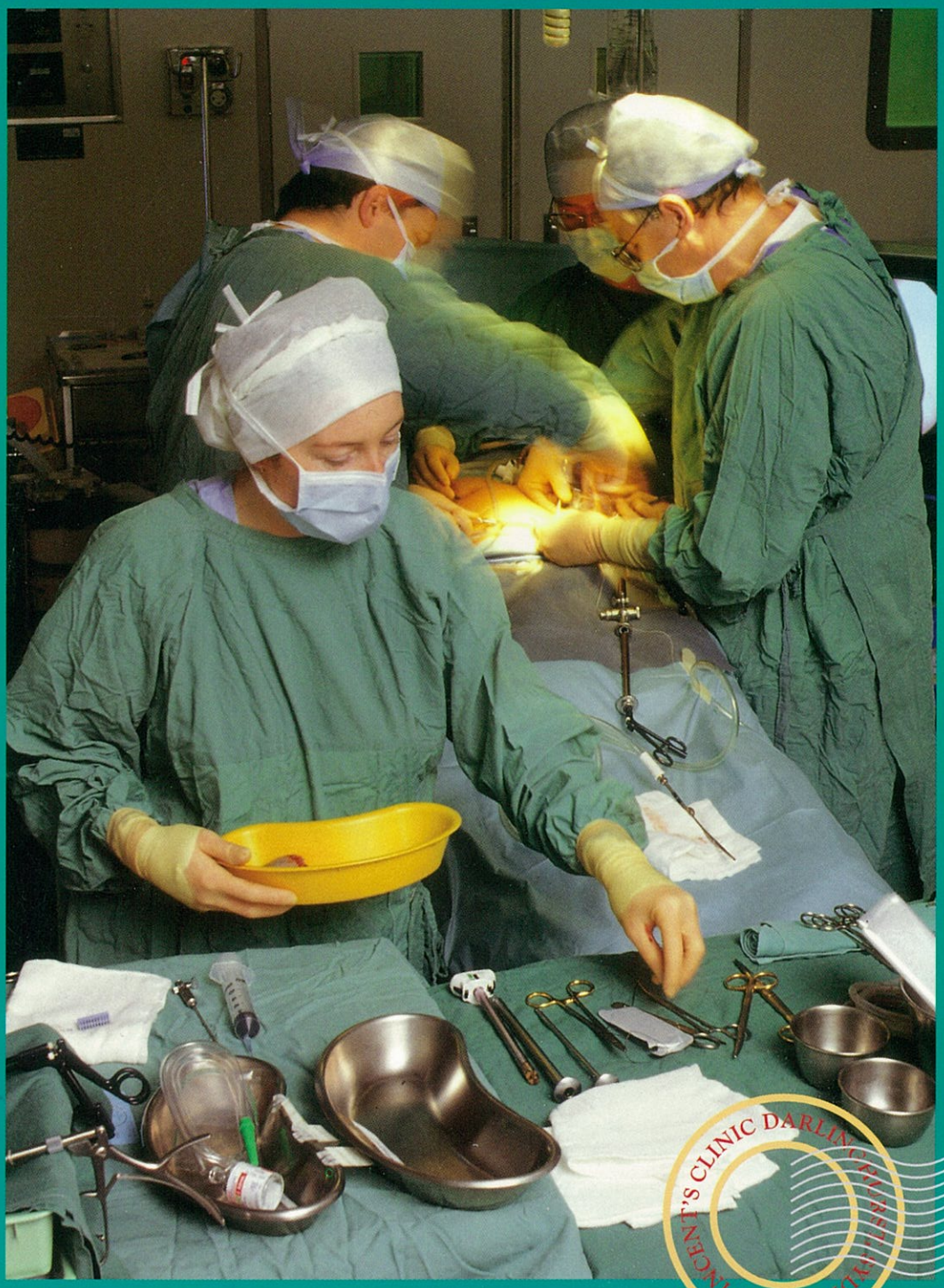
PROCEEDINGS

ST VINCENT'S CLINIC, SYDNEY

VOLUME 2 No:1 JUNE 1994



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EDITORIAL

Dr John Roarty

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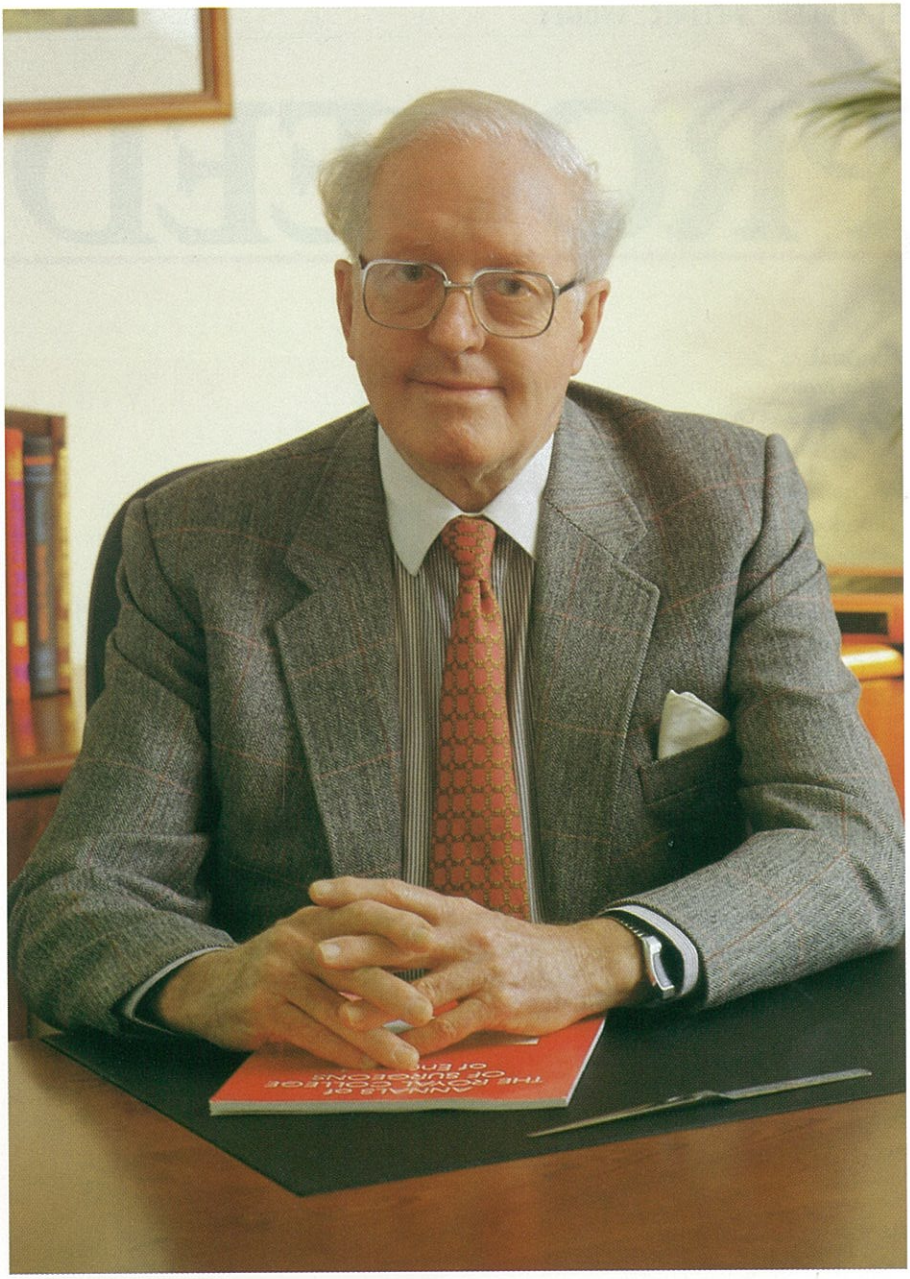


This issue of Proceedings brings reports of remarkable advances and new technology in the fields of heart disease, neurosurgery and otology, and in the diagnosis and management of prostate cancer which is increasingly prevalent.

Drs Richard Yeend, John Morgan and Paul Roy describe their current attitude to the treatment of mitral stenosis. A little over a decade ago, patients suffering from heart failure due to pathology of the mitral valve could only be helped by open heart surgery and valvotomy or replacement of the valve itself. The late Dr Harry Windsor of this hospital performed the first such procedure in Australia. Many of these patients are young and the prospect of a normal life expectancy has been uncertain. Now with the technique of percutaneous balloon valvuloplasty, open heart surgery can be avoided. There has been a 95 per cent success rate in 77 cases to date.

Drs Malcolm Pell and Paul Fagan relate significant improvements in the diagnosis and treatment of many cerebral conditions, hearing loss and management of vertigo. The co-operation of neurosurgeons, otologists and head and neck surgeons operating together have opened a whole new field of 'skull base surgery'. Pre-operative planning of brain lesions by computer imaging and stereotaxy has made the approach to intracerebral tumours safer and more accessible. In 200 procedures since 1992 morbidity is as low as one per cent.

Dr Stricker draws attention to the importance of early diagnosis of prostate cancer. New methods of treatment of prostatic hypertrophy by trans-urethral needle ablation (TUNA), laser prostatectomy and early results with medical management using beta-blocker drugs is described. Early diagnosis of prostate cancer by regular rectal examination in men over 45, PSA estimations, and where indicated radical prostatectomy, give the best results for cure.

Smokers Clinic Director, Renee Bittoun, reports on research of a different nature concerning the downside of using nicotine patches as part of smoking cessation.

St Vincent's Clinic aspires to excellence in patient care. These reports of new advances in therapy are made to improve the comfort and quality of life for patients who attend the Clinic.

Paul Roy

Percutaneous Balloon Mitral Valvuloplasty with the Inoue Single Balloon: The St Vincent's Experience

Abstract

Percutaneous transvenous mitral valvuloplasty (PTMV) is a safe effective therapy for selected patients with symptomatic mitral stenosis. It was first introduced by Inoue et al[1] into clinical practice in 1984 and now replaces the need for surgery in many patients with mitral stenosis. At St Vincent's Hospital, 77 patients have undergone percutaneous mitral valvuloplasty with the single Inoue balloon since 1989. The procedural success rate is 95% with only one patient requiring urgent surgery for cardiac tamponade. This article will describe the Inoue single balloon method of mitral valvuloplasty and present our experience at St Vincent's Hospital.

Richard Yeend, M.B.B.S., F.R.A.C.P., John J Morgan, M.B.B.S., F.R.A.C.P., F.A.C.C., and Paul Roy, F.R.C.P., F.R.A.C.P., F.A.C.C.

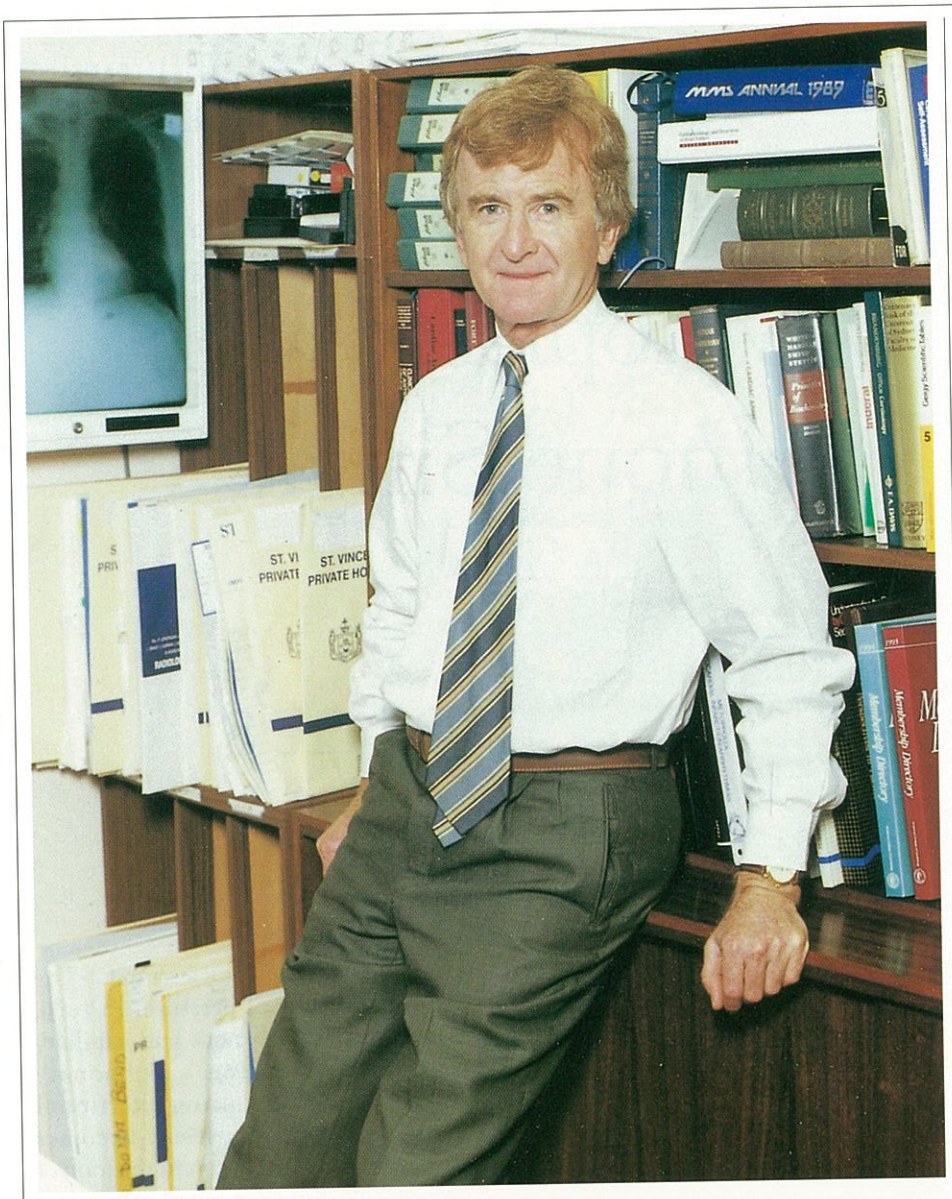
All correspondence to Dr P R Roy, Consultant Cardiologist, St Vincent's Clinic.

Introduction

Mitral stenosis is usually secondary to rheumatic fever or (more rarely) it is congenital. The valve leaflets are diffusely thickened by fibrous tissue and/or calcific deposits. The mitral commissures fuse, the chordae tendinae fuse and shorten, the valvular cusps become rigid, and these changes in turn lead to narrowing at the apex of the funnel-shaped valve. The latent period between the initial attack of rheumatic carditis (often a history of rheumatic fever is not obtained from the patient) is usually over two decades. Once a patient with mitral stenosis becomes symptomatic, continuous progression of the disease to death usually occurs in two to five years.

In normal adults the mitral valve orifice is 4-6 cm^2. When the orifice is reduced to approximately 2 cm^2, which is considered mild mitral stenosis, blood can flow from the left atrium to the left ventricle only if propelled by an abnormal pressure gradient. When the mitral valve opening is reduced to 1cm^2, which is considered critical mitral stenosis, a left atrial pressure of approximately 25mmHg is required to maintain a normal cardiac output. The elevated left atrial pressure, in turn, raises pulmonary venous and capillary pressures reducing pulmonary compliance and causing exertional dyspnoea. Once a patient becomes symptomatic, intervention in the form of surgical closed or open mitral valvotomy, or even mitral valve replacement, has traditionally been the management of choice. However, over the last decade percutaneous mitral valvuloplasty with single or double balloon techniques has been used successfully in patients with rheumatic mitral stenosis particularly when stenosis results primarily from commissural fusion with associated leaflet thickening. Since its introduction in 1984[1], percutaneous mitral valvuloplasty has provided results which are comparable with the results obtained with closed mitral valvotomy, with lower morbidity and mortality.

At St Vincent's Hospital, the first mitral valvuloplasty using the Inoue single balloon was performed in August 1989. Before that time a small number of patients had undergone mitral valvuloplasty using the double balloon technique. Using the single balloon has the advantage of taking less time to perform and has a lower incidence of significant mitral regurgitation.[2,3]



Kanji Inoue the inventor of the ingenious balloon, while speaking at the American College of Cardiology meeting, was invited to visit St Vincent's. We were pleased to welcome him here in August 1989. While spending a few days with us he demonstrated the procedure on the first six patients done at the hospital. He proved to be an excellent teacher and taught us not only the technique of transeptal puncture and mitral valvuloplasty but also gave us very good advice on selecting the appropriate patients. Since then 71 mitral valvuloplasties have been performed using the Inoue balloon. Of the 77 patients in total, 65 were female and 12 male. A majority of the patients have been immigrants to this country. Rheumatic fever is no longer a common problem here in Australia. Their mean age was 48 ∓ 12 years with most patients being in New York Heart Association Classes II and III. Twenty-nine patients (28%) were in atrial fibrillation at the time of the procedure.

Patient Selection

Candidates for PTMV should be carefully evaluated by history, physical examination and laboratory tests including electrocardiography, chest x-ray and echocardiography. Colour doppler two-dimensional echo-cardiography is essential to decide which patients are most suitable for valvuloplasty and which would be better off with mitral valve replacement. Commissural splitting is the dominant mechanism by which mitral valve area is increased by the balloon.[3] Therefore the extent of fusion, fibrosis or calcification of one or both commissures is a major determinant of the outcome of mitral valvotomy. Echocardiography allows careful analysis of mitral valve morphologies. Patients with pliable valves without severe subvalvular lesions are ideal candidates. Patients with poorly mobile mitral leaflets, severely fused commissures, and significant subvalvular lesions may obtain less than optimal results and are of higher risk of developing mitral regurgitation.[4]

We therefore rely heavily on the echo data before undertaking mitral balloon valvuloplasty. We have been fortunate to have excellent help from both Diane Fatkin and Michael Feneley in our Echo Department. Following our first 30 patients they analysed the echo data and found that commisurral splitting was the dominant mechanism by which the mitral valve area is increased with the Inoue balloon and they also confirmed that the success of commissural splitting can be predicted echocardiographically by a careful assessment of the morphology of the commissures (Fatkin et al).[5]

The procedure is not usually performed if there is more than trivial to mild mitral regurgitation or if there is a history of a recent embolisation. As the atrial septum is punctured during the procedure any thrombus in the left atrium can be dispersed into the circulation by either the transeptal needle or the balloon. For this reason if a left atrial thrombus is suspected transoesophageal echocardiography is performed. The patient with a thrombus should be warfarinised for four to six weeks before valvuloplasty.

The balloon catheter can be inserted irrespective of orifice size. Generally symptoms do not occur until the orifice size is less than 1.5 cm^2. In the presence of less severe mitral stenosis the procedure may be made necessary by disabling symptoms, particularly if the patient is performing heavy physical work. In those patients whose valve morphology is not ideal for balloon valvuloplasty it can also be considered if associated illnesses make open heart surgery prohibitive (renal, hepatic and respiratory disease). Occasionally during pregnancy pulmonary oedema will result from severe mitral stenosis and the balloon procedure can be performed with much less risk to the foetus than open heart surgery. It is ideally performed after five months under these circumstances, so that the impact of any x-ray irradiation on the foetus is minimal.

Valvuloplasty Procedure

Preparation

Patients are usually admitted to hospital the day of the procedure. Those on warfarin may be admitted earlier for cessation of warfarin and commencement of heparin. The patient is given light sedation (lorazepam 1 mg orally) prior to the procedure but may be given intravenous midazolam (1-2 mg) if transoesophageal echocardiography is also performed. All patients undergo right and left heart catheterisation prior to the procedure to assess mitral valve gradient. In patients over 40 or with a history of angina, selective coronary arteriography has usually been performed previously along with right and left heart catheterisation. Echodoppler either via transoesophageal route (if tolerated) or transthoracic is performed during the procedure to assist with the site of septal puncture and aid in positioning the balloon across the stenosed valve. Increase in mitral valve area and the development of mitral regurgitation can be immediately assessed with the aid of echodoppler.

Inoue Balloon Catheters

The Inoue balloon has a 12. Fr. polyvinyl chloride tube shaft with a coaxial double lumen (as shown in Figure 1).[6] The inner lumen of the catheter (a) permits pressure measurements, blood sampling, and insertion of a metal tube, guide wire, or stylet. The outer lumen connects proximally with a two-way stopcock (b), used to connect the catheter to an inflation/deflation syringe and a vent (c), and distally with a balloon mounted at the end of the shaft. The balloon is made of double layers of latex tubing. It can be transformed to various shapes from its natural form to serve different functions. The balloon is stiffened and slenderised when the rubber balloon is stretched by inserting a metal tube. The standardised balloon allows a smooth entry of the balloon catheter into the femoral vein without the use of an introducer set. It also permits an easy passage of the catheter across the atrial septum. The balloon changes its shape in three stages, depending on the extent of inflation. Initially only the distal half inflates followed by the proximal half with a constriction remaining in the middle. The constriction finally disappears when the balloon attains full inflation.

Balloon Selection

Selection of the balloon catheter is important for each individual patient. If the balloon is too small, dilatation may be ineffective. On the other hand, a balloon that is excessively large may cause avulsion of the commissures and significant mitral regurgitation. The balloon size can be calculated according to set formulae depending on the patient's height and weight.

The Procedure

The key to successful balloon dilatation of the mitral valve depends largely on successful puncture of the interatrial septum. This is a procedure that is not done commonly in the Catheter Lab and must be learned very carefully to avoid problems. In performing transeptal catheterisation one attempts to find the small fossa ovalis which is an indentation on the venous side of the atrial septum. Unfortunately, with high left atrial pressures the bulge that is caused by the interatrial septum may sometimes make it difficult to find the fossa ovalis. If the procedure is not performed with care the transeptal puncture can easily result in penetration of the aorta or penetration of the atrial wall into the pericardial space. Following right femoral vein puncture a pigtail catheter is passed to the right atrium and a right atrial angiogram is performed to outline various markings to guide in the transeptal puncture. The patient is anticoagulated with 10,000 units of heparin.

Using a Brockenbrough needle, careful puncture of the interatrial septum is then made at the site of the fossa ovalis. A stiff guide wire is then introduced into the left atrium across the interatrial septum. The femoral entry

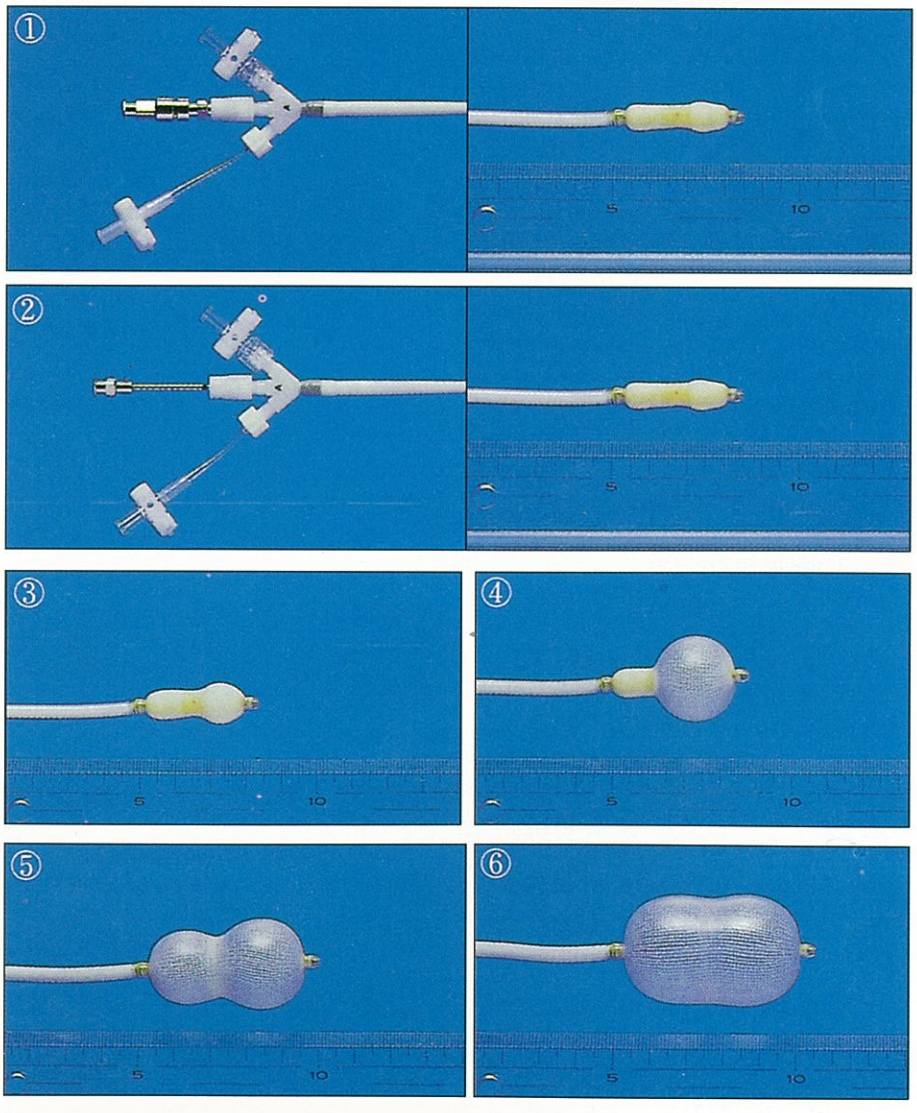
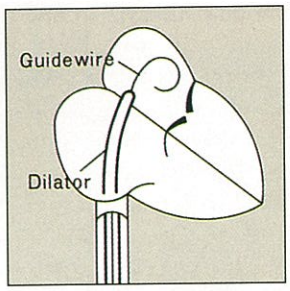
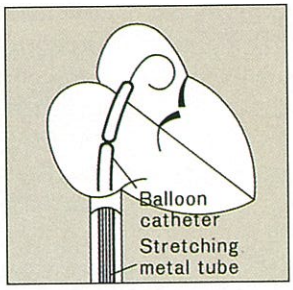


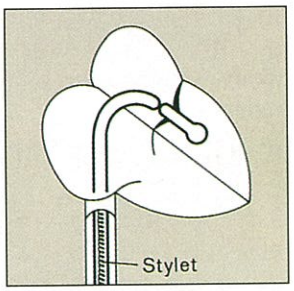
Figure 1



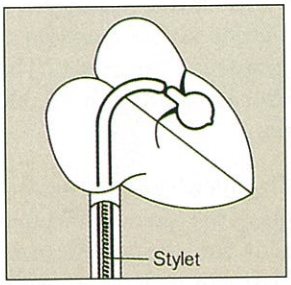
1. *After inserting the guide-wire into the left atrium, expand atrial septal puncture with the dilator.*



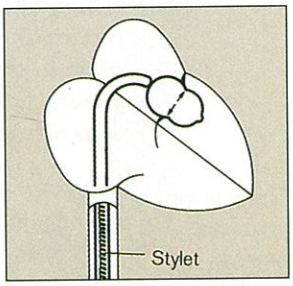
2. *Insert the balloon catheter with the stretching metal tube incorporated.*



3. *Place the balloon at the valvular opening using the stylet.*



4. *Inflate the end of the balloon to place it at the valvular opening.*



5. *Inflate the entire balloon to expand the opening of the valve.*

Figure 2

site and the atrial septum are dilated using a rigid dilator. The Inoue balloon is then passed along the wire across the interatrial septum and into the left atrium. Once in the left atrium the balloon has to be coaxed across the mitral valve and this can sometimes prove difficult. The balloon is inflated sequentially. First the distal portion is inflated with 1 or 2 ml of diluted contrast medium and this allows the operator to see the balloon clearly and also allows the balloon to act as a floating catheter to cross the mitral valve. Once across the valve and moving freely in the left ventricle away from the support apparatus of the valve the distal part of the balloon is then further inflated. With the distal part of the balloon inflated the balloon is pulled back until firm resistance is felt against the mitral orifice. The remainder of the balloon is then inflated so that the proximal segment (which is on the atrial side of the balloon) inflates and the last part to inflate is the central waist of the balloon which will disappear at full inflation (Figure 2).

A stepwise dilation technique with echocardiographic guidance is used. The first inflation is performed 4 mm below the maximal balloon size and the balloon size is gradually increased. After each inflation the balloon is deflated and withdrawn into the left atrium. If mitral regurgitation, as assessed by echocardiography, has not increased and the gradient has not been reduced across the mitral valve, the balloon is readvanced and on subsequent inflation the balloon is enlarged by 2mm. Commissural separation can be immediately assessed with the aid of the echodoppler and a good outcome from the procedure occurs when the final mitral valve area exceeds 1.5 - 2 cm^2 and there is a significant fall in the mitral valve gradient. The total duration of the procedure is usually from 60-90 minutes.

Following the procedure the catheters are withdrawn immediately and manual compression of the femoral vein site is applied for 30 minutes. Oral anticoagulation is continued in cases of atrial fibrillation. The patient is discharged the following day. The procedure can therefore be performed with a one or two night stay in hospital.

Results and Complications

In our series of 77 patients the average mitral valve gradient was 18 ∓ 7 mmHg before valvuloplasty. Following the procedure the immediate gradient had reduced to 7 ∓ 4 mmHg. This corresponded to an increase in mitral valve area from 1.3 ∓ 0.3 cm^2 to 2.1 ∓ 0.5 cm^2. These results are similar to those in large published series of PTMV[7] (see Table 1). Reported failure rates range from 1 to 17%.[8] In our series we had a 95% procedural success rate. Of the four failures, three of the patients had successful atrial septal puncture but the balloon could not be positioned across the mitral valve. The fourth failure occurred during the first 10 patients, when one patient developed cardiac tamponade secondary to inadvertent aortic puncture during the atrial septal puncture. This was repaired successfully at operation.

Five of our patients developed at least moderate mitral regurgitation following valvuloplasty with three of the patients proceeding to elective mitral valve replacement. Two patients with concurrent aortic stenosis had initial

Haemodynamic data before and after valvuloplasty : Comparison with Inoue's results.

	St Vincent's	Inoue[7]
	n=77	n=527
Mitral valve gradient (mmHg)		
Before	18 ∓ 7	12 ∓ 0.3
After	7 ∓ 4	5.5 ∓ 0.1
Mitral valve area cm^2		
Before	1.3 ∓ 0.3	1.13 ∓ 0.02
After	2.1 ∓ 0.5	1.97 ∓ 0.04

Table 1

Complications and failures : Comparison with Inoue's results.

	St Vincent's	Inoue [7]
	n=77	n=527
Failures	5%	2.3%
Mortality	0%	0%
Mitral Regurgitation		
Increase	19%	19%
Severe	3%	2%
Emergency Surgery	1%	1.4%
Thromboembolism	0%	0.6%

Table 2

symptomatic improvement but recurrence of symptoms after two and 12 months, respectively, with subsequent replacement of both the mitral and aortic valves. In one patient, who initially had successful balloon valvotomy, recurrence of mitral stenosis occurred requiring further valvotomy one year later. There have been no reported deaths during valvotomy in our series. No patient has yet required closure of an atrial septal defect and no embolic events have occurred (see Table 2).

Although immediate results of mitral valvuloplasty are good, long term follow up data is limited due to the short history of the device being used. Vahanian's series[9] shows that if PTMV is initially successful, survival rates are excellent, the need for secondary surgery is infrequent, and functional improvement is present in 75 to 90% of cases two to three years after PTMV. The incidence of restenosis (defined as a loss of greater than 50% of initial gain with a valve area of less than 1.5 cm^2) is usually between 10-20%. Block et al.[10] in their two year follow up of successful valvuloplasties, showed ongoing improvement in clinical status two years after their procedure with 75% of their patients improving at least one New York Heart Association class. Prospective, randomised trials comparing valvuloplasty and surgical closed mitral commissurotomy showed no change in the acute results, at eight month follow up and at 3.5 year follow up in mitral valve area calculated by cardiac catheterisation.[11] Thus PTMV is now providing results which are comparable with the results attained with closed mitral valvotomy, with a lower morbidity and mortality.

Conclusion

PTMV using the Inoue balloon technique is a safe and effective treatment for a significant number of patients with mitral stenosis. Patients with pliable valves without severe subvalvular stenosis and valvular calcification are ideal candidates for PTMV. The long-term effect of PTMV in this group of patients is similar to those treated with surgical commissurotomy. In the event that restenosis occurs in these patients the procedure may be repeated. The cost of the procedure is a fraction of that of surgical treatment and hospital stay is reduced from 10 days to one or two days.

The efficacy of PTMV is less optimal in patients with calcified and thickened valves and/or severe subvalvular lesions. These patients are usually referred for mitral valve replacement but PTMV can be considered if there are contraindications to surgery. While rheumatic fever is no longer a common problem in Australia, with continuing migration to this country the need for treatment of mitral stenosis will continue. The Inoue balloon represents a significant advance in the management of these patients.

At St Vincent's we were fortunate to have Kanji Inoue give us the benefit of his enormous experience with this procedure in Asia and also his excellent teaching skills. We have had a high procedural success rate in the 77 patients done so far with few complications.

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Dr Malcom F Pell

Computer Assisted and Frameless Stereotaxy in Neurosurgery

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Introduction

With the rapid and dramatic improvement in neuro-radiological imaging and current technology assisted by the increasing use of computer hardware and related software, modern stereotactic neurosurgery has become an important part of mainstream neurosurgery, and is now available throughout the world. Future progress will be involved with image integration and computer software developments, new instrumentation with the trend towards frameless and open stereotaxy, relocatable frames and increasing use of stereotaxy in therapy. Conventional stereotactic frame systems allow for precise spatial information from computerised tomography (CT), magnetic resonance imaging (MRI) and angiography to be used for operative procedures such as biopsy, excision, or aspiration of various intracranial lesions.[1-5]

A variety of stereotactic systems with these head frames are in commercial use. Target localisation with these head frames has been shown to be accurate, but its use in open craniotomy has been limited by the presence of the frame during the procedure and the need for the frame to remain fixed in the same position to allow reproduction of information from different imaging modalities. These limitations have been somewhat overcome by the development of modern target-centred arc-quadrant stereotactic devices such as the Cosman-Robert-Wells (CRW) system, which may be rotated out of the operative field with no loss of spatial co-ordinates.[4]

St Vincent's Hospital Sydney has a stereotactic system located in use both in St Vincent's Private and St Vincent's General Hospitals and since 1992 almost 200 procedures have been performed using this equipment, with morbidity as low as 1%.

More recent developments have evolved in the stereotactic technique that require no mechanical linkage with a frame. Reference points on a patient's skull can be identified on imaging studies. Touching these points (three or more) with a digitiser at the time of the actual surgical procedure defines the plane which allows construction of the sterotactic co-ordinate system.

Modern developments in computer interaction with imaging techniques allow intraoperative imaging of intracranial lesions either from external cranial landmarks such as the external auditory meatus, bridge of nasion, or fixed fiducials such as staples which are applied prior to scanning. Intracranial

structures and lesions are shown on preoperative imaging. An assigned stereotactic co-ordinate can be reproduced during the operation using the combination of a digitiser in the operating suite and computer interaction with the preoperative images.

Several systems based on this method have been developed that incorporate frameless stereotactic co-ordinates including the Operating Arm System (Radionics, Massachusetts) developed by Drs Barton Guthrie and John Adler of the George Washington University and the University of Alabama.[6,7] The Operating Arm System facilitates minimally invasive surgery for a variety of procedures such as biopsies, resections and shunt placements. It provides for the visualisation of trajectories so that optimal surgical openings and paths to anatomical targets can be easily determined prior to the surgical incision as well as throughout the procedure. The arm system includes an ergonomically designed articulated mechanical arm together with a more friendly interface and powerful graphic software. The patented `arm as a mouse' software interface is simple to use and entirely controlled by the surgeon without an assistant and without breaking sterility.

St Vincent's Hospital Sydney has now installed an Operating Arm System in its neurosurgical theatre. This is the first such installation in the whole of Australia of any computer assisted or frameless stereotactic system. It is only the third centre in the world outside the University of Alabama and the Boston General Hospital to use the Operating Arm System. St Vincent's Hospital is involved in clinical trials using this system to check the accuracy and reliability of the frameless system as compared to the CRW frame based system in current use. The initial results have been promising.

Components of the Operating Arm System (OAS)[8]
Operating Arm (six-jointed digitiser)
Case-specific end attachments
Mayfield Compatible Table Mount Floor Stand
Graphics Computer with user interface

Table 1

System Components

The Operating Arm System or (OAS) has several functional components.[8] (Table 1) The Operating Arm (Figure 1) is a mechanical digitiser accurate to within 0.5mm. For clinical data gathering, the arm is mechanically linked to the patient's head in the operating room by the starburst clamp that attaches to the Mayfield Head holder. Four end attachments have been devised for the operating arm - a simple probe, a spring loaded depth probe, a shunt-passing stylet and a small cannula through which a probe or string can be passed towards the point at which the arm is aimed.

Reference points consist of at least three surgical staples fixed to the scalp. These are applied under local anaesthetic at the time of CT scanning,

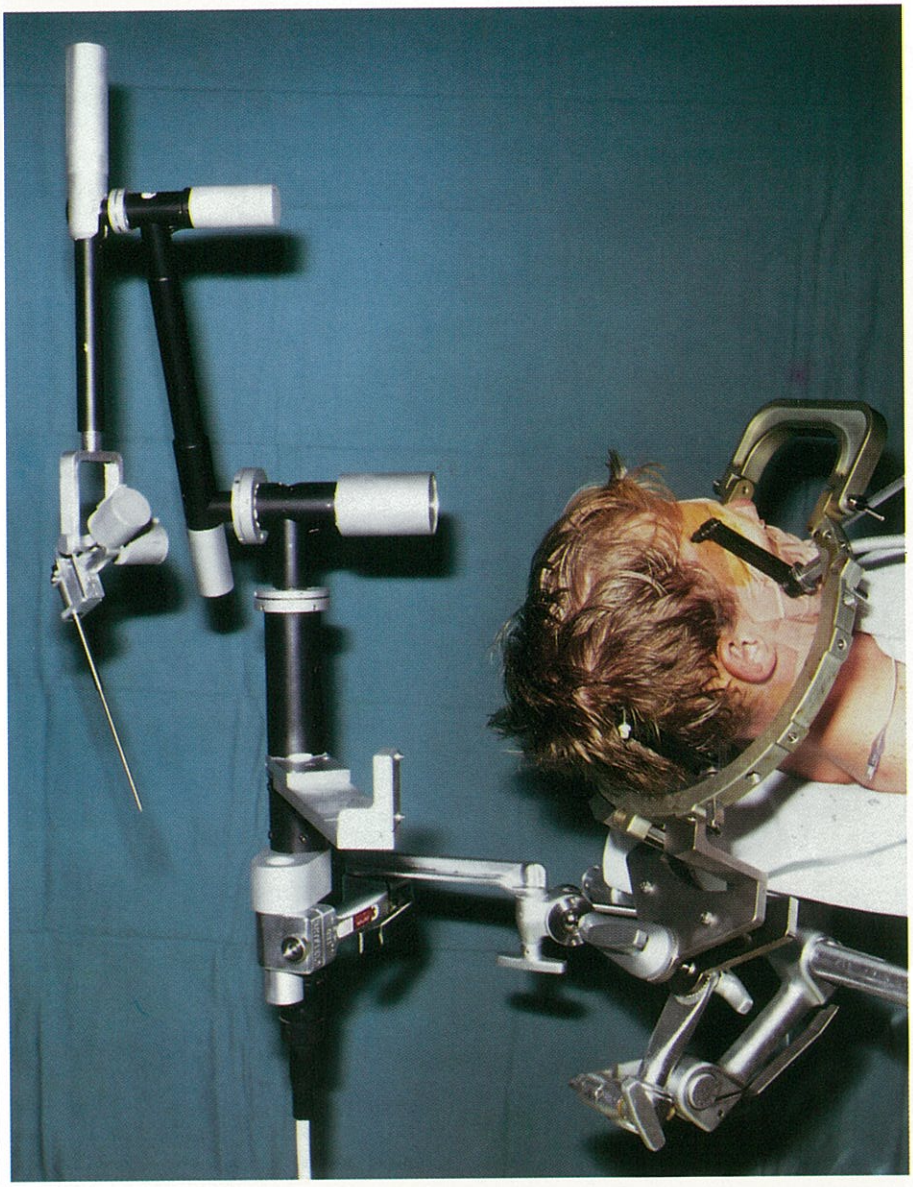

Figure 1. The Operating Arm System is a mechanical digitiser linked to the patient's head in the operating room.

which allows the scanning part of the procedure to be done at a different time from the actual operation as long as the staples remain attached to the scalp.

The OAS computer (Figure 2) is a graphic workstation that can display the CT data as desired by the surgeon. The computer is mounted on a cart that should allow movement in and around the operating room. The OAS computer user interface is designed for maximum convenience for the operating surgeon both before and during the surgery.

Use of the Operating Arm System

The steps in performing the procedure using the operating arm system are as follows:

- **Data acquisition** - with skin staples affixed to the scalp the patient undergoes a CT scan with slices of three millimetre separation. This can be done at the time of or prior to surgery as long as the staples remain in place. Currently, as a double check, the stereotactic frame is applied prior to the scanning, and co-ordinates are taken for the frame-based system in the usual fashion.
- **Data input** - the image data are loaded into the OAS system via a cartridge tape. On starting the system the user is provided with a number of options controlled by a standard "mouse". Once a new patient is selected the system reads the data tape and automatically processes the image.
- **Data review** - after the image is loaded into the OAS it is available for use in a variety of ways all prompted by simple "mouse" control venues. Most commonly the surgeon will select reference markers at this time. The system will prompt the user to select at least three reference marks and store their co-ordinates.
- Additionally, the user can page through the image data, view it in multiplanar formats and investigate various trajectories. (Figure 3) The relationship of the arm probe relative to the patient's imaging data is displayed in a variety of formats. A three dimensional view of cutaways is particularly helpful for overall orientation. The standard axial, sagittal and coronal slice at the probe location can be interactively updated. The surgeon's eye view (Figure 4) and plane of probe view (Figure 5) greatly facilitate the planning of the optimal incision size and trajectory. Switching between different modes of viewing is easily accomplished, without the need for a technician and without leaving the sterile field, by use of the arms and mouse interface. If the arm tip is pulled more than 15 centimetres away from the head, a menu appears and the arm becomes a "mouse" allowing the surgeon to control the OAS under sterile conditions.

Craniotomy Planning

The main use of the OAS to date has been to plan craniotomy for small lesions. Registration procedure is carried out as described above and the arm is used to determine an entry point directly over the tumour site. This process typically takes the form of trial and error by touching a variety of scalp locations and examining a number of trajectories. After localisation with the OAS, a small craniotomy can be performed and the tumour quickly resected. With the use of a stable arm, biopsies and shunt placements can also be performed.

Using this method the spring loaded depth probe allows the computer to imagine trajectories at various depths along the trajectory path.

It can also be used for placement of catheters for ventricular drainage and for evacuation of haematomas.

The concept of graphic interactive surgery is part of the progressive technology being increasingly employed during neurosurgical procedures. Its application is wide-ranging, from simple case planning to the execution of biopsies or complex skull base procedures. Intraoperative imaging with continual updating of anatomical position will allow the surgeon to approach lesions with intraoperative updating of position which will lead to less morbidity and mortality for those undergoing the operation.

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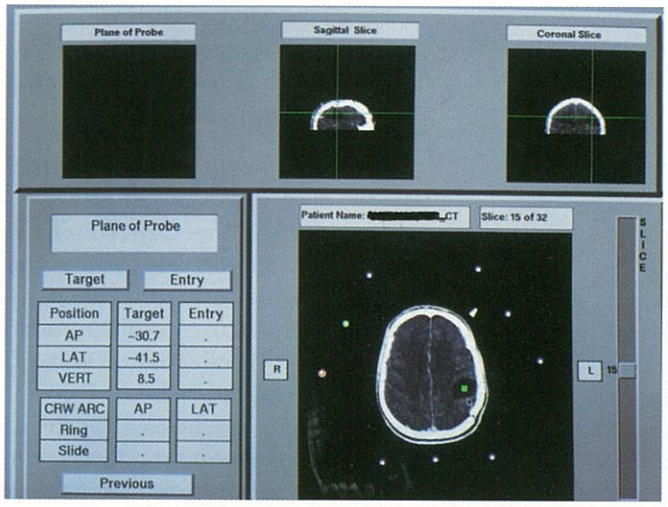

Figure 2. The OAS computer showing the axial, coronal and sagittal slice information of a cystic tumour of the right parietal lobe.

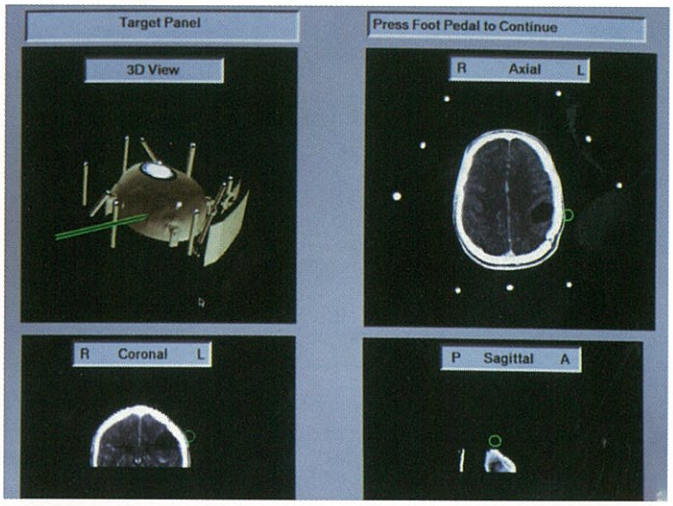

Figure 3. The position of the OAS in relationship to the lesion is shown by touching the arm on the patient's scalp and referring to the planes of view on the computer console.

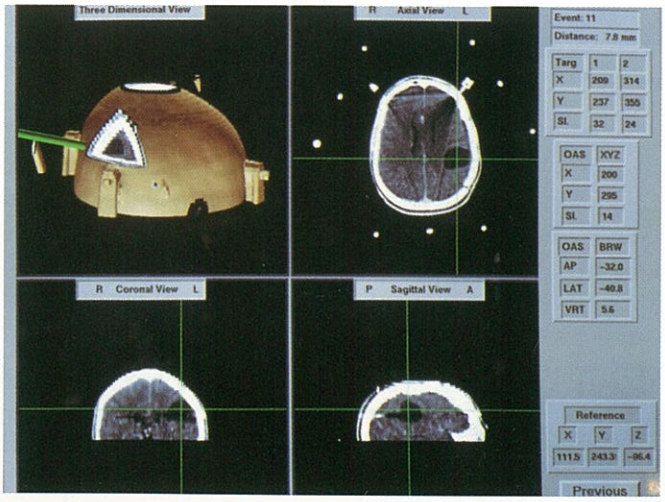

Figure 4. The surgeon's eye view using the OAS.

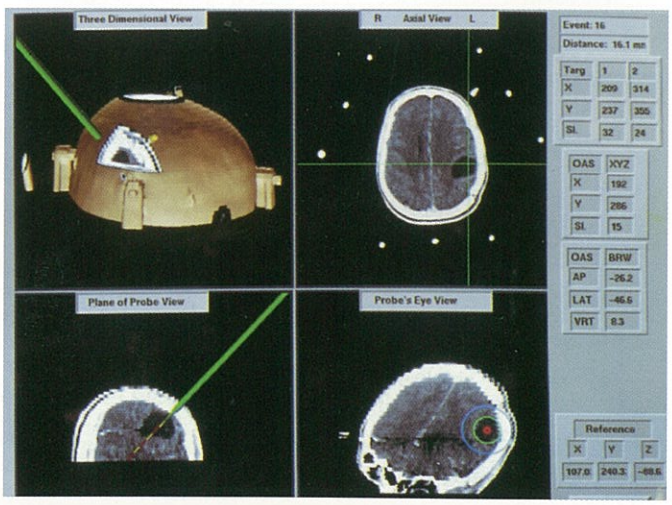

Figure 5. Probe's eye view using the OAS.

Paul Fagan

New Concepts in Otolaryngology and the Surgery of Vertigo

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Introduction

The specialty of otolaryngology (ENT) has expanded rapidly since the days when the field was confined to clearing blocked airways, removing tonsils and carrying out crude surgery for acute mastoiditis. This latter condition was almost abolished at the beginning of the antibiotic era. In recent times with the introduction of modern technology, the specialty has expanded into the fields of endoscopy of the aerated spaces of the upper and lower respiratory tract, facial plastic surgery, head and neck surgery and the sophisticated fields of modern microscopic otology and neuro-otology. The operating microscope, in a primitive form, was first used some 50 years ago. With the introduction of fibreoptic lighting and advanced optics, surgeons are now able to do operations on miniature surgical structures undreamed of a few decades ago.

At St Vincent's the emphasis, especially in recent years, has been on otology. Hearing restoration is now routine in otosclerosis and attainable in many cases of chronic discharging ear disease. The first case of cochlear implantation in Australia was carried out by Dr John Tonkin some 15 years ago and interest in this field continues. By this technique, patients who are totally deaf, who cannot gain any benefit at all from a hearing aid, can have useful hearing restored. Recent electronic developments even enable patients to use the telephone, ie. to understand speech without benefit of visual clues. Surgery involves the implantation of a multi-electrode coil into the cochlea. This converts pressure waves arriving in the ear into electrical impulses and transmits them directly to the cochlear nerve. This technology has been expanded more recently to enable the electrode array to be implanted directly into the brainstem in those patients who have lost both cochlear nerves, either through trauma or bilateral acoustic tumours.

Neuro-otology is a specialty which has been developed in close co-operation with the Department of Neurosurgery and on this Campus that co-operation has been harmonious and mutually beneficial. Vestibular nerve section for the control of vertigo, acoustic tumour removal, in which this hospital has an unparalleled experience in Australia, is routinely carried out by the two Departments, with success rates that are the equal of all published series throughout the world. The first time that operating microscope was used for acoustic tumour removal in this country was by Dr Tonkin, who published his early experiences in 1964.

Tumours of the skull base are those which originate in the floor of the skull (ie. at the jugular foramen, in the petrous bone, in the greater wing of the sphenoid, the roof of the nose or paranasal sinuses) and which extend not only superiorly into the cranial cavity and intra-durally, but inferiorly into the neck.

Skull base surgery is best defined as being the technique which approaches these tumours by the removal of bone so that the entire tumour can be visualised in one surgical field. Tumours formerly

regarded as inoperable are now able to be removed safely and the patient returned to a useful life.

Perhaps the most rewarding of all these endeavours is the surgery that cures intractable vertigo.

VERTIGO

Vertigo is, by definition, an alteration of orientation which nearly always involves a sense of motion of the subject or environment. It is not only rotation but can be a sense of oscillation, a sense of staggering imbalance 'as if one were on the deck of a pitching ship' and, in late Menière's disease, drop attacks without loss of consciousness.

When investigating vertigo, it is necessary to exclude syncopal attacks of all types and nonspecific sensations that are often associated with nonorganic disease. The latter can be suspected when the patient feels that the head is 'stuffed with cotton wool' or 'in a bag' or that there is a sense of déjà vu.

DIFFERENTIAL DIAGNOSIS

Labyrinthine vertigo

Classically vertigo that arises from the labyrinth or its central connections is associated with rotation, oscillation or staggering imbalance. Typical of labyrinthine vertigo is Menière's disease which characteristically is associated with a unilateral hearing loss, aural fullness and pressure, wild episodes of rotation, nausea, vomiting and prostration. The episodes last three to four hours at most and very often much less.

Rotatory vertigo

Rotatory vertigo is also found in benign positional peripheral vertigo, a viral disorder of the utricle in which the rotatory episodes last a few seconds at most and are not associated with aural symptoms.

Vestibular neuronitis

In vestibular neuronitis the rotatory episodes, in the beginning, last for 12 to 24 hours but there are no aural

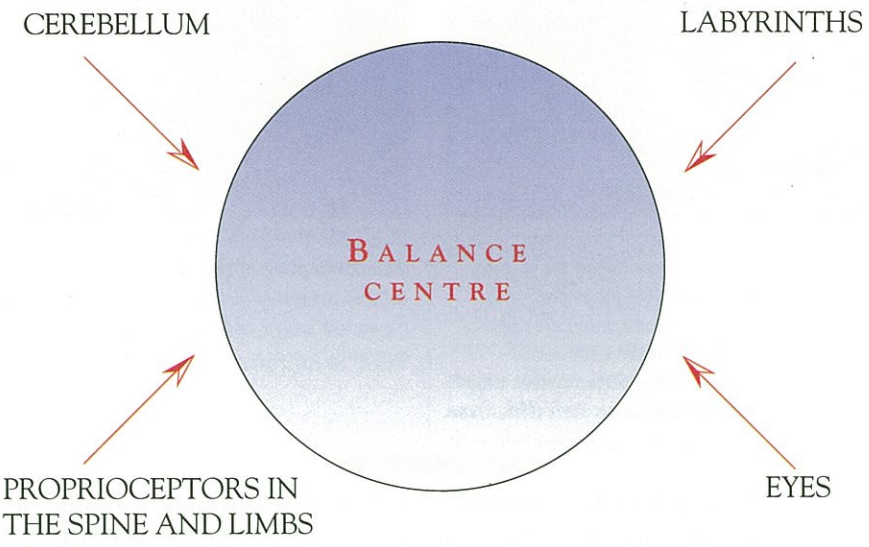

Figure 1. The balance centre is a concept rather than a physiological or anatomical entity. It receives information constantly from the cerebellum, the inner ears, the eyes and the proprioceptor centres of the limbs and spine.

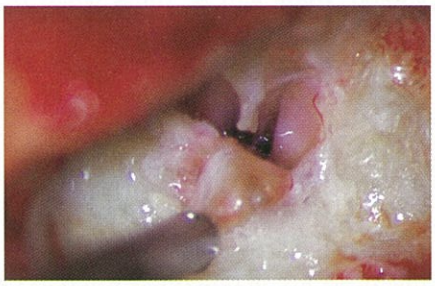

Figure 2. A surgeon's view of the lateral end of the left internal auditory canal. The vestibular nerve has been sectioned and is held by the sucker tip. A prominent bar of bone, the falciform crest separates the facial nerve on the viewer's right from the cochlear nerve on the left.

Figure 3. Valved shunt tube designed by I Kaufman Arenberg of Denver and sometimes called the Denver valve. The valve lies in the body of the shunt and opens when the endolymphatic pressure exceeds a certain value. On the viewer's top left is the very fine capillary tube which is inserted into the endolymphatic sac near its junction with the endolymphatic duct. Bottom right is a tail of silastic which is used to stabilise the device.

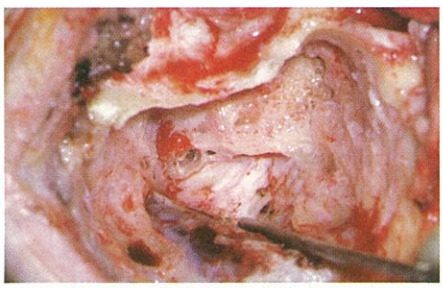

Figure 4a. The endolymphatic sac has been displayed in the left ear. The blue mass at the lower edge of the picture is the sigmoid sinus devoid of bone and in front of this, somewhat stretched by the sucker tip, is the white, relatively avascular endolymphatic sac.

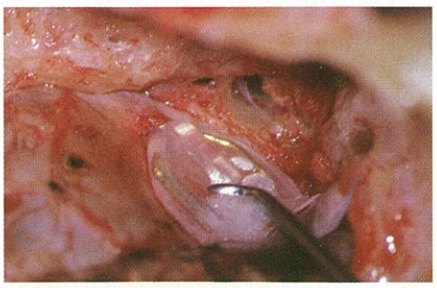

Figure 4b. The tip of the Denver valve has been placed in the endolymphatic sac.

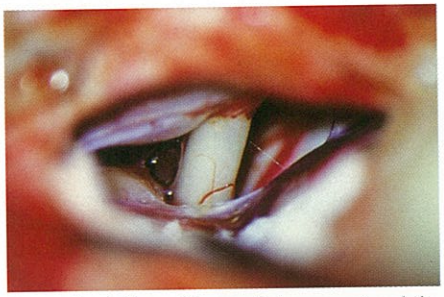

Figure 5a. The cochleovestibular nerve in a left ear runs vertically in the middle of the picture. The cerebellum occupies the lower part of the picture and petrous temporal bone, the upper. A small part of the brainstem with vessels running over it can be seen on the viewer's right, in a plane somewhat anterior to the VIIIth nerve.

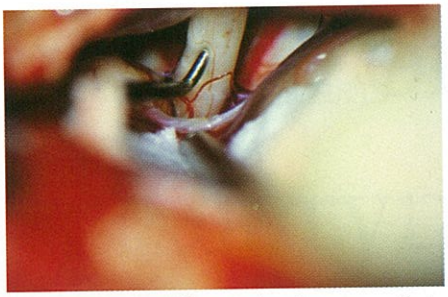

Figure 5b. Using a blunt probe, the surgeon finds the natural plane of cleavage between the vestibular nerve which lies superiorly, that is on the viewer's right and the cochlear nerve which lies inferiorly.

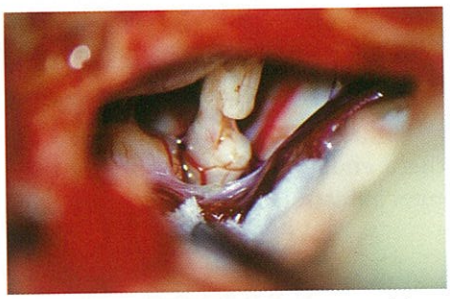

Figure 5c. Section of the vestibular portion of the nerve has been completed. The intact cochlear nerve is seen inferiorly, that is, to the viewer's left.

symptoms. Repeated episodes tend to be of lesser severity and the interval between them increases.

Acoustic tumour

An acoustic tumour rarely is associated with rotatory vertigo but tends to produce a sensation of drunken imbalance. Hearing loss and tinnitus accompany it. Similar symptoms are also found after head injury with or without fracture of the temporal bone. Even when hearing loss is complete after head injury, there can be residual function of the vestibule and semicircular canals which produces chronic instability. The results of surgery for post-traumatic vertigo tend to be less satisfactory than for Menière's disease.

Perilymph fistula

Perilymph fistula is a leakage of fluid from the inner ear to the air filled middle ear. It is a contentious issue. Generally there is a history of a precipitating incident, for example a blow to the head, lifting a heavy weight, violent sneezing, diving or flying with a cold. A fistula cannot be diagnosed other than by surgical exploration of the middle ear. If detected, repair of the weakened area is undertaken with fine connective tissue.[6]

Physiology

The balance centre is a concept rather than a physiological or anatomical entity (Figure 1). Information is constantly fed to this centre from the labyrinths, the cerebellum, the eyes, and the proprioceptive centres in the spine and limbs. In most cases of labyrinthine vertigo, one labyrinth is in order while the other is working abnormally. If, as is commonly the case, other organs such as the cerebellum are working normally, the body can be compared to a twin engine plane. When both engines are running smoothly, the pilot has little work to do to keep the aeroplane on an even keel. If one engine is faulty, the pilot needs to intervene. Similarly, when one labyrinth is not functioning as it should, there will be times when the brain is not able to process correctly the false information coming from the diseased labyrinth and vertigo ensues.

Menière's disease is the major cause of labyrinthine vertigo. Its natural history and medical treatment (salt reduction, diuretics) and the differential diagnosis are detailed elsewhere. Few cases of Menière's disease come to surgery.

The time to intervene surgically in labyrinthine vertigo is when:

- the patient's life is grossly disrupted
- other forms of treatment have failed
- the diagnosis and side of the lesion are clearly identifiable
- it has been shown that the other labyrinth and the cerebellum are normal
- the patient is in general good health and has a good locomotor system, that is, a strong pair of legs.

In this context a preoperative electronystagmogram (ENG) is essential, not only to confirm which labyrinth is at fault but to ensure that the other labyrinth is working normally. Electronystagmography will also help to confirm that cerebellar function is as it should be.

Surgery for Menière's disease

There are three types of surgery performed for Menière's disease:

- destructive operations
- operations on the saccus endolymphaticus, and
- vestibular nerve section with preservation of hearing.

Destructive operation

The original destructive operation was labyrinthectomy which involved opening the labyrinth to destroy the neuroepithelium therein. This procedure was done either through the middle ear, opening the cochlea, or through the mastoid, opening into the semicircular canals. The neuroepithelium and vestibular nerve ends always persist to some degree; therefore results are not as good as those operations in which the internal auditory canal is approached through the labyrinth (translabyrinthine vestibular nerve section). This approach not only destroys the neuroepithelium of the labyrinth, it enables the vestibular nerve to be sectioned under vision in the internal auditory canal (Figure 2). The advantage of this operation is that the cochlear nerve can be sectioned at the same time and this has an unpredictable but sometimes beneficial effect on tinnitus.

This procedure is less often done these days, even when the hearing is severely depressed, as there is a small chance that Menière's disease could develop in the other ear and proceed to a significant hearing loss. Fortunately this is a rare occurrence. The advances in cochlear implantation have led to a swing away from destructive surgery so that the cochlear nerve is there to use, as it were, if total deafness should supervene.

Surgery of the saccus endolymphaticus

The aim of surgery on the endolymphatic sac is to decrease the fluid pressure in the endolymphatic system. The endo-lymphatic sac is an outpouching of the endolymphatic system, somewhat remote from the cochlear and semicircular canals. This remoteness enables the sac to be opened without undue risk of hearing loss. Simple decompression allows expansion of the sac and causes a decrease in fluid pressure in the endolymphatic space. Drainage of the sac can be carried out by inserting either a simple silastic sheet or a more complicated valve-like mechanism (Figure 3). The valve opens when endolymphatic pressure increases allowing fluid to escape into the mastoid.

Surgery of the saccus endolymphaticus is carried out through an incision behind the ear. The greater part of the mastoid bone is removed to provide access to the sac which lies between the sigmoid sinus on one side, and the posterior semicircular canal and the facial nerve on the other (Figure 4).

The advantage of this procedure is that the hospital stay is short, and the recovery period is much quicker than in nerve section. The procedure carries the risk of meningitis if the subarachnoid space is entered; however, the theoretical risks of damage to the arteries and veins of the posterior cranial fossa are avoided.

The drawback of this procedure is that it has a significant failure rate of between 20 and 50%.[1] Many patients therefore opt to proceed directly to vestibular nerve section.

Vestibular nerve section

Vestibular nerve section preserves the patient's cochlear nerve and hearing, and is carried out in the posterior cranial fossa. The approach may be either through the mastoid and behind the labyrinth (transmastoid-retrolabyrinthine approach) or through a small posterior fossa craniotomy, the so called retrosigmoid approach. There is little to choose between the two approaches both giving excellent access to the cerebellopontine angle. As cerebrospinal fluid escapes the cerebellum falls backwards to expose the eighth nerve (Figure 5). This view of the operative field can be obtained in most cases without the use of mannitol or fixed retraction.

Complications of Surgery

Cerebrospinal fluid leak

Cerebrospinal fluid leak is a risk in all operations in this area. In the transmastoid-translabyrinthine approach and the transmastoid-retrolabyrinthine approach, abdominal wall fat is taken from the left iliac fossa to obliterate the mastoid and seal the cerebrospinal fluid space. In the retrosigmoid approach, the dural opening is sealed with temporalis fascia and covered with the disc of bone which was removed to give access. Bone wax applied to the mastoid air cells completes the seal. In saccus surgery, the cerebrospinal fluid space can be opened inadvertently through the very thin dura above the upper margin of the sac. Such a leak of cerebrospinal fluid presents generally as fluid dripping from the nose and rarely through the wound. It can almost always be controlled by the use of a drain inserted into the lumbar spine for a few days. Formal re-exploration is rarely required.

Meningitis

Meningitis can follow a cerebrospinal fluid leak. This is a formidable complication that may be fatal. The author has not encountered meningitis after vertigo surgery.

Damage to the anterior inferior cerebellar artery

Strokes, paralysis of all sorts and even death can result if the anterior inferior cerebellar artery, which loops around the eighth nerve (Figure 6) is damaged. These complications have not been encountered by the author in the surgery of vertigo.

Facial paralysis

The facial nerve can be damaged either in the mastoid or in the cerebello-pontine angle, even when the greatest of care and skill is exercised, as its course can be very atypical. The Table summarises data obtained from a series of patients operated on by the author during May 1984 to May 1989. There were four cases of facial paralysis in the series. These cases were of delayed onset and recovered completely, confirming that the nerve was structurally intact.

Total hearing loss

Total hearing loss can occur in any operation on the ear and its surrounds, and is due either to disturbance of the blood flow to the inner ear or to the opening of the labyrinth itself.

Staggering imbalance

After surgery to one ear, staggering imbalance, which can be long lasting, may replace rotatory vertigo if the patient's proprioceptive system (the legs) or the other ear are not entirely normal. Despite the most careful preoperative testing, it is not possible to anticipate the onset of these symptoms in some patients.

Air embolus

The author has had no cases of air embolus (which can be fatal) in his experience, and believes that this complication is more theoretical than real.

Subarachnoid haematoma

The author has had one case of subarachnoid haematoma arising from surgery. The patient complained of severe headache which rapidly resolved with the use of steroids (Figure 7).

Outcome of Surgery

In Menière's disease, rotatory vertigo is controlled in the great majority of cases when the vestibular nerve has been sectioned. Some fibres of the vestibular nerve run within the cochlear nerve on occasion so that the results of translabyrinthine vesibulocochlear nerve

section are slightly better than when the cochlear nerve is preserved.

With endolymphatic sac surgery, vertigo is controlled in a varying number of cases. Sac surgery itself is a controversial treatment. Some authors, notably Silverstein[2] and Glasscock,[1] have abandoned it due to the failure rate. Others, like Arenberg,[4] continue to carry out sac surgery using the valved shunt device (Figure 3) and report a vertigo cure rate of 75% or more. It is noteworthy that many authors carrying out operations on the sac do not begin to assess the results until 12 months after surgery because attacks of vertigo can continue during that time.

In the series of patients operated on by the author between May 1984 and May 1989 (Table 1) there were two cases of significant inner ear hearing loss and 13 cases of cerebrospinal fluid leak, 12 of which were controlled by the use of a nonsuction lumbar drain for a few days. One case required re-exploration to seal the leak. There were no cases of meningitis.

Facial paralysis developed as a late complication in two cases of patients undergoing saccus surgery. Both recovered completely. There were two cases of facial paralysis after translabyrinthine vestibular nerve section, both cases were similarly of delayed onset and recovered completely.

Hospital stay is of the order of three days after saccus surgery and seven to 10 days after vestibular nerve section. Wound infection is rare.

Patients who underwent vertigo surgery at St Vincent's Hospital from May 1984 to May 1989

Type of surgery	Number of patients	
Decompression or drainage		
Endolymphatic sac	60	
Vestibular nerve section		
Translabyrinthine (hearing destruction)	15	
Retrolabyrinthine (hearing preservation) }	51	
Retrosigmoid (hearing preservation) }		
Total number of procedures for vertigo	**126**	
Complications (all types of surgery)		
Cerebrospinal fluid leaks	13/126	10%
Total hearing loss*	2/111	2%
Conductive hearing loss†	1/111	<1%
Facial paralysis•	4/126	3%
Chronic imbalance	6/126	5%
Subarachnoid haematoma	1/126	<1%
Meningitis	0	0
Strokes, paralysis etc	0	0
Deaths	0	0
Complete or adequate control of vertigo**		
Translabyrinthine vestibular nerve section	15/15	100%
Saccus surgery	32/60	53%
Vestibular nerve section (hearing preservation)	46/51	90%

* Translabyrinthine cases excluded from this calculation (total number of patients = 111).
† Due to prolapse into the middle ear of transposed abdominal fat (total number of patients = 111).
• Of late inset, full recovery.
** According to the type of surgery.

Table 1

What the patient can expect after surgery

Saccus endolymphaticus surgery

Pain after sac surgery is generally not severe as there are no moving parts as in an abdominal wound. Hearing is decreased for some days to months after surgery until blood in the middle ear and mastoid resorbs and the inner ear recovers from surgical manipulation. The occurrence of vertigo is variable, but is commonly noted in the immediate postoperative period and is not to be interpreted as a sign of failure of the surgery (Table 1). Sutures are removed at 10 days and there is generally no pack in the ear canal; water need not be excluded. The operative wound can be exposed to water during showering and hair washing on the second postoperative day.

Return to work, driving and other usual daily activities is a matter for the patient's own judgement.

Vestibular nerve section

Vertigo is significant after vestibular nerve section and accounts for the prolonged hospitalisation time vis-à-vis saccus surgery. If the preoperative electronystagmogram shows that there is good residual caloric function, vertigo will be severe and vice versa. This vertigo is relatively easily controlled by drugs and begins to wear off on the second or third postoperative day, but leaves the patient with a staggering imbalance which may take six weeks to settle. Vestibular exercises[5] speed the recovery of balance. In essence, the exercises consist of regulated eye and head movements to produce minor episodes of vertigo supplemented by early mobilisation – patients being encouraged to walk as much as their fatigue will permit.

Cerebrospinal fluid leaks manifest as a steady dripping of clear fluid from the nose, almost always on the side of the surgery. It is relatively easy to distinguish from a cold or a nasal mucoid drip. Cerebrospinal fluid leaks occur within the first few days after surgery and can be precipitated by straining; avoidance of constipation is helpful. The head dressings left in place for three or four days after nerve section to help prevent such a cerebrospinal fluid leak. After its

Figure 6. Left vestibular nerve. In this patient the anterior inferior cerebellar artery is prominent. In the bottom left of the picture a large branch runs to the brainstem which is at the bottom of the picture. At the top, the nerves are entering the internal auditory canal on their way to the ear.

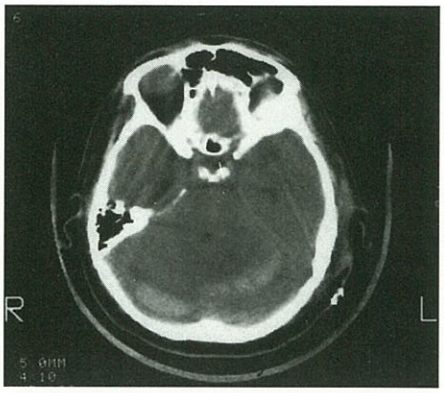

Figure 7. Blood is seen outlining the cerebellar hemisphere on either side, the result of a bleed during surgery to section the vestibular nerve. There was only one such incident in the series of patients operated on by the author.

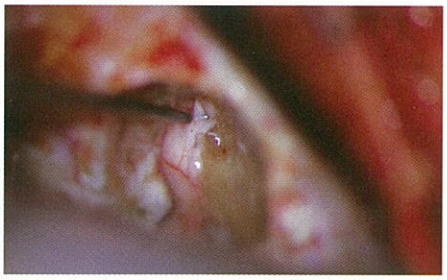

Figure 8. The back wall of the internal auditory canal has been drilled away showing the vestibular nerve after its division into a superior branch (on the viewer's left) and two inferior branches (on the right) lying in the crook of a blunt probe. In rare cases of benign positional vertigo, the lower divisions are sectioned, preserving the function of the superior nerve which supplies the superior and lateral semicircular canals and the saccule.

removal showering, hair washing and so on are permitted.

There is no pack in the ear; water can be allowed to enter the ear canal.

The amount of time lost from work or normal daily activities after nerve section is generally a good deal more than after sac surgery and can be as long as six weeks. Similarly a return to driving is delayed. No-one can judge better than the patients themselves when this should be. Obviously a sedentary clerk will be able to return to work earlier than, say, a cat burglar!

Benign positional peripheral vertigo

Benign positional peripheral vertigo rarely comes to surgery. In those patients incapacitated by the severity and duration of their symptoms, the internal auditory canal is approached via the posterior cranial fossa.

The posterior wall of the canal is drilled away to give access to the singular nerve (Figure 8) that supplies the ampulla of the posterior semicircular canal which is believed to be the site of pathology in this condition. This procedure has been designed to preserve the function of the rest of the labyrinth and to avoid the severe vertigo which results from section of the entire nerve to a labyrinth which is, in other respects, functioning normally. The procedure is technically difficult and the risk of losing hearing and function of the rest of the labyrinth is quite high.

Summary

Surgery for vertigo is obviously a last resort, when all else has failed. The timing of surgery will generally be indicated by the patient. The long term major complications of surgery of the inner ear and cerebellopontine angle have proved to be more theoretical than real with the exception of significant hearing loss (1 to 2% of cases) and cerebrospinal fluid leaks (10%). Further, the results of surgery for Menière's disease are better than for other forms of vertigo particularly those following head injury and other specific, short-lived insults to the labyrinth.

Acknowledgement: Some of this material, including illustrations, is published with kind permission of the Editor, Modern Medicine of Australia.

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Renee Bittoun

Two cases of apparent Nicotine Poisoning associated with nicotine patches

Abstract

Objective: To describe the probable misdiagnosis of nicotine poisoning in two women using a nicotine transdermal patch. Clinical features: Two women presented to Accident and Emergency Centres extremely distressed, irritable and agitated. They were diagnosed as suffering nicotine poisoning. Conclusion: The patients were probably suffering from severe symptoms of nicotine withdrawal. Nicotine plasma levels should be measured if toxicity is suspected. This is a report on two cases which were referred recently to the Smokers' Clinic at St Vincent's Hospital, Sydney, for comment. They concern the usage of the newly available nicotine patch.

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Clinical Record

Case One

A female aged 35 was admitted to the Accident and Emergency Unit of a Sydney teaching hospital in February 1993 with extreme anxiety and distress.

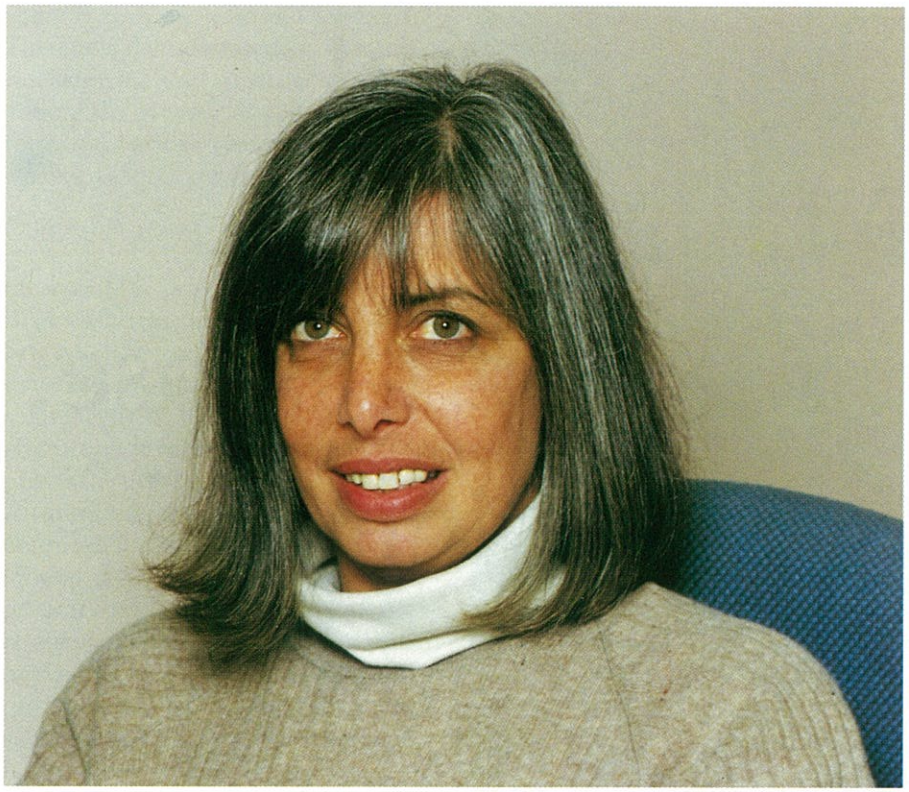
Relevant history: she was otherwise well and had no previous history of psychiatric illness. She had smoked approximately 20x1mg nicotine cigarettes per day for many years. She had procured 30cm Nicotinell transdermal patches (Ciba-Geigy, Australia) from New Zealand which she began to use late in January 1993. On applying the first patch she stopped smoking but became increasingly agitated and voluble and was described by her friends as 'motor mouth'. She began drinking large quantities of coffee and Coca Cola. She continued to wear a new patch daily and continued not to smoke for several weeks with symptoms of anxiety steadily worsening. She was commenced on Acyclovir for Herpes Zoster and immediately became more anxious and distressed. She presented to the hospital in this state of distress, anxiety and irritability. All tests carried out were normal. The woman was diagnosed as having nicotine poisoning and the patch was removed. She remained hospitalised for several days and continues to refrain from smoking. On discharge she was referred to a psychiatrist who immediately referred her case to the St Vincent's Smokers' Clinic for comment.

Case Two

A female aged 51 was admitted to a country hospital Accident and Emergency Centre in May 1993 with acute distress and anxiety, depression and neuralgia.

Relevant history: she had a long history of ischaemic heart disease over many years but had no previous history of psychiatric illness. She had smoked 20-25x0.9mg nicotine cigarettes per day for decades. Previous attempts to quit 'cold turkey' lasted five days and in each case she suffered extreme anxiety, aggressiveness and cravings which led to her relapsing.

She was prescribed the nicotine patch 30cm Nicotinell (Ciba-Geigy, Australia) through her general practitioner in May



1993. On application of the patch she stopped smoking and began to have symptoms of aggressiveness, anxiety, headache and numb feelings in her arms within hours of applying the first patch. These symptoms continued for six days as she became increasingly aggressive and depressed. She was brought to Casualty by her husband who had thrown her out of the family home due to her extreme aggressiveness and irritability.

On admission to casualty all tests showed no abnormality. The patch was removed immediately and she was diagnosed as having nicotine poisoning. Throughout her recorded in-patient notes the patch she wore was referred to as Nicorette patch by the medical staff, although no such patch exists. She remained hospitalised for two weeks for investigations. She continued to have symptoms for the following eight weeks during which she lived in a women's refuge and did not smoke. She relapsed to smoking at the refuge and felt immediately improved and was able to return to her home and family. She continues to smoke.

Discussion

It seems likely that in both cases there was a misdiagnosis of nicotine toxicity or poisoning, as in fact both patients presented with symptoms of severe nicotine withdrawal. The symptoms of nicotine withdrawal are well documented.[1] They may include severe aggressiveness, anxiety and depression over many days and weeks. The 30cm nicotine transdermal patch, Nicotinell, may achieve approximately 10ng/ml of nicotine in the plasma whereas the nicotine blood levels of these two women when they were smoking would have been at least two to three times this level at any time. Average plasma levels of smokers attending the St Vincent's Smokers' Clinic, Sydney, is approximately 40ng/ml plasma. Both women may in fact have suffered severe withdrawals, as blood levels of nicotine would have shown levels greatly under those achieved by their smoking. It must be noted with concern that neither nicotine blood levels, nor its metabolite Continine, were measured in either case during their respective admissions.

In cases where these types of symptoms occur in this clinic, nicotine plasma levels or urine cotinine levels are assayed and symptoms of withdrawal are treated successfully, often by increasing the initial nicotine intake.

Neuralgia is a common side-effect of wearing a 24-hour patch and is listed in the product information inserted with the patches.

In Case One it should be noted that caffeine intoxication is a commonly reported phenomenon in nicotine withdrawals.[2] Nicotine is known to increase elimination of caffeine thus removal of nicotine can result in symptoms of caffeine toxicity such as agitation, irritability and distress as well as tachycardia. Also in this case it is possible that the Acyclovir exacerbated her symptoms. It is recommended that such cases in future have nicotine blood levels measured to exclude nicotine poisoning, that adequate therapy be prescribed if nicotine replacement therapy is to be initiated and that referral to specialised units take place if these sorts of symptoms occur.

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Dr Phillip Stricker

Benign and Malignant Prostatic Disease: Management, Present and Future

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Introduction

Prostatic diseases both benign and malignant are becoming increasingly prevalent in our ageing population. Factors which will affect their management include better understanding of their causes, financial restrictions, patient expectation, lengthening life span, new technologies and availability of medical resources. With all these factors the ideal treatment in any one patient is difficult to define, although some kind of consensus is essential.

The magnitude of the problem can be seen by the incidence of benign and malignant conditions. Benign prostatic hyperplasia (BPH) is thought to affect 50 to 70 per cent of men over the age of 50. It is estimated that three out of every 10 men will eventually require surgical treatment for BPH unless an effective medical therapy becomes available. Cancer of the prostate on the other hand appears to have overtaken lung cancer as the most common malignancy in males. It is the second most common cause of death in males due to malignancy.

Besides BPH and prostate cancer there exists a third condition known as prostatitis. This is where there is inflammation or congestion of the prostate and it is more likely to occur in a younger age group.

Knowing how common these conditions are, and the variable diagnoses of prostatic disease, it is essential to diagnose the problem correctly, and if possible prevent it, and most importantly treat it appropriately.

Benign Prostatic Hypertrophy

Incidence

BPH begins in the forties and increases in frequency with age. It will affect all males if they live long enough. The cause of enlargement of the prostate

appears to have a hormonal basis. There is a delicate interplay between testosterone and oestrogen which affects the stroma of the prostate, releasing various growth hormones which create the condition.

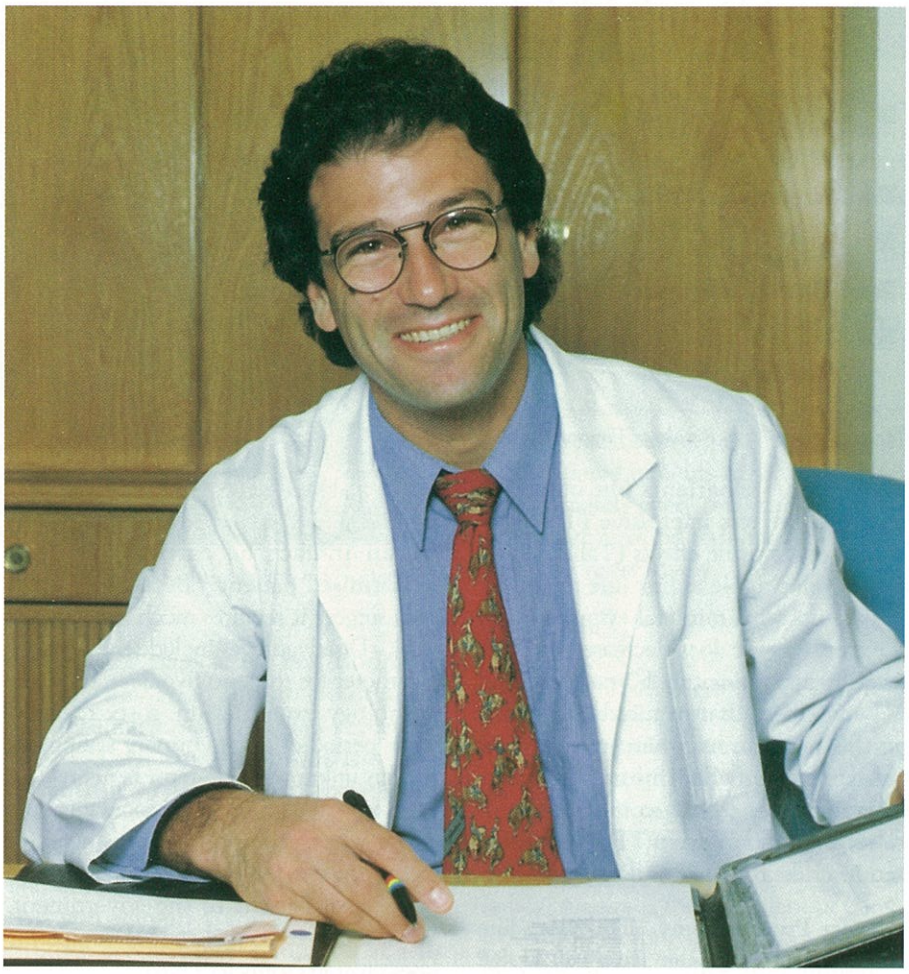
Clinical Features

In general the prostate enlarges due to BPH. Whereas cancer has a hard feel, benign enlargement generally has a softer or more rubbery feel. Symptoms relating to BPH occur due to the obstruction it causes by narrowing the prostatic urethra. Size is not an accurate predictor of the degree of obstruction. Other factors such as the tension of smooth muscle within the prostate and the direction of the prostatic growth have a major bearing on the severity of symptoms and obstruction. The only accurate assessment of the degree of obstruction is by voiding pressure-flow studies.

The symptoms that accompany BPH must be carefully separated from other causes of urinary symptoms. The accurate diagnosis of BPH requires clinical assessment and investigation. Investigations include digital rectal examination (DRE), flow rate, urodynamic studies, prostate specific antigen (PSA) measurement, transrectal ultrasound (TRUS), and abdominal ultrasound to assess urinary residual. Not all these investigations are required in any one patient and the urologist will generally individualise the number of tests depending on the difficulty in diagnosis.

Prostate cancer is present in less than two per cent of these patients if the rectal examination reveals benign enlargement and the PSA is within normal limits, when taking into consideration the patient's age and size of the gland. If there is any suspicion of prostatic malignancy from these investigations, transrectal ultrasound can be performed and (under ultrasound guidance) biopsies of suspicious areas or multiple sextant biopsies can be performed.

The exclusion of cancer of the prostate is extremely important in the younger age group as more radical treatment is likely in this category.



Treatment of BPH

Once the symptoms have been attributed to BPH several treatment options exist. Whereas previous treatment options included 'wait and watch' or transurethral resection of the prostate (TURP) there now exist a large number of options although many are still in their infancy. Options include:

Wait and Watch. This is especially suitable for patients who have mild to moderate symptoms and no deleterious effects on the urinary tract. Less than 10 per cent of these patients will eventually experience a severe complication.

TURP. This is still the gold standard of treatment. It opens up a channel through the centre of the prostate to remove the obstructing section of the prostate. It is known to have an excellent success rate in correctly chosen patients and if carried out expertly has an excellent long term cure rate. Side effects include retrograde ejaculation in most patients, impotence in less than five per cent, strictures or bladder neck obstructions in less than five per cent, and secondary haemorrhage in less than five per cent. The incidence of these complications vary from centre to centre.

TURP is ideal in those patients with complications of prostatic disease such as retention, chronic renal failure, recurrent bleeding, recurrent infections and severe symptoms. It is also indicated in those patients where symptoms have a major adverse effect on the quality of life.

Medical Treatment. Two groups of medications are presently available for the treatment of BPH. Prazosin is an alpha-blocker which can relax the smooth muscle component of the prostate and relieve patients with mild to moderate symptoms. Approximately 50 per cent of patients will respond, but this effect often wears off with prolonged use. Side effects include postural hypotension. Finasteride (Proscar) is an alpha-reductase inhibitor which decreases the size of the prostate. This has a better than placebo effect on prostatic symptoms and may be of benefit in patients with mild to moderate symptoms. It is successful in improving symptoms in approximately

PROSCAR: SUMMARY OF CLINICAL EFFICACY

- Marked decrease of DHT, testosterone usually maintained within normal limits
- Regression of hyperplastic prostate, reduced levels of PSA
- Urinary flow rate slightly increased
- Total and obstructive symptoms improved in 50% of subjects
- Three-year results suggest alteration in natural history of BPH on continuous medication[3]

Table1. Summary of Results of Finasteride treatment

50 per cent of patients but objective responses are less impressive (Table 1). It has very few side effects (Table 2) and may develop a role as first line treatment in patients with minimal symptoms but is expensive. It does decrease the PSA level by approximately 50 per cent and one must bear that in mind in patients on this medication, when screening for prostate cancer. St Vincent's is one of several centres testing combinations of Finasteride and Prazosin. This may offer better results than either drug alone.

Laser Prostatectomy. This procedure aims to create the same cavity as TURP with a laser energy source. The advantage is that there is no bleeding and it can in fact be carried out on a warfarinised patient. Because it is day only surgery it requires much less time off work. Disadvantages include the need for a catheter for three to five days, no tissue pathology examination, a six to eight week period of severe urinary symptoms, and an unknown long-term benefit. It is ideal for patients on anti-coagulants, and those where time off work is a major factor. In the long term this may have a major cost benefit to the government. We are one of several centres comparing laser prostatectomy to TURP.

THERAPY WITH PROSCAR DEMONSTRATED A VERY LOW INCIDENCE OF ADVERSE EVENTS DURING CONTROLLED CLINICAL TESTS

Adverse Effects (occurring in less than 0.5% of patients)	PROSCAR (n = 543)	Placebo (n = 555)
Abdominal pain	0.9%	0.4%
Asthenia	0.9	0.7
Decreased libido	3.3	1.6
Decreased volume of ejaculate	2.8*	1.1
Dizziness	0.6	0.7
Flatulence	0.6	0.5
Headache	0.9	0.5
Impotence	3.7*	1.1
Orgasm dysfunction	0.6	0.2
Rash	0.6	0.2
Testicular pain	0.6	0.4

Percentages shown may represent multiple adverse events reported by a single patient. Percentages may therefore not be added together.
12-month, double-blind, randomised, placebo-controlled phase III studies
* Statistically significant difference from placebo (P less than 0.05)
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Table 2. Summary of side effects of Finasteride compared to placebo

Trans-Urethral Needle Ablation (TUNA) of the Prostate. (Figure 1) This is an experimental procedure which relies upon radio frequency waves delivered by needles to the prostate which create cavities in the prostate and thereby shrink it. This is a day only procedure. After 11 cases at St Vincent's there are very encouraging early results but long-term results are unknown. The advantages above and beyond laser prostatectomy are the lower likelihood of urethral catheterisation and the less irritative symptoms in the first six to eight weeks. Encouraging early results are also being observed in the other investigative centres in Australia and internationally.

Prostatic Stents. (Figure 2) Metallic coils can be inserted endoscopically under local anaesthesia into the prostate to hold open the prostatic urethra. This is ideal in old or frail patients who cannot undergo surgery, especially where there is a limited life expectancy. Success rate is extremely high in this group of patients. Complications include migration of the stent until it becomes epithelialised.

With all these options and many others, including herbal medicines, microwave and heat therapy available for the one condition, treatment has become more complex. It is essential to give patients full information regarding these options but to avoid the so called 'cascade of treatments' whereby the patient experiences three or four treatments before a definitive successful one is performed. Individualisation is the key to treatment here.

PROSTATE CANCER

Incidence

Approximately 17 patients per 100,000 will develop prostate cancer each year in Australia. There is a one in 11 chance of a man developing clinical prostate cancer in his life time. This excludes the occult prostate cancers which are often found on autopsy studies.

Etiology

Prostate cancer appears to be related to fat intake. Hormones seem to play a permissive role, as this disease never occurs in eunuchs. There is an increased

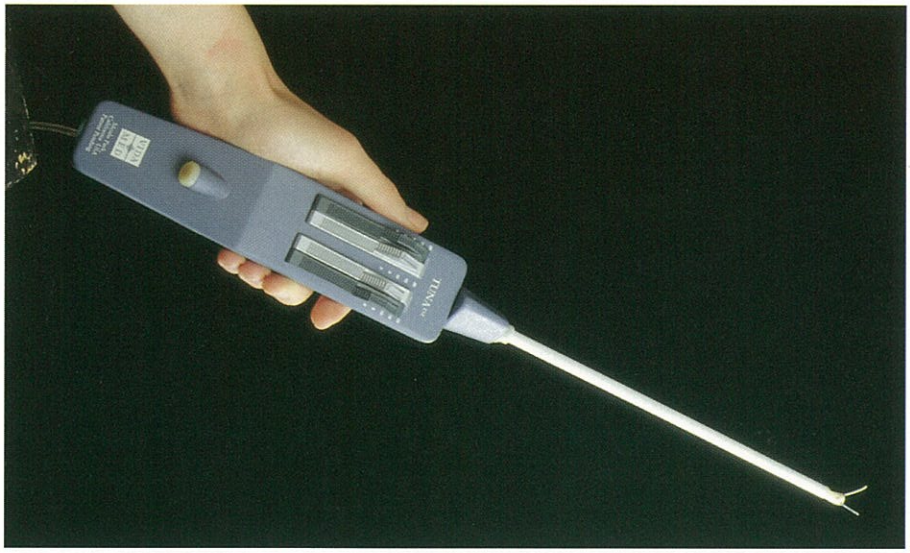

Figure 1. TUNA Device. This is placed in the urethra and the needles advanced into the prostate

chance of prostate cancer when first degree relatives also have the condition, especially in the younger age groups. Several studies have shown that a person with a first degree relative has a two- to four-fold increased chance of developing prostate cancer in his lifetime. This is especially so if the relative had the same condition at a young age. In this group it is essential to screen patients early for the onset of prostate cancer, similar to patients with breast cancer. Studies of chromosomal abnormalities and oncogenes are being carried out at present to establish the cause of such malignancy and there has been some success in this area. Future research is looking at genetic engineering, immunotherapy and making non-hormonally sensitive tumours hormonally sensitive. Research into prevention, early detection and better treatments is also ongoing.

Diagnosis

The aim of diagnosis is to detect prostate cancers early before they have spread. This can be done by regular rectal examination or by the use of Prostate Serum Antigen. Generally, patients with early prostate cancer have few, if any, urinary symptoms. If either digital rectal examination or PSA suggests a tumour then diagnosis is made by transrectal ultrasound with ultrasound guided biopsies of the prostate. In general, patients over the age of 45 should have yearly rectal examination by their local practitioners and if they have symptoms or are in a high risk category they should also have a PSA estimation. Controversy exists at the present time as to whether PSA should be done in asymptomatic patients as a screening tool. Until there is proof that the detection of very early tumours by screening the general population has a definite benefit for the community above and beyond the side effects of treatment, this will remain a controversial issue. Studies are at present looking at this aspect very closely. As a working principle all patients from the age of 40 in a high risk situation should have a yearly digital rectal examination and PSA, whilst those in a low risk situation should have a yearly rectal examination from the age of 45 and a PSA added only when clinically indicated. However this may change.

A new technique of picking up early cancers can be by serial monitoring of PSA levels. These levels can be related to prostate size and the speed at which PSA increases (PSA velocity) to help increase the accuracy of early diagnosis of prostate cancer.

Clinical Assessment

To assess the extent of prostate cancer, information from digital rectal examination, TRUS, bone scan, and abdomen/pelvic CT scan and prostate acid phosphatase and the level of PSA is necessary. This will give a reasonable idea as to whether the tumour is localised or not. Occasionally laparoscopic sampling of the pelvic lymph glands is necessary. The grade of the tumour on biopsy will also influence treatment as tumours with very high grade are much more likely to have spread while those with low grade are less likely to do so.

Information about the patient is also critical. The patient's age and estimated life span as well as his expectations need to be included in the decision making process. Occasionally, quality of life issues may influence management, such as the effect of surgery or radiotherapy on sexual functioning, continence and rectal damage.

Finally, the size of the tumour may influence treatment as small, well-differentiated tumours only double in size approximately every two years and in the older age groups this may be better treated conservatively.

Treatment

The mainstay of prostate cancer control is radical surgery or radiotherapy when the tumour is confined to the gland, and hormonal ablation when it extends beyond the prostate and becomes advanced. There have been many debates as to whether radiation or radical surgery is the treatment of choice when the tumour is localised. With a decrease in morbidity after surgery, it would appear that completely destroying all tumour cells located in the prostate by removing them is the best means of ensuring complete cell inactivation. Radiation kills a certain percentage of cells per unit time of treatment and it is the author's opinion that we may be able to decrease the tumour mass to a level where it would not grow back during the

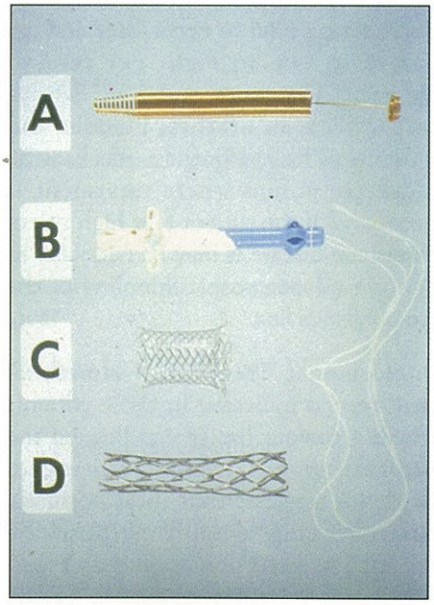

Figure 2. Prostatic stents - four different types of stents currently available

life of the patient. However, removing the prostate removes the danger of any malignant cells remaining within the gland. With decreased morbidity, it would seem that surgery is the preferred option to treat localised tumour although the issue is still being debated.

Options therefore include:

Wait and Watch. This option is only suitable for older patients with a small well-differentiated tumour and a limited life expectancy. In this group the chance of this type of small tumour causing death in their natural lifetime is so low that this is a very real treatment option.

Radical Prostatectomy (RP). With careful anatomical surgical dissection, it is now possible to have a very low incidence of complications with this surgery. The aim of surgery is to completely eradicate the tumour, at least in patients with a 10-year life expectancy. Side effects include impotence (50 to 70 per cent) and incontinence (approximately two per cent). Anastomotic strictures occur in approximately four per cent. All these side effects are easily treatable. At St Vincent's we have treated 247 patients with radical prostatectomy with a very low incidence of complications. The cure rate from this procedure is dependent on diagnosis of tumour while it is still contained within the prostate. (Table 5)

Radiation Therapy. Radiation therapy to the prostate is given over six to seven weeks on a daily basis. It has approximately the same local control rate as surgery in studies that have looked at 10 year results. Complications of radiotherapy tend to occur later and are severe in two to eight per cent of patients. The major effects are damage to the rectum, urethra, bladder and prostate. This treatment is ideal in the older age groups where treatment is necessary. If the patient is at high risk of metastatic disease it may be necessary to perform a laparoscopic sampling of the lymph glands first.

Hormonal Treatment. Hormonal treatment is indicated in those patients where a tumour has spread beyond the prostate or has become advanced. Evidence suggests that total hormone ablation using leuteinising hormone releasing agonists plus an anti-androgen has greater benefit compared to LHRH analogues alone. There are now many ways of delivering the same hormonal treatment. These include orchidectomy, LHRH analogues, anti-androgens, or total androgen ablation with either of the first two and an anti-androgen. There is also evidence that early treatment with hormones carries a benefit over later treatment, although quality of life issues must be taken into consideration when making this decision. The main issue here is sexual functioning. In a patient with metastatic cancer to bone, 50 per cent of cases treated with hormone treatment will survive an average of three years. Patients with less advanced disease will naturally survive longer and a sub-group of those with total androgen ablation will also survive longer.

Cryotherapy. This is a new experimental technique in which freezing probes are placed into the prostate. Long-term results of this method are unknown. Preliminary results suggest a high local recurrence rate and significant impotence rate.

Interstitial Radiotherapy. This is the placement of small radioactive seeds using an accurate computer lattice into the prostate. It is done as a day-only procedure. Previously the results of this technique were not as good as radical surgery but new, more accurate placement of seeds may have a more promising role.

Occult Tumour

Autopsy studies have confirmed that the incidence of tiny, well differentiated tumours of the prostate can be as high as 80 per cent in 80-year-olds. This does not reflect our experience with clinical tumours. One of the dilemmas for the future is to ensure that the enthusiasm for treatment of prostate malignancy is directed at those tumours which will become clinically significant rather than those which are simply occult. Indicators that tumours are clinically significant at present are the grade of the tumour, the size, and the rate of rise of the PSA. These factors should help us avoid over treatment of this exceedingly common condition.

Conclusion

- RP is a safe operation with low morbidity with increasing experience
- Impotence rate is high - 66%
- Frozen section has false negative rate of 7%
- Incontinence can be minimised to less than 2% with experience
- 40% of clinical stage Aor B will be pathological stage C or D
- Correct treatment of positive margin and PSA recurrence is unknown
- Effective in localised (intraprostatic) disease

Table 3. Summary of Results of Radical Prostatectomy at St Vincent's Hospital

Prostate Clinic Concept

It is apparent from the above discussion that new diagnostic techniques and new technologies for the treatment of prostatic disease have made this not only a difficult diagnostic dilemma but also a perplexing treatment problem. In order to rapidly assess all aspects of prostatic disease and evaluate new technologies, at St Vincent's we have decided to establish a Prostate Clinic. All aspects of treatment of benign and malignant disease will be offered and a full educational service to all patients will be available. This will improve the opportunity for patients to make their own informed decisions about treatments. By computerising all data, future information about the success of each treatment modality can be documented. This can then be published to benefit all our patients. The future of diagnosis and treatment of prostatic diseases will rely heavily upon a close interplay between clinical and research arms especially into molecular biology and genetic engineering. I believe the next 10 years will herald enormous changes in this area.

St Vincent's Clinic Foundation

1993 Research Grant Recipients

Dr. J Rimmer	Assessment of cellular activation of asthma.
Dr. P Kelly	The prevention of cortico-steroid bone loss after cardiac transplantation.
Ass. Prof. M Feneley	Non-invasive measurement of the left ventricular pressure – volume relationships and derivative indices of contractility.
Dr. N Pocock	Dual energy x-ray absorptiometry in the assessment of femoral head prosthetic implants.
Dr. B Courtenay	International documentation and evaluation system for the assessment of hip replacements.
Prof. L Lazarus	The use of mass spectrometry in the diagnosis of non-classical congenital adrenal hyperplasia.
Dr. T Campbell	Intracellular control mechanisms for ion channels in cultured vascular smooth muscle cells.
Dr. T O'Connor	Development of screening methods for colo-rectal neoplasms by detection of point mutations.
Dr. D. Golovsky	Construction of recombitant immunotoxins from tumour associated-lymphocytes in renal cancer.
Prof. R Lord	An investigation of acute platelet kinetics following endarterectomy and patch angioplasty in sheep.

1994 Research Grant Recipients

Dr. M Atlas	Immune basis of inner ear hearing loss.
Prof. P Brooks	The effect of treatment of joint pathology in athritis.
Ass. Prof. T Campbell	Effectiveness of drugs to control abnormal heart rhythm.
Dr. P Edward	A study of how the bacterium – helicobacter pyloric causes duodenal and gastric ulcers in humans.
Dr. D Golovsky	Construction of recombinant immunotoxins from tumour-associated lymphocytes in renal cancer (continuation of 1993 Grant Project).
Prof. R Lord	The use of glue in performing vascular and intestinal surgery.
Dr. T O'Connor	Do mMuscles around the aAnus become weaker after operation on the rectum because the nerves to those muscles are divided during operations?
Dr. N Pocock	Bone densitometry in prediction of loosening of artificial hips (continuation of 1993 Grant Project).
Dr. P Stricker	Comparing a new needle minimally invasive teatment of prostate enlargement to laser aAblation.
Dr. P Spratt	A study of new methods in the preservation of the heart and lungs during experimental transplantation of these organs in a rat.