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Editorial

Point of View: Top-down or Bottom-up? A Cardiologist's View Point on the Proposed Hospital Authority Initiative in Safe Introduction of New Interventional Service

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In this issue of the Journal, Chang et al1 describes a proposal mechanism for introducing new interventional procedure in the Hospital Authority (HA). As practising cardiologists, we would like to express a different view on the proposed mechanism.

It is important first to define the scope of the current initiative. The initiative addresses the territory-wide application of new interventional procedures in HA hospitals. As such, these procedures should be relatively well established, with either international or local evidence. Indeed, a formal ethics committee approval is unnecessary, because this introduction is service-oriented and is not a clinical trial. Chang et al1 quoted the application of brachytherapy as an example, a procedure that has already been shown to be efficacious and safe in several international randomized controlled trials.2-3 New innovations which may be novel treatment, usually carried out as a clinical trial would need to go through hospital (or university) ethics committee as stated in the current proposal, and these trials will not need to go through the proposed HA initiatives.

The proposed HA initiative is a typical "top-down" mechanism by which an administrative unit in the HA, in conjunction with a few interested chosen experts in the field, takes up "the governance and management approval procedure" for new interventional procedures. Such a structure has the advantage of ensuring a uniform protocol and training requirements for all centers, and a central monitoring of quality. The disadvantage of this mechanism is the "representativeness" of the chosen experts, and the necessary delay introduced by the administrative process. For instance, a 6-month delay was encountered between the application for $\beta$-brachytherapy to treat coronary restenosis and the first case performed. In addition, because of the rapid evolution of technology, it may be necessary to repeat the whole process should a close alternative be introduced. Thus, the mechanism should build in an alternative is more expedite process, to allow similar procedures to be approved. In some hospitals such as the Queen Mary Hospital and Prince of Wales Hospital, a third mechanism is operative: a hospital based "Technology and Therapeutic Subcommittee" is available to "approve" new interventional procedures at the hospital level.

Traditionally, new interventional cardiology procedures are introduced in Hong Kong by local experts in the field, usually in the form of a clinical trial. For example, the first radiofrequency ablation in the Asia-Pacific region for paroxysmal supraventricular tachycardia was introduced in Hong Kong in 1990.4 With training in the technique from the initiating center in Hong Kong and centers overseas, this procedure is now generally available in most of the HA hospitals with catheterization laboratory. This process of "evolution" from "bottom-up" has the advantage of being highly flexible with minimal administrative cost and burden, and with professional freedom that all of us are used to and would like to continue. Patients' welfare is safeguarded by the requirement of the ethics committee, and by the expertise of the initiating cardiologists. The quality of the service in subsequent

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Opinions expressed are views of the authors and not necessarily the view of the editorial board or the Hong Kong College of Cardiology.
centers are guaranteed by appropriate training, often with participation of the cardiologists from the more experience centers in the initial cases. Quality assurance and accountability are in the hands of the practising cardiologists and centres concerned. In the present funding limitation in the HA in which there are little additional funds for new procedures/services, these procedures are introduced with "productivity gain" by the unit concerned and is highly cost-effective.

Which system should we adopt? We think that the "old" and "new" are not mutually exclusive, but complementary. Most of the innovative treatments will be carried out as clinical trials, under the auspicion of individual hospital/university ethics committee. When these innovations have matured to wider clinical application, or when an established new interventional procedure is for introduction, there may be a choice between the "top-down" and "bottom-up" approach. We believe that the clinicians, acting in the best interests of the patients should have a freedom of choice in their initiatives. Should additional funding from the HA be available for introduction of new procedures, a "top-down" initiative would be a logical option.

References

Evaluation of Percutaneous Laser Myocardial Revascularization in Chinese Patients with Refractory Angina Pectoris

CAIYI LU, XUAN WEI, CONGCHUN HUANG, HUILAN LUO, SHUSEN MAO

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LU ET AL.: Evaluation of Percutaneous Laser Myocardial Revascularization in Chinese Patients with Refractory Angina Pectoris. The study aims to evaluate the feasibility and effect of percutaneous laser myocardial revascularization (PMR) in patients with refractory class III-IV angina. Patients were selected by: (1) angina class ≥III; (2) unsuitable to CABG and PTCA; (3) LVEF ≥30%; (4) absence of myocardial infarction in 6 months; (5) maximum diastolic wall thickness of left ventricle (LV) ≥8 mm in echocardiography. Eclipse Holmium laser generator and catheter were used. Eighteen patients (17 male and 1 female) with age of 63.3±7.5 years and a history of angina for 9.6±7.0 years were studied. They were refractory to 5.8±0.7 antianginal drugs. The angina class was IV in 11 patients and III in 9 patients. Maximum diastolic LV wall thickness was 10.2±0.8 mm. LVEF was 41.2±6.2%. Eleven and 9 patients had triple vessel and double vessel diffuse disease, respectively. A mean of 19.7±3 endomyocardial channels were made. Procedure time was 78.2±12.5 minutes and radiation time 24.3±7.4 minutes. There were no complications. During the follow-up of 18.7±1.6 months, angina class decreased from 3.8±0.7 to 2.1±0.8 (P<0.05). Ischemia in SPECT was significantly improved. PMR using Eclipse Holmium laser generator and catheter is safe in Chinese patients. This results suggest that patients with refractory class III or IV angina could be controlled by conjunctive use of PMR and regular antianginics drugs. (J HK Coll Cardiol 2000;9:3-8)

Angina pectoris, Holmium laser, myocardial revascularization

摘 要
本研究的目的是評價經皮激光心肌血運重建術（PMR）治療頃固性III-IV級心絞痛的可行性和療效。病例選擇標準為：
(1) 心絞痛級別≥III級，(2) 不適合合CABG和PTCA；(3) LVEF ≥30%；(4) 6個月內無心梗病史；(5) 超聲心動圖測定左室壁最大舒張期厚度≥8mm。使用Eclipse钬激光發生器及其導管系統。18例病人中男17例，女1例，年齡63.3±7.5。
心絞痛級別9.6±7.0年，平均5.8±0.7種抗心絞痛藥物效果不好。心絞痛中級11例，III級9例。左室壁最大舒張期厚度10.2±0.8 mm。LVEF 41.2±6.2%。三支心絞痛9例，兩支心絞痛9例，均為管壁性病變。每例病人打孔19.7±6.3個。操作時間78.2±12.5 min，透視時間24.3±7.4 min。無併發症。随訪18.7±1.6月，心絞痛級別從3.8±0.7下降到2.1±0.8 (P<0.05)。ECD示心肌缺血明顯改善。採用Eclipse钬激光發生器及其導管進行PMR操作安全可行。本文結果表明，PMR配合常規藥物治療能很好控制頃固性III-IV級心絞痛。

關鍵詞：心絞痛，钬激光，心肌血運重建術
Introduction

The principle of percutaneous laser endomyocardial revascularization (PMR) is to make endomyocardial channels in the ischemic left ventricular walls by translating laser energy via a steerable optic fiber catheter. From these channels, new capillary network is reconstructed by angiogenesis development. The channels are 6 mm in depth and 2 mm in diameter and are apart from each other by 10 mm. Unlike angioplasty (PTCA) or coronary bypass (CABG), PMR is not limited by the characteristic and degree of coronary vessel lesions, and is suitable to all kinds of end-stage ischemic heart disease patients who cannot be revascularized. Therefore, PMR will be a very important supplement to PTCA/STENT and CABG.1-3 In order to evaluate the feasibility and safety of PMR in the treatment of Chinese patients with ischemic heart disease, we analysed the clinical and follow-up data of 18 patients who received PMR procedures in our center in the recent 2 years.

Material and Methods

Patient Selection

Patient selection has been described in previous publications.1-5 The 18 cases were selected by the criteria of: (1) angina pectoris of class III-IV (Canadian Heart Association Class),6 (2) refractory to more than 4 antianginal drugs, (3) left ventricular ejection fraction (LVEF) on echocardiography ≥30%, (4) absence of acute myocardial infarction in the recent 6 months, (5) multi coronary vessel diffuse lesions in paroxysmal and distal parts on coronary angiography, (6) cardiac ischemia confirmed by treadmill test and/or single positron emission computerised tomography (SPECT), (7) the thickness of target left ventricular wall in maximum diastolic period on echo ≥8 mm, and (8) without catheter interventional complications.

Equipment

MLAS-1 Holmium: YAG laser generator (Eclipse Corp., San Francisco, CA, USA) was used. The machine has the parameters of: (1) wavelength 2100 nm, continuous adjustable energy from 1 to 6W, (2) pulse width 200 µ, 2J per pulse and 1-3 pulse delivered per burst, (3) automatic active energy calibration system, (4) synchronization with ECG R wave and adjustable delay triggered window, (5) Holmium: YAG laser, (6) usable for both PMR and transmyocardial laser revascularization. The laser catheter (PMRL-1, Eclipse Corp., Figure 1) was 110 cm long, comprised of a 9F XL2 guiding catheter (100 cm) and a 5F L1 laser catheter (the inner laser fiber, 500 cm). At the tip of the laser catheter, there is a mirror with a dimension of 1.75 mm and 4 limiting petals mounted on it.

Procedure

A 9.5F artery sheath was introduced into right femoral artery by Seldinger technique. Ten thousand units of heparin was given via the sheath. The LV was entered with a 6F pigtail catheter, through which a 9F long sheath was reel rolled into LV. A LV angiogram was performed with biplane DSA during quiet breathing. The maximum diastolic LV imaging was fixed and major LV landmarks were marked on the video screens. Then the pigtail was withdrawn, and the laser catheter advanced. The laser generator was controlled at following parameters: 2 pulses per burst, 2J per pulse, synchronization window lasted 30 ms and located before the first third of T wave ascending limb. Delivered energy was calibrated before washing the catheter system.

The following steps was adapted to make endomyocardial channels in targeted ischemic LV walls. Coronary and LV angiograms and echo results were reviewed to confirm the targeted LV wall. The LV wall was divided into anterior, lateral, inferior, septal and blunt apical. The 9F sheath was then directed to the targeted wall. By the continuous flushing of pressurised normal saline, the laser catheter and its outer sheath
PMR TREATMENT IN ANGINA PECTORIS

were introduced into the LV chamber. The radiopaque mark at the tip of the laser catheter enabled the operator to visualize the catheter at the tip of the 9F sheath. The laser catheter was then advanced until its tip was in contact with the endomyocardium perpendicularly (Figure 2); and a laser application was made. The created channel was marked on the biplane video screens to ensure the channels were evenly distributed and to avoid two channels were made at the same point (Figure 3). The laser catheter was then withdrawn and the process repeated, until all targeted LV walls were revascularized. During above procedure, ECG, arterial pressure and the fluoroscopic heart movement were monitored.

Follow Up

The following parameters were assessed during follow-up: (1) Angina class, (2) standard 12 lead ECG,

Figure 2. Laser channels were marked on the right anterior oblique 30° (A) and left anterior oblique 45° (B) fluoroscopic screens of left ventricular angiogram.

Figure 3. When perpendicularly pointed to the ventricular endocardium, the tip mark of the laser catheter could be visualized as a filled rectangle on right anterior oblique 30° (A) and an open circle on left anterior oblique 45° (B), respectively.
(3) treadmill test, (4) echocardiography, (5) SPECT, (6) cardiac enzymes, (7) LV late potential, and (8) Holter monitoring.

**Statistic Analysis**

Categoric data were expressed in percent and value data in mean ± standard division (M±SD). Student t test or χ² test was used to analyse the data and a P<0.05 was considered to be statistically significant.

**Results**

**Patient Data**

Eighteen patients (17 male and 1 female) with age of 65.4±8.2 (51-78) years were studied. Their angina history was 9.6±7.0 (1-42) years. Their angina class was 3.8±0.7 (class IV in 11 cases and III in 7 cases). They were refractory to the combination of 4.8±1.7 (3-7) types of antianginal agents. On SPECT, the ischemic LV walls were demonstrated in anterior, lateral and inferior walls (9 patients), anterior, lateral and septal walls (5 patients), and anterior, lateral and blunt apical walls (4 patients). All had normal cardiac enzyme, liver and kidney function and negative LV late potential. On echocardiography, all patients showed normal cardiac chamber size without aneurysm and thrombus. The maximum diastolic LV wall thickness was 10.2±0.8 (9-14) mm with regional motion amplitude of 7.4±0.7 (5-9) mm. On coronary angiogram, fourteen patients (78.6%) showed triple vessel disease and 4 patients (21.4%) had double vessel disease. The LVEF was 43.5±3.7 (42-58)%.

**PMR Procedure Data (Table 1)**

A mean of 19.7±6.3 (9-30) laser channels were made on 3±0.9 (2-4) LV walls. A mean of 70.3±11.5 (38-106) laser pulses and 137.9±20.4 (74-210) J were delivered.

**Complications**

During laser delivery, all patients did not experience abnormal sensation. There were no complications of cardiac perforation, aortic or mitral valve damage. Ventricular premature contraction was provoked in 14 (77.8%) patients and nonsustained ventricular tachycardia was induced in 9 (50.0%) by intracardiac laser catheter manipulation. Total procedure time was 78.2±12.5 (48-126) minutes and X-ray radiation time was 24.3±746 (12-36) minutes.

**Early Observation after PMR Procedure**

All patients showed normal cardiac enzyme at 6, 12 and 24 hours after PMR procedure. Seven patients had ST segment resolution in ECG.

| Table 1. Channel distribution, pulse and energy data of 18 patients receiving PMR |
|-------------------------------|---------|-----------------|-----------------|
| LV wall | n | laser channel | laser pulse | laser energy |
| single wall | | | | |
| anterior | 18 | 11.7±5.1 (7-14) | 47.5±9.8 (36-62) | 93.6±23.5 (68-118) |
| lateral | 14 | 10.4±2.5 (7-11) | 37.0±7.5 (27-42) | 69.5±11.9 (26-74) |
| inferior | 7 | 7.8±3.2 (5-9) | 31.2±3.5 (23-34) | 41.6±7.4 (32-49) |
| septal | 6 | 8.1±1.8 (6-10) | 30.1±4.5 (22-36) | 64.1±9.4 (32-76) |
| two walls | | | | |
| A and L | 18 | 18.5±3.5 (7-26) | 66.7±9.1 (36-87) | 119.3±16.3 (70-206) |
| A and I | 7 | 14.4±4.6 (6-18) | 49.6±9.1 (27-94) | 109.7±13.2 (68-182) |
| A and S | 6 | 13.8±2.6 (5-21) | 53.2±11.2 (37-86) | 110.2±16.3 (67-176) |
| three walls | | | | |
| A, L and I | 7 | 17.7±3.4 (7-26) | 68.3±8.3 (34-96) | 138.7±14.6 (72-204) |
| A, L and S | 6 | 16.2±3.4 (9-21) | 66.2±7.4 (36-101) | 129.3±16.5 (69-197) |
| Total | 14 | 17.6±4.3 (9-26) | 68.3±9.5 (36-104) | 136.4±17.2 (72-208) |

Note: A: anterior wall, I: inferior wall, L: lateral wall, LV: left ventricle, S: septal wall
Follow-up Results (Table 2)

The angina class of all patients was improved significantly in the follow-up period of 8.7±1.6 (3.5-11.5) months. The mean reduction in angina class was 1.7±0.4 (1.5-3.5).

Discussion

In this study, we have reported the favorable experience of PMR in 18 patients with angina who were refractory to conventional therapy. To ensure safety of the procedure, the following items should be noted during PMR operation: (1) Measuring the actual delivered laser energy to avoid possible abnormal connection between the catheter fiber and the generator. The latter can cause the delivered laser energy abnormally high or low. High energy will lead to cardiac perforation or damage the cardiac structure, whereas low energy will decrease the PMR effect. (2) The maximum number of laser channel for any ischemic LV wall was limited by the potential complications such as cardiac perforation, at present the channels for one LV wall is limited under 12, nearly approaching the density of one channel per cm². (3) To prevent cardiac perforation, the stiff sheath should be manipulated smoothly and without any resistance in the LV chamber. Pushing forward and pulling back the sheath as well as the fiber catheter always under the direction of continuous fluoroscopy, and biplane X-ray screens were used to locate and mark the channels. Continuously monitoring electrocardiogram, arterial pressure and cardiac movement amplitude were useful. (4) During PMR, arrhythmias could be provoked by the mechanical stimulation of catheter manipulation and the delivery of laser energy. The former could be decreased by the use of softer or lower profile laser catheters, individualizing the catheter type and size, adjusting the catheter contact with the endomyocardium according to the cardiac movement and ensuring a stable catheter tip in the LV chamber. Arrhythmia induced during laser delivery could be prevented simply by synchronizing the laser energy delivery to the safe period of the cardiac electric interval.

Conclusion

It is feasible and safe to conduct PMR by Eclipse Holmium laser generator and catheter in Chinese patients. PMR allows patient with refractory class III or IV angina despite conventional treatment to be controlled.

References


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<th>Table 2 Follow-up results of 18 patients receiving PMR</th>
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<td>VPC on Holter (no./24h)</td>
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<td>ischemia on ECG (%)</td>
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VPC: ventricular premature contraction
Coronary Artery Fistula

WAI-FAT LAM

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Case Report

An 85 years old gentleman presented with retrosternal chest pain for six months. There was no heart murmur. Echocardiogram showed mild anterior hypokinesia; a persantin thallium scan showed partial reversible defect of the distal LAD territory. The patient underwent a coronary angiogram, which revealed a patent arteriovenous fistulae originated from a large first diagonal artery and draining into the pulmonary artery (Figures 1 and 2). This resulted in a distal LAD "steal" with subsequent myocardial ischaemia. The LV ventriculogram revealed a mild anterior hypokinesia.

Figure 1. Right anterior oblique view of the left coronary system injection. A coronary fistula drained upwards into the pulmonary artery.

Figure 2. Left caudal view showing the orifice of the fistulae from the diagonal branch.
CORONARY ARTERY FISTULA

Discussion

Coronary artery fistula is uncommon cardiac lesion but it is the most common congenital coronary anomaly with haemodynamic consequence. The incidence of coronary artery fistula in adult population undergoing coronary angiography study is reported to 0.1-0.2%. The natural history of such fistula has not been studied in large numbers of patients. It is believed that most of the small lesions are asymptomatic. Eccleshall et al reported a series of 17 fistulae in 14 heart transplant patients followed for a median of six years. The majority closed spontaneously, none increased in size and no clinical complications occurred. Large lesions, however, generally require closure to prevent complications such as myocardial ischaemia from a steal phenomenon, endocarditis and potential aneurysmal dilatation and rupture.

Treatment options include coil embolisation, transcatheter occlusion with covered stents and surgical ligation. The method of closure depends on the individual anatomical features of the fistula. Transcatheter closure with Rashkind double umbrella or Amplatzer septal occluder has been widely used in paediatric cases of congenital coronary arteriovenous fistula and less frequently in adults.

References

ECG Quiz

NGAI-YIN CHAN

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A cardiac consultation about a 76-year-old lady with chest pain and congestive heart failure was received. The cardiologist was asked to comment on an "abnormal ECG" (Figure 1) which was done 10 days after admission.

What was the rhythm diagnosis ?
1. a) Sinus rhythm
   b) Atrial fibrillation
   c) Accelerated junctional rhythm
   d) Others

The busy cardiologist reviewed the history and all ECG's. The patient immigrated from China two months ago. She had history of heart disease and chronic lung disease. She has been given frusemide and some unknown medicine. The patient presented with exertional shortness of breath and atypical chest discomfort. Clinical examination revealed a 39 kg lady with tachycardia and congestive heart failure. The potassium level and renal function was within normal on admission. The following was the ECG on admission. (Figure 2)

What was the ECG diagnosis ?
2. a) Atrial fibrillation
   b) Atrial flutter with variable block
   c) Atrial tachycardia with variable block

Figure 1. "Abnormal ECG" 10 days after admission.
The patient was given aspirin, nitrate and frusemide. Digoxin loading of 0.25 mg Q8H for four doses followed by 0.125 mg per day was given orally.

The patient developed nausea, vomiting, confusion and easy forgetfulness 10 days afterwards. Clinically she was dehydrated. Serum electrolytes and blood glucose were normal. Renal function test was impaired with urea 13.1 mmol/L and creatinine 201 umol/L. CT brain was normal. ECG was done at that time and was the one mentioned in the cardiac consultation. (Figure 1)

3. What was the likely unifying cause for the symptoms and the "abnormal ECG" 10 days after admission?

The digoxin level was 5.6 nmol/L. Digoxin and frusemide were stopped. The patient was cautiously rehydrated. The symptoms gradually subsided over 2 weeks' time. The renal function test was then normalised and the digoxin level dropped to 2.0 nmol/L. The cardiac rhythm reverted back to that of admission.

**Answers**

1. d) Accelerated junctional rhythm with underlying atrial fibrillation
2. a) Atrial fibrillation
3. Digoxin toxicity

**Discussion**

Digoxin toxicity is not an uncommon clinical problem partly because of its widespread use. Timely recognition and appropriate management requires knowledge on the risk factors predisposing to and clinical manifestations of digoxin toxicity.

Factors predisposing to digoxin toxicity include hypokalaemia, hypomagnesemia, hypercalcaemia, renal impairment, advanced age, pulmonary disease and thyroid disease. In this thin elderly lady with history of chronic lung disease, a lower maintenance dose of digoxin should probably be given. The subsequent renal function
impairment which contributed to digoxin toxicity was likely to be due to overdiuresis with frusemide.

This patient demonstrated the classical constellation of gastrointestinal and neurologic symptoms of digoxin toxicity. Dementia like symptoms should alert one to look out for chronic digoxin overdose. Noncardiac manifestations of digoxin toxicity include anorexia, nausea, vomiting, headache, malaise, neurologic pain, disorientation, alteration in color perception, scotoma and halo vision.

Digoxin toxicity produces two major electrophysiologic effects. The first one is a direct and/or vagally mediated slowing of conduction and block in the sinus node and atrioventricular node. This may cause sinus rate slowing, sinus pauses and atrioventricular conduction disturbances. The second one is an enhanced abnormal automaticity and triggered activity in atrial muscle, atrioventricular junction, His-Purkinje system and ventricular muscle. Specific arrhythmias of digoxin toxicity include (1) paroxysmal atrial tachycardia with variable blood, (2) atrial fibrillation with complete heart block, (3) second or third-degree AV block, (4) supraventricular tachycardia with alternating bundle branch block, (5) complete heart block with accelerated junctional rhythm or accelerated idioventricular rhythm, (6) fascicular ventricular tachycardia. In this patient, the ECG shown in Figure 1 demonstrated a very specific arrhythmia due to digoxin toxicity. Regularisation of RR interval with underlying atrial fibrillation shown in leads II, III, V1 and V2 often represents complete heart block with accelerated junctional rhythm (with ventricular rhythm >60 bpm).

Apart from arrhythmias, digoxin therapy may also cause alterations in ST segment and T wave. The T wave amplitude is lowered and ST segment is depressed and shortened with occasional appearance of a prominent u wave. The characteristic ST segment sagging is also found in this patient. However, it is always difficult to differentiate it from ST depression of other causes like myocardial ischaemia.
Safe Introduction of New Interventional Procedures: A New Initiative in Hospital Authority

DICKSON T S CHANG, HING-WING LIU, SIEW-PENG LIM

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Background

Progress in medicine and breakthroughs from bio-medical research have resulted in a rapid proliferation of healthcare technologies including drugs, equipment and interventional procedures. They are often numerous, costly and holding great promises, with safety and efficacy yet to be fully established. Healthcare providers are thus under constant pressure to decide for timely introduction of appropriate and worthy technologies for benefit of patients, despite all the uncertainties involved.

Worldwide experience demonstrates that regulatory controls over emerging drugs and equipment are better established than for interventional procedures. It is not uncommon for the latter to involve intricate elements of innovation, new consumables, variations in application, and a high demand on operator skill to achieve the intended outcome. Such degrees of complexity often make the situation difficult to manage. As no interventional procedures are free from hazards, the decision to introduce a new procedure with its associated uncertainties is not a simply task. A number of government agencies and professional bodies have made attempts to devise assessment tools to manage this challenge, in an effort to safeguard patient's wellbeing and uphold professional accountability.

The Hospital Authority Scenario

In Hong Kong, the Hospital Authority (HA) has long established mechanisms to evaluate new drugs and equipment for safety and efficacy prior to their introduction into the system. Similar mechanism, however, is not available for interventional procedures. Section 22(e) (revised in June 1996) of the Professional Code of Conduct issued by the Hong Kong Medical Council stipulates that "The medical practitioner should consult and obtain approval from the relevant ethical committee in regard to the use of such surgical procedures, grafts, implants or medications". When the HA requested hospitals (or hospital clusters) to set up their own ethics committees in 1995, it was intended that they would deal with the introduction of new interventional procedures as well. Yet the prevailing practice is that only proposals on clinical trials would be considered in the hospital ethics committees. Out of the 12 major acute public hospitals surveyed in April 2000, few had established mechanism to evaluate new interventional procedures prior to their introduction, and most did not have explicit or sufficient documentation requirements for such reviews. Situation does not seem to be more assuring in the private sector (personal enquiry). Anecdotal reports that new procedure of unproven efficacy had been performed on patients highlight the need for an explicit mechanism in HA and perhaps Hong Kong as a whole.

Evolution of HAMSINP

In January 2000, the Coordinating Committee in Surgery reported to the Medical Services Development Division...
Committee (MSDC) that a mechanism would be set up to vet new surgical procedures prior to their introduction into HA. Members of MSDC received the proposal with great enthusiasm. Thus, the Chairman, Dr the Honourable CH Leong requested an explicit mechanism to be established and implemented on the 1 January 2000 to cover all clinical specialties.

The 'HA mechanism for the safe introduction of new procedures' (HAMSINP) was designed to close a loophole in the existing system and to provide guidelines and tools for HA staff to appraise new interventional procedures and to document such activities. It was planned with the following principles in mind:

1. It is considered unethical to plan an introduction of new interventional procedure into the HA service without going through proper peer review.
2. The mechanism must not stifle clinical innovation but should, instead, facilitate timely assessment of new procedures aiming at their safe and effective introduction.
3. The mechanism would enhance accountability to public, protecting interests of patients as well as the clinicians and hospitals, through compliance with an impartial process that is explicit, transparent and benchmarked against international best practice.
4. The mechanism provides due recognition of staff initiative, originality and fosters spirit of shared learning.

Key results shall include:
1. Establishing Standard Operating Procedures (SOP) for collecting, collating and analyzing evidence concerning the safety and efficacy of submitted new procedure, and making recommendations regarding appropriate method of introduction into the HA services.
2. Harmonizing vetting standards by providing a set of unified procedures and appraisal tools.
3. Establishing documentation requirements that permit retrospective evaluation of the conduct of the review and the quality of the decision reached.
4. Enhancing cooperation and implementation planning to minimise patient risks in going through many learning curves of individual operators and centres.
5. Setting up a central register to facilitate information dissemination.
6. Developing a culture of accountability through evidence-based decision making, independent peer review and procedural transparency.

The Approach

We scanned websites for similar set ups in the developed countries and conducted meetings to solicit inputs from leading surgical specialists from both Universities and HA hospitals. It was generally agreed that the Australian Safety and Efficacy Register of New Intervention Procedure - Surgical (ASERNIP-S) was a model suitable for our adaptation. In April 2000, we were fortunate to be offered an opportunity by Pamela Youde Nethersole Eastern Hospital to test this model on an application of intracoronary brachytherapy. We subsequently developed a set of SOP and appraisal tools using the evidence-based medicine approach. These documents, grouped as HAMSINP during consultation, constituted a common platform of discussion whereby all interested staff could contribute their ideas. In developing the SOP, we took care to align the governance and management approval procedure with the existing accountability structure in the HA hierarchy (Figure 1).

HAMSINP is application driven and its success is thus contingent upon professional integrity and a culture of accountability. Our professional obligation dictates that all clinicians must assess safety and efficacy issues before making changes or incorporates new innovations in interventional procedure to their practice. HAMSINP simply states these requirements and emphasizes the need for systematic searching and appraisal of evidence. The single unitary public hospital system in Hong Kong which, covers over 90% of the market, provides a unique opportunity to enable a healthcare technology assessment tool with high likelihood of success.

Noting that mutual understanding and trust are prerequisite for the successful implementation of HAMSINP. We would be holding more than 30 briefing
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Figure 1. An overview of the HAMSINP mechanism.

Abbreviations:
CE: Chief Executive
CEU: Clinical Effectiveness Unit
COC: Coordinating Committee
COS: Chief of Service
DD(MSD): Deputy Director (Medical Services Development)
HA: Hospital Authority
HCE: Hospital Chief Executive
HGC: Hospital Governing Committee
MSDC: Medical Services Development Committee
sessions and open forum for major specialty Coordinating Committees, Hospital Governing Committees and frontline practitioners to solicit their comments.

What Have Been Confirmed in the Consultation Process?

During consultation, both heat and light were generated for HAMSINP. Concepts such as professional autonomy, public accountability and practicability were rigorously examined and debated upon among enthusiastic colleagues. No one was left in doubt of the principles and concepts of the proposed mechanism but many had shown concerns over how much could be achieved at the end. Many had pointed out difficulties such as resources constraint and a prevailing culture of competition among some hospitals that might obstruct shared learning.

HAMSINP is application driven. It is not a policing tool. The actual appraisal will be performed by peers utilizing methods established in evidence-based medical practice. This heavy involvement by clinicians should strengthen the basis and further promotes professional autonomy rather than limiting it as feared by some colleagues. HAMSINP would not infringe upon a clinician's sacrosanct privilege and duty in taking care of his/her patients. In unforeseen circumstances where a new procedure may be life saving, the accepted practice to "act in good faith" would prevail over a prescribed mechanism for normal use. Despite all considerations and efforts to design a "perfect" mechanism, the HAMSINP would need to evolve over the years to fully achieve its intended objectives.

Innovations and hypothesis that needs to be tested by clinical trials should be referred to the ethics committee for consideration. The latter's scope is much wider, covering issues such as bio-medical ethics, scientific values and quality standards in the designing, conducting, recording and reporting of clinical trials. It is the authors considered view that the existing hospital ethics committee infrastructure needs further development to match our community's expectation.

Conclusion

The HAMSINP helps to close a "loop hole" in the existing system where some new procedures will escape proper assessment by bypassing the ethics committee. The limited experience we have gained suggested reasonable confidence on its feasibility and practicality. By making the best evidence and sound recommendations clearly documented and readily available, it will certainly facilitate better decision-making at all levels of healthcare in the Authority.

Readers interested in obtaining a copy of the SOP, and or providing any comments, should contact Dr SP Lim at splim@ha.org.hk.

References