

TheSynapse

The Medical Professionals' Network

M E N ' S H E A L T H

Prostate Cancer

Part III – Surgical Management

by **Pierre Vassallo**
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The other articles in this series dealt with aetiology, clinical presentation, investigations, staging and management. In Part III, Dr Vassallo deals specifically with surgical management of prostate cancer.

Good candidates for surgical treatment of prostate cancer should have one or more of the following characteristics: they should be otherwise healthy, under 70 years of age, expected to live for at least another 10 years, the disease should be confined to the prostate (T1 or T2) and no bony metastases should be present. There are several surgical options for prostate cancer.

Cryoablation can be used to destroy cancer cells by twice rapidly freezing and thawing cancerous tissue. It is recommended for patients who cannot tolerate surgery or radiation therapy, tumors confined to the prostate (T3 or less) or in cases where radiation therapy has failed. Transrectal ultrasound and prostate biopsy are performed prior to cryosurgery to determine the exact size and location of the tumor. The procedure is performed under epidural nerve block or general anesthesia.

With the patient in the supine position, the surgeon inserts a warming catheter into the urethra to protect it from freezing temperatures. An ultrasound transducer is inserted into the rectum, so that the surgeon can see the prostate and surrounding tissue and monitor placement of the cryoprobes. The surgeon then makes 5 to 8 needle punctures in the perineum and advances the needles to preselected locations in the prostate tumor. Liquid nitrogen or argon gas circulates through the probes and freezes cancer cells to -40°C .

The temperature in and around the prostate is monitored with thermosensors, also inserted through the perineum. Once the spheres of tissue surrounding the cryoprobes are covered with ice, the liquid nitrogen or argon circulation is stopped

and the area is allowed to thaw. The freeze-thaw cycle is repeated and then the instruments are removed. The procedure lasts about 2 hours and the patient may be discharged on the same day. A urethral catheter is necessary for about 3 weeks. Most patients report very little discomfort and recover fully within days. Recent studies show that 97% of cryosurgery patients are cancer free at 1 year and 82% are cancer free at 5 years following surgery. Cryosurgery usually can be repeated safely if recurrence occurs. Incontinence or urethral obstruction occurs in about 1% of patients. There is an 85% chance that freezing will result in nerve damage with resulting erectile dysfunction. However, nerve-sparing techniques are being developed to help reduce that risk.

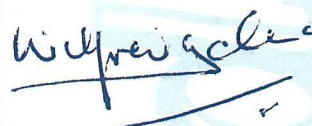
High intensity focused ultrasound (HIFU) is currently undergoing clinical trials. HIFU is a noninvasive treatment that uses precision-focused ultrasound waves to ablate targeted prostatic tissue. It has been shown to effectively treat localized prostate cancer as well as benign prostatic hypertrophy. In clinical trials, HIFU is performed on an outpatient basis, under anesthesia. HIFU can be repeated as necessary, and each treatment takes 1-3 hours. Following treatment, a catheter is necessary for about 1 week and most patients are able to resume regular activities within days. Impotence occurs in 1-7% of patients.

Radical prostatectomy may be performed in selected individuals with tumor localized to the prostate (T1 and T2). This involves surgical removal of the prostate and surrounding tissues, including the seminal vesicles and pelvic lymph nodes.

continues on page 2

Editor's Word

Hello and welcome to the first issue of TheSynapse magazine for 2006. In this issue you will read the third and last part of the series on **Prostate Cancer**, this part deals with surgical management. We continue with our focus on Cardiovascular Disease and we present an article on **Diet and Cardiovascular Disease** by Alicia Galea. Prof. Albert Fenech presents part 1 of a series of articles on Cardiology Today, the first article deals with **Ischaemic Heart Disease**. The interesting Interrelationship between Periodontal Health and Cardiovascular Disease is tackled by Dr Alex Cassar in the Sweet Tooth Section. The focus then shifts to **Cardiovascular Nursing Care in Malta** presented by Vincent Gatt. On a different note we have an interesting article by Dr Charles Savona-Ventura writing on **Medieval Dermatological Hospitalier Orders**. Last but not least we have an update on the **Avian flu and Pandemic influenza** by Dr Tanya Melillo Fenech. Unfortunately the Moneywise article will not be published in this issue. May I take this opportunity to invite you to stay in touch with TheSynapse on the Internet. TheSynapse web portal is the ubiquitous resource for relevant information with daily updates. A well deserved thank you to all the dedicated staff, contributors and advertisers for their support. Keep up the good work.

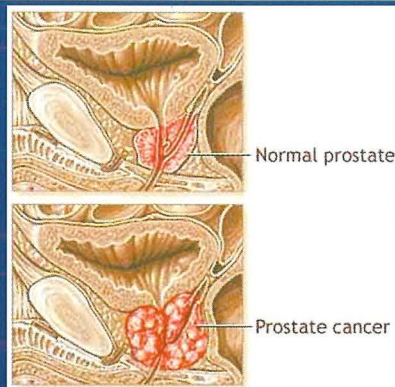
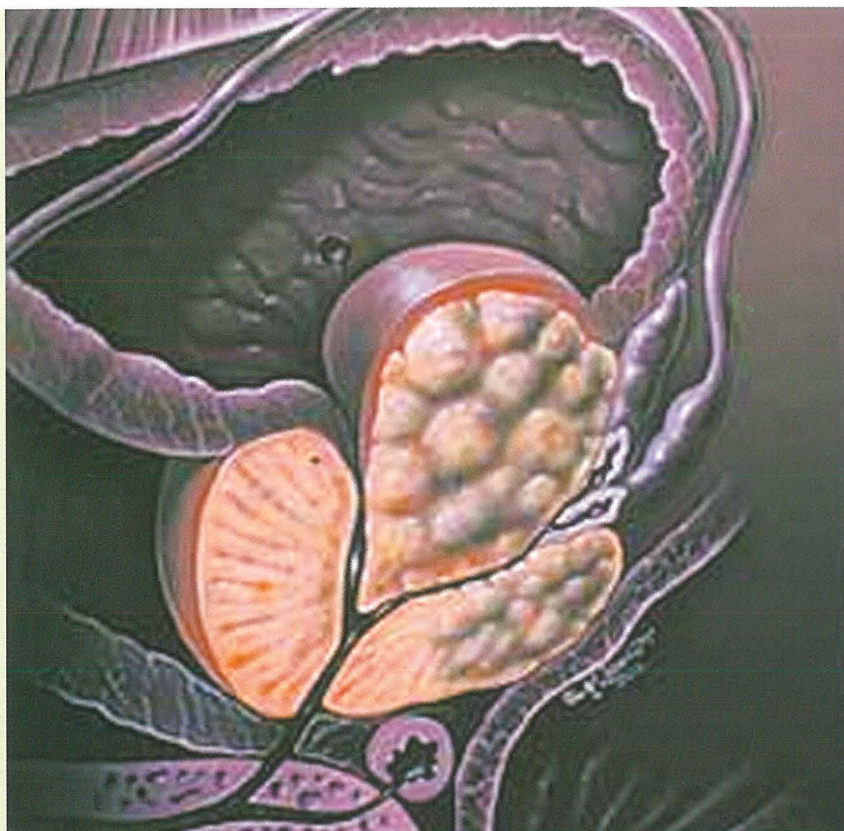


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Prostate Cancer

Part III – Surgical Management



Two surgical techniques are available, retropubic prostatectomy or perineal prostatectomy. With perineal prostatectomy, a second procedure (lymphadenectomy) is required to remove the pelvic lymph nodes. Both open surgical procedures require a 3-7 day hospital stay and catheterization for 2-3 weeks. The 10-year survival rate after radical prostatectomy ranges from 75-97% for patients with well and moderately differentiated cancers and 60-86% for patients with poorly differentiated cancers. Incontinence and impotence are potential complications, however 40-65% of men retain their erectile function.

Laparoscopic radical prostatectomy and robotic laparoscopic radical prostatectomy are performed through several small incisions to allow insertion of the laparoscope and surgical instruments. The procedure has also been performed remotely using robotic equipment (e.g. da Vinci[®] surgical system). The robotic surgical system provides a high magnification and a high resolution view of the operative field and surgery is performed using robotic arms and instruments under direct control of the surgeon. Not all surgical patients are good candidates for the laparoscopic approach. Laparoscopic radical prostatectomy causes less morbidity.

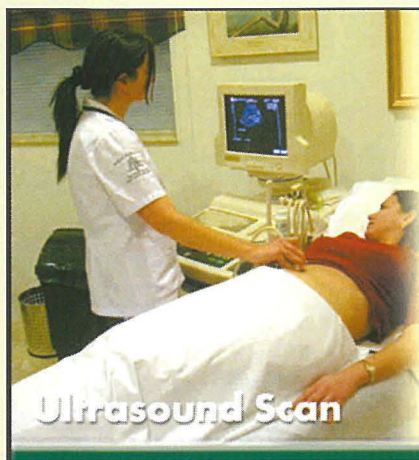
Catheterization is required for approximately 3 days following the procedure.

Lymphadenectomy may be performed to minimize the possibility of metastases appearing in lymph nodes at a later stage. This is more likely in patients with very high Prostate-Specific Antigen results. Open or laparoscopic lymphadenectomy may be performed.

Prognosis and Prevention

When cancer is confined to the prostate gland, the disease is usually curable. A number of patients with locally spread cancer die within 5 years. Once cancer has spread to distant organs, life expectancy is usually less than 3 years. While prostate cancer cannot be prevented, measures can be taken to prevent progression of the disease. It is important for men over 40 to have an annual prostate examination. When identified and treated early, prostate cancer has a high cure rate.

Dr Pierre Vassallo can be reached at the Medical Imaging Centre on 21 491 200 or by email on pvassallo@mic.com.mt



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Diet in the Prevention and Prognosis of Cardiovascular Problems

by Alicia Galea

B. Pharm. (Hons.) P.Q. Dip Nutr & Diet
Nutritionist

Cardiovascular disease is a major health problem and dietary intake has a great influence on its risks and prognosis. Cardiovascular risk factors include high fat intake, diets high in sodium and deficiencies in vitamins, minerals and essential fatty acids. A diet low in fat, salt, sugar and high in fibre is recommended.

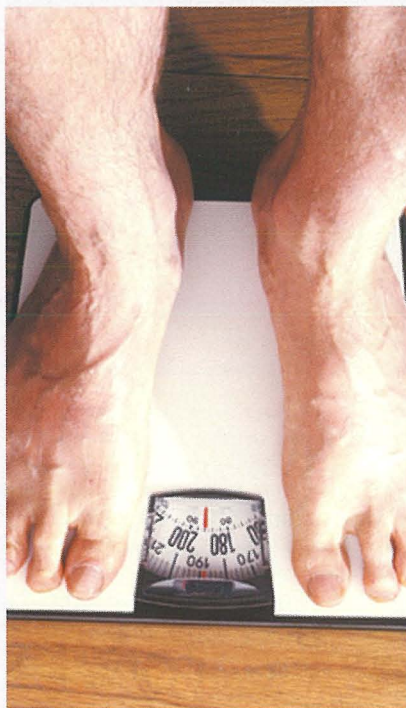
Diet is an important contributory factor in the development and regression of cardiovascular disease and atherosclerotic plaques. It has been established that high concentration of cholesterol in the blood can cause these plaques and that dietary intervention is beneficial. Research has shown that the formation of atherosclerotic plaques begins in infancy. Therefore a preventive diet is recommended for all healthy children over the age of two years.

Dietary practices which contribute to this disease include high fat intake as well as deficiencies in anti-oxidants like vitamin C, E and selenium. Magnesium, chromium, niacin, vitamin B₆, essential fatty acids, linoleic acid and linolenic acid may also play a part.

Diets low in total fat, saturated fat, hydrogenated fats, cholesterol and sodium are important. In particular, fat intake should not exceed 30% of the total calories (whilst limiting saturated fat intake to less than 10% of calories). Very low fat intake can be consumed safely with supplemental fatty acids or the use of good-quality cold-pressed vegetable oils to obtain our necessary linolenic acid. Cholesterol intake is limited to no more than 300 mg/day.

A high fibre diet is also recommended, as it reduces the risk of cardiovascular disease by improving the HDL to LDL ratio. In fact it is suggested that fibre intake is increased to up to 25g/day in patients suffering from cardiovascular disease. Salt and excess sugar intake are also well known to be detrimental to this condition. In addition to a low-fat and high-fibre intake, a low-salt and low-sugar diet is thus also suggested. Avoiding salted and pickled or cured foods is recommended. More complex carbohydrates, including mostly whole grain and vegetable foods are recommended.

The types of fat which are consumed are also important. Saturated fats are



best avoided. Particularly important oils are contained in the coldwater fish such as salmon, mackerel, sardines and herring. These contain eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which have a positive effect on lowering cholesterol and triglycerides. Recent research suggests that the anti-inflammatory effect of long chain n-3 polyunsaturated fatty acids (PUFAs) may stabilize atherosclerotic plaques. These PUFAs are found only in fish oils. In contrast, the n-6 PUFAs found in vegetable oils may produce inflammation and increase plaque instability. Consuming these oil-containing fish two or three times a week will result in cardiovascular benefit.

A well-balanced diet will help people minimize the tendency of cholesterol levels to rise with age. People with high levels of blood cholesterol will benefit by controlling their diet as well. Lowering intake from saturated fats and dietary cholesterol, while increasing

intake of dietary fibre, will decrease blood cholesterol levels. It will also improve the effectiveness of lipid lowering drugs. In addition to cholesterol levels, reduction of salt intake can help to alleviate high blood pressure. Finally, a good diet plays a role in reducing cardiovascular disease by helping people to maintain proper body weight. ☒

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Ischaemic Heart

by **Albert Fenech**

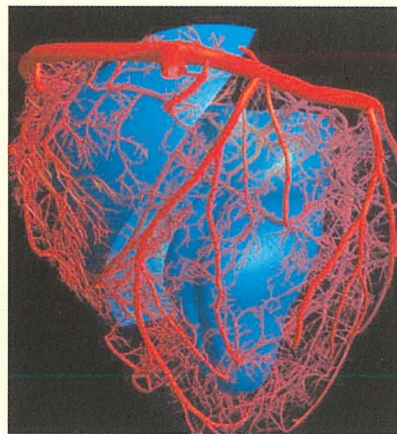
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It is said that in order to know where you are and where you are going necessitates the knowledge of where you have come from. I recently had one of those memorable 'once in a lifetime' experiences celebrating a 30 year graduation anniversary with cherished friends and colleagues, some of whom I had not seen for years.

It seemed a good starting point for this article to attempt and outline where Cardiology has arrived since I qualified and the exciting tomorrow that beckons. Space will limit the discussion to 2 major clinical problems that face us in our clinical practice, mainly Ischaemic Heart Disease (IHD) and Congestive Cardiac Failure (CCF). This article will mainly discuss issues relating to IHD leaving the topic of CCF for the next issue.

Thirty years ago our management of Acute Myocardial Infarction was limited to monitoring patients in the Coronary Care Unit (CCU) for a couple of days and keeping our fingers crossed for the patient's survival without too many limitations on his or her quality of life. Indeed we did manage to salvage some of those who had a life-threatening arrhythmia or heart failure with the use of a defibrillator, pacemaker and/or medication that was available at the time. The concept of myocardial salvage and patient rehabilitation was an interesting theoretical topic while that of myocardial regeneration was considered entirely to be in the realms of science fiction.

The pharmacological advances that have made a significant impact since those days have been many. ACE inhibitors (ACEi) appeared in the early 80's and were the first drug that actually improved mortality in CCF and now have a role to play in patients with IHD. Another group of drugs that were very helpful in the treatment of IHD were considered absolutely contraindicated in the presence of CCF yet have emerged to be precisely the opposite in the 90's - Beta Blockers. These two groups of drugs (together with Spironolactone) are the only ones that actually improve survival in patients with CCF. A group of drugs released in the past 10 years, Angiotensin-2 Receptor Blockers (ARBs), seem to have the same clinical benefits as their ACEi



cousins. Other drugs that have made a significant impact in the treatment of IHD are Statins and Clopidogrel which together with Aspirin, Calcium Channel Blockers, Nicorandil and Trimetazidine complete the array of medication available to us in the pharmacological management of IHD.

The development of Percutaneous Transluminal Coronary Angioplasty (PTCA) towards the end of the 70's has been without doubt the greatest leap forward in the management of IHD since the introduction of Coronary Artery Bypass Grafting (CABG) in the mid 60's. The end of the 80's saw the development of intracoronary stents which reduced the incidence of abrupt closure and restenosis of lesions and the innovation of drug eluting stents (DES) a few years ago has greatly reduced the Achilles' heel of coronary angioplasty namely that of restenosis. Because of the availability of other devices that can 'debulk' atheromatous plaque such as the Rotablator or Cutting tools, the procedure is now referred to as Percutaneous Coronary Intervention (PCI).

Atheromatous plaque that is likely to cause acute problems is referred to as 'Vulnerable Plaque' and a number of newer devices are available in order

to try and identify these areas that are likely to rupture or dissect and lead to an Acute Coronary Syndrome (ACS). These include intravascular ultrasound that may also be modified to identify lipid, calcium and necrotic areas inside the plaque. This 'Virtual Histology' can assist in delivering therapy to specific areas inside a diseased coronary artery considered to be dangerous.

The ever increasing role of PCI in the management of IHD has changed the balance of indications for patients such that over the past few years the number of patients undergoing this procedure has exceeded the number of patients referred for CABG. Other percutaneous procedures which are able to occlude Patent Foramen Ovale (PFO), Atrial Septal Defect (ASD) and Ventricular Septal Defect (VSD), dilate stenosed Mitral and Pulmonary valves, 'clip' mitral regurgitant leaflets, perform a mitral annuloplasty or implant an Aortic Valve over a diseased one, have reduced the number of patients referred for conventional surgery. The net effect of these developments has resulted in a further bonding of Cardiologists and Cardiac surgeons sharing the interventional care of patients in ways hitherto unimagined and there is no doubt that this 'team' approach will evolve even further in the future.

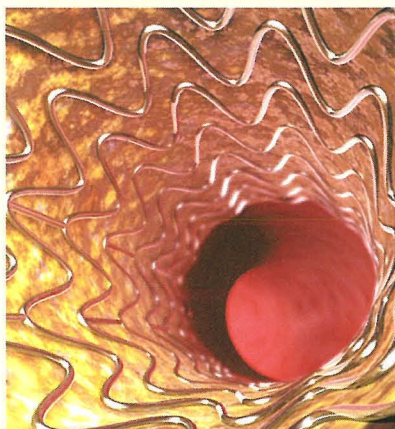
The management of Unstable Angina (UA) and Acute Myocardial Infarction (AMI) has changed radically over the past 20 years. Recognising that early intervention dramatically reduces both morbidity and mortality in these conditions has established roles for thrombolytic therapy and PCI particularly in the early hours after the onset of pain in AMI. The need for a 24 hour availability of an experienced PCI team is an essential part of any modern and effective health service though sadly many countries have still not implemented the necessary procedures.

Disease

There are very few contraindications to performing Primary PCI and a recent study (The Senior PAMI Trial) has shown that PCI remains significantly superior to thrombolytic therapy in patients up to 80 years of age.

Serious complications of AMI such as Acute Mitral Regurgitation and acute Ventricular Septal Defect have been reduced with early intervention and the high mortality associated with their occurrence has been significantly reduced with PCI. Together with haemodynamic support (which will be discussed in the next issue) prompt PCI has also changed the bleak outlook for patients in cardiogenic shock, which condition carried a mortality of greater than 95%. Early institution of these measures is capable of halving this grim statistic.

It makes little sense to spend so much time, effort and money on treating a disease without addressing its prevention and maximising the outcome of its successful treatment.

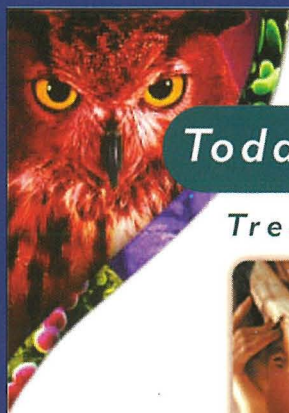


Intra-coronary stents which reduced the incidence of abrupt closure

Health education is essential if any impact on the future health and healthcare of a nation is to be improved. Not only must the individual be informed and educated about healthcare at an early age but this process has to include adults, who have a major role in bringing up children as well as acting as role

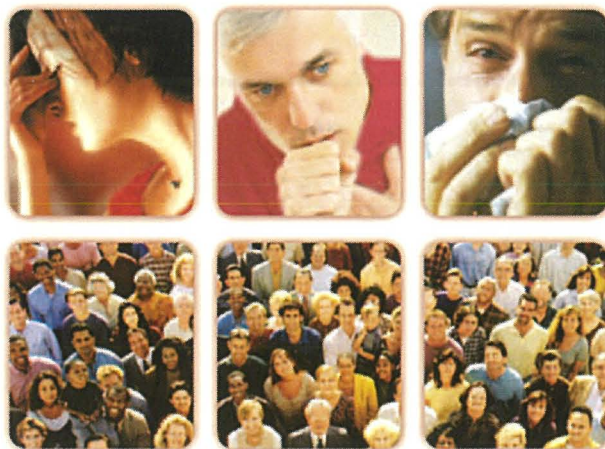
models. Governments, be they local or national, can help by introducing measures that encourage a healthier diet and facilitate the possibility of unencumbered physical exercise for all ages.

Since the beginning of time we have had available a therapy that only recently is being accepted as being of any significant benefit. There exists a four letter word that is almost never seen in medical textbooks or articles. It seems that the use of this word seems somehow unscientific or unrealistic and as a result such bland expressions as 'emotional support' are used. This expression goes nowhere near the actual experience of the word 'love', yet it is a scientific fact that those who experience love both on a personal level as well as in the environment in which they live reduces the likelihood of illness and prolongs life. It really makes living a far more enjoyable experience – it is such a great shame it is not available on prescription! ☒



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*Clinical cure rates for KETEK[®] were 86% in AECB, ranged from 75-85% in acute bacterial sinusitis, and ranged from 88-95% in mild to moderate CAP.

[†]Minimizes induction of macrolide type (*erm*_B) resistance in vitro.



The Interrelationship between Periodontitis and Systemic Diseases

by **Alex Cassar**
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Cardiovascular diseases such as atherosclerosis and myocardial infarction occur as a result of a complex set of genetic and environmental factors. Analysis of all the common risk factors for stroke and heart attack, including age, smoking, high levels of serum lipids, diabetes and socioeconomic status can only account for one-half to two-thirds of the variation in the incidence of cardiovascular disease.

Numerous studies show that oral infection, especially periodontitis, may affect the course and pathogenesis of a number of systemic diseases, such as cardiovascular disease, bacterial pneumonia, diabetes mellitus and low birth weight. Evidence in support of an association between periodontal and cardiac conditions has been demonstrated and several theories have been proposed to explain the link.

In the early 20th century, Sir William Osler fully appreciated what was killing his patients with endocarditis. The theory of focal infection was firmly believed in and promulgated during that period. A focal infection is a localized infection that can disseminate microorganisms or toxic products to contiguous or distant tissues. The teeth and jaws, tonsils, sinuses, fingers

and toes, bronchi and the gastrointestinal tract were the obvious sources blamed for such diseases as arthritis, nephritis and endocarditis. As a result of this theory, many physicians of the era often recommended preventive full mouth extractions whenever a 'focal infection' became suspected. These ideas were anecdotal and in time the theory fell on the wayside because these drastic treatments never quite reversed the course of the disease. Furthermore, many patients with the same diseases had no evident focus of infection and foci of infection are as common in apparently healthy persons as those with disease. With the recent progress in classification and identification of oral microorganisms and the realization that certain microorganisms are normally found only in the oral cavity this idea of bacterial

dissemination via the blood stream through discontinuities of the oral tissues, has resurged.

The teeth are the only non-shedding surfaces in the body and bacterial levels can reach more than 10^{11} microorganisms per mg of dental plaque. Periodontal diseases are bacterial infections that destroy the attachment fibers and supporting bone (periodontium) that hold teeth. The consequence of such events can be measured as the 'gums' separate from the teeth, forming pockets. These are shallow at first but can eventually deepen, at a variable rate, depending on bacterial and host factors that set the stage. Increasing pocket depths are a sign of the disease progressing as more periodontal tissues

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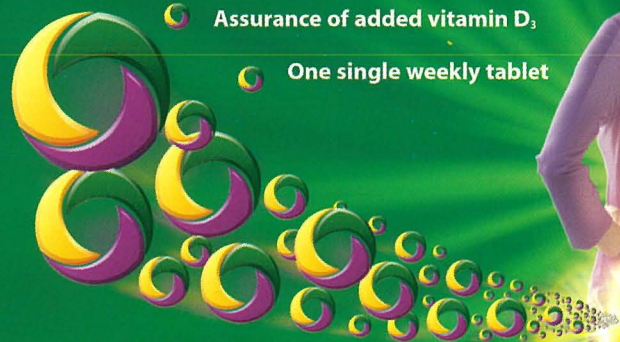
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T O O T H

Periodontal and Cardiovascular Disease

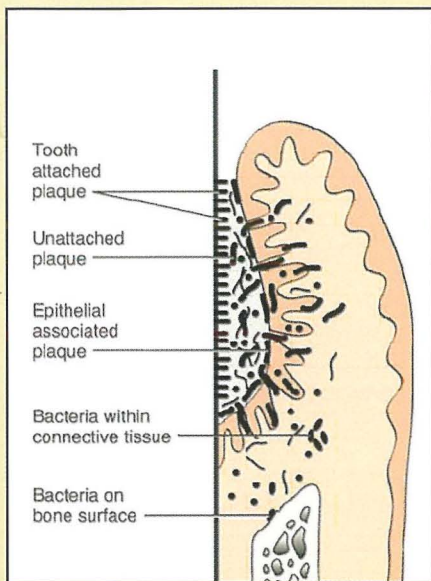


Figure 1: Plaque–bacteria associated with the crown / root surface and periodontal tissues

which approximately 500 species have been encountered. These infections are predominantly anaerobic, with gram-negative rods being the most common isolates. Their endless presence burden and challenge the host continuously. In the depths of periodontal pockets, the anatomic closeness of these microfloras and the bloodstream facilitates bacteremia and systemic spread of bacterial products, components and immunocomplexes.

Microorganisms may gain entrance to the blood and circulate throughout the body but are usually eliminated by the reticuloendothelial system within minutes (transient bacteremia) and as a rule lead to no other clinical symptoms. However, if the disseminated microorganisms find favorable conditions, they may settle at a given site and, after a certain time lag, start to multiply (infective endocarditis, brain abscess, cavernous sinus thrombosis, sinusitis, lung abscess/infection, prosthetic joint infection).

Some gram-positive and gram-negative plaque bacteria have the ability to produce diffusible proteins, or exotoxins which are lethal poisons which cause local injury. Conversely, endotoxins are part

of the outer bacterial membranes released after cell death. When introduced into the host, these lipopolysaccharides give rise to a large number of pathological manifestations not just locally but even at a distance from the site (cerebral infarction, acute myocardial infarction, abnormal pregnancy outcome, persistent pyrexia, idiopathic trigeminal neuralgia, toxic shock syndrome, systemic granulocytic cell defects, chronic meningitis).

Inflammation in tissues distant from the infection may also develop through the effects of soluble antigen entering the bloodstream and reacting with circulating specific antibody. These immunocomplexes may give rise to a variety of acute and chronic inflammatory reactions at the sites of deposition (Behçet's syndrome, chronic urticaria, uveitis, inflammatory bowel disease, Crohn's disease).

Most researchers believe that the increased risk to the progression of coronary heart disease is caused by an exaggerated inflammatory response to periodontal pathogens such as *Porphyromonas gingivalis* in a susceptible host.

are destroyed and the teeth eventually become loose.

Human periodontal infections are associated with complex microfloras in

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- Do not lie down until after the first food of the day which should be at least 30 minutes after taking the tablet.
- Do not lie down for at least 30 minutes after taking Fosavance™.
- Do not take at bedtime or before rising for the day.

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PRECAUTIONS

Alendronate can cause local irritation of the upper gastro-intestinal mucosa and potentially worsen any underlying disease. Use with caution in patients with active upper gastro-intestinal problems, such as dysphagia, oesophageal disease, gastritis, duodenitis, or ulcers, or with a recent history (within the previous year) of gastro-intestinal disease such as peptic ulcer, or active gastro-intestinal bleeding, or surgery of the upper gastro-intestinal tract other than pyloroplasty. Oesophageal reactions (sometimes severe and requiring hospitalisation, such as oesophagitis, oesophageal ulcers and oesophageal strictures, rarely followed by oesophageal stricture, have been reported in patients receiving alendronate. Physicians should be alert to any signs or symptoms of a possible oesophageal reaction, and patients should be instructed to discontinue alendronate and seek medical attention if they develop symptoms of oesophageal irritation such as dysphagia, pain on or following, retrosternal pain, or new or worsening heartburn. The risk of severe oesophageal adverse reactions appear to be greater in patients who fail to take alendronate properly and/or continue to take alendronate after developing symptoms suggestive of oesophageal irritation. It is very important that the full dosing instructions are provided to, and understood by the patient. Patients should be informed that failure to follow these instructions may increase their risk of oesophageal problems. While no increased risk was observed in extensive clinical trials with alendronate, there have been rare (post-marketing) reports of gastric and duodenal ulcers, some severe with complications. A causal relationship cannot be ruled out. Bone or joint muscle pain has been reported in patients taking bisphosphonates. In post-marketing experience, these symptoms have rarely been severe and/or incapacitating. From start of treatment, onset of symptoms varied from one day to several months. A subset had recurrence of symptoms when re-challenged. Patients should be instructed that if they miss a dose of Fosavance™, they should take one tablet on the morning after they remember. They should not take two tablets on the same day, but should return to taking one tablet once a week, at originally scheduled

on their chosen day. Cause of osteoporosis other than oestrogen deficiency and ageing should be considered. Correct hypocalcaemia before initiating therapy. Other disturbances of mineral metabolism should also be effectively treated. The content of vitamin D in Fosavance™ is not suitable for correction of vitamin D deficiency. In patients with these conditions, serum calcium and symptoms of hypocalcaemia should be monitored during therapy with Fosavance™. Calcitriol (vitamin D₃) Monitor urine and serum calcium in patients with disease associated with unregulated overproduction of calcitriol (e.g. leukaemia, lymphoma, sarcoidosis) as vitamin D may increase the magnitude of hypercalcaemia and/or hypocalcaemia. Patients with malabsorption may not adequately absorb vitamin D. **Excipients:** Patients with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrose intolerance (insufficiency should not take Fosavance™ because it contains lactose and sucrose. **Drug interactions:** Food, beverages (including mineral water), calcium supplements, antacids, and some oral medicinal products may interfere with absorption of alendronate. Therefore, patients must wait at least 30 minutes after taking Fosavance™ before taking any other medicinal product. **Use in pregnant and lactating:** alendronate has not been studied in pregnant or breastfeeding women and should not be given to them.

SIDE EFFECTS

The following adverse experiences have been reported during clinical studies and/or post-marketing use of alendronate. No new adverse reactions have been identified for Fosavance™. **Common (>2.0% and <10%) Gastro-intestinal:** abdominal pain, dyspepsia, constipation, diarrhoea, flatulence, oesophageal ulcer, dysphagia, abdominal distention, acid regurgitation. **Musculoskeletal (bone, muscle or joint pain):** Myalgia/aches, **Common (>1% and <10%) Gastro-intestinal:** nausea, indigestion, vomiting, gastritis, oesophageal, oesophageal erosions. **Skin rash, pruritus, erythema:** Rare (<0.1% and <0.1%) **Rare (<0.1%)** as a whole hypersensitivity reactions including urticaria and angioedema. Transient symptoms as in an acute-phase response. **Symptomatic hypocalcaemia,** often in association with predisposing conditions (see Precautions). **Gastro-intestinal:** oesophageal stricture, oesophageal ulceration, upper gastro-intestinal (UGI) perforation, ulcers, bleeding (see Precautions). **Local infection** of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing. **Skin rash** with photosensitivity. **Special senses:** uvulitis, scleritis, episcleritis. Isolated cases of severe skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported. **Laboratory test findings:** In clinical studies, asymptomatic, mild and transient decreases in serum calcium and phosphate were observed in approximately 18 and 10%, respectively of patients taking alendronate 10 mg/day versus approximately 12 and 3% of those taking placebo. However, the incidences of decreases in serum calcium to < 8.0 mg/dl (2.0 mmol/l) and serum phosphate to < 2.0 mg/dl (0.65 mmol/l) were similar in both treatment groups.

PACKAGE QUANTITIES AND BASIC UNIT COST

Fosavance™ Tablets £22.80 for 4 tablets.

PLM Date of review: September 2005

Marketing Authorisation Numbers:
Fosavance™ Tablets EU 1/05/310/02

Marketing Authorisation Holder:
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S PATIENTS



alendronate sodium/co-calciferol

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continues on page 8

Medieval Dermatological

by **Charles Savona-Ventura**

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Dermatological lesions were long regarded with suspicion bringing to mind the admonitions detailed in the Old Testament (Lev 13, 1-46). When the lesions became chronic, a suspicion of leprosy was made and the person thus affected was made to “wear torn clothes, leave his hair uncombed, cover the lower part of his face, and call out, Unclean Unclean!. He remains unclean as long as he has the disease, and he must live outside the camp, away from others” (Lev 13, 45-46). Those diagnosed as lepers were considered as living dead with the loss of their rights and belongings. During the Medieval period, this outlook was tempered by the concept of nursing being a Christian duty which led to the establishment of several leprosaria throughout Europe and the Middle East. The latter establishment was in the 12th century to be organised in a formal hospitaller Order.

The Order of St. Lazarus

In the Holy Land, a leprosarium was originally established up by Bishop St. Basil of Caesarea [329-379 AD] at Acre. St. Basil's followers assumed responsibilities for further leprosaria established in Jerusalem, Bethlehem and Nazareth. During the 11th century, the hospitaller services available in the Holy City included three establishments – St Mary Latin, St John the Almoner and St Lazarus. The Crusader conquest of Jerusalem in July 1099 led to the re-organization of these services with the eventual setting up of the *Xenodochium* [hospice services for pilgrims] under the patronship of St. John the Baptist and the *Leprosarium* under the patronship of St. Lazarus. Both were initially placed under the direction of Blessed Gerald; but the two establishments were eventually to separate resulting in the establishment of two hospitaller Orders – the Order of St. John of Jerusalem [eventually of Rhodes and Malta] and



Figure 1: Praying Knight of St. Lazarus (Source: corbel at Grattemont, France; 15th century)

the Order of St. Lazarus of Jerusalem. The Jerusalem *Domus Leprosorum Sancti Lazari* was situated outside the walls of

the northwestern point of the city. Members of the Order of St. Lazarus adopted a black habit with a green Latin cross. The Lazarites received several benefices in the Holy Land and in Europe. In the early decades on the 12th century, the Order assumed military duties contributing towards the defence of the Holy Land from the continuous threat of Islam occupation. The Order was expelled from Jerusalem after the Christian forces were driven out of Jerusalem by Sultan Salah al-Din after the battle of Hattin in Tiberias in October 1187. It subsequently re-established itself in Acre and after 1254 transferred its Magisterial Headquarters to France. The Christian forces, including the defending Lazarites, were expelled from the Holy Land after the siege of Acre in 1291.

While assuming military duties, the Order retained its original *raison d'être*, that of caring for lepers. It maintained this role throughout the subsequent centuries, even after the apparent decrease in the prevalence

continued from page 7

The diseased periodontium in periodontitis acts as a cytokine reservoir, where proinflammatory cytokines such as tumour necrosis factor (TNF α), interleukin (IL-1), and gamma interferon as well as prostaglandin E₂ (PGE₂) reach high tissue concentrations. This arena can therefore serve as a renewing reservoir for spillover of these mediators, which can enter the circulation and induce and perpetuate



Figure 2: Localized bone loss around the mesial root of the first molar

systemic effects. IL-1 β favours coagulation and thrombosis and retards fibrinolysis. IL-1, TNF α and thromboxane can cause platelet aggregation and adhesion, formation of lipid-laden foam cells and deposition of cholesterol.

Epidemiologic studies show this consistent link between periodontal infection and coronary artery disease and stroke; this appears to be a dose-response relationship – that is, the more severe the periodontal disease, the higher the risk of developing a cardiac

Hospitaller Orders

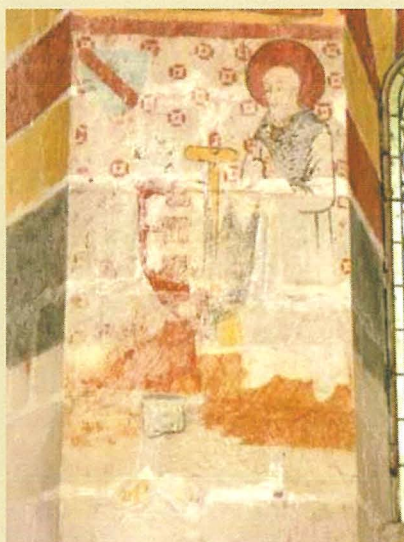


Figure 2: St. Anthony the Hermit (Source: Chapelle Saint-Antoine, Martizay, France; early 13th century)

of leprosy following the Great Bubonic Plague of the 14th century. In spite of papal attempts in 1489 to amalgamate the Order of St. Lazarus with the Order of St. John, the Order of St. Lazarus managed to survive so that by the 18th century it was represented by two branches: the French Order of St. Lazarus and Our Lady of Mount Carmel and the Savoyan Order of St. Lazarus and St. Maurice. The French Order was to suffer further from the turmoil brought about by the French Revolution, but apparently managed to maintain a presence up to the 20th century. After 1929 the Order undertook to expand its recruitment in France and beyond – notably Spain, Poland and the New World. The Military and Hospitaller Order of St.

Lazarus of Jerusalem does not appear to have any Medieval links with the Maltese Islands, though it did establish dealings with the Order of St. John during the 18th century. The Order of St. Lazarus established a presence in the Maltese Islands in 1966. After 1973, the Islands became the Administrative Headquarters of the Order. The Grand Priory of the Maltese Islands has retained its interest in leprosy supporting throughout the years the small leper colony in Malta and other centres overseas particularly in Africa. With the extinction of leprosy from the Maltese Islands, the Grand Priory of the Maltese Islands has adopted other philanthropic activities adopting the Step-by-Step Foundation which works with brain-injured children and the St. Lazarus Special Rescue Corps which provides first-aid services.¹

The Order of St. Anthony

Another condition which has marked dermatological manifestations was ergotism or St. Anthony's Fire which assumed epidemic proportions in Europe during the 11th century. Caused by a fungal infestation of rye, ergotism was characterised by a sense of lassitude, painful contractures, peripheral neuritis, hallucinations, and the onset of dry gangrene. The epidemic prompted Gaston of Dauphine (c.1095) to found the Order of St. Anthony in thanksgiving for the miraculous relief from the disease. The Order built a hospital at Saint-Didier de la Mothe, which became its central house. The members devoted themselves to the care of the sick, particularly those afflicted with ergotism

and other skin disease. They wore a black habit with the Tau or St Anthony's Cross in blue. The congregation established shelters or *domus elemosynaria* throughout France, Germany, England, Tuscany, Bohemia, Spain, Italy, Palestine and Constantinople. With wealth came relaxation of discipline and a reform was ordained (1616) and partially carried out. In 1777 the congregation was canonically united with the Order of St. John of Malta but was suppressed during the French Revolution. The Order of St. Anthony had earlier Medieval links to the Maltese Islands. A 1373 document in the Cancellaria Regia of the State Archives, Palermo (Cancellaria 12, f.198) refers to a petition by *Frater Johannes Venancij Cole de Busano*, representing the *domibus Sanctj Antonij* to enable him to exercise his rights as procurator over property in the realm of Sicily and the Maltese Islands.^{2,3} ☒

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condition. However, at present, due to a lack of intervention studies that assess the impact of successful periodontal therapy on systemic disease outcome, these relationships can only be interpreted as 'associations'. The calculation of a summary estimate of risk for the moment remains difficult and awaits further research.

The fact that there is currently no evidence

to demonstrate the potential benefits of periodontal therapy poses a dilemma for dentists. We may be treating both an oral disease and an exposure for systemic diseases, so until guidelines are established, one continues treating periodontal disease knowing that it will at least improve oral health and assumes it may be good for overall health as well.

In the future, it is hoped that laboratory

diagnostic tests such as blood lipids, glucose, liver proteins, genetic testing, antibody testing and microbial analyses will be integrated into the practice of periodontal medicine to identify patients at risk and monitor the effects of therapy. ☒

Acknowledgements

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Cardiovascular Nursing Care in Malta

by Vincent Gatt RN Dip. CVT.
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Nursing, with its professional delivery of care to the general population, is a major asset for the national healthcare system. Evidence based nursing practice needs excellent support from the vocational, functional and managerial aspects. Cardiology is a major nursing practice area due to the size of population affected. Local cardiovascular nursing is evolving continuously and thus needs good support to provide better care.

Cardiology is a priority in the public health agenda as it covers a large population, causing one of the greatest morbidity and mortality rates.¹ Nursing practice requires constant amelioration in care delivery to meet the latest research-based guidelines. On the other hand the patients' rights should be respected when delivering care. The patient should be treated in a holistic way.²

Cardiovascular nursing developed as a response to the requirements of the local healthcare system. Sporadic visits by foreign-based cardiologists and their teams brought over newer ideologies and practices, together with the need for different and better equipment, medications and nursing management. In 1995, resident cardiologists started the first local fully-fledged cardiology clinics thus providing better overall patient support.

Nursing continued to evolve into supporting and managing patient care. Ever since, various cardiology units were developed for a comprehensive care. The different clinics include the Coronary Care Unit, Cardiothoracic Surgery Unit, Cardiac Catheterisation Laboratory (Cath Lab), Cardiac Intensive Care Unit, Cardiac Laboratory, Cardiac Surgery Operating rooms, Pacemaker Clinic, Cardiology out-patients clinics and the various areas supporting the system.

The Cath Lab is one such clinic, utilising state of the art equipment and advanced practice. A multifunctional and multidisciplinary team covers both diagnostic and interventional cardiology procedures. In supporting patients' needs with an ever-changing research based delivery of care methodologies and equipment, the nursing practice has shown to be an important part of this field of specialisation.³

The Cath Lab was primarily considered solely as an operating theatre. Later, the care methodologies and the nursing practice changed to cover pre-procedure patient preparation, procedural sterile equipment preparation, scrub assistance and circulating nurse support during procedures, post procedure nursing care, nurse review of post procedure outpatients and home telephone support. All these services are targeted towards patients and their families as a comprehensive delivery of care.

Diagnostic and interventional cardiology procedures carry a reduced hospitalisation

stay and patient discomfort as most of them are carried out on a day stay basis with the vascular access done via a small puncture. The most common procedure is the Coronary Angiography, a procedure done to examine the arterial circulation supplying blood to the heart muscle. A narrowing to any of these important arteries may give rise to angina, heart attack or even sudden cardiac death. Another procedure, the Coronary Angioplasty, is carried out to stretch open a narrowing in a heart artery. During this procedure a stent, a very thin metal tubular structure, is used to help keep the artery open from the inside thus maintaining an adequate blood supply. These are the commonest procedures carried out at the Cath Lab. During the year 2004, the Cath Lab statistics show that 1952 Coronary Angiographies and 541 Coronary Angioplasties were carried out. Any indications of heart problems that require a cardiac angiography test need a fairly early appointment to reduce the possibility of major adverse events.

Professional nursing care and client support should be delivered on a continuous basis. Specific professional education and clinical training is only obtainable if there is an ongoing personal commitment and organisational support. One such important aspect of care is the *nurse to patient ratio*. The Agency for Health Research and Quality published research data stating that low hospital nurse levels result in reduced nurse to patient discussion time and that centres with low levels of qualified nurses have a reduced patient prognosis. Therefore adequate knowledgeable manpower availability is the basis for safer and proper care delivery.⁴

Patients who undergo cardiovascular interventions tend to experience a lot of anxiety. The main methods used at the Cath Lab to help patients during their stay include the adoption of a friendly reception and approach, a quiet environment, nurse professionalism, knowledgeable personnel and the use of music. Studies carried out by Bitten Thorgaard (2003) show that music could be used to reduce anxiety levels.⁵ Music was found most effective when used at low sound levels as a background support and in personal player format. The latter format targets individual likes.

Together with the personnel, Cath Lab

nurses offer an important emergency service as well. This 24 hour service offers emergency angioplasty and cardiac pacing procedures that are carried out in people with acute heart attacks and / or with problems arising from the timing mechanism controlling the heart beats. Personnel commit themselves completely to their profession and sacrifice their social lives to participate in such procedures. Adequate support from management is thus imperative to sustain the effectiveness of this service.

Malta, being a small island, could offer a wider and better type of care utilising the nursing profession. Nurse-led cardiology clinics have yielded excellent results in different countries by disseminating health information, giving specific home care and support and reporting changes of clinical importance to cardiologists for a faster response.⁶ An increase in the involvement of nurses may help the local population which has cardiovascular disease to lead a better life. This wider service provision would result in an enhanced professional status of the local nurses and an improvement in the Maltese healthcare system. □

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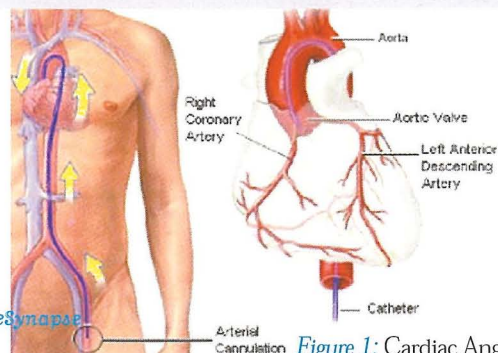


Figure 1: Cardiac Angiography Catheter Insertion

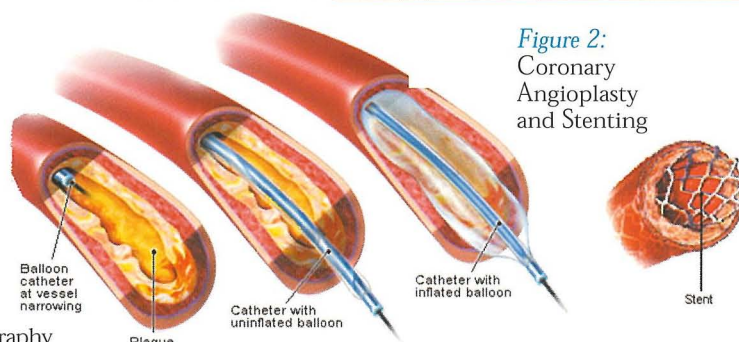


Figure 2: Coronary Angioplasty and Stenting

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recommended that caution should be observed in patients who have previously had convulsions and been subject to mania. Patients who have recently suffered from myocardial infarct or heart disease should be kept under appropriate observation. **Interaction with other medicaments and other forms of interaction:** As is the case with other serotonin reuptake inhibitors, paroxetine inhibits the specific hepatic enzyme cytochrome P450 isoenzyme (2D6). Drugs that are metabolised by cytochrome P450 (2D6) include specific tricyclic antidepressants (e.g. nortriptyline, amitriptyline, imipramine and dextipramine), specific serotonin reuptake inhibitors (e.g. fluoxetine), sedative phenothiazine drugs (e.g. perphenazine and thioridazine) and drugs for arrhythmia (e.g. propafenone and flecainide). Caution should be observed with the administration of Paxetin concurrently with sedatives (neuroleptics) and oral anticoagulants. Drugs that inhibit (e.g. cimetidine) or activate (e.g. phenytoin) microsomal enzymes that are necessary for the metabolism of paroxetine can affect its metabolism and pharmacokinetic properties. The adaptation of doses at the start of the treatment is not considered necessary when the drug is to be administered together with a drug that activates enzymes necessary for the metabolism of drugs. If doses are adapted later, this should be done on the basis of the clinical effects. Patients should be advised to avoid taking alcohol during Paxetin treatment. The use of Paxetin together with tryptophan is not recommended as it can lead to side effects, mainly headache, nausea, increased perspiration and dizziness. The use of paroxetine together with anticonvulsive drugs (e.g. phenobarbital) can lead to an increased frequency of side effects. Paroxetine can interact with drugs that are mostly bound to plasma proteins thus leading to increased side effects. Utmost caution should be observed when administering Paxetin together with lithium as the experience with such patients is limited. Following repeated doses, a study of the interaction between paroxetine and diazepam showed no changes in the pharmacokinetic properties of paroxetine which would recommend changes

in the dosage for patients taking both drugs. **Pregnancy and lactation:** Paxetin should not be used during pregnancy and lactation. **Effects on ability to drive and use machines:** Patients should be advised not to drive a car or operate dangerous machinery until they are sure that Paxetin does not affect them. **Side effects:** The most common: Malaise, pains, Hypertension, syncope, tachycardia, Pruritus, Nausea and vomiting, Weight gain, weight loss, Stimulation of the nervous system, impaired concentration, depression, emotional instability, vertigo, Increased coughing, rhinorrhea. **Overdose:** A wide margin of safety is evident from available data. Experience of paroxetine in overdose has indicated that, in addition to those symptoms mentioned under Side Effects, vomiting, dilated pupils, fever, blood pressure changes, headache, involuntary muscle contractions, agitation, anxiety and tachycardia have been reported. Treatment should consist of general measures employed in the management of overdose with any antidepressant. Early administration of activated charcoal may delay the absorption of Paxetin.

For full prescribing information please contact the local representative of the Marketing Authorisation Holder.

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Current Status of Avian/Pandemic Influenza

by Tanya Mellilo Fenech MD MSc
Chairperson of the National Influenza Pandemic Standing Committee

The current pandemic alert phase is still at alert level 3 where a new influenza viral subtype is causing disease in humans but is not yet spreading efficiently and sustainably among humans.

20 human cases of infection with the highly pathogenic avian influenza in Turkey have been confirmed (3 have died). 18 of them were children between 4-18 years of age. Although virology sampling shows that the H5N1 virus is the same as in East Asia, Turkey is seeing a fatality rate of 20%, which is lower than the fatality rate observed in Asia, which is around 58%.

There has also been a 5th cluster of cases in Indonesia. 20 cases and 13 deaths have been reported in this country. Evidence indicates that patients acquired infection following close contact with infected poultry.

Syria and Iran have destroyed thousands of birds to create a buffer against the spread of the bird flu. Outbreaks of avian influenza in birds

are also occurring in Romania, Ukraine, Russia and China. There was a suspected human avian case in Iraq on the 18th January 2006.

In Japan, the H5N2 strain has been found in poultry. This is a low pathogenic avian influenza. A number of poultry workers have also been found to be seropositive to this virus.

On the 14th January 2006, the US Centers for Disease Control and Prevention (CDC) announced that two drugs typically prescribed to fight the virus will be ineffective this season and should not be prescribed. The CDC found that amantadine and rimantadine were ineffective 91% of the time against H3N2 influenza, the dominant strain this season. Resistance to amantadine and

rimantadine has been climbing in recent years, particularly in Asia. There has been a huge leap this year (2006) in the United States for reasons that are still unclear. In fact, 2 years ago, 2% of circulating flu viruses were resistant to the 2 drugs. During the last flu season, 11% were resistant. This season, 91% of virus samples tested have been found to be resistant. However, 2 other antiviral drugs, Tamiflu® (oseltamivir) and Relenza® (zanamivir) are still effective.

Following a recent article in the New England Journal of Medicine, senior World Health Organization Officials have stated that some resistance to Tamiflu® is inevitable as this is expected to happen with usage of antibiotics and antivirals. However this is not alarming. More research is needed to understand whether the dosage regime is contributing towards resistance. Tamiflu® still remains an 'excellent choice' among the limited antivirals available against the H5N1 virus. ☐

(More regular free updates on the Avian/Pandemic Influenza can be accessed on the TheSYNAPSE Web Portal on <http://www.thesynapse.net/>)

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