NEWSPAPER POST

TheSynapse

The Medical Professionals' Network

MEDICAL IMAGING

Imaging Oesophageal Cancer

by Pierre Vassallo
MD PhD FACA Artz für Radiologie
Consultant Radiologist

The prevalence of oesophageal cancer has increased dramatically in the past 30 years, with increases of 350% – 800% reported during this period. Oesophageal cancer is often detected late with 75% of patients having diseased lymph nodes at initial diagnosis.

The 5-year survival rate is only 3% for patients with lymph node involvement, whereas it is 42% for patients who do not have nodal involvement. Approximately 18% of patients will have distant metastases; of these 45% will be to abdominal lymph nodes, 35% to the liver, 20% to the lungs, 18% to supraclavicular nodes, 9% to bone, and 5% to adrenal glands. Consequently, the prognosis is poor, with surgical cure achieved in less than 10% of patients. Surgeons differ in their approach to patients with advanced-stage disease. Palliative therapies include surgery, laser resection, radiation therapy or chemotherapy, and oesophageal stent placement or dilation. Surgery, whether curative or palliative, carries a significant risk of mortality that ranges from 5% to 20% depending on the surgeon's experience. Therefore, accurate preoperative staging, particularly with regard to depth of wall invasion, mediastinal invasion, nodal involvement, and distant metastases, is vital in determining the most appropriate therapy and in helping avoid inappropriate attempts at curative surgery.

Clinical Presentation

Dysphagia is the most common presenting complaint in patients with oesophageal cancer, however it is also present in patients with benign oesophageal strictures. The duration of dysphagia is a useful clinical parameter for differentiating benign from malignant strictures. In general, benign strictures are associated with long-standing, intermittent, nonprogressive dysphagia, whereas malignant strictures are associated with recent onset of rapidly progressive dysphagia and weight loss.

Chronic or severe esophagitis from a variety of causes may lead to scarring and fibrosis with the development of oesophageal strictures. Therefore, the clinical setting is crucial in determining the underlying cause of these strictures. In some cases, the correct diagnosis may be suggested by a temporal relationship between stricture formation and precipitating factors such as mediastinal irradiation, ingestion of caustic substances, and nasogastric intubation. In other cases, important clinical clues may be provided by findings such as high serum gastrin levels in Zollinger-Ellison syndrome, an allergy history or peripheral eosinophilia in eosinophilic esophagitis, or bullous skin eruptions in epidermolysis bullosa dystrophica or benign mucous membrane pemphigoid. Therefore, all strictures should be evaluated in the clinical context in which they develop.

Imaging Methods

Oesophageal strictures are best evaluated with biphasic oesophagography (also known as Barium Swallow) that includes both double-contrast and single-contrast spot X-ray images. The single-contrast phase optimises distension of the oesophagus, thereby improving detection of strictures, whereas the double-contrast phase optimises visualization of the mucosa for nodules, ulcers, or other radiographic findings associated with these strictures.

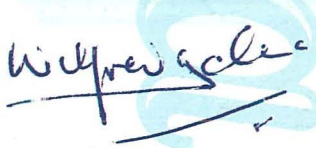
Reflux-induced (gastro-oesophageal reflux disease – GORD) strictures classically appear as smooth, tapered areas of concentric narrowing in the distal oesophagus and range from 1 to 4 cm in length (Figure 1). Other peptic strictures may be associated with a focal cluster of oesophageal intramural pseudodiverticula (Figure 1).

Figure 1. *Peptic stricture (large arrow) above a hiatal hernia with oesophageal intramural pseudodiverticulae (small arrows) some forming track like structures (open arrows).*

continues on page 2

Editor's Word

Welcome to second issue of TheSynapse Magazine for 2007. This issue is once again packed with articles which will surely be enjoyed by all healthcare professionals. Apart from the regular contributions on radiology and avian influenza, you will also find articles on **Management of Behavioural and Psychological Symptoms of Dementia, Negligence and Malpractice, Do's and Don'ts in the management of acne,** part 2 of **Invertebrates in the medical service of man** and **The diversity of Occupational Therapy Services for older persons in Malta.** We also proudly present the second interviewee for this year – Dr Victor Camilleri.



TheSynapse Magazine is published by Medical Portals Ltd. The Professional Services Centre, Guzi Cutajar Street, Dingli, Malta.

Editor: Dr Wilfred Galea
Designer: Conrad Bondin

Imaging Oesophageal Cancer

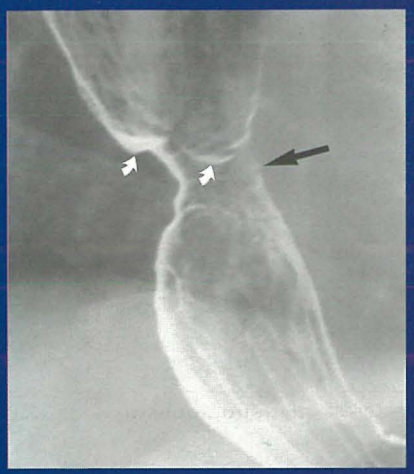


Figure 2. *Asymmetric peptic stricture (arrow) due to scarring from reflux esophagitis (white arrows indicate wide pseudodiverticulae).*

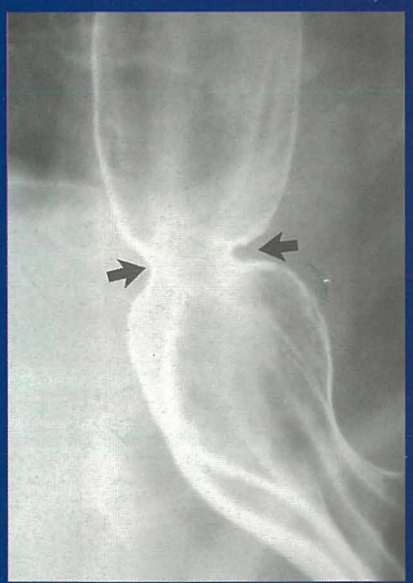


Figure 3. *Ring-like peptic stricture (arrows) above a hiatal hernia, resembling a Schatzki ring, but more asymmetric, having more tapered borders and a greater length than do most Schatzki rings.*

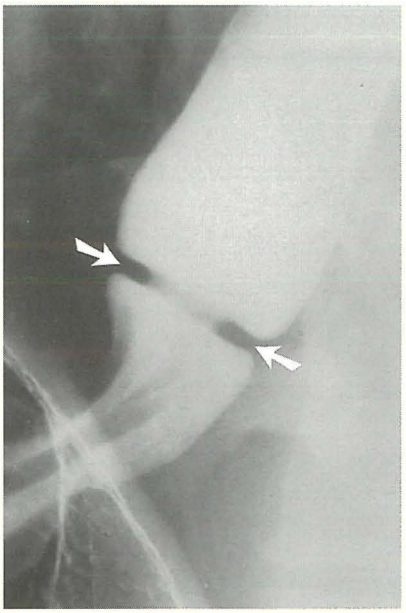


Figure 4. *Schatzki ring (arrows) appears as a smooth, symmetric, ring-like constriction at the gastroesophageal junction above a hiatal hernia with a length of only 2 mm and has more abrupt borders than does a ring-like peptic stricture.*

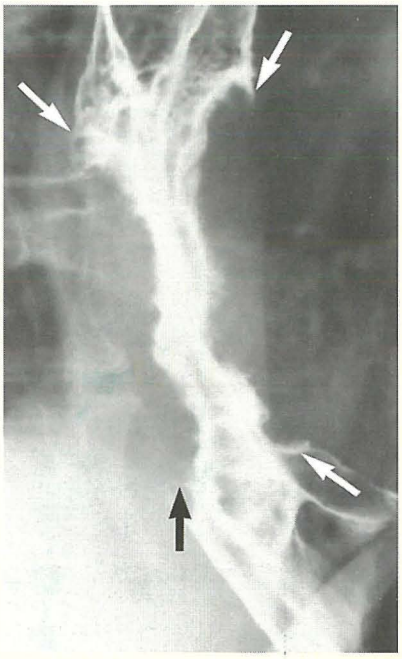


Figure 5. *Infiltrating esophageal carcinoma presenting as a stricture with a markedly irregular contour and abrupt, shelflike proximal and distal margins (arrows).*

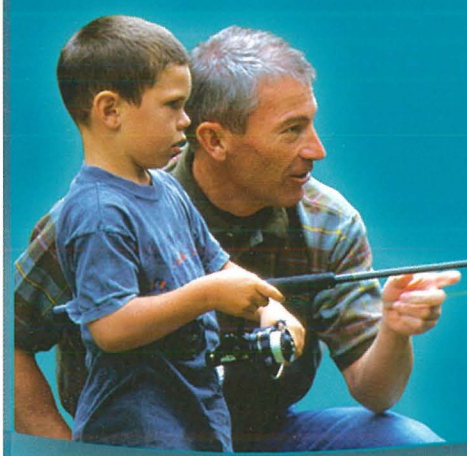
However, asymmetric scarring can lead to asymmetric narrowing and may resemble malignant strictures (Figure 2).

Some patients may have a very short segment of ring-like narrowing at the gastro-oesophageal junction above a hiatal hernia (Figure 3). This may resemble a Schatzki ring (Figure 4), which is a normal oesophago-gastric sphincter. Schatzki rings usually appear as smooth, symmetric ring-like constrictions with abrupt borders and a length of only 1–3 mm, whereas annular peptic strictures have more tapered borders and a length of over 4 mm.

Hiatal hernias are seen at barium examination in more than 90% of patients with peptic strictures, so that the possibility of malignant tumor should be considered when a distal oesophageal stricture is detected in the absence of a hernia. Nevertheless, malignant strictures usually have more irregular and nodular contours and more abrupt or "shouldered" proximal and distal margins than do benign peptic strictures (Figure 5).

Barrett esophagus is an acquired condition in which there is progressive columnar metaplasia of the distal oesophagus as a result of chronic gastroesophageal reflux and reflux esophagitis. Barrett oesophagus is only detected by oesophagoscopy and requires confirmation by endoscopic biopsy.

continues on page 20

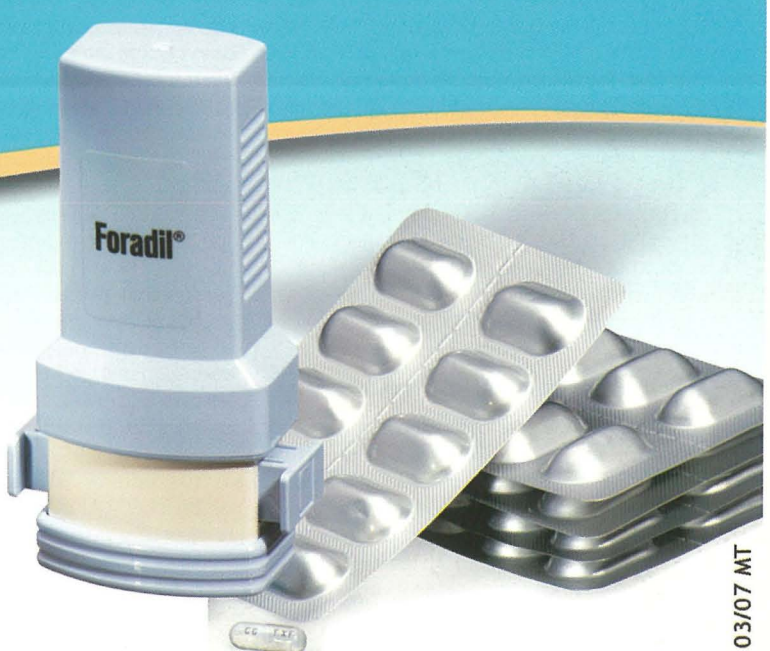


Lasting Control is Just a Breath Away

- **Foradil®** is an effective bronchodilator for patients with asthma and COPD[1].
- **Foradil®** provides twin benefits of fast onset of action (within 1 to 3 minutes) and long-lasting control (up to 12 hours) for adults and children[1].
- Only **Foradil®** has the unique **Aerolizer®** device with low resistance and reassuring dosing[2].

References:

1. Novartis Pharma. Foradil® Inhalation powder Summary of Product Characteristics, November 2005.
2. Bronsky EA et al. Inspiratory flow rates and volumes with the Aerolizer® dry powder inhaler in asthmatic children and adults. Curr Med Res Opin 2004; 20:131-7



Foradil® Inhalation powder, hard capsules
Presentation: each capsule contains 12 micrograms formoterol fumarate dihydrate. **Indications:** Prophylaxis and treatment of bronchoconstriction in patients with asthma. Prophylaxis of exercise, cold air or allergen-induced bronchospasm. Prophylaxis and treatment of bronchoconstriction in patients with reversible or irreversible chronic obstructive pulmonary disease (COPD). **Dosage: Adults:** Regular maintenance therapy (asthma and COPD): 1 to 2 capsules (12-24 micrograms) twice daily. If needed, 1 or 2 additional capsules per day but on no more than 2 days per week. Prophylaxis against exercise or allergen-induced bronchospasm: 1 capsule used at least 15 minutes prior to exercise or exposure. In patients with history of severe bronchospasm, 2 capsules may be necessary as prophylaxis. **Children 5 years of age and older:** Regular maintenance therapy (asthma): 1 capsule twice daily. Prophylaxis against exercise or allergen-induced bronchospasm: 1 capsule used at least 15 minutes prior to exercise or exposure. **Contraindications:** Hypersensitivity to formoterol or the excipient (lactose monohydrate which contains milk proteins). **Precautions/Warnings:** Increased rate of asthma related death observed with another LABA (salmeterol). Treatment not to be increased beyond maximum recommended dose. Not to be used with another LABA. To be used only as additional therapy. When treating patients with asthma, must only be used together with anti-inflammatory therapy which should continue unchanged after introduction of Foradil. Not to be initiated or dose increased during asthma exacerbation. Not to be used for acute asthma attacks. Caution is recommended in patients with ischaemic heart disease, cardiac arrhythmias (especially third-degree atrioventricular block), severe cardiac decompensation, idiopathic subvalvular aortic stenosis, hypertrophic obstructive cardiomyopathy, thyrotoxicosis, known or suspected prolongation of the QT interval, diabetes mellitus. Risk of serious hypokalaemia especially in severe asthma. Discontinue if paradoxical bronchospasms occur. Persistent symptoms require medical reassessment. Avoid use during pregnancy or lactation. Refrain from driving or operating machines if experiencing dizziness or similar side effects. Adhere strictly to storage instructions. **Interactions:** Caution when used concomitantly with sympathomimetics, xanthine derivatives, steroids, diuretics, beta-blockers, monoamine oxidase inhibitors, tricyclic antidepressants, quinidine, disopyramide, procainamide, phenothiazines, antihistamines. **Adverse reactions:** Serious asthma exacerbations observed in some clinical trials. Common: headache, tremor, palpitations. Uncommon: agitation, anxiety, nervousness, insomnia, dizziness, tachycardia, bronchospasm, throat irritation, muscle cramps, myalgia. Very rare: hypersensitivity (including hypotension, urticaria, angioneurotic oedema, pruritus, exanthem), oedema peripheral, nausea, dysgeusia. Reported with other Foradil formulations: cough and rash. **Note:** Before prescribing, please read full prescribing information.

Full prescribing information is available from: Novartis Pharma Services Inc

Malta (MAH)
Novartis Pharmaceuticals UK Ltd.
Frimley Business Park, Frimley, Camberly
Surrey GU16 7SR,
United Kingdom

Local Representative of the MAH
Novartis Pharma Services,
P.O. Box 124,
Valletta CMR 01 Malta
Tel +35622983217

NOVARTIS

Foradil® formoterol

FOR AD 03/07 MT

Do's and Don'ts management of

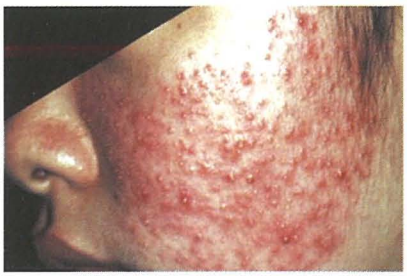
by **Lawrence Scerri**
MD FRCP (Lond & Glasg) CCST Derm (UK) FAAD
Chairman, Department of Dermatology,
Sir Paul Boffa Hospital

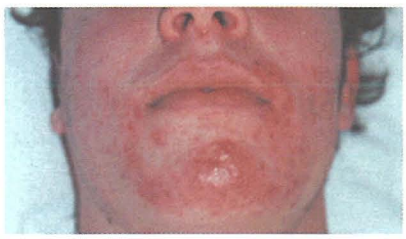
Acne vulgaris is the reason behind 10 to 25% of attendances in a general dermatology clinic in most dermatology clinical practices. It is therefore of utmost importance that clinicians dealing with acne patients are familiar with current recommendations for managing this common dermatosis, which may be associated with a significant negative psychosocial impact in a considerable number of cases.

Before embarking on drug treatment it pays to explain the prolonged albeit fluctuating course of acne and to stress the importance of long term management, not just to clear the acne but also to maintain remission. The clinician should stress the real risk of irreversible scarring that may result from inadequately treated inflammatory acne, as well as the fact that squeezing and picking inflammatory lesions is likely to increase this risk. Patients should be educated about aggravating factors particularly the avoidable ones namely greasy cosmetics and androgenic drugs. Conversely, one should actively strive to dispel popular myths, such as those in relation to the diet,[1] which only serve to add to the patients' misery.

When prescribing topical agents, particularly benzoyl peroxide or retinoids one should warn patients in advance about the likelihood of irritation which tends to wear off with continued use. Irritancy may be minimized by starting the acne agent at night-time on an alternate-day basis for the first two weeks or so, before switching to daily application. Co-prescribing a non-comedogenic moisturizer in the morning helps to counteract irritancy, and consequently enhance compliance. Topical treatment must be applied to the whole acne-prone site and not only to any existing spots at the time. This is done in order to treat early micro-comedones which are the precursors of visible acne lesions[2]. Hence the concept of 'spot prevention'. Patients should be warned about the usual slow onset of clinical response to both topical (3-6 weeks) as well as oral treatment (4-8 weeks).

Topical and oral antibiotic courses should generally be limited to 4-6 months, and given in combination with a topical non-antibiotic agent with a view to achieving clearance of acne. Long-term remission should be maintained with non-antibiotic agents so as to limit development of *Propionibacterium acnes* resistance[3]. Patients with severe seborrhoea





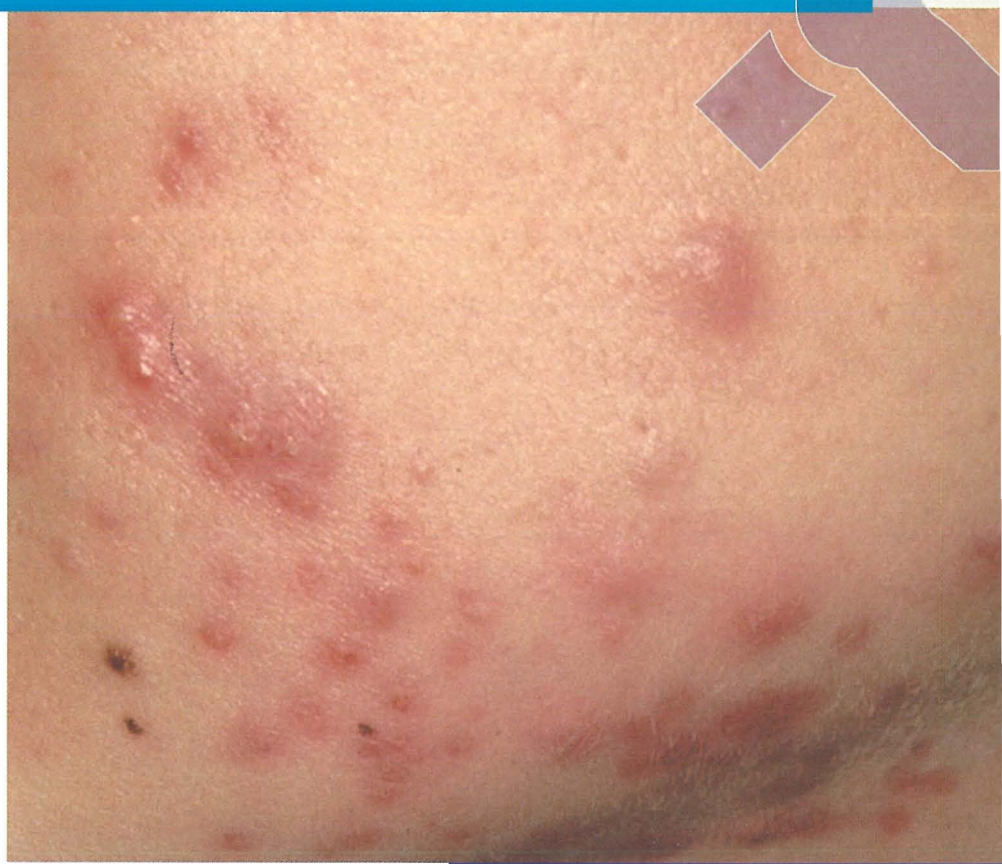
respond poorly to antibiotics, in which case one should opt for higher antibiotic doses (such as minocycline 200mg/day)[4], or the employment of sebum secretion-reducing agents such as cyproterone acetate, spironolactone or oral isotretinoin. Tetracycline is the antibiotic of choice for oral treatment. One must bear in mind that the various tetracyclines have been shown to exhibit similar clinical efficacy in trials, but lymecycline and doxycycline are more convenient than oxytetracycline, and safer than minocycline, although the latter is superior in patients with greasy skin due to its greater lipophilicity.

Hormonal therapy (oral contraceptive pill containing an anti-androgenic progestogen such as drospirenone or cyproterone acetate, which may be supplemented by additional cyproterone acetate or spironolactone for added anti-androgenic effect) is appropriate for females with acne who also require contraception and/or menstrual control, as well as for patients with polycystic ovary syndrome. This therapeutic option is also indicated in patients with a strong history of pre-menstrual acne flares as well as in those with persistent adult acne even when there is no evidence of underlying endocrinopathy[5]. It would be prudent to switch from a higher oestrogen-content pill to a lower oestrogen-content pill (such as Yasminelle) once acne is under control. One should not forget that the oral contraceptive pill (particularly with low oestrogen content) may show a negative interaction with oral tetracyclines running a risk of contraceptive failure. A family history of breast cancer is not an absolute contraindication for hormonal therapy since there is insufficient evidence to link this with an increased risk of breast cancer.

There is no need to investigate routinely for endocrinopathy in females. Most cases of 'hormonal acne' are due to increased local production of androgens in the pilosebaceous unit, which does not show up on blood investigation. On the other hand, a hormone profile should be requested in adult females with sudden onset of severe acne, female patients whose acne is resistant to conventional therapy, and patients with acne that is associated with irregular menstrual cycle or clinical signs of hyperandrogenism, especially hirsutism. Furthermore, delayed-onset congenital adrenal hyperplasia should be excluded in adult male and female patients with persistent severe acne.

In patients with moderate to severe acne the total cumulative dose of isotretinoin should be at least 120mg/kg in order to minimize post-treatment relapse[6]. However there is no added benefit when exceeding 150mg/kg. It is recommended that one opts for a lower dose regimen spread over 6-8 months rather than going for the full dose given over a 4 month period. This achieves the same end-result with less side-effects (particularly mucocutaneous dryness), and is hence better tolerated by most patients. Pharmacokinetic studies show that absorption of isotretinoin can be doubled when this is taken with meals. In order to minimize the risk of a severe inflammatory flare on starting oral isotretinoin in patients with abundant macrocomedones it is advisable to treat the comedonal lesions with light cautery prior to commencing the drug. Patients

in the acne



should be warned to avoid traumatic interventions such as wax depilation or skin peeling during the course of oral isotretinoin therapy due to the likelihood of severe reactions. Furthermore all necessary precautions must be taken to prevent pregnancy occurring during isotretinoin therapy and up to one month after completing the course of treatment as outlined in the current pregnancy prevention programme of the EMEA and FDA.

Severe inflammatory acne flares occurring during the initial phase of oral isotretinoin therapy may be effectively controlled with a reducing course of oral corticosteroid (starting at 0.5-0.75mg/kg) given over 3-4 weeks while at the same time continuing the isotretinoin, the dose of which being kept low initially and increased gradually. On the same note, it is advisable to co-prescribe a reducing course of oral corticosteroid together with an incremental oral isotretinoin regime right from the start in patients with severe inflammatory acne or acne conglobata. The same applies to patients with acne fulminans and pyoderma faciale although one should proceed more cautiously in such patients, giving the oral corticosteroid over a longer period and increasing the isotretinoin dose more slowly.

Although not absolutely indicated in otherwise young healthy patients, it might be prudent to carry out routine baseline liver function tests and lipid profile. Evidence to date shows that elevations in these tests occur in most patients but return to pre-treatment levels after stopping treatment[7]. There is no real need to routinely repeat these tests during the course of treatment except in high risk patients such as those suffering from diabetes or hyperlipidaemias. Oral tetracyclines should not be prescribed together with oral isotretinoin due to the increased risk of benign intracranial hypertension. Oral isotretinoin should not be prescribed in the presence of a clear history of suicidal depression. Furthermore it is advisable to withdraw isotretinoin should patients develop signs of depression during the course of treatment.

Patients with retentional acne may benefit from abrasive agents and scrubs in addition to topical retinoid therapy. However the former modalities should be avoided in the presence of an inflammatory component due to the likelihood of aggravation. Likewise facial saunas, heat applications and massage are best avoided as these are likely to induce inflammatory lesions. Blue light and photodynamic therapy are mainly of benefit in cases of mild to moderate acne.

Patients with acne excoriee having more inflamed lesions than excoriations are best treated with oral antibiotics, whereas the more difficult patients who tend to have mainly excoriations with minimal inflammatory lesions are best managed with psychoactive drugs and psychotherapeutic support. Potentially irritating topical treatments such as benzoyl peroxide and retinoids are best avoided in such patients. Patients with body dysmorphic disorder and acne need to be treated enthusiastically with more aggressive therapy such as high dose minocycline or oral isotretinoin with or without the addition of an antidepressant due to the significant risk of suicide[8]. Psychiatric referral should ideally be avoided since these patients tolerate psychiatrists very badly.

In conclusion, choice of therapy in patients with acne should not only be based on clinical indications but must also be influenced by consideration of potential risks, and the patient should be given the opportunity to make an informed decision.

References

1. Rosenberg WE, Kirk BS. Acne diet reconsidered. *Arch Dermatol* 1981; 117:193-5.

2. Gollnick H, Cunliffe WJ, Berson D et al. Management of acne. Report from a global alliance to improve outcomes in acne. *J Am Acad Dermatol* 2003; 49 (Suppl.):S1-37.

3. Eady EA. Bacterial resistance in acne. *J Invest Dermatol* 1997; 108:379.

4. Goulden V, Glass D, Cunliffe WJ. Safety of long term high dose minocycline in the treatment of acne. *Br J Dermatol* 1996; 134: 693-5.

5. van Vloten W, van Haselen CW, van Zuuren EJ. The effect of two combined oral contraceptives containing drospirenone or cyproterone acetate on acne and seborrhoea. *Cutis* 2002; 69:1-15.

6. Cunliffe WJ, Van de Kerkhof P, Caputo R et al. Roaccutane treatment guidelines: results of an international survey. *Dermatology* 1997; 194:351-7.

7. Altman RS, Altman LJ, Altman JS. A proposed set of new guidelines for routine blood tests during isotretinoin therapy for acne vulgaris. *Dermatology* 2002; 204:232-5.

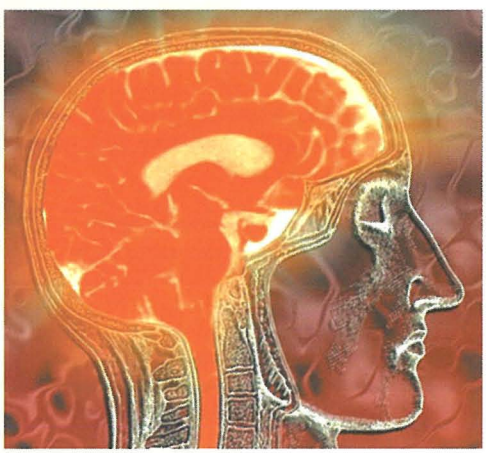
8. Cotteril JA, Cunliff WJ. Suicide in dermatological patients. *Br J Dermatol* 1997; 137:246-50.

Management of Behavioural and Psychological Symptoms of Dementia

by **Stephen Abela**
MD MRCP(UK) M PHIL MHSc HSM
Consultant Geriatrician
Department for the Elderly and Community Care

Last year we have published an article which focused on the initial assessment of people presenting with symptoms suggestive of dementia (Issue 03/06, May 2006. It is available on www.thesynapse.net). The following article will now focus on important developments in the management of behavioural and psychological symptoms in dementia. This second article is directed in particular to primary care professionals and serve to highlight some important principles and newer approaches that are being recommended. This is a very important subject especially since there are many misconceptions on how to deal with these complaints.

Recently, there have been many publications expressing concern towards the inappropriate and excessive use of neuroleptic medication in dementia. In 2004, a safety message was issued by the Committee on Safety of Medicines of the United Kingdom concerning the use of atypical antipsychotics in patients with behavioural and psychiatric symptoms of dementia. This alert followed the analysis of manufacturer data which showed an increased risk of cerebrovascular adverse events with risperidone and olanzapine. The magnitude of increased risk in the studies analysed was in the region of three times. It has been recommended that these drugs are prescribed only following a careful assessment of benefits and risks, are used in the lowest possible dose and for a specified period of time. Although the other 'typical' neuroleptic drugs are commonly prescribed to treat behavioural and psychiatric symptoms in dementia, there is little evidence-base to support this practice. Typical antipsychotic drugs are known only to be modestly effective and can have potentially serious side-effects especially in older adults. There have been many studies on the overuse of antipsychotic medication, especially in people with dementia and those living in nursing homes. These drugs are associated with extrapyramidal side effects, increased risk of falling, excessive sedation and accelerated cognitive decline. Several trials have also shown that these drugs can be safely discontinued in many of these situations.



It is now recommended that patients have appropriate assessment and investigation leading to a definite diagnosis of dementia. This gives the advantage of offering the person with dementia specific treatment and the ability to plan future care and needs. The anti-dementia drugs such as the acetylcholinesterase inhibitors (donepezil, rivastigmine and galantamine) and the NMDA antagonist memantine have all been shown to confer benefit in improving behaviour and psychiatric symptoms of dementia. Studies have shown that these drugs also reduce the need for prescribing antipsychotic medication. Depression may co-exist in a person with dementia and is potentially treatable. A trial of antidepressant medication such as a selective serotonin reuptake inhibitor is warranted.

Experience has shown that an underlying physical cause may well be the reason for a sudden worsening in behavioural and psychological symptoms of dementia. The family doctor is in an ideal position to identify whether there is a physical component which obviously calls for the management of the underlying cause first. A patient's disturbed sleep pattern could be related to pain from arthritis and which may well respond to simple analgesia rather than prescribing a hypnotic drug. The original complaint may be 'urinary incontinence', but a cautious doctor would examine and exclude the possibility of urinary retention with overflow, a urinary tract infection or polyuria secondary to diuretics or secondary to uncontrolled diabetes. A review of the patient's medication may help to identify drugs that may worsen confusion such as cimetidine, digoxin, anticholinergic and antihistaminic medication, hypnotics and psychotropic drugs.

Over the last decade, there has been a growing interest in the non-pharmacological management of dementia. A person centred philosophy to care is being recommended, with an emphasis on maintaining respect and dignity, and encouraging an enjoyable and active life for people with dementia. Recreational and social activities such as those provided in community day centres help to maintain stimulation and social interaction. Aromatherapy with lemon balm or lavender oil have been studied and shown to have a significant effect on agitation. Music and drama therapy have also been used to help improve the psychological and physical wellbeing of people with dementia. Environmental interventions to improve the design and layout of home environments for people with dementia maximize the potentials and functional abilities of patients and increase their safety especially if living on their own. Over recent years, technological devices are increasingly being developed and installed to assist safety living in the community.

Education of caregivers plays an important part in the proper management of these symptoms. Information on how to deal with these Alzheimer's related behaviours is now available from Alzheimer Associations around the globe and can be downloaded from their websites for free.

continues on page 24

EXELON® hard capsules

Presentation: Capsules containing 1.5 mg, 3.0 mg, 4.5mg or 6.0 mg rivastigmine (as the hydrogen tartrate salt).

Indication: Mild to moderately severe dementia associated with Alzheimer's disease or Parkinson's disease.

Dosage: Treatment should always be started at a dose of 1.5 mg twice daily at initiation and re-initiation of therapy. If well tolerated, it may be increased after a minimum of 2 weeks of treatment to 3 mg twice daily, subsequently to 4.5 mg twice daily, up to a maximum of 6 mg twice daily. Adverse effects may respond to omitting one or more doses. If they persist, the daily dose should be reduced to the previous well-tolerated dose.

Contraindications: Known hypersensitivity to rivastigmine, other carbamate derivatives, or other ingredients of the capsules. Severe liver impairment. **Precautions/Warnings:** As with other cholinomimetics, caution is recommended in patients with sick sinus syndrome, conduction defects (sino-atrial block, atrio-ventricular block), gastroduodenal ulcerative conditions, history of or current respiratory disease, urinary obstruction, and seizures in predisposed patients. The safety of Exelon is not established in pregnant and lactating women. If treatment is interrupted for longer than several days treatment should be re-initiated with the lowest daily dose to reduce the possibility of adverse reactions (e.g. severe vomiting). As with other cholinomimetics, adverse effects have been observed shortly after dose increase. **Interactions:** Cholinomimetic drugs, anticholinergic medications, succinylcholine-type muscle relaxants during anaesthesia. **Adverse reactions:** Nausea, vomiting, diarrhoea, abdominal pain, loss of appetite, dyspepsia, dizziness, headache, somnolence, tremor, agitation, confusion, sweating, weight loss, malaise, fatigue, asthenia and syncope. Rarely, angina pectoris, gastric and duodenal ulcers, seizures and rashes. Very rare cases of cardiac arrhythmia (e.g. bradycardia, atrio-ventricular block, atrial fibrillation and tachycardia), hypertension, gastrointestinal haemorrhage and mild pancreatitis have been reported. **Packs and prices:** Country specific. **Note:** Before prescribing please read full prescribing information.

References

1. Potkin SG, Anand R, Hartman R. et al., 2002, Impact of Alzheimer's disease and rivastigmine treatment on activities of daily living over the course of mild to moderately severe disease. Prog Neuropsychopharmacol Biol Psychiatry, 26(4),713-720. **2.** Cummings J, Anand R, Koumaras B, Hartman R., 2000, Rivastigmine provides behavioural benefits to Alzheimer's disease patients residing in a nursing home : findings from a 56-week trial. Neurology, 54(Suppl. 3): A468-9. **3.** Corey-Bloom J, Anand R, Veach J, for the ENA 713 B352 Study Group, 1998, A randomized trial evaluating the efficacy and safety of ENA 713 (rivastigmine tartrate), a new acetylcholinesterase inhibitor, in patients with mild to moderately severe Alzheimer's disease. Int J Geriatr Psychopharmacol, 1:55-65. **4.** Summary of Product Characteristics Exelon. **5.** Summary of Product Characteristics Aricept. **6.** Summary of Product Characteristics Reminyl. **7.** www.drug-interactions.com **8.** Grossberg G, Stahelln J, Messina J, Anand R., 2000, Lack of adverse pharmacodynamic drug interactions with rivastigmine and twenty-two classes of medications. Int J Geriatr Psychiatry, 15;242-7. **9.** Giacobini E., 1997, From molecular structure to Alzheimer therapy. Jpn J. Pharmacology, 74;225-241. **10.** Liebel J., 2001, Results of a 12-months postmarketing surveillance study with rivastigmine in patients with mild to moderately severe Alzheimer's disease. Poster presented at a Novartis satellite meeting "Pathways from Science to Effective Patient Management in Dementia". Istanbul, Turkey.

Keep us from drifting apart

- Exelon® - dual inhibition on AChE and BuChE.[9]
- Exelon® - excellent efficacy on all key domains - ABC. [1,2,3]
- Exelon® - unique safety profile with minimum potential for drug interactions. [4,5,6,7,8]
- Exelon® - individual dosages for optimal tolerability and efficacy. [8,10]

NOVARTIS NEUROSCIENCE

EXELON® (rivastigmine)
Stability in a time of change

Full prescribing information is available from: Novartis Pharma Services Inc.

Malta (MAH):
Novartis Pharmaceuticals UK Ltd,
Frimley Business Park, Frimley, Camberly
Surrey GU16 7SR,
United Kingdom

Local Representative of the MAH:
Novartis Pharma Services,
P.O. Box 124,
Valletta. CMR 01. Malta
Tel. : +35622983217

EXE AD 03/07 MT

FLORA LOVE YOUR HEART

FLORA PRO.ACTIV MINI-DRINK – SUPERIOR FORMULA IN THE FIGHT AGAINST CHOLESTEROL

Flora pro.activ now boasts a new superior formula to provide consumers with a truly effective and nutritionally balanced product that is easy to incorporate into an everyday diet.

Flora pro.activ mini-drink provides 2g of plant sterols (optimal amount clinically proven to significantly reduce cholesterol), probiotic bacteria for a healthy digestive system, but also contains added fish Omega-3 fatty acids to promote heart health, and a reduced sugar content that is up to three times lower than most mini-drinks available on the market.

Plant sterols, the key cholesterol-lowering ingredient in Flora pro.activ mini-drink, occur naturally in foods such as fruit, vegetables, seeds and nuts. However, their concentration in foods is not sufficient to reap the benefits of their cholesterol-lowering properties through a regular diet alone. The International Atherosclerosis Society recommends a daily intake of 2g of plant sterols as part of a cholesterol-lowering diet[1] – an amount that can only be achieved by eating an equivalent of 150 apples, 425 tomatoes or 70 slices of wholemeal bread.

Each bottle of Flora pro.activ mini-drink contains 2g of plant sterols. This amount is clinically proven to lower Low-Density Lipoprotein (LDL) cholesterol by 10-15 percent within three weeks when moving to a healthy diet.[2]

There is significant scientific evidence that regular consumption of fish Omega-3 fatty acids reduces the risk of cardiovascular disease. Since the consumption of fish Omega-3 in Europe is generally below the recommended daily amount, incorporating Flora pro.activ mini-drink in everyday diet is an effective way to boost the intake of these heart-healthy fatty acids.

Kate Mitchell, from Unilever says: *"We reduced the sugar content of Flora pro.activ mini-drink and added Omega-3 in order to create a healthier product our customers want. With its familiar yoghurt taste and convenient packaging for consumption at home or on the go, Flora pro.activ mini-drink can be easily incorporated in a daily routine, providing an effective boost to a cholesterol-lowering regimen."*

To ensure best effects of Flora pro.activ mini-drink, research shows that it is best to consume one mini-drink a day with a meal.[3]

References

1. International Atherosclerosis Society Executive Board, Harmonised Clinical Guidelines on Prevention of Atherosclerotic Vascular Disease. March 2003.
2. Katan MB, Grundy SM, Jones P, Law M, Miettinen T, Paoletti R; Stresa Workshop Participants. Efficacy and safety of plant stanols and sterols in the management of blood cholesterol levels. *Mayo Clin Proc* 2003 Aug; 78(8): 965–978. Review.
3. Doornbos AME, Meynen EM, Duchateau GSMJE, Knapp HCM, Trautwein EA. Intake occasion affects the serum cholesterol lowering of a plant sterol-enriched single dose yoghurt drink in mildly hypercholesterolemic subjects. Eur J Clin Nutr 2006; 60: 325–333.

Pro.activ way to lower cholesterol

Consumption of plant sterol-enriched Becel pro.activ mini-drink can significantly lower LDL cholesterol within 2-3 weeks when moving to a healthy diet.

It is a well-known fact that elevated Low-Density Lipoprotein (LDL) cholesterol, one of the key risk factors for coronary heart disease, can be largely prevented and managed through adoption of dietary and lifestyle changes such as engaging in physical activity and stopping smoking. The difficulty comes when advising patients on how to improve their diet as the prescribed dietary changes must be both effective and likely to be adopted permanently by the patient.

There are numerous food products available on the market that claim cholesterol-lowering properties. The key challenge is identifying those that are truly effective, nutritionally balanced, and easy to incorporate in everyday diet.

Potency of plant sterols

Plant sterols, naturally occurring in foods such as fruit, vegetables, seeds and nuts, reduce the absorption of cholesterol from the intestine by 30-40 percent. Their efficaciousness has been proven by over 140 scientific studies published in peer-reviewed journals. However, plant sterols are present in foods in small amounts only, making it difficult to benefit from their cholesterol-lowering properties through a regular diet alone. The International Atherosclerosis Society recommends a daily intake of 2 grams of plant sterols for cholesterol management[1] - an amount that can only be achieved by eating an equivalent of 150 apples, 425 tomatoes or 70 slices of wholemeal bread. Consuming foods enriched with plant sterols can thus prove an effective addition to the overall cholesterol-lowering diet.

SUPERIOR MINI-DRINK FORMULATION

- **2g of plant sterols clinically proven to lower cholesterol**
- **80mg fish Omega-3 EPA and DHA for a healthy heart**
- **Probiotic for healthy digestion**
- **Reduced sugar**
- **Only 52kcal/220kj per bottle**

Becel pro.activ mini-drink – superior formula

Becel pro.activ, a yoghurt mini-drink, contains the recommended 2g of plant sterols in each bottle. Clinical studies have shown that eating 2-2.5g of plant sterols a day can lead to a 10-15 percent reduction in LDL cholesterol in 2-3 weeks when moving to a healthy diet.[2] The cholesterol-lowering properties of Becel pro.activ mini-drink are proven in clinical studies, and are most effective when consumed with a meal.[3]

Apart from plant sterols, each bottle of Becel pro.activ mini-drink also contains 80mg of heart healthy Omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), and contains up to three times less sugar than most other mini-drinks available on the market.

1 International Atherosclerosis Society Executive Board. Harmonised Clinical Guidelines on Prevention of Atherosclerotic Vascular Disease. March 2003.

2 Katan MB, Grundy SM, Jones P, Law M, Miettinen T, Paoletti R; Stresa Workshop Participants. Efficacy and safety of plant stanols and sterols in the management of blood cholesterol levels. Mayo Clin Proc 2003 Aug; 78(8): 965–978. Review.

3 Doornbos AME, Meynen EM, Duchateau GSMJE, Knapp HCM, Trautwein EA. Intake occasion affects the serum cholesterol lowering of a plant sterol-enriched single dose yoghurt drink in mildly hypercholesterolemic subjects. Eur J Clin Nutr 2006; 60: 325–333.

Taking the pain out of osteoarthritis

Today's increasingly elderly population means that conditions associated with the ageing process, like osteoarthritis (OA), are becoming more prevalent. For patients with OA, self-help through a combination of lifestyle modifications and analgesia is fundamental to the successful management of the condition.

Osteoarthritis is the most common joint disorder, with 190 million people diagnosed worldwide.[1] Radiographic evidence of OA is practically universal in at least some joints in people aged over 60 years,[2] a significant burden and one that is set to increase dramatically in the near future.

Population studies predict that the proportion of people aged over 65 will increase to 800 million by 2025, over double the figure reported in 1997.[1] Already OA is the eighth most common cause of disability worldwide,[3] and a rise in the elderly population will increase the socio-economic burden of the condition on already stretched healthcare systems.

OA – the condition

OA is a joint disease characterised by the breakdown of cartilage. In normal joints, the synthesis and degradation of the cartilage matrix are in equilibrium. In OA, however, the turnover becomes poorly regulated.[4] The result is a loss of normal cartilage architecture. Although replacement cartilage is produced it is less resistant to wear.[5] Thus, the underlying bone is exposed to abnormal stress, leading to a proliferative response with manifestations such as hypertrophy, cyst formation and the development of osteophytes.

When the rich network of nerve endings near the joint is affected, this can result in pain and restricted movement, as well as muscle tension and fatigue. In some cases, synovial inflammation may cause swelling of the joint and prolonged morning stiffness. However, the contribution of inflammation to joint pain in OA is controversial[4] as the condition is not characterised by a systemic inflammatory process.[6] Where synovial inflammation is present, it is usually mild and localised to the affected joint,[7] unlike other types of arthritides, such as rheumatoid arthritis, ankylosing spondylitis and psoriatic arthropathy.

OA commonly affects the hands and weight-bearing joints, such as the knees and hips, as well as the feet and back.[8] Although changes in the joint structure are seen on an X-ray, this does not always correlate with symptoms, which affect around 10–20% of patients.[2] Diagnosis relies on clinical features, such as the pattern of joint involvement, presence of osteophytes, and the history and nature of the joint symptoms.[9]

Risk factors for OA

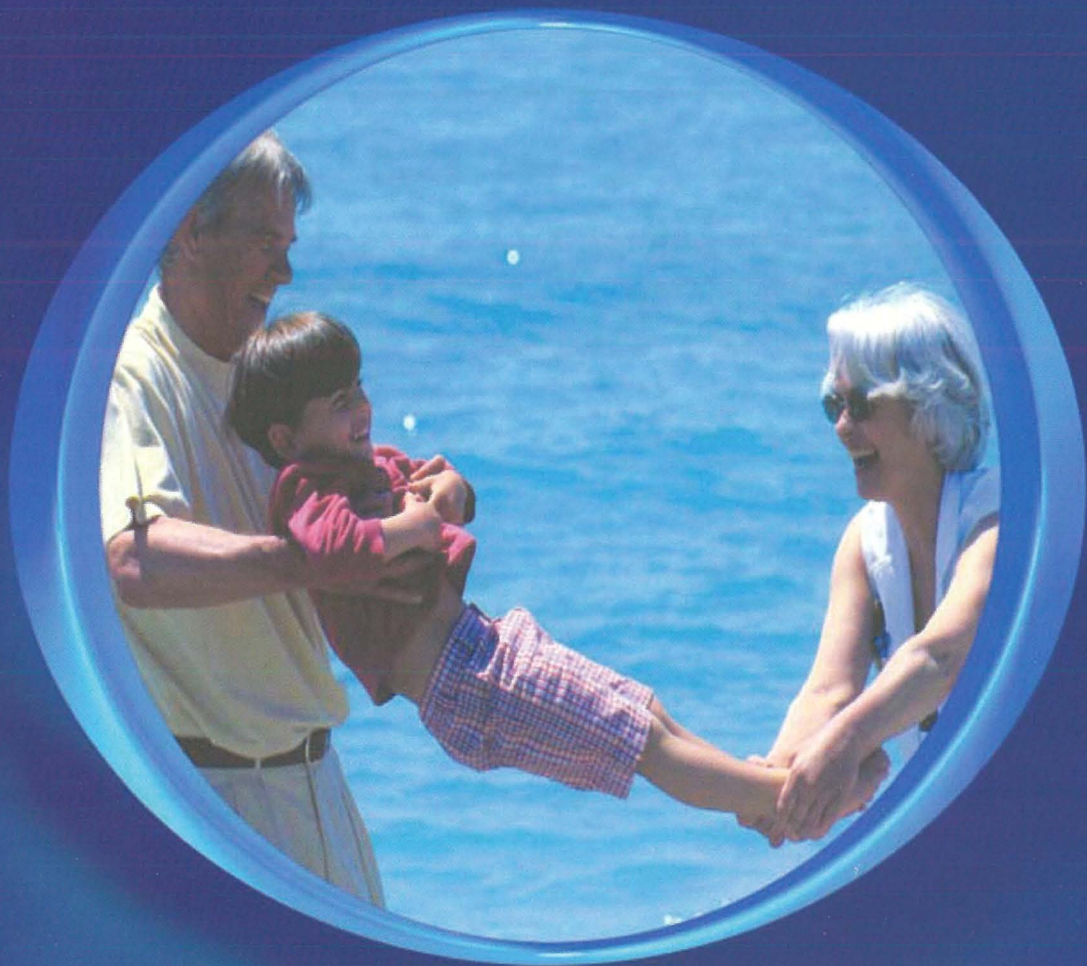
Although the exact cause of OA remains unknown, a number of factors have been identified which contribute to the onset of the condition. These include:

- age – prevalence of OA in all joints rises with increasing age[4]
- gender – women are at higher risk of developing OA than men, particularly after the menopause[4]
- obesity – being overweight increases the mechanical stress on weight-bearing joints, and has been strongly linked to OA of the knee and implicated in hip OA[4]
- joint injuries or 'wear and tear' – people with injuries to their joints, because of sports, accidents or work-related activities, may be at increased risk of developing OA[4]
- genetics – there appears to be a genetic component to OA:
  - early polyarticular OA is associated with mutations in a gene encoding a certain type of collagen[4]
  - however, it is unlikely that one gene alone fully explains the genetic role.[4]

References

1. World Health Organization. *The World Health Report 1998: Health in the 21st Century: A Vision for All.* Geneva: World Health Organization, 1998; 47.
2. Dieppe P, Chard J, Faulkner A, Lohmander S. Osteoarthritis. *Clin Evidence* 1999; 2: 437–448.
3. World Health Organization. *The Bone and Joint Decade Consensus Document.* Geneva: World Health Organization, 1998.
4. Creamer P, Hochberg MC. Osteoarthritis. *Lancet* 1997; 350: 503–508.
5. LaPrade RF, Swiontkowski MF. New horizons in the treatment of osteoarthritis of the knee. *JAMA* 1999; 281: 876–878.
6. Skeith KJ, Brocks DR. Pharmacokinetic optimisation of the treatment of osteoarthritis. *Clin Pharmacokinet* 1994; 26: 233–242.
7. American College of Rheumatology Subcommittee on Osteoarthritis Guidelines. Recommendations for the medical management of osteoarthritis of the hip and knee. *Arthritis Rheum* 2000; 43: 1905–1915.
8. Hutton CW. Osteoarthritis. In: *Oxford Textbook of Medicine.* 1998; 2975–2983.
9. Altman R, Asch E, Bloch D, *et al.* Development of criteria for the classification and reporting of osteoarthritis. Classification of osteoarthritis of the knee. Diagnostic and Therapeutic Criteria Committee of the American Rheumatism Association. *Arthritis Rheum* 1986; 29: 1039–1049.

Paracetamol is the initial-choice oral analgesic for mild-to-moderate Osteoarthritis (OA) pain[1, 2]



Paracetamol effectively relieves OA pain[6]

- For many patients, paracetamol provides comparable OA pain relief to traditional Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)[7] — even prescription dose ibuprofen[8] and naproxen[9]
- Even in inflammation, paracetamol offers comparable pain relief to anti-inflammatory doses of ibuprofen[10]

Recommended by arthritis experts around the world as first-line analgesic:

- The American College of Rheumatology[1]
- The European League Against Rheumatism[2]
- Joint Working Group of the British Society for Rheumatology and the Research Unit of the Royal College of Physicians[3]
- The North of England NSAID Guideline Development Group[4]
- The British National Formulary[5]

Panadol®

References:

1 American College of Rheumatology. Arthrit Rheum2000; 43: 1905–1915.
2 Pendleton A et al. Ann Rheum Dis2000; 59: 936–944.
3 Scott DL. Report of a joint working group of the British Society for Rheumatologyand the research unit of the Royal College of Physicians. J Royal Coll PhysiciansLon1993; 27: 391–396.
4 Eccles M et al. BMJ1998; 317: 526–530.
5 British National Formulary. Edition 41. 2001.
6 Amadio P et al. Curr Ther Res1983; 34: 59–66.
7 American College of Rheumatology. Arthrit Rheum2000; 43: 1905–1915.
8 Bradley JD et al. N Engl J Med1991; 325: 87–91.
9 Williams HJ et al. Arthrit Rheum1993; 36(9): 1196–1206.

gsk GlaxoSmithKline

Negligence and Malpractice

by **Pierre Mallia** *MD MPhil PhD FRCGP*
Director, Centre for Bioethics, Medical School

Negligence is a departure from a due standard of care.[1] Standards of care are set up by the profession not merely as a guideline to doctors, but as a minimum requirement. It is about proper management and also about patient rights. Continuing Medical Education programmes that do not aim to divulge what the standard of care is, may not be imparting to professionals what is expected from them. Although practices may vary before they become actual 'standards', some practices may also be abandoned, and those who continue to practice them may of course be guilty of malpractice.

However, doctors may hold different standards of care. This is often referred to as the Bolam[2] principle following a case where a GP was not found guilty for giving treatment which did not meet the standard which would have been expected from a specialist giving that same treatment. Of course this inherently also means that doctors may not go outside the boundaries of their practice into more specialised areas, unless there is absolutely no alternative. In life-saving circumstances a doctor may be exempt from not keeping state-of-the-art equipment at hand – everyone knows that a defibrillator is becoming standard practise in advanced CPR, but doctors are not expected to purchase such instruments.

Breaches of duty need not only consider deliberate acts but also unintentional ones and omissions as well as commissions

We need to distinguish between malpractice and negligence. Negligence is a legal term with a specific definition derived from Tort law. In essence, for health care professionals to be found negligent, four conditions[2] must apply:

1. The professional must have a duty to the patient
2. The professional must breach that duty
3. A harm must be caused
4. The harm must be a direct result of that breach of duty.

The fourth condition is the 'nexus' condition, which means that there must be a connection between the first two conditions and the third. A closer look at these conditions reveals that it is important, in assessing situations, to define the duties of the individuals. This becomes more complicated with our concepts of teamwork etc. But each individual must function properly – a chain is as strong as its weakest link, and sometimes that weak link must be rectified.

Harm defines *invasive* actions; injury, on the other hand can involve other issues besides harm – such as loss of work. The above implies that not all injury may be claimed as a result of the breach of duty; but this depends on interpretation of the facts and on the court.

An important consideration is that breaches of duty need not only consider deliberate acts but also unintentional ones and omissions as well as commissions. Thus, failing to impart proper informed consent as described in the previous two articles, makes one negligent and legally liable should harm be caused – such as a recognized complication of which the patient was not made aware of.

An unfortunate consequence of these adversarial systems is that it may encourage patients and doctors to see themselves as adversaries; and as illogical as it may sound, even though medical protection societies encourage doctors to remain silent once proceedings have started[3], admitting a prompt, sympathetic and truthful account at the beginning has been shown to be satisfactory to many patients, who feel the need not to be left in the dark, and perhaps actually decreased litigation. In the UK there are suggestions to impose a duty on health care professionals to give candid explanations when things go wrong.[3] Even if it is not law, such a suggestion takes indeed the higher moral ground.

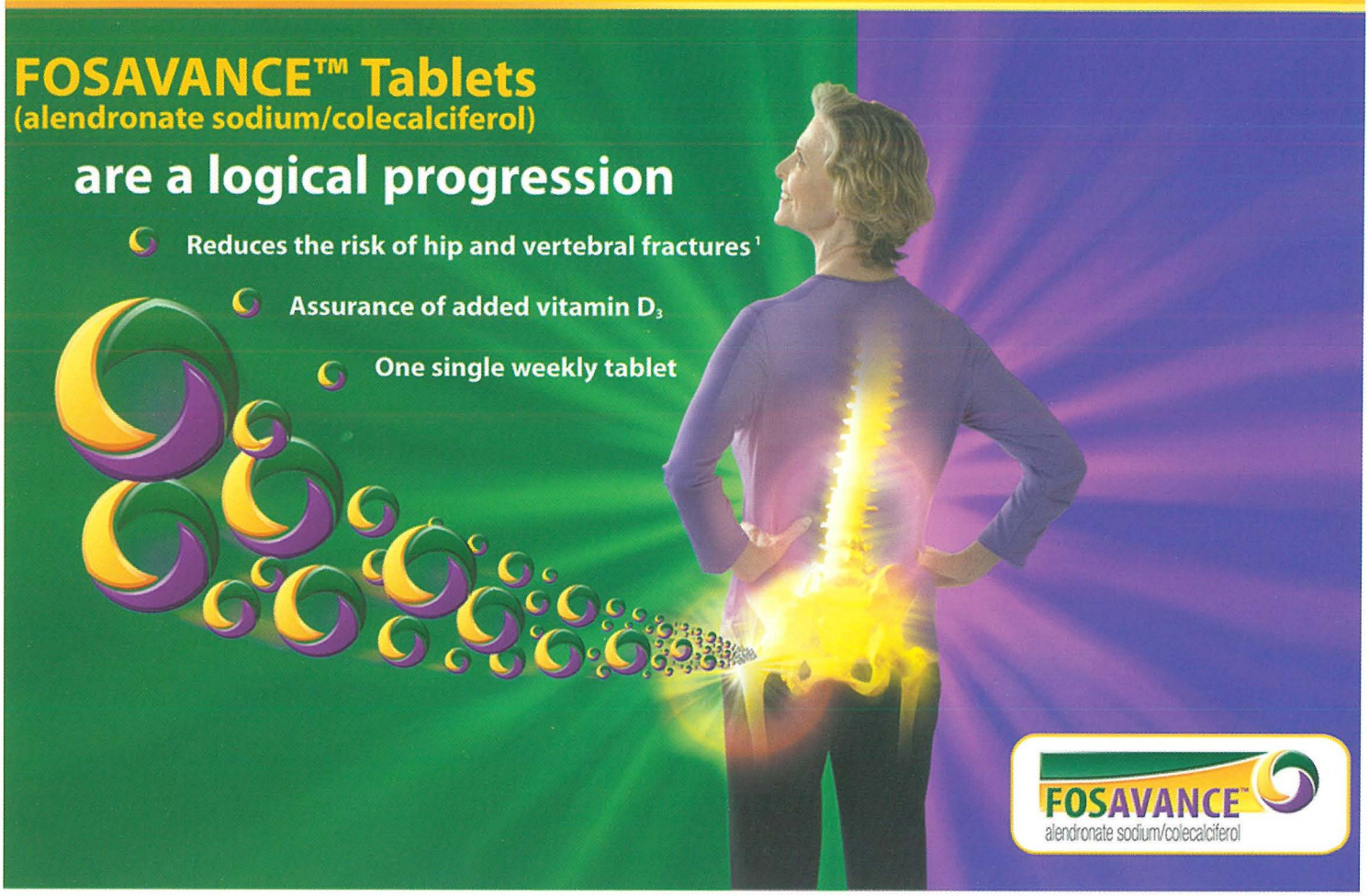
References

1. Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 4th ed. England: Oxford University Press, 1994: 194.

2. Baxter C, Brennan MG, ColdicottY, Moller M, Medical Ethics and law. England: PasTest, 2005: 46, 195.

3. Montgomery J. Health Care Law. 2nd ed. England: Oxford University Press, 191.

TREATING YOUR POST-MENOPAUSAL OSTEOPOROSIS PATIENTS



FOSAVANCE™ Tablets (70 mg Alendronic Acid as Alendronate Sodium Trihydrate and 70 micrograms [2,800 IU] Colecalciferol [vitamin D_3])

ABRIDGED PRODUCT INFORMATION

Refer to Summary of Product Characteristics before prescribing.

PRESENTATION

Capsule-shaped, white to off-white tablets marked with an outline of a bone image on one side, and '710' on the other, containing 70 mg alendronic acid as alendronate sodium trihydrate and 70 micrograms (2,800 IU) colecalciferol (vitamin D_3).

USES

Treatment of post-menopausal osteoporosis in patients at risk of vitamin D insufficiency. 'Fosavance' reduces the risk of vertebral and hip fractures.

DOSAGE AND ADMINISTRATION

The recommended dosage is one (70 mg/ 70 microgram) tablet **once weekly.**
Patients must be advised to follow the instructions below:
For adequate absorption of alendronate: Take at least 30 minutes before the first food, beverage, or medicinal product (including antacids, calcium supplements and vitamins) of the day with plain water only. Other beverages (including mineral water), food and some medicinal products are likely to reduce the absorption of alendronate.
The following instructions should be followed exactly in order to minimise the risk of oesophageal irritation and related reactions:

- Swallow 'Fosavance' only upon arising for the day with a full glass of water (not less than 200 ml or 7 fl.oz.).
- Do not chew the tablet or allow the tablet to dissolve in the mouth because of a potential for oropharyngeal ulceration.
- 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.

Patients should receive supplemental calcium if intake is inadequate. Additional supplementation with vitamin D should be considered on an individual basis taking into account vitamin D intake from vitamins and dietary supplements. Equivalence of 2,800 IU of vitamin D_3 weekly in 'Fosavance' to daily dosing of vitamin D 400 IU has not been studied. *Use in the elderly:* No dosage adjustment is necessary. *Use in renal impairment:* No dosage adjustment is necessary for patients where GFR is greater than 35 ml/min. Alendronate is not recommended for patients with renal impairment where GFR is <35 ml/min. *Use in children:* Not recommended.

CONTRA-INDICATIONS

Oesophageal abnormalities and other factors which delay oesophageal emptying, such as stricture or achalasia. Inability to stand or sit upright for at least 30 minutes. Hypersensitivity to alendronate or to any of the excipients. Hypocalcaemia.

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 erosions, 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 swallowing, 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, joint and/or 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 rechallenged. 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, as 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'. *Colecalciferol:* Monitor urine and serum calcium in patients with disease associated with unregulated overproduction of calcitriol (e.g. leukaemia, lymphoma, sarcoidosis) as vitamin D_3 may increase the magnitude of hypercalcaemia and/or hypercalciuria. Patients with malabsorption may not adequately absorb vitamin D_3. *Excipients:* Patients with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrase isomaltase 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 pregnancy and lactation:* alendronate has not been studied in pregnant or breast-feeding women and should not be given to them.

09-06 FSM.05.GB.62175.J

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 (≥1.0% and <10%) Gastro-intestinal:* abdominal pain, dyspepsia, constipation, diarrhoea, flatulence, oesophageal ulcer, dysphagia, abdominal distension, acid regurgitation. *Musculoskeletal:* musculoskeletal (bone, muscle or joint) pain. *Neurological:* headache. *Uncommon (≥0.1% and <1%) Gastro-intestinal:* nausea, melaena, vomiting, gastritis, oesophagitis, oesophageal erosions. *Skin:* rash, pruritus, erythema. *Rare (≥0.01% and <0.1%) Body 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, oropharyngeal ulceration, upper gastro-intestinal PUBs (perforation, ulcers, bleeding) (see 'Precautions') localised osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing. *Skin:* rash with photosensitivity. *Special senses:* uveitis, 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 NHS COST

'Fosavance' Tablets £22.80 for 4 tablets.

POM Date of review: September 2005

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

Marketing Authorisation Holder:
Merck Sharp & Dohme Limited
Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK

REFERENCES

1. Black DM, Thompson DE, Bauer DC et al. Fracture risk reduction with alendronate in women with osteoporosis : the Fracture Intervention Trial. *J Clin Endocrinol Metab* 2000;85(11):4118-4124.

MSD

Merck Sharp & Dohme Limited
Hertford Road, Hoddesdon, Hertfordshire EN11 9BU

Strengthening the Medical Professionals Network

In collaboration with Attard & Co., TheSYNAPSE is now organising Wine Education Events which are being held every month. During these relaxing evenings, Mr Marco Vella and Mr Simon Azzopardi from Attard & Co. enthusiastically share their knowledge on the deep culture of wine, always enticing guests to appreciate more the distinctiveness of the wine they drink. Anyone who wishes to join TheSYNAPSE in these highly interesting and pleasant events may send us an email at editor@thesynapse.net or contact us on telephone number 21453973 and we will send a formal invitation.

One of the aims of these evenings is to get together casually and reinforce further the knowledge sharing community that TheSYNAPSE has been building now for more than 10 years. In today's world, it has become so vital when medicine has become increasingly specialized and incessantly evolving.

One of TheSYNAPSE initiatives is this bi-monthly magazine which is broadly read within the local medical community. But TheSYNAPSE chiefly values the internet in this context. In fact its first launch was TheSYNAPSE Portal – http://www.thesynapse.net; its membership is continually growing and has become popular both locally and also overseas. This website contains up-to-date medical news released by reliable sources and is also complemented by useful informative articles contributed mainly by corporate network associates. In addition, other value added services are offered such as **e-news**, a weekly news update which is delivered to the members' email boxes every weekend,
e-info, an electronic distribution channel for circulating informative messages at the specific request of third parties and also another highly interactive service – **TheSYNAPSE e-QUIZ**.

TheSYNAPSE e-QUIZ – a fun and easy way to become better acquainted with the products and, possibly, also a *Winner!*

Nowadays, with such a busy life, it is becoming very difficult to appreciate in more depth the products available on the market. TheSYNAPSE has designed this amusing idea of promoting a product not by means of lengthy informative literature or through the usual ordinary means of advertising, both of which are in a way one-sided, but through the participation of an online quiz – TheSYNAPSE e-QUIZ.

This innovative concept is a relaxing way to obtain an insight of the publicised product whilst enjoying an intriguing challenge and why not, looking forward to see who will be the lucky winner!

For any type of support please contact us either by sending an email at mpl@thesynapse.net or through telephone number 21453973.

Student compiles English-Maltese Diction

by **Marika Azzopardi**

Eliza Camilleri

Fifth year Pharmacy University student Eliza Camilleri has touched upon one of the hottest issues concerning medicine and pharmacy in Malta today – the translation of English terms into Maltese, by proceeding to create an English-Maltese Dictionary of Medical and Pharmaceutical Terms for her final thesis.

Today the dictionary which is being offered in compact disc format, covers 5,400 terms which she translated after a work process that has taken up three years of intense study.

"This translation process is very important and many private companies are presently already working hard to translate their dossiers and product information packages. However they are facing many difficulties due to the fact that a Maltese dictionary related to this genre simply does not exist."

According to EMEA (European Agency for the Evaluation of Medicinal Products) guidelines, a translated term has to be understandable not only to the professional but, more importantly, to the layman, hence members of the general public.

The long process of seeing this freshly completed task through was immense, "I consulted many publications namely dictionaries by Aquilina, Serracino Inglott and books by Lanfranco and Gatt, apart from standard pharmacy reference material.

Winning with TheSYNAPSE

The winner of the Prevenar E-Quiz, drawn from the respondents who answered all questions correctly, is Dr. Tania Van Avendonk. Wyeth was pleased to present her with a multimedia remote controller and laser pointer.

Prevenar, a pneumoccal conjugate vaccine, is indicated for the active immunization of children under 5 years of age against invasive disease caused by *Streptococcus pneumoniae*. Prevenar confers immunity against the 7 most common serotypes of *Streptococcus pneumoniae* and elicits a T-cell dependent response. The routine immunization schedule for Prevenar is 2, 4 and 11 months of age. For additional information on usage in previously unvaccinated older infants and children, please see the prescribing information.

Dr Julian Mamo – winner of Terbisil E-Quiz

ary of Medical and Pharmaceutical Terms

I had to find existent terms, go back to Semitic origins or romantic roots and trace English loan words in order to fork out the proper Maltese word for each English term. 3,700 words out of the 5,400 translated were non-existent and depended on this thorough research. 1,938 words were elicited from various sources. In some instances I had to study the mechanism of each specific drug class in order to bring out a reasonable translation."

Her translations were also supported by a validation study to which contributed a number of Maltese nationals aged 18 – 82 from various parts of Malta, who were asked to provide their most familiar meaning to certain terms. Pharmacists were also consulted on the matter.

Eliza was greatly encouraged by Dr Stanley Farrugia Randon who reviewed her final work in thorough detail, by Prof Anthony Serracino Inglott who was her tutor for the thesis and Prof Lillian Azzopardi who suggested the title with him.

The dictionary which extends from the letter A to the letter E, had to reach a halt because of time restraints. "I am due to present this work as my final thesis and whilst I had originally only planned to work from the letter A through to the letter C, I found that as I went along, the work became easier. I got accustomed to the pattern of translation, so I extended my project further up to the letter E."

Asked whether she intends completing the dictionary through to a Z in the near future, Eliza explains that she does not plan to continue mainly because her studies have already extended five years and now she wishes to start working professionally in what she trained. Her work has now been passed on to another pharmacy student who will pick up from where she left.

By combining her love of the Maltese language with her passion for pharmacy Eliza is aware of a very simple fact, "I disappointed my secondary school Maltese teacher who had encouraged me to take up the study of the Maltese language seriously, as I went ahead and veered into pharmacy. But I believe I have today contributed much more to the Maltese language than had I simply furthered a career in the language."

For further information about the English-Maltese Dictionary of Medical and Pharmaceutical Terms, please call 99310884/21464551 or email: elizacamilleri@gmail.com

Invertebrates in the m
Part II – The I

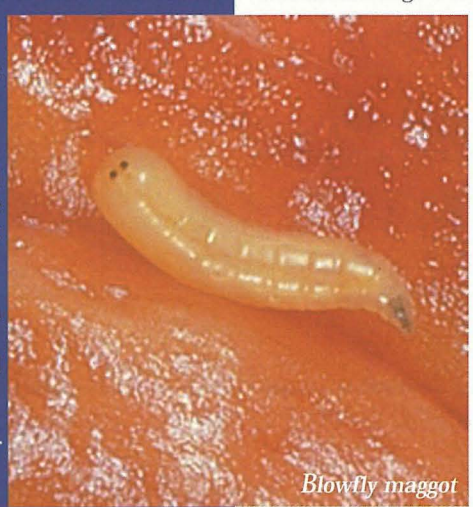
by **Charles Savona-Ventura** *MD DScMed FRCOG AccrCOG MRCPI*
Professor of Obstetrics & Gynaecology, Faculty of Medicine & Surgery, University of Malta

The invertebrates have generally been regarded as direct or indirect harbingers of disease conditions. Some species throughout history have however been used in lieu of surgical procedures.

The example par excellence is the leech which was introduced in medical practice to perform venesection aimed at restoring the body humors envisaged by the Galenic theory of disease. These invertebrate surgeons were considered as a more gentle method for the procedure. Their use for venesection has slowly decreased in the latter part of the 20th century, but the use of these animals has been resurrected in surgical practice for the biotherapeutic properties of their secretions.[1] Beside the Medicinal leeches, other insect species have been used as surgical assistants.

Phylum Arthropoda; Class: Insecta; Order: Diptera; Family: Calliphoridae
Bluebottle Fly – Calliphora vicina [Maltese – Zarzura]
Greenbottle Fly – Lucilia sericata [Maltese – Dehbija tal-Hmieg]

The primitive, carrion-breeding habit of the blowflies has been known and recorded for centuries. A very early reference can be found in the *Hortus Sanitatus* published at Mainz in 1491. The use of maggots to clean suppurating wounds was graphically demonstrated during the film 'Gladiator' when the protagonist played by Russell Crowe was healed of his battle wounds through the use of maggots. It was however at the turn of the 19th century that the beneficial role of maggots was noted. Napoleon's Surgeon in Chief, Baron Dominic Larrey reported that when maggots developed in battle injuries, they prevented the development of infection and accelerated healing. "*These insects, so far from being injurious to their wounds, promoted rather their cicatrization by cutting short the process of nature and causing the separation of cellular eschars which they devoured. These larvae are indeed greedy only after putrefying substances and never touched the parts endowed with life.*" There is no evidence, however, that Larrey deliberately introduced maggots into his patients' wounds. Similarly, during the American Civil War, a Confederate medical officer Joseph Jones noted the beneficial effects of wound myiasis commenting that "*I have frequently seen neglected wounds filled with maggots, as far as my experience extends, these worms only destroy dead tissues, and do not injure specifically the well parts. I have heard surgeons affirm that a gangrenous wound which has been thoroughly cleansed by maggots heals more rapidly than if it had been left to itself.*" During that same conflict, the Confederate surgeon J. Zacharias may have been the first western physician to intentionally introduce maggots into wounds for the purpose of debriding the wound, writing that "*During my service in the hospital in Danville, Virginia, I first used maggots to remove the decayed tissue in hospital gangrene and with eminent satisfaction. In a single day they would clean a wound much better than any agents we had at our command.... I am sure I saved many lives by their use, escaped septicaemia, and had rapid recoveries.*"


Blowfly maggot

The thought of intentionally introducing wriggling worms in gangrenous wounds rather than opt for a clean surgical debridement brings visions of medieval horror to doctors trained in a modern sterile hospital environment. Few of the doctors practicing in Malta today have experienced the surgical capabilities of fly maggots. I do however recollect one case of a maggot-performed amputation during the late 1970s. This occurred in a rather neglected geriatric female patient who had been admitted to the surgical ward with gangrene of the terminal part of one foot. When her home dressings were removed, the nurses were shocked to see a mass of wriggling maggot within the dead tissue of the foot. The Consultant Surgeon shocked everyone by deciding to utilize the maggots as his assistants rather than undertake surgical debridement in a medically-unstable individual. Within a few days the dead tissue had been completely removed by the insects and the dead bone remnants fell off, leaving a clean "surgical" healed plane. The patient recovered fully enabling discharge into a residential home.

The real founder of modern maggot therapy or wound myiasis was William Baer (1872-1931), Clinical Professor of Orthopaedic Surgery at the Johns Hopkins School of Medicine in Maryland. He first experienced the therapeutic potentials of maggot surgeons during the First World War. In 1928, he set out to experiment with the use of maggots in the treatment of intractable osteomyelitis in children. Repeated successes encouraged him to use the technique more widely, until several of his patients developed tetanus. In response to this complication, Baer set out to develop a suitable sterilizing process of the larvae and the eggs. Other workers enthusiastically took up this work and in the absence of any equally effective alternative for the treatment of osteomyelitis or infected soft tissue injuries, the use of maggots spread quickly during the 1930's. These developments however coincided with the development of the antibiotic era which gave an effective medical therapeutic option. By the mid-1940s, the enthusiasm for maggot therapy virtually ceased and maggot therapy was only used sporadically.

ıedical service of man:
ınsect Surgeons

A resurgence of interest in maggot therapy recurred in the late 1980's when Robert Sherman, an entomologist and physician in Los Angeles, noticed healthy infection-free tissue in a leg wound crawling with 'worms'. He established an insectary in California to breed maggots for clinical use, and carried out the first controlled study showing that maggot therapy significantly increases the rate of healing of chronic pressure sores – at much lower cost than the usual regimen of repeated surgery and antibiotic treatments. The results of these preliminary investigations indicated that maggot therapy offered several advantages over other wound treatments currently employed. Maggot therapy has since grown in popularity and has met with success in Europe. It has recently been used in Germany, Hungary, Sweden, Belgium and the Ukraine. In 1996, the International Biotherapy Society was founded to investigate and develop the use of living organisms, or their products, in tissue repair, and the first in a series of international conferences on maggot therapy and other similar topics also took place in that year.[2,3]

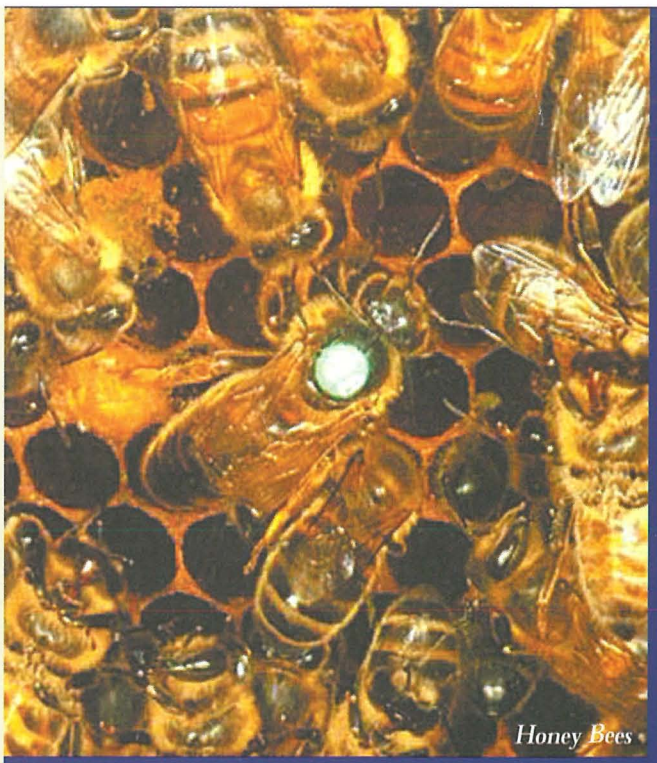
Order: Hymenoptera; Family: Formicidae
Carpenter ant – Camponotus barbaricus [Maltese: Zokkrin]

Other members of the insect family have also been utilized in surgical practice since ancient times. Hindu writings dating to 1000 B.C. describe the use of ant mandibles for closing incisions and wounds. The insect's head is positioned so that the two parts of the mandible are situated on either side of the cut. They are then allowed to bite thus holding the wound shut like staple-stitches. The ants' bodies are then pulled off, leaving only the heads and jaws locked in place until the wound heals. Ant stitching is reportedly still used by primitive societies in Brazil today. In Algeria and Turkey, beetle mandibles were the stitches of choice.

Carpenter ant

Order: Hymenoptera; Family: Apidae
Honey Bee – Apis mellifera [Maltese: Nahla ta' l-Ghasel]

Honey has long been recognized as a sweetening food product and an 'over-the-counter' medicine being utilized not only to make certain medicines palatable but also to sooth chest infections. It has also found use as a wound dressing, this medicinal function being described by the ancient Egyptians.



Honey Bees

Its role in controlling bacterial invasion and growth is based on its low pH value of 3.9, its hyperosmolarity and the presence of inhibine or glucose oxidase which liberates peroxide acting as a strong antibacterial agent. Apitherapy, i.e. the medical use of honeybee products, is also gaining momentum. Anecdotal claims from the beekeeping community have suggested that bee-venom has a therapeutic value for joint inflammatory conditions. Bee-venom can be injected artificially via a syringe or simply by allowing live bees do the stinging. Bee-venom contains dozens of active chemical substances; some of which are known to have analgesic and anti-inflammatory properties. Bee-venom has been said to be useful for the management of migraine headaches and chronic pain. Bee-stings have also been reported to ease the symptoms of arthritis, bursitis and rheumatism. The sting regimen for arthritis includes several stings per treatment performed two to three times per week for a period of up to three months. □

References

1. Savona-Ventura C. Invertebrates in the medical service of man: Part 1 – The Biotherapeutic Worms. *TheSynapse*, January 2007.

2. Shinkman RR. Worms and squirms. Maggots, leeches are making a comeback in modern medicine. *Modern Healthcare* 2000; 30(43):54-5

3. Maggot therapy: Website created by RA. Sherman, January 1996, *http://www.ucihs.uci.edu/com/pathology/sherman/cases.htm* [accessed March 2006].

Human Papillomavirus (HPV)

What is HPV?

- Human papillomavirus (HPV) is a common virus.[1]
- There are more than 100 types of HPV, most of which are relatively harmless,[2] do not cause any noticeable symptoms and will go away on their own.[3]
  - Of these, about 30 infect the genital areas of women and men.[4]

How common is genital HPV infection and who gets it?

- Approximately 630 million people are infected with HPV worldwide[5]
- At least half of all sexually active women and men acquire genital HPV infection at some point in their lives.[6]
  - A significant majority of women – 80 percent – will become infected by age 50.[7]
  - HPV infection is most common among young adults between the ages of 18 and 28.[8]
- Most HPV infections have no signs or symptoms, and the virus can be transmitted even when no symptoms (such as warts or other visible signs) are present. Centers for Disease Control and Prevention.[9]

What impact can HPV infection have?

- Most HPV infections clear on their own in 1-2 years through the body's natural immune response.[10]
- Infection with "high-risk" types of HPV – types 16, 18, 31 and 45, among others – if persistent, can lead to cervical cancer and other cancers of the genital area.[11]
  - HPV 16 and 18 account for an estimated 70 percent of all cervical cancers.[12]
- "Low-risk" HPV types can cause the formation of genital warts, fleshy, non-cancerous growths that appear on and around the genitals.[13]
  - HPV types 6 and 11 are responsible for 90 percent of all genital warts cases.[14]
  - In rare cases, transmission of HPV types 6 or 11 from their mothers can cause infants to develop recurrent respiratory papillomatosis (RRP),[15] a disease in which benign lesions in the respiratory tract can result in hoarseness, and in some situations, difficulty breathing.[16]
- Both high- and low-risk HPV types can cause cervical lesions and abnormal Pap smears[17] (the test used to detect cancer and other cellular changes in the cervix).[18]

How does HPV progress to cancer?

Infection with HPV will typically clear, but some infections with high-risk HPV types may ultimately lead to cervical cancer. Cervical lesions are due to abnormal cervical cells, known as cervical intraepithelial neoplasia (CIN). Following initial HPV infection, the course of progression to cervical cancer depends on the type of HPV.

- Low-risk HPV types (such as HPV 6 or 11) have a negligible risk of progressing but may persist.[19] Overall, the majority of HPV infections spontaneously clear within the first 24 months[20]
- High-risk types (such as types I IPV 16 and 18) are often associated with CIN 2 or higher lesions. Although CIN caused by HPV infection often clears without treatment, the likelihood of progression to invasive cancer is greater in more severe grades (CIN 2/3).
- CIN2/3 – moderate and severe dysplasia, respectively (high grade cervical lesions or pre cancerous lesions).
- CIN1 – mild dysplasia, includes anogenital warts[21]

How is HPV diagnosed?

- Pap tests, which screen for abnormalities of the cervix, often identify abnormalities caused by HPV.[22]
  - Because Pap tests do not screen directly for HPV, results cannot definitively confirm that infection with HPV does or does not exist.[23]
- For women over 30, a recently developed, molecular test can identify infection with HPV more definitively and is especially useful in conjunction with Pap test results which reveal minor abnormalities that may be due to HPV infection.[24]

How is HPV infection treated?

- Currently, there are no available anti-viral medications to treat HPV infection.[25]
- There are a variety of treatments for HPV-related diseases – genital warts, pre-cancerous lesions and cervical cancer.[26]

How can HPV infection be prevented?

- A person can reduce his or her risk of infection by staying in a long-term, mutually monogamous relationship with an uninfected partner or limiting the number of sexual partners.[27]
- If used correctly, condoms can help reduce the risk of HPV infection. However, the level of protection from HPV infection with condom use has not yet been determined.[28]
- Keep in mind that HPV often has no symptoms or signs,[29] so it is difficult to know if a person is infected.[30] The only 100 percent effective method for preventing HPV infection is to refrain from any sexual/genital contact with someone who has the virus.[31]
- Women should talk to their healthcare providers about having regular Pap screening tests, and discuss results with them.

References

1. Stevens LM, Lynm C, Glass RM. Papillomavirus. *JAMA*. May 8, 2002. 287(18):2452.
2. Human Papilloma viruses and Cancer: Questions and Answers. Cancer Facts. National Cancer Institute Date reviewed: 12/01/2004. Available at http://cis.nci.nih.gov/fact/3_20.htm. Accessed January 2005.
3. American Social Health Association, National HPV & Cervical Cancer Prevention Resource Center, HPV Myths and Misconceptions. Available at http://www.ashastd.org/hpvccrc/hpvmyth.html.
4. Centers for Disease Control and Prevention. CDC Fact Sheet. Genital HPV Infection. Content Reviewed: May 2004. Technical Update: December 2, 2004. Centers for Disease Control Web site. Available at: http://www.cdc.gov/std/HPV/hpv.pdf. Accessed January 2005
5. World Health Organisation; 2001. Available at: http://www.who.int/vaccines/en/hpvrd/shtml. Accessed July 12, 2004.
6. Centers for Disease Control and Prevention. CDC Fact Sheet. Genital HPV Infection. Content Reviewed: May 2004. Technical Update: December 2, 2004. Centers for Disease Control Web site. Available at: http://www.cdc.gov/std/HPV/hpv.pdf. Accessed January 2005
7. Centers for Disease Control and Prevention. CDC Fact Sheet. Genital HPV Infection. Content Reviewed: May 2004. Technical Update: December 2, 2004. Centers for Disease Control Web site. Available at: http://www.cdc.gov/std/HPV/hpv.pdf. Accessed January 2005
8. Koutsky L. Epidemiology of Genital Human Papillomavirus Infection. *Am J Med* 1997;102:3-8
9. Centers for Disease Control and Prevention. CDC Fact Sheet. Genital HPV Infection. Content Reviewed: May 2004. Technical Update: December 2, 2004. Centers for Disease Control Web site. Available at: http://www.cdc.gov/std/HPV/hpv.pdf. Accessed January 2005.
10. Centers for Disease Control and Prevention. CDC Fact Sheet. Genital HPV Infection. Content Reviewed: May 2004. Technical Update: December 2, 2004. Centers for Disease Control Web site. Available at: http://www.cdc.gov/std/HPV/hpv.pdf. Accessed January 2005
11. Mu–oz N, Bosch FX, de Sanjosé S, et al. Epidemiologic classification of human papillomavirus types associated with cervical cancer. *N Engl J Med*. 2003;348:518–527
12. Mu–oz N, Bosch FX, de Sanjosé S, et al. Epidemiologic classification of human papillomavirus types associated with cervical cancer. *N Engl J Med*. 2003;348:518–527.
13. Human Papilloma viruses and Cancer: Questions and Answers. Cancer Facts. National Cancer Institute Date reviewed: 12/01/2004. Available at http://cis.nci.nih.gov/fact/3_20.htm. Accessed January 2005.
14. International Journal of STD & AIDS 2001, European Guidelines for the management of anogenital warts, G. von Krogh
15. The Recurrent Respiratory Papillomatosis Foundation, *What is RRP?* Available at http://www.rrpf.org/whatisRRP.html.
16. The Recurrent Respiratory Papillomatosis Foundation, *What is RRP?* Available at http://www.rrpf.org/whatisRRP.html.
17. Centers for Disease Control & Prevention. Prevention of Genital HPV Infection and Sequelae: Report of an External Consultants' Meeting. Available at http://www.cdc.gov/nchstp/dstd/Reports_Publications/99HPVReport.htm.
18. Centers for Disease Control and Prevention. Highlights in Minority Health, January 2005. Last updated January 2005. Available at http://www.cdc.gov/omh/Highlights/2005/HJan05.htm. Accessed June 2005.
19. Pinto AP, Crum CP. Natural history of cervical neoplasia: Defining progression and its consequence. *Clin Obstet Gynecol*. 2000;43:352–362.
20. Ho GYF, Bierman R, Beardsley L, Chang CJ, Burk RD. Natural history of cervicovaginal papillomavirus infection in young women. *N Engl J Med*. 1998;338:423–428.
21. Bonnez W. Papillomavirus. In: Richman DD, Whitley RJ, Hayden FJ, eds. *Clinical Virology*. 2nd ed. Washington, DC: American Society for Microbiology Press; 2002: 569–612. make the page numbers near 2002
22. Centers for Disease Control, Office of Minority Health, Highlights in Minority Health, January 2005. Available at http://www.cdc.gov/omh/highlights/2005/hjan05.htm.
23. American Society for Colposcopy and Cervical Pathology. Medical FAQs about Diagnosing HPV. 2001-2005. Available at http://cme.asccp.org/faq/diagHPV.cfm. Accessed July 21, 2005.
24. Apgar B, Brotzman G. HPV Tesing in the Evaluation of the Minimally Abnormal Papanicolaou Smear. *American Family Physician*. May 15, 1999; 59(10).
25. Papillomavirus: Clinical Virology, Churchill Livingston: 2002:557-596, D. Richman, R. Whitley & F. Hayden.
26. Papillomavirus: Clinical Virology, Churchill Livingston: 2002:557-596, D. Richman, R. Whitley & F. Hayden.
27. Centers for Disease Control and Prevention. CDC Fact Sheet. Genital HPV Infection. Content Reviewed: May 2004. Technical Update: December 2, 2004. Centers for Disease Control Web site. Available at: http://www.cdc.gov/std/HPV/hpv.pdf. Accessed January 2005
28. Centers for Disease Control and Prevention. CDC Fact Sheet. Genital HPV Infection. Content Reviewed: May 2004. Technical Update: December 2, 2004. Centers for Disease Control Web site. Available at: http://www.cdc.gov/std/I IPV/hpv.pdf. Accessed January 2005
29. Maw RD, Reitano M, Roy M. An international survey of patients with genital warts: Perceptions regarding treatment and impact on lifestyle. *Int J STD AIDS*. 1998;9:571–578.
30. Centers for Disease Control and Prevention. CDC Fact Sheet. Genital HPV Infection. Content Reviewed: May 2004. Technical Update: December 2, 2004. Centers for Disease Control Web site. Available at: http://www.cdc.gov/std/HPV/hpv.pdf. Accessed January 2005
31. Centers for Disease Control and Prevention. CDC Fact Sheet. Genital HPV Infection. Content Reviewed: May 2004. Technical Update: December 2, 2004. Centers for Disease Control Web site. Available at: http://www.cdc.gov/std/HPV/hpv.pdf. Accessed January 2005

Announcing a new era in vaccination ...

SILGARD®

The one and only quadrivalent vaccine that protects against

CERVICAL CANCER	100%
CERVICAL DYSPLASIA	95%
GENITAL WARTS	99%

caused by Human Papillomavirus Types 6, 11, 16, and 18.

SILGARD® is a vaccine for the prevention of high-grade cervical dysplasia (CIN2/3), cervical carcinoma, high-grade vulvar dysplastic lesions (VIN 2/3), and external genital warts causally related to Human Papillomavirus (HPV) types 6,11,16,18. The indication is based on the demonstration of efficacy of SILGARD® in adult females 16 to 26 years of age and on demonstration of immunogenicity of SILGARD® in 9- to 15-year old children and adolescents.

As with any vaccine, vaccination with SILGARD® may not result in protection in all vaccine recipients. The vaccine is therefore not indicated for treatment of cervical cancer, high-grade cervical, vulval and vaginal dysplastic lesions or genital warts

Now is the time to vaccinate girls and young women 9 to 26 years of age

ABRIDGED PRESCRIBING INFORMATION: SILGARD®(Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)). Refer to Summary of Product Characteristics for full product information. **Presentation:** Silgard is supplied as a single dose pre-filled syringe containing 0.5 ml of suspension. Each dose of the quadrivalent vaccine contains highly purified virus-like particles (VLPs) of the major capsid L1 protein of Human Papillomavirus (HPV). These are type 6 (20 Ig), type 11 (40 Ig), type 16 (40 Ig) and type 18 (20 Ig). **Indications:** Silgard is a vaccine for the prevention of high-grade cervical dysplasia (CIN 2/3), cervical carcinoma, high-grade vulvar dysplastic lesions (VIN 2/3), and external genital warts (condyloma acuminata) causally related to Human Papillomavirus (HPV) types 6, 11, 16 and 18. The indication is based on the demonstration of efficacy of Silgard in adult females 16 to 26 years of age and on the demonstration of immunogenicity of Silgard in 9- to 15-year old children and adolescents. Protective efficacy has not been evaluated in males. The use of Silgard should be in accordance with official recommendations. **Dosage and administration:** The primary vaccination series consists of 3 separate 0 5 ml doses administered according to the following schedule: 0, 2, 6 months If an alternate vaccination schedule is necessary, the second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period.The need for a booster dose has not been established. **Paediatric population:** Silgard is not recommended for use in children below 9 years of age due to insufficient data on immunogenicity, safety and efficacy. The vaccine should be administered by intramuscular injection. The preferred site is the deltoid area of the upper arm or in the higher anterolateral area of the thigh.Silgard must not be injected intravascularly. Subcutaneous and intradermal administration have not been studied, and therefore are not recommended. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of Silgard should not receive further doses of Silgard. Administration of Silgard should be postponed in subjects suffering from an acute severe febrile illness. However, the presence of a minor infection, such as a mild upper respiratory tract infection or low-grade fever, is not a contraindication for immunisation. **Warnings and precautions:** As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine.As with any vaccine, vaccination with Silgard may not result in protection in all vaccine recipients.Also, Silgard will only protect against diseases that are caused by HPV types 6, 11, 16 and 18. Therefore, appropriate precautions against sexually transmitted diseases should continue to be used.Silgard has not been shown to have a therapeutic effect. The vaccine is therefore not indicated for treatment of cervical cancer, high-grade cervical, vulvar and vaginal dysplastic lesions or genital warts. It is also not intended to prevent progression of other established HPV related lesions. Vaccination is not a substitute for routine cervical screening. Since no vaccine is 100% effective and Silgard will not provide protection against non vaccine HPV types, or against existing HPV infections, routine cervical screening remains critically important and should follow local recommendations. There are no data on the use of Silgard in subjects with impaired immune responsiveness. Individuals with impaired immune responsiveness, whether due to the use of potent immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may not respond to the vaccine.This vaccine should be given with caution to individuals with thrombocytopaenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. The duration of protection is currently unknown. Sustained protective efficacy has been observed for 4.5 years after completion of the 3-dose series. Longer term follow-up studies are ongoing The data on Silgard administered during pregnancy did not indicate any safety signal. However, these data are insufficient to recommend use of Silgard during pregnancy. Vaccination should, therefore, be postponed until after completion of pregnancy. Silgard can be given to breastfeeding women. **Undesirable effects:** Very common: pyrexia and at the injection site: erythema, pain, swelling. Common: at the injection site: bleeding, pruritus. In addition, in clinical trials adverse reactions that were judged to be vaccine- or placebo-related by the study investigator were observed at frequencies lower than 1%: rare: urticaria and very rare: bronchospasm.
Package quantities: Single pack containing one 0.5 millilitre dose pre-filled syringe with a needle guard and two needles.
Marketing authorisation holder: Merck Sharp & Dohme Ltd, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom.
Marketing authorisation number: EU/1/06/358/015. **Legal category:** POM. **Date of last revision of the text :** September 2006.

Before administering Silgard®, please read the Physician Circular.

SILGARD®
[Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine]

SILGARD® is a registered trademark of Merck & Co., Inc., Whitehouse Station, NJ, USA.

Today, you can do more

MSD

06-2007-GRD-2006-MEA-(CY-MA)-1108-J

Imaging Oesophageal Cancer

continued from page 2

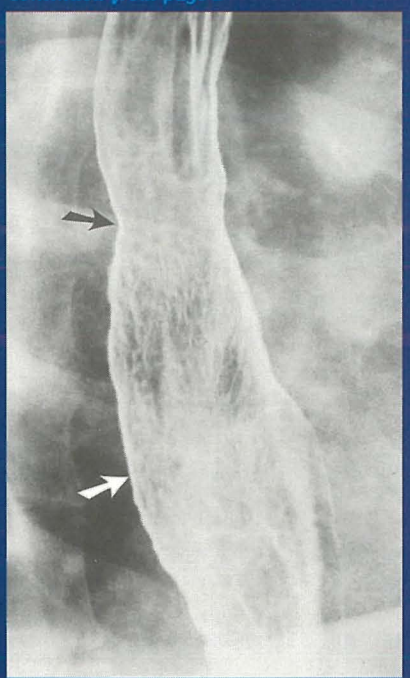


Figure 6. *Barrett's esophagus with a midesophageal stricture (black arrow) and a reticular mucosal pattern (white arrow) thought to result from intestinal metaplasia in Barrett mucosa.*

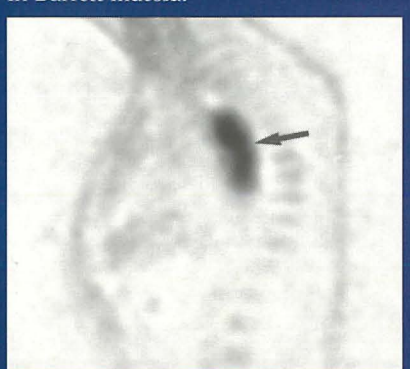


Figure 7. *PET-FDG scan showing a proximal oesophageal squamous cell carcinoma.*

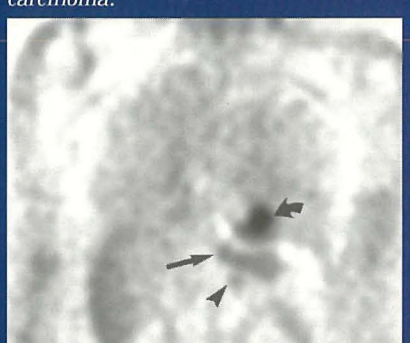


Figure 8. *Coronal FDG PET showing primary adenocarcinoma of the gastroesophageal junction (straight arrow), a left-sided gastric lymph node (arrowhead) and normal uptake in the left ventricle (curved arrow).*

Because Barrett esophagus is a premalignant condition associated with an increased risk of developing oesophageal cancer, many investigators advocate endoscopic surveillance of patients with known Barrett esophagus to detect dysplastic or early carcinomatous changes before the development of overt carcinoma (Figure 6).

Spiral Computed Tomography (CT) determines the extent of oesophageal cancer based on morphologic features such as direct infiltration of adjacent structures and on the size of mediastinal and coeliac lymph nodes. Nodes measuring 10mm or larger are considered malignant while smaller ones are deemed reactive, however this threshold is only based on statistical analyses and consequently smaller nodes may contain metastases and larger ones may be reactive. CT can also detect metastases to other structures such as the lungs, liver and bone.

Most malignant tumours metabolise glucose at a much higher rate than normal tissue; as a result, there is an increased accumulation of the glucose analog 2-[fluorine-18]fluoro-2-deoxy-d-glucose (FDG) in malignant tissue. Positron emission tomography (PET) provides diagnostic information based on this increased FDG uptake and may demonstrate early-stage disease before any structural abnormality is evident. Studies have shown that 90% of oesophageal cancers demonstrate avid FDG uptake (Figure 7), while normal or inflamed gastric mucosa may demonstrate significant FDG uptake and may be difficult to differentiate from tumors. Therefore PET-FDG is not ideal for the detection of the primary tumour in oesophageal cancer due to lack of specificity and the financial expense of the test. Furthermore, FDG PET is not helpful in detecting local invasion by the primary tumor or involved local lymph nodes due to its limited intrinsic spatial resolution, which is approximately 5 mm (Figure 8).

The major advantage of FDG PET over anatomic imaging modalities is its ability to detect distant metastases. The limited spatial resolution of FDG PET is not a problem with metastases that are distant from the primary tumour and from sites of normal increased uptake. Metastases to the liver, lungs, and skeleton can readily be identified at FDG PET (Figure 9). Involvement of the supraclavicular, cervical, and celiac nodes by oesophageal cancer is

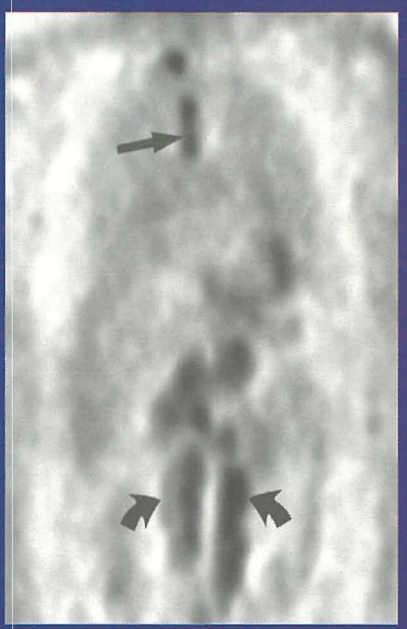


Figure 9. *Coronal FDG PET shows nodal metastases in the paratracheal region (straight arrow) and extensive retroperitoneal involvement (curved arrows) from adenocarcinoma of the gastroesophageal junction.*

considered distant metastasis (M1) rather than nodal metastasis (N1) and precludes curative surgery; FDG PET can also detect disease at these sites. Thus an FDG PET covering the whole body (skull base to pelvis) can improve the ability to classify disease as either resectable or unresectable based on the presence of distant metastases. CT or magnetic resonance (MR) imaging may at times be unable to distinguish postoperative scar from tumor recurrence. FDG PET may be useful in this setting and for monitoring response to radiotherapy or chemotherapy.

In summary, oesophageal cancer is usually detected by oesophagography and oesophagoscopy. Accurate staging of oesophageal cancer is crucial for therapeutic planning and is best done with Spiral CT, which can assess resectibility and can provide a baseline study to assess subsequent response to therapy. FDG PET is useful as an adjunct to Spiral CT for detecting distant metastatic disease and for distinguishing scar from recurrent tumour when CT findings are equivocal.

Dr Pierre Vassallo can be reached at the DaVinci Hospital on 21 491 200 or by email on pvassallo@davincihospital.com.mt

Update on Avian Influenza

by **Tanya Melillo Fenech** *MD MSc*
Principal Medical Officer at Disease Surveillance Unit, Department of Public Health

The cumulative number of cases is 274 and the deaths are 167. Since the beginning of the year there have been 11 confirmed human cases (in Indonesia, Nigeria and Egypt) of which 9 have dead.

The Food and Agriculture Organization of the United Nations expressed concern about new flare-ups of avian influenza since the beginning of this year in China, Egypt, Indonesia, Japan, Vietnam, Nigeria, South Korea, Thailand, Hungary, UK, Russia and Afghanistan but stressed that the number of outbreaks in the first weeks of 2007 has been significantly lower than the epidemic waves of 2006. The United Nations agency urged countries to remain vigilant and cooperate fully with international organizations.

Latest on H5N1 virus

Writing in the journal *Nature*, published in January 2007, a group of international scientists revealed the critical clue of how the 1918 influenza virus killed so quickly and efficiently. They showed that the 1918 virus was indeed different from all the other viruses. The team was able to show that the 1918 virus prompted a deadly respiratory infection that echoed historical accounts of how the disease claimed its victims. They showed that infection with the virus prompted an immune response that seemed to derail the body's typical reaction to viral infection and instead unleashes an attack by the immune system on the lungs. As immune cells attack the respiratory system, the lungs fill with fluid and victims, in essence, drown.

The **same excessive immune reaction** is characteristic of the deadly complications of H5N1 avian influenza, the strain of bird flu present in Asia. However, the H5N1 avian influenza has not yet shown a capacity to spread easily among people.

Knowing that the virus does something during the early stages of infection to trigger such a devastating immune response may provide biomedical researchers with clues about how to intervene and stop or mitigate the potentially lethal effects of the virus.

Latest on Antiviruses

Amantadine resistance

Published recently in the *New England Journal of Medicine*, a study has shown that there has been a dramatic increase in resistance to amantadine by 70-90% in communities in Asia and North America on patients who have never been previously treated with amantadine.

Latest update in Research

Recent research done by scientists on mice at St. Jude Children's Research Hospital in Memphis, Tennessee is suggesting that it is possible that some people previously infected with or vaccinated against influenza may have slight protection from H5N1. It is not protection from infection but enough immunity is available to keep the new infection from being deadly.

There are hundreds of 'H' and 'N' designations. The 'H' referes to haemagglutinin, the protein that the flu virus uses to get into cells and the 'N' refers to neuraminidase which is used to get back out of infected cells and spread to others.The H1N1 has been circulating since the 1918 pandemic and a descendant of H1N1 ciculates today and is part of the seasonal flu vaccine.

The scientists concluded that having some immunity to N1 might protect people from the worst effects of H5N1. Antibodies to the human version of N1 do cross-react to some extent with the H5N1.

Victor Camilleri ... a p

by Marika Azzopardi

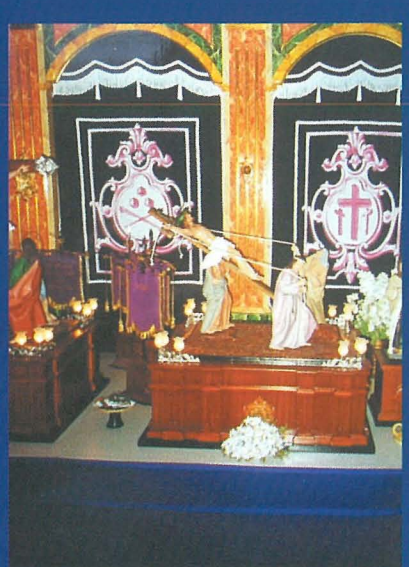
Victor Camilleri is well known in Zurrieq and its environs as an established family doctor with a busy practice. However, not everybody knows that he is actually a Gozitan hailing from Rabat, whose wife brought him to Zurrieq for keeps, and whilst he keenly misses his native island, he does enjoy fishing in locations that allow him a glimpse of its shores, namely Marfa and Cirkewwa

But certainly, when Good Friday approaches, Gozo is put slightly aside as Dr Camilleri's workload doubles dramatically. This is when a good number of village folk and not only, make it a point to visit his annual exhibition of statues depicting Christ's Passion through the Stages of the Cross.

"It all started quite a considerable number of years ago, through a vow I made. Way back in 1979, when I first visited Zurrieq, I was invited to see the village feast. I was dismayed to experience a lot of negativity, fighting and underhanded behaviour, which did not do justice to the people of this village. I swore that I would do something to unite all the folks of Zurrieq together."

At the time it was just a wish that was kindled in his heart. The wish turned into a firm idea that developed in 1997 when he visited the Good Friday procession of Cospicua. That was to be the last Good Friday procession he attended, as his decision to create a Good Friday exhibition took shape there and then.

"As a young boy I often participated



in Good Friday processions in Gozo. But this was something different I had in mind."

Together with a close friend, Alfred Grima, he set about getting things organized. He designed two sets of statues to be executed in clay, whilst Grima designed one set for the wax medium. These were made to their specifications by two expert statue makers – Lino Fardell from Zejtun who made the clay statues and Luigi Magri from Siggiewi who made the wax statues.

The exhibition was to be set up in Dr Camilleri's basement garage – a good 100ft by 21ft of space that would, ultimately contain an exhibition of 260 statues.

"The statues are in three different sizes, the smallest being one foot high and the highest nearly two feet high. There are 22 large statues (vari), then there are 18 biblical personages and there is the Holy Sepulchre."

Initially the statues were displayed against a plain black background. But each year saw marked innovations, so that the statues today reside in a fully fledged church-like ambience – a veritable miniature church.

"First we designed and had wooden framework rigged up to set off the statues, as they would be in a typical church. The following year, I decided that I wanted traditional black damask for a background. This I could not find in Malta, so I ordered it from the States."

The damask made a strident impact, which was intensified when the artistic designs of Jeremy Cachia were incorporated at a following stage of the decoration proceedings.

It was then decided that the interior of this impromptu miniature church would need ceiling paintings. The wooden framework extended onto the walls and ceiling, is today embellished by original biblical paintings by Cachia and provide an even more impressive backdrop for the whole exhibition.

This year's innovation is seeing the inclusion of craftwork done by Dr Camilleri's daughter in the form of Ganutell flower bouquets in front of each 'vara'.

Speaking of the preparations for the exhibition, Dr Camilleri explains, "It takes two months to put up, and two more to dismantle everything. Preparations include the mammoth task of bringing all 260 statues down three flights of stairs from their storage. This is done two at a time, and I allow absolutely nobody to carry out this job, because the clay and wax are so very fragile. Unfortunately I do cause damages myself, and that is a massive problem, because breakages cannot be fixed very rapidly."

Setting up the exhibit involves great patience and work, both his and his friend's Alfred Grima and they do all the handiwork themselves, including lighting and woodwork installation.

But what about the exhibition proper? Work is done with the intent of creating an even more dramatic impression on the visitors who turn up in their hundreds, actually thousands, as last year registered a record attendance of 3000 people. This is very heartening for the exhibitors whose main aim is to gather funds for charity. This year, as in the most recent past, the proceeds all go to Dar tal-Providenza.

assion for Good Friday

"We have also helped other charities, including the Eden Foundation, but the Siggiewi home is always in dire need of assistance, so we have repeatedly offered what we get by way of donations to this cause. Most of the visitors are Maltese but we do have a few tourists who come in and these are always incredibly amazed by the work put in."

Seeing the whole set up of this very effective exhibition, makes one believe there could not possibly be any other additions. But Dr Camilleri thinks otherwise. "My next ambition is to create an audio multilingual interpretation to help foreigners understand what it is all about, the different stages and information about the biblical characters depicted. It might not happen next year, because each project usually requires a lot of input both personal and financial. But once we are ready to do it, we will."

Exhibition is held at 89, Triq Mon. P.P. Pullicino, Zurrieq. This year it will be officially inaugurated on March 28 at 19.30. All Synapse readers are invited to attend. The exhibition closes on April 6. Opening hours: Daily from 09.30 – 12.30 & 16.00 – 21.30 except on: Maunday Thursday, Good Friday, Easter Saturday from 08.30 – 13.00.

All donations made by visitors will be in aid of Dar tal-Providenza.

Management of Behavioural and Psychological Symptoms of Dementia

continued from page 6

The key is to understand that these behaviours are in most cases resulting from an altered sense of reality that people with dementia are experiencing. This makes them prone to feeling afraid whenever they cannot understand clearly what is happening around them. Psychiatric symptoms such as hallucinations and delusions may be very frightening experiences to patients. In most cases, one can identify a trigger – a situation which started the behaviour. If this can be dealt with beforehand, it may well solve the problem without resorting to medication. Sometimes an environmental cause can be identified which is causing the person to become upset. Some people with dementia may perceive their own image in a mirror as being an intruder trying to attack them. This problem can be easily solved by covering the mirror with cardboard. Relatives are instructed not to start any unnecessary arguments and are told not to challenge a person with a delusion or who is experiencing a hallucination. Redirecting and distracting the person with dementia to another activity works much better than confrontation. Relatives and carers of people with dementia require much support and counseling so that they can come to terms with such challenging behaviours. Socially inappropriate behaviour may be very upsetting to caregivers who will need reassurance and advice on how to deal with the situation. Carer support also involves admitting the patient for a period of respite care in a hospital or nursing home setting which will also serve as an opportunity for continuing assessment.

The article has drawn attention to the current trends in improving the care of people with dementia. It calls primarily for an appropriate evaluation of the situation in all instances and for an effort to treat behavioural symptoms positively through the use of non-pharmacologic approaches, education and understanding.

Bibliography

Alzheimer's Society. Policy Position Paper – Prescribing of Neuroleptic and Antipsychotic Drugs. Available from: http://www.alzheimers.org.uk/News_and_campaigns/Policy_Watch/neuroleptics.htm

Burns A, Byrne J, Ballard C, Holmes C. Sensory Stimulation in Dementia. *BMJ* 2002; 325:1312-3.

Committee on Safety of Medicines. Atypical antipsychotic drugs and stroke. Press Release. 2004.

Lee P, Gill SS, Freedman M et al. Atypical antipsychotic drugs in the treatment of behavioural and psychological symptoms of dementia: systematic review. *BMJ* 2004; 329:75-9.

Royal College of Psychiatrics Faculty for the Psychiatry of Old Age. Atypical antipsychotics and behavioural and psychiatric symptoms of dementia – Prescribing Update For Old Age Psychiatrists. Available from: http://www.rcpsych.ac.uk/college/faculty/oap/BPSD.pdf

Sink KM, Holden KF, Yaffe K. Pharmacological Treatment of the Neuropsychiatric Symptoms of Dementia. A review of evidence. *JAMA* 2005; 293:596-608.

The diversity of Occupational Therapy Services for older persons in Malta

by **Antoinette Laferla** *Dip Ger Dip OT*
Assistant Principal Occupational Therapist
Occupational Therapy Department
St Vincent de Paul Residence

Occupational Therapy has become part of the multidisciplinary rehabilitation team, however, a number of professionals still do not understand the work carried out by the therapist especially in a long-term setting. This article highlights the services which are presently being offered by occupational therapists working at St Vincent de Paul Residence. Still, one should also keep in mind that other services are offered by occupational therapists working with older persons who receive acute care at St Luke's Hospital, subacute rehabilitation at Zammit Clapp Hospital, psychiatric care at Mount Carmel Hospital and also in Gozo.

An occupational therapist (OT) working with the elderly makes use of purposeful activities in order to maintain the optimal level of functional independence of that person in all areas of life.[1,2]

A. Residential Services

Persons being admitted to SVPR are assessed by an OT to identify any areas where rehabilitation is needed. Each ward at SVPR has an OT who is responsible for the rehabilitation of the residents. Specific assessments such as bathing, dressing, feeding, toileting and perceptual are carried out when necessary and appropriate techniques are taught and aids given on loan after training sessions. Every client needs a tailor-made package of treatment due to the diversity of needs and interests.[3] All services are also given to older persons who are admitted to SVPR as respite. Sessions with relatives of residents are held, especially at the respite ward, when new techniques need to be taught in order to encourage more independence and decrease the amount of anxiety experienced during activities of daily living.[4]

Group Therapy

OTs carry out a number of group activity sessions ranging from high mobility, reminiscence, discussion, creative and cookery groups, to groups for specific conditions such as dementia. During a group therapy session, any physical, cognitive and psychosocial goal may be achieved for different individuals at the same time.[5]

Activity Centre

The activity centre within the occupational therapy department offers therapeutic diversional activities which include cane work, rug wool, fretwork, woodwork, knitting, sewing, crochet and tapestry. There has been a time when these activities have been put aside, even by OTs, since they were not giving the profession a very scientific look! However, through evidence based research it is now proved that diversional activities contribute to optimal rehabilitative care. It is up to the 0therapist to grade and adapt the activity according to the abilities and needs of each resident. Through these activities, the older person achieves not only hand or arm function, strength and coordination, but also learns how to remain mentally active, how to function socially and maintains a high level of self-esteem.[6] It was also proved that participation in activities has a positive influence on variables that contribute to adaptation to ageing.[7] One of the present challenges of OTs working at SVPR is to decrease the number of residents (presently 25.8%) who voluntarily choose not to participate in any form of activity.[8]

Social Activities

OTs try to help elderly persons at SVPR to remain part of society as much as possible by encouraging residents to participate in activities outside the residence such as carnival, horticulture exhibitions and Christmas Festivities.

continues on page 26

The diversity of Occupational Therapy Services for older persons in Malta

continued from page 25

Through all the above mentioned activities the OT tries to minimize what Goffman has described as 'the total institution' i.e. that there is no separation between work, leisure and family and that residents are treated all alike, doing the same things and following a set routine. Through participation in these activities the residents are given an amount of diversity, autonomy and choice.[9]

B. Out-patients

A number of older persons are seen as out-patients. Most cases are referred from other hospitals, from the therapist visiting the day centres or directly from general practitioners. Rehabilitation is carried out at SVPR, and home visits are carried out when necessary.

C. Community Services

Government Homes for the Elderly

Occupational Therapy Service is provided to residents in the five different Government homes. An OT visits each home at least once a week and is involved not only in the rehabilitation of residents, but also in giving advice to provide a safer environment within the home.

Day Centres

Normal ageing is not synonymous with disease and disability. [10] For the past four years an emphasis has been made to educate older persons who are still living in the community and who attend the church and government day centres for the elderly. A health promotion programme has been drawn up in which different issues concerning the elderly population are discussed. Advice is given on how a person may adapt his/her lifestyle and everyday routine in order to combat any limitations which might set in.

Home Visits

Home visits are arranged for out-patients or for older persons using the respite facility prior to returning home. Sometimes this service is also offered to persons residing at SVPR who visit relatives during weekends and who are finding some difficulty in the other setting. The OT gives advice on adaptations or any structural changes needed in the home in order to maintain independence and promote safety.

Conclusion

All the above mentioned services are offered by the OTs at SVPR as part of the ongoing rehabilitation provided by a multidisciplinary team. The collaboration of every person within this team will lead to a better quality of life for the residents. Also, the community services help to provide a more independent lifestyle which will delay the need for older persons to apply for residential care.

References

1. College of Occupational Therapists website. Available from: http://.www.cot.org.uk/newpublic/otandme/what.php.
2. American Occupational Therapy Association, Inc website. Available from: http://www.aota.org/featured/area6/index.asp.
3. Reynolds PJ, Allen SC. Rehabilitation of the elderly – an overview. In: Shukla RB, Brooks D, editors. A guide to care of the elderly. London: HMSO, 1996.
4. Boone A, Rodrigues BJ. Working with families and caregivers of elders. In: Lohman H, Padilla RL, Byers-Connon S, editors. Occupational Therapy with elders: strategies for the COTA. USA: Mosby, 1998.
5. Byers-Connon S, Hoff S. Group treatment with elders. In: Lohman H, Padilla RL, Byers-Connon S, editors. Occupational Therapy with elders: strategies for the COTA. USA: Mosby, 1998.
6. Drake M. Crafts in therapy and rehabilitation. 2nd ed. USA: Slack Incorporated, 1999.
7. Garc'a-Martin MA, G-mez-Jacinto L, Martimportugués – Goyenechea C. A structural model of the effects of organized leisure activities on the well-being of elder adults in Spain. *Activities, Adaptation and Aging* 2004; 28(3):19-34.
8. Occupational Therapy Department Report - Audit of SVPR residents re: activities. 2006. (reproduced with permission).
9. Bond J. Living Arrangements of Elderly People. In: Bond J, Coleman P, Peace S, editors. Ageing in society: an introduction to social gerontology. 2nd ed. London: Sage Publication, 1993.
10. Swift CG. Disease and disability in older people – prospects for intervention. In: Squires AJ, editor. Rehabilitation of Older People – a handbook for the multidisciplinary team. 2nd ed. London: Chapman and Hall, 1996.

Advice – Value or Price?

by J. G. P. Bonello, *F.L.I.A., Managing Director*
Financial Planning Services Limited
Financial Adviser since 1967

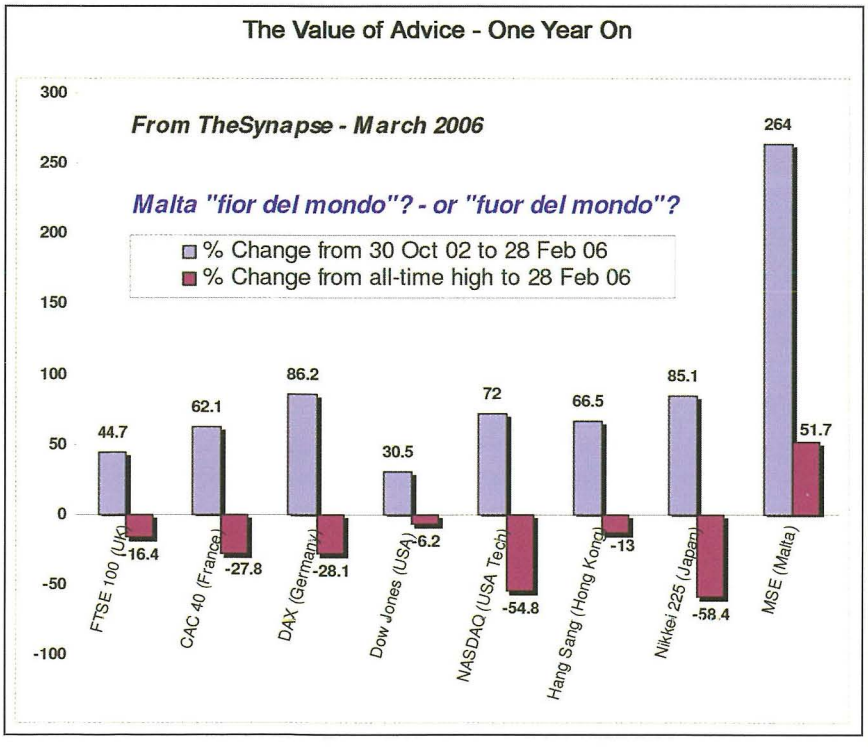
In the March 2006 Moneywise column in TheSynapse, I penned an article under the title "What price advice?" The article included a bar chart (reproduced below) headed "Malta 'fior del mondo'? – or 'fuor del mondo'?" This highlighted the percentage change, from their all-time high to the 28th February 2006, in seven of the world's major stock indices (Dow Jones, Nasdaq, FTSE 100, CAC 40, DAX, Nikkei and the Hang Seng), and the Malta Stock Exchange (MSE) index.

Every single foreign index was then below its own respective all-time high. The Dow Jones was the closest, just 6.2% short, whilst the Nikkei was by far the most distant – a substantial, mirage-like, 58.4% away. By comparison, the MSE index was not simply ahead of its previous all-time high, reached on 24th January 2000, but – to boot – a colossal 51.7% higher!

The same graph compared the percentage increase of these markets in the forty months from their 30th October 2002 bear market low, to the 28th February 2006 close. Again the Maltese index had a stratospheric 264% increase. This was *three* times as much as the top performing foreign market – the German Dax – which had increased by 86.2%, and close to *nine* times as much as the Dow Jones, with the smallest recovery of 30.5%. (These percentages do not include dividends paid by the companies which make up the index components.)

I had then commented: "The conclusion vis-à-vis which markets have the better potential is obvious".

Well, how accurate was that foresight saga? The answer lies in the bar graph below, headed "The Value of Advice – One Year On". It gives the percentage changes in the 12-month period between the 28th February of last year and the 20th February of this. It crystallises the "obvious better potential" referred to in the previous paragraph, and taken from last year's "What price advice?"



The MSE index has in fact turned out to be the worst performer with a 16.4% decline. Readers of the Moneywise column a year ago who acted on the advice – even if lacking the inclination to switch into foreign markets – would not only have 16.4% more money in their pockets, but would also have earned interest on the money deposited. Minimal interest, no doubt, but still far better off than the 16.4% capital loss. Readers who did switch into foreign equity markets would have seen a near 30% gain from Hong Kong's Hang Seng.

The six other indices all enjoyed double digit gains, with Germany's DAX at just over 20%, the Dow Jones 16% and 14% on the CAC 40. The "bottom" three all achieved a gain of 10%, or slightly above.

The article had then put the question: "But how do you distinguish between market highs and market hype?" I need not repeat the closing two paragraphs.

Many have found out that all the hype and publicity generated by share splits and bonus issues, is similar to that surrounding the launch of new financial products. Both attract a lemming-like rush into something that, had proper pre-investment advice been sought, might have been found out to be either unsuitable or untimely.

Therein lies the value of seeking proper advice – without scrimping about price. It has been said that "free" advice is worth exactly what you pay for it! Anyone can get it wrong – as experience has taught me. But there is a growing awareness of the need to have instant access to a (truly) independent, experienced, wealth management consultant.

Where does one find such a consultant and adviser? For one thing, they do not advertise "free" financial planning reviews. Neither are they likely to be employed by product manufacturers, each with a 50-outlet network, and 1500 employees, whose income and career promotions are directly linked to performance-related bonuses.

continues on page 28

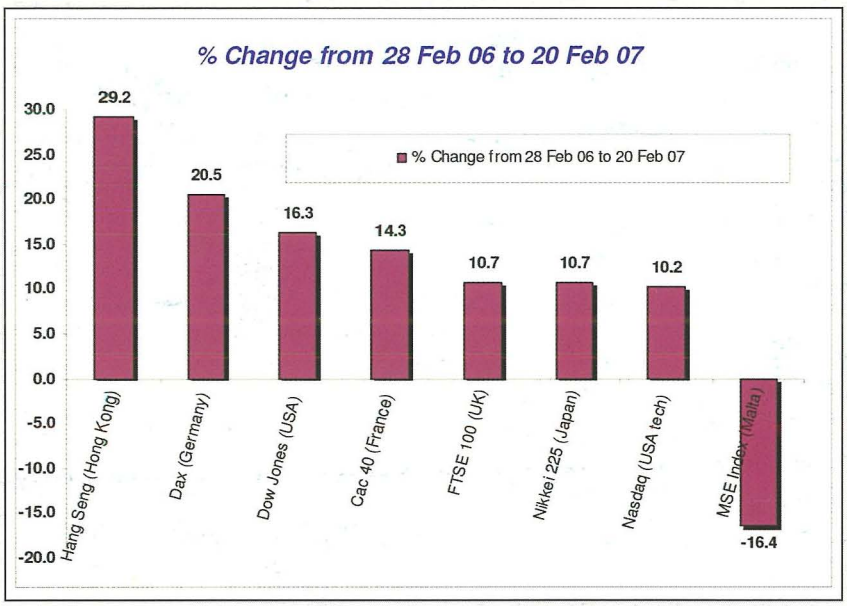
Advice – Value or Price?

When you add a bottomless pit of shareholders' funds, effectively utilised to promote their own products and enhance their employees' efforts, you will understand why they now even pester you with telephone calls at home.

At least, Malta's two major fast food outlets do not indulge in the latter high-pressure, highly-orchestrated procedures, as Malta's new army of McAdvisers now do, incessantly egged on by their burger meisters.

No. The analogy for the growingly sophisticated investor would be much more in line with slow food traditional restaurants like Rules, or The Ivy, in London, or Taillevent in Paris. Shrewd Maltese investors, aligning their wealth management tastes in parallel with the development of their palate, today tend to read A.A. Gill in the London Sunday Times. They know that the likes of Gordon Ramsay and Marco Pierre White did not earn their Michelin stars by chucking chicken McNuggets onto a plate.

P.S. Since submitting the first draft of this article, international markets have seen a substantial sell-off,



triggered by worries about the U.S. sub-prime mortgage market. The MSE index – though obviously totally unrelated – has fallen further and, as at the close of trading on March 14th, is now 20.7% lower than the 28th February 2006 close. The other seven foreign markets, notwithstanding the slide since 27th February this year, are all still in healthy, positive territory.

So, extremely recent and current events highlight the point made earlier about the need for instant access to a truly independent, experienced, wealth management consultant. Someone whose function it is to first prevent nightmares – not to sell you dreams.