

The Synapse

The Medical Professionals Network

Exclusive

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How to save a limb – Part II

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Anthony Aquilina

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PRESENTATION: Onbrez Breezhaler 150mcg and 300mcg inhalation powder hard capsules containing indacaterol maleate, and separate Onbrez Breezhaler inhaler. **INDICATIONS:** For maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). **DOSAGE AND ADMINISTRATION:** Recommended dose is the inhalation of the content of one 150mcg capsule once a day, administered at the same time of the day each day, using the Onbrez Breezhaler inhaler. Capsules must not be swallowed. Dose should only be increased on medical advice. The inhalation of the content of one 300mcg capsule once a day has been shown to provide additional clinical benefit with regard to breathlessness, particularly for patients with severe COPD. Maximum dose is 300mcg once daily. No dose adjustment required in elderly patients, for patients with mild and moderate hepatic impairment or for patients with renal impairment. No data available for use in patients with severe hepatic impairment. No relevant use in the paediatric population. **CONTRAINDICATIONS:** Hypersensitivity to the active substance, to lactose or to any of the other excipients. **WARNINGS/PRECAUTIONS:** **Asthma:** ONBREZ BREEZHALER SHOULD NOT BE USED IN ASTHMA. **Paradoxical bronchospasm:** If paradoxical bronchospasm occurs Onbrez Breezhaler should be discontinued immediately and alternative therapy substituted. **Deterioration of disease:** Not indicated for treatment of acute episodes of bronchospasm, i.e. as rescue therapy. **Systemic effects:** Indacaterol should be used with caution in patients with cardiovascular disorders (coronary artery disease, acute myocardial infarction, cardiac arrhythmias, hypertension), in patients with convulsive disorders or thyrotoxicosis, and in patients who are unusually responsive to beta2-adrenergic agonists. **Cardiovascular effects:** Indacaterol may produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, and/or symptoms. ECG changes. In case such effects occur, treatment may need to be discontinued. **Hypokalaemia:** Beta2-adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce cardiovascular effects. In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment which may increase the susceptibility to cardiac arrhythmias. **Hypertension:** Inhalation of high doses of beta2-adrenergic agonists may produce increases in plasma glucose. Upon initiation of treatment with Onbrez Breezhaler plasma glucose should be monitored more closely in diabetic patients. **Hyperglycaemia:** During clinical studies, clinically notable changes in blood glucose were generally more frequent by 1-2% on Onbrez Breezhaler at the recommended doses than on placebo. Onbrez Breezhaler has not been investigated in patients with not well controlled diabetes mellitus. **Pregnancy and Lactation:** No data available from the use of indacaterol in pregnant women. Onbrez Breezhaler should only be used during pregnancy if the expected benefits outweigh the potential risks. Not known whether indacaterol / metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or discontinue Onbrez Breezhaler therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. **INTERACTIONS:** Concomitant administration of other sympathomimetic agents may potentiate the undesirable effects of Onbrez Breezhaler. Onbrez Breezhaler should not be used in conjunction with other long-acting beta2-adrenergic agonists or medicinal products containing long-acting beta2-adrenergic agonists. Concomitant hypokalaemic treatment with methylxanthine derivatives, steroids, or non-potassium-sparing diuretics may potentiate the possible hypokalaemic effect of beta2-adrenergic agonists, therefore use with caution. Indacaterol should not be given together with beta-adrenergic blockers (including eye drops) as these may weaken or antagonise the effect of beta2-adrenergic agonists. Where required, cardioselective beta-adrenergic blockers should be preferred, although they should be administered with caution. Inhibition of the key contributors of indacaterol clearance, CYP3A4 and P-gp, does not raise any safety concerns given the safety experience of treatment with Onbrez Breezhaler. Indacaterol has not been shown to cause interactions with co-medications. **ADVERSE REACTIONS:** The most common adverse reactions with Onbrez Breezhaler are: nasopharyngitis, upper respiratory tract infection, sinusitis, diabetes mellitus and hyperglycaemia, headache, ischaemic heart disease, cough, pharyngolaryngeal pain, rhinorrhoea, respiratory tract congestion, muscle spasm, peripheral oedema. **Uncommon:** paraesthesia, atrial fibrillation and non-cardiac chest pain. **Please refer to SmPC for a full list of adverse events for Onbrez Breezhaler.** **LEGAL CATEGORY:** POM **PACK SIZES:** Onbrez Breezhaler 150mcg - carton containing 10 or 30 capsules and one Onbrez Breezhaler inhaler. Onbrez Breezhaler 300mcg - carton containing 30 capsules and one Onbrez Breezhaler inhaler. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimborhurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/103453/001, 002, 007. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available on request from Novartis Pharma Services Inc, Representative Office P.O. Box 124, Valletta, VLT 1000 Malta. Tel: +356 22983217 2010-MT-01-ONB-01-Feb-2010

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References:
1. Cazzola M, Matera MG. Novel long-acting bronchodilators for COPD and asthma. *Drugs* 2008; 68: 291-306.
2. Novartis Europharm Ltd. Onbrez® Breezhaler® Summary of Product Characteristics.

Editor's word

5000 years after the first condom was invented in Egypt, most probably made from animal hide (although the primary reason for use is unknown), last Mother's Day we have celebrated the 50th birthday anniversary of the Contraceptive Pill. And obviously one question springs to mind. What spurred research in this direction? Surprisingly the Pill was the idea of a conservative Catholic nurse called Margaret Sanger who opened the first birth control clinic in America in 1916. Interestingly, in parallel, Cyrus McCormick is diagnosed with schizophrenia. His wife, Katherine, dreads passing on the mental illness to future children and later on forms a partnership with Sanger, funding contraception research with her sizeable fortune. Initial clinical trials were conducted by Catholic gynaecologist, John Rock. This work eventually leads to the development of the birth control pill as we know it today.

So this was the birth of the oral contraceptive. Interestingly, the Pill was initially approved by FDA in the mid-1950s for treatment of menstrual problems but doctors and women both understood that it stopped ovulation. The instant it became available half a million women rushed to their doctors claiming they had menstrual irregularity! But today I will not be discussing this discovery, hailed by many as one of the greatest inventions of this century, nor its social and economic reverberations. I will however revert my attention to the other side of the coin ... the male contraceptive pill. Several chemicals studied in clinical trials have shown to be potential candidates, however research is still largely being conducted, with some clinical trials also sponsored by the WHO. However patient non-

compliance, lower effectiveness, irreversibility of pharmacological action and various side-effects, have highlighted the superiority of female birth control pills ... even though the frequency of administration of the female pill indeed mimics Edinburgh Castle's firing of the One O'Clock Gun (except that one has also to take it on Sundays, Good Friday and Christmas Day!).

But why has the male contraceptive pill never been marketed successfully in this Brave New World in which we are living? Culture has obviously been the major determinant to undermine research in male contraception. It is largely acclaimed that the advent of Sildenafil (Viagra®) was the first time that the male reproductivity emerged in the limelight (on a side note, as what happens with some blockbusters, the primary endpoint of Sildenafil was not impotence, but a reduction in blood pressure. This was discovered by the reluctance of subjects to hand in their leftover pills!) In addition one of the greatest questions is *Would women trust their male counterparts to take the pill?* I hope that my future wife would, however I would also like to delve in this issue a bit more deeper. It is true that after all, if men forget to take the pill, it is not they who get pregnant. So in this scenario, compliance and trust are two closed linked dilemmas. This is what Glasier et al (<http://www.thesynapse.net/articles/viewarticle.asp?artic=12335>) actually investigated, as reported in *Human Reproduction*. Despite the widespread belief that women would not accept a 'male pill' because they would not trust their partners to use it reliably, this study actually suggests that a hormonal method for men would be very popular and that women, regardless of culture, would

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trust their partners to use it. More choices of contraceptive methods for men will also allow increasing numbers of men to accept more responsibility for reproductive health. But if you are still believing that male contraception is still science fiction check out the article published last year in *The Journal of Clinical Endocrinology and Metabolism* (www.thesynapse.net/mcp) - effective, reversible, acceptable, and readily delivered contraception may quite be at the horizon!

Ian C Ellul
Ian C Ellul

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MedClub Card news

Over the past weeks, many Synapse members have been receiving their MedClub membership card. Please call us on 21453973 if you have applied to become a Medclub member but did not receive your membership card yet.

We are delighted to inform the MedClub members that we have secured further offers exclusive for them.

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- **Corinthia Hotels** are offering 20% discount off Corinthia™ Hotels Best Availability Rate on bookings made directly through www.corinthia.com. To benefit from the discount, MedClub Members must simply present their MedClub card on check-in at any Corinthia Hotel and the discount will be immediately applied to their hotel bill.
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- **Bridgestone Tyre Center** in Marsa is offering 10% discount.

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More information on these offers will be announced on The Synapse Portal in the coming weeks. The list of MedClub Benefits is always growing so join as a MedClub member and enjoy these discounts too.

Please visit www.thesynapse.net/medclub to apply for your free membership



Issue Guide

Contributors



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Front Page

Adonis annua L. (Pheasant's eye, Ghajn is-Serduk)

Adonis annua L. is a scarce, annual, winter and spring flowering herbaceous plant which prefers disturbed ground.

Medicinal uses

It has been used in medicines as a diuretic, as a tonic to improve health, and as a cardiostimulant.

Photography: Guido Bonetti ARPS AMPS
Reference: Lanfranco G. Hxelljex medicinali u oħrajn il-gzejjer Maltin. Media Centre Print; Malta. 1993.





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References: 1.Mancia G, Laurent S, et al. *Blood Pressure* 2009;18:308-347. 2.Calhoun DA, Lacourcière Y, Chiang YI, Glazer RD. *Hypertension* 2009;54:32-38. 3.Lacourcière Y, Glazer R, Critchley N, Yen J, Calhoun D. Poster presented at: 19th Scientific Meeting of the ESH; 12-16 June 2009; Milan, Italy. 4.Lacourcière Y, Glazer R, Yen J, Calhoun D. Poster presented at: 19th Scientific Meeting of the ESH; 12-16 June 2009; Milan, Italy.

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Avoid use in women planning to become pregnant and while breast-feeding. * Caution when driving or using machinery. **INTERACTIONS:** * Monitoring recommended when used concomitantly with lithium. * Caution when used concomitantly with drugs that may increase potassium levels. * Caution if combined with other antihypertensives, curare derivatives, NSAIDs, corticosteroids, ACTH, amphotericin, carbamazepine, digoxin, CYP3A4 inhibitors and inducers, anti-diabetic agents, allopurinol, probenecid, sulfonpyrazone, pressor amines, amantadine, diazoxide, cytotoxic drugs, anticholinergic agents, methyllopa, cholestyramine, cholestipol resins, vitamin D, calcium salts, carbamazepine and clozapine, alcohol, anaesthetics and sedatives. **ADVERSE REACTIONS:** * Exforge HCT (amlodipine/valsartan/HCT): Common: hypokalaemia, headache, dizziness, hypotension, dyspepsia, pollakiuria, oedema, fatigue. Uncommon: anorexia, hypercalcaemia, hyperlipidaemia, hyperuricaemia, hyponatremia, insomnia/sleep disturbances, abnormal coordination, postural and exertional dizziness, dysgeusia, lethargy, paraesthesia, peripheral neuropathy, neuropathy, somnolence, syncope, visual disturbance, vertigo, tachycardia, orthostatic hypotension, phlebitis, thrombophlebitis, cough, dyspnoea, throat irritation, abdominal discomfort, upper abdominal pain, breath odour, diarrhoea, dry mouth, nausea, vomiting, hyperhidrosis, pruritus, back pain, joint swelling, muscle spasm, muscular weakness, myalgia, pain in extremity, elevation of serum creatinine, acute renal failure, erectile dysfunction, abasia, gait disturbance, asthenia, discomfort, malaise, non cardiac chest pain, increased blood urea nitrogen, increased blood uric acid, decreased serum potassium, weight increase. * Additional adverse reactions with amlodipine monotherapy: Common: palpitations, flushing. Uncommon: mood swings, tremor, tinnitus, rhinitis, change of bowel habit, alopecia, exanthema, purpura, skin discoloration, arthralgia, micturition disorder, nocturia, gynaecomastia, pain, weight decrease. * Additional adverse reactions with HCT monotherapy: Common: increased lipids. Uncommon: hypomagnesaemia, decreased appetite, urticaria. Rare: thrombocytopenia, hyperglycaemia, depression, arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation), constipation, intrahepatic cholestasis, jaundice, photosensitivity reaction, renal failure and impairment, glycosuria. **LEGAL CATEGORY:** POM. **PACK SIZES:** Packs of 28 film-coated tablets. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wembley Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBER:** Exforge HCT 10 mg/160 mg/25 mg - EU/1/09/569/038. Exforge HCT 10 mg/320 mg/25 mg - EU/1/09/569/050. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available on request from Novartis Pharma Services Inc., Representative Office Malta, P.O. Box 124, Valletta, VLT 1000, Malta. Tel: +358 22983217 2010-MT-01-EXFH-18-OCT-2009

EXF Ad 08/10 MT

Research Article

Does minor head injury cause cochlear concussion?

By Anthony J Fenech

Key words: temporal bones, head injury, otoacoustic emissions

Abstract

Does minor head injury have any effect on the human cochlea? 50 patients under 30 years of age admitted to hospital with minor head injury had a detailed history of head trauma, ENT examination and full audiological investigations on admission and six weeks later. No cochlear concussion occurred in both instances and no statistical significant difference was observed. Minor head injury does not cause any cochlear concussion. Otoacoustic emissions are a measure of cochlear function.

Introduction

It is a well known fact that head injury has various effects on the inner ear labyrinth causing morbidity. In this study, we have investigated the clinical manifestations, if any, in minor to moderately severe head injuries on the audiological and vestibular organs. Most of the subjects were involved either in a motor vehicle accident (MVA) or falls from height (FFH).

Methodology

A total of 50 patients admitted to hospital with minor to moderate head injury were investigated audiotically. Their age varied between 4 months to 30 years and these were studied over a 7 month period. An audiological assessment was performed consisting of ear examination, tympanometry using the automatic Impedance audiometer AT22 (Interacoustics Ltd), otoacoustic emissions (OAEs) using the ILO82

(Otodynamics Ltd) (both transient and distortion products otoacoustic emissions - TOAEs and DPOAEs) and pure tone audiometry (PTA) using the diagnostic audiometer AD 22 (Interacoustics Ltd) (both air and bone conduction) soon after the head injury. They were investigated audiotically within the first 24 hours post head injury and all the tests were again repeated after approximately 6 weeks to detect any cochlear concussion. The inclusion criteria were an age less than 30 years, no history of hearing loss or significant noise exposure, mild to moderate head injury with or without simple fracture and admission to hospital for observation.

Results

Out of the 50 cases, 32 were males and 18 were females. 20 males and 13 females were found to have suffered a head injury due to FFH while 4 males and 3 females were involved in a MVA. Another 8 males and 2 females sustained a head injury other than MVA or FFH. None of the minor head injury cases suffered from tinnitus, vertigo or facial palsy. The majority of patients had a normal middle ear pressure on initial examination (table 1). Both types of otoacoustic emissions (TOAEs and DPOAEs) were obtained in high quantities and most of the cases had normal hearing on pure tone audiometry. When tested again 6 weeks later, practically the same results were obtained and this applied for both males and females (table 2). CT scans were not routinely taken in cases of minor head injury.

		MEP			TOAE			DPOAE			PTA				
		N	n	F	H	M	m	A	H	M	m	A	N	C	SN
Males	Rt	28	3	1	23	4	3	1	26	1	-	4	17	5	3
	Lt	28	3	1	25	3	1	2	29	2	-	-	24	2	2
Females	Rt	13	-	2	16	-	-	1	17	-	-	1	8	-	-
	Lt	14	-	2	16	1	-	1	15	-	1	2	8	-	-

Table 1 - Data obtained from the initial examination within the first 24 hours post head injury of 50 cases (100 ears) under 30 years of age

		MEP			TOAE			DPOAE			PTA				
		N	n	F	H	M	m	A	H	M	m	A	N	C	SN
Males	Rt	23	2	6	25	1	5	1	24	2	-	5	22	1	2
	Lt	21	3	7	22	8	1	1	24	2	-	5	22	1	2
Females	Rt	10	2	1	15	1	-	2	16	-	-	2	6	1	1
	Lt	8	3	4	15	3	-	-	15	-	-	2	7	1	1

Table 2 - Data obtained after 6 weeks post head injury of 50 cases (100 ears) under 30 years

Key:

Rt - right side
Lt - left side
N - normal middle ear pressure
H - high otoacoustic emissions
M - moderate otoacoustic emissions
Min - minimal otoacoustic emissions
A - absent response
F - flat middle ear pressure
n - negative middle ear pressure
C - conductive hearing loss
SN - sensor-neural hearing loss - not performed
MEP - middle ear pressure / tympanometry
TOAEs - transient otoacoustic emissions
DPOAEs - distortion products otoacoustic emissions
PTA - pure tone audiometry

Discussion

The average height involved in FFIIs was of a metre and those involved in an MVA were minor accidents. From the audiological investigations performed in the first 24 hours post head injury, it was observed that in the presence of a normal middle ear pressure, both TOAEs and DPOAEs were reproduced in high amounts – thus showing a normal cochlea. In those paediatric cases that were co-operative enough to perform a pure tone audiogram, normal hearing thresholds were also obtained. This showed that the initial head injury did not cause any cochlear concussion, as shown by normal otoacoustic emissions.

All the tests were again performed after 6 weeks and the same results were obtained. No signs of cochlear concussion were observed. Where a negative pressure was present in the middle ear this led to moderate amounts of otoacoustic emissions while a flat curve on tympanometry produced no emissions. This was expected since it is a known fact that to record otoacoustic emissions the status of the middle ear must be normal – thus the presence of Eustachian tube dysfunction or serous otitis would jeopardize the recording of otoacoustic emissions. Both TOAEs and

DPOAEs could be quantified regarding their amplitude and frequency and both could be diminished or absent in sensori-neural hearing loss.¹ One must bear in mind that OAE measurement is not a substitute for PTA. OAEs findings are an almost direct measure of outer hair cell functional integrity. 'Almost' because middle ear function is also a factor in OAE measurements. PTA is dependant on the status of the cochlea, VIII cranial nerve, central auditory system and auditory perceptual factors, as well as the middle ear. OAE stimuli typically include many frequencies that are not assessed with PTA.

Conclusion

The severity of head injury must be high for cochlear concussion to occur. This has been confirmed in another study on major head injuries conducted by the same author² where it was found to result in permanent sensori-neural hearing loss while tinnitus, vertigo and facial palsy disappeared or decreased in severity during the 1st year of follow-up.³ During this particular study no cochlear concussion and none of the other signs and symptoms (tinnitus, vertigo, hearing loss or facial palsy) were observed to occur neither initially nor at a later stage.

There was no funding for this study and all patients gave their consent prior to all investigations.

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2. Fenech A J. Pathology of temporal bones following head injuries: The macro and microscopic effects on the inner ear. PhD thesis (2007), University of Malta.
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Healing & Disease Reversal

THE SERIES

by Albert Cilla-Vincenti

This series explores Dean Omish's 30-year research experience into healing & disease reversal by dietary and lifestyle changes. He is a California University Professor of Medicine in San Francisco. This instalment continues to explain his claims why his programme works, whilst others prove unsustainable

In Professor Dean Omish's experience, there are two basic strategies that work to achieve and maintain dietary and lifestyle changes. The first approach is making small, gradual changes, so they don't seem too intimidating. You walk a little more, and you eat a little less, every day. Over time, small changes add up and are often sustainable.

The second approach is to make comprehensive lifestyle changes all at once. This seems unbelievable, especially to doctors, who often say that they can't even get their patients to take pills, let alone getting them to change their diet, start exercising and meditating, and spending more time with their friends and family. In Omish's experience however, it's sometimes easier to make big changes than small ones. When you make big changes, you experience big improvements. Most people feel so much better so quickly that joy of living replaces fear of dying.

Another reason why making big changes can be easier than making small ones is, that when you make big dietary transformations, your taste preferences often change. When you first switch from whole milk to skimmed milk, it tastes like water – not satisfying. After a while, you get used to it and, if someone puts whole milk by mistake in your tea, it tastes too fatty and too rich. However, if you use whole milk, and occasionally some skimmed milk, your palate will never adapt to the skimmed.

Omish's programme is all about freedom of choice. Depending where you want and need to get to, you can make small or big changes. The more you move to the healthy end of a range of choices, the faster, greater and quicker the benefits.

There's no point in giving up something you enjoy unless you get something back that's even better – and quickly. People are always making choices and they are not afraid of making big changes in their lives if they understand the benefits and how quickly they may occur. People are not afraid of even monumental lifestyle changes like having and raising a child – lots of

people do it, and often more than once

If it's fun, it's sustainable. If we view diet and lifestyle change as deprivation and sacrifice, well, forget it. Instead, if we understand that what we gain is so much more than what we give up, it doesn't feel like a sacrifice. Lifestyle choices can be seen as opportunities to transform our lives in ways that make us happier. For example, I'm writing this article instead of spending the day out because it brings meaning to my life knowing that the feature may be helpful to some people – transforming work into joy. Having a child can be viewed as a sacrifice or as a joy. You would choose to eat healthier foods because they make you feel better, not because someone told you to do so.

How we approach food is how we approach life. Choosing not to do something that we otherwise could do helps define who we are, reminds us that we have free will. When we consciously choose to limit what we're doing, it liberates us. Discipline can be liberating if it's freely chosen rather than imposed. Many people think that we have to choose between living a moral, spiritual life that's dry and boring or an immoral, secular life that's exciting and interesting. Fortunately, that's not the choice. We can go through the world any way we want to. Some approaches lead to health and joy, others lead to illness and suffering. We have a range of choices in all aspects of our lives.

People are always making choices, sacrifices. The word "sacrifice" has an austere, depriving connotation. But people don't usually think about it that way when they put their money aside for their kids' education or wedding, and so they don't buy a new car when they could do so. These choices – what not to do as well as what to do – bring meaning to our lives. Choosing to eat and live differently can be a joyful practice rather than one leaving you feeling deprived or depressed. You can enjoy life more fully by making these conscious choices. Instead of resolving to make diet and lifestyle changes out of a sense of austerity and deprivation, Omish finds it much more effective and fun to be motivated by feelings of love and joy.

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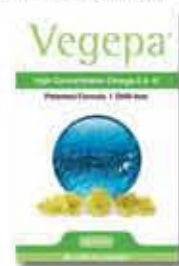
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igenus



Intestinal Allergy: Food hypersensitivity in infancy and childhood

by Thomas Attard

Gastrointestinal symptoms are frequently attributed to food hypersensitivity both by patients and increasingly by the medical community. Indeed, up to 35% of the general population in Western countries think they have food allergy¹ although this is objectively confirmed in only 1-2% of the population.² The incidence of food hypersensitivity appears to be on the rise, in parallel with the overall rise in atopic disorders over the last 30-40 years and concurrent with a decline in infectious disorders. This has led to the emergence of the 'hygiene hypothesis' which raised awareness of the role of microbes and their products in immune regulation; more recently, this has prompted important observations on the impact of beneficial bacteria (probiotics) in the prevention of allergic processes.

The mechanisms underlying food hypersensitivity are complex and only partially understood: the atopic individual appears susceptible to a variety of allergic processes. This is in part a result of disordered mucosal immune function including IgA deficiency, increased epithelial permeability allowing the migration of larger, allergenic proteins over a more 'porous' interface and, as noted above, disordered epithelial microbial interaction. There are important differences in the cellular patterns of immune responsiveness to potential allergens in atopic compared with non-atopic individuals. These differences are based on both genetic factors, reflected by the clustering of atopic diseases in families, and the modulation of the immune system by extraneous factors including the intestinal flora (microbiome).³ The latter is supported by observations that children born by caesarean section have a different microbial profile in the large intestine and are more susceptible to milk allergy,⁴ and that probiotics exert a beneficial effect in childhood atopic eczema. Milk allergy is, on the other hand, less common in exclusively breast fed infants.⁵

Clinical Scenarios of Food Hypersensitivity

Food hypersensitivity in infancy:

Cows milk allergy (CMA; milk-soy protein intolerance, allergic enterocolitis) is a relatively common disorder in infancy; it appears to decrease in prevalence with age and affected infants are very likely to eventually outgrow it by the second year of life. Children with CMA are however at risk of other atopic disorders including asthma, hay fever and eczema ('atopic march') later in life. Affected infants typically present with gastrointestinal or skin manifestations

in the first weeks in life. Gastrointestinal symptoms can run the gamut of irritability which overlaps with colic, severe reflux-type emesis, poor intake and failure to thrive, and colitis, including bloody diarrhea. Typical atopic dermatitis is also common.

Some misconceptions on CMA stem from confusion with lactose intolerance as discussed elsewhere. CMA is a clinical diagnosis and cannot rest on a single laboratory test. It is noteworthy that non-IgE-mediated allergic reactions are common in CMA so RAST testing is of very limited usefulness. In cases with severe manifestations, including hematochezia and hypoalbuminemia, endoscopy including colonoscopy may show patchy eosinophilic enteritis. It is also important to appreciate that breastfed babies, although far less likely, can still be affected through passage of allergenic epitopes of cows milk in the maternal diet passing intact through breast milk.⁶ A strict milk and dairy exclusion diet in the breastfeeding mother is probably the best approach since persistent excretion of cows milk protein in maternal breast milk will delay symptom resolution, even though many parents find adherence to the diet particularly stressful. Although traditionally a switch to soy-based formula was advocated, since allergic infants can sensitize to soy in one third to half the time, management guidelines currently recommend a switch to a hypoallergenic, completely hydrolyzed formula.^{7,8} More severe cases may warrant an elemental, or amino acid-based formula, and in infants who refuse to eat or who have a persistent poor weight gain, nasogastric drip feeds may be used.

Food hypersensitivity in the older child and young adult

Food allergies in the older child include both IgE mediated and IgE independent mechanisms. In general IgE dependent reactions more closely follow allergen exposure and include more systemic cutaneous symptoms such as hives. Gastrointestinal upset includes cramps, nausea, diarrhea and fecal urgency. T-cell mediated reactions may not involve IgE production and are usually more restricted to gastrointestinal manifestations in their presentation. The symptoms of food allergy in the older child overlap with the clinical presentation of functional abdominal pain in childhood and irritable bowel syndrome (IBS) in adults.⁹ In the older child, unlike the infant with CMA, food hypersensitivity is an unlikely explanation for gastrointestinal hemorrhage or unexplained weight loss. This is a clinical diagnosis, sometimes supported by response to an empiric food exclusion diet although the

sometimes long interval (weeks) between exclusion and clinical response needs to be explained to the parents and patient. Liaison with an experienced dietician is desirable insofar as strict exclusion of multiple allergens is extremely time consuming and stressful to some families. In some patients the diagnosis can be supported by gastroscopy and colonoscopy with biopsy that may show eosinophilic enteropathy in a patchy distribution and can rule out other etiologies including celiac disease and inflammatory bowel disease (IBD). Management rests with long term exclusion of allergen exposure. Pharmacologic therapy is limited; sodium cromoglicate,¹⁰ montelukast¹¹ and ketotifen¹² have all been used with variable success. Immunotherapy, including oral desensitization, has not yet been established beyond experimental protocols in the treatment of food allergies in childhood.¹³

Eosinophilic Esophagitis (EE)

A more recently recognized pattern of allergic enteropathy is eosinophilic esophagitis. Although initially described in children, it is now also established as an adult diagnosis.¹⁴ Patients with EE typically present with vague, upper gastrointestinal symptoms which overlap with gastroesophageal reflux disease.¹⁵ Both pain on swallowing as well as a sensation of food getting stuck (dysphagia and odynophagia) are common. Food bolus impaction in a previously asymptomatic individual is a classic clinical presentation. The patient's background including family history may suggest atopy although not necessarily food allergy. The hallmark of EE is the persistence of symptoms despite maximal medical treatment with associated characteristic endoscopic - histopathologic findings (Figure 1). Indeed, EE is over-represented in cohorts of patients with esophagitis refractory to surgery (fundoplication).¹⁶ The treatment for EE includes both an intensive exclusion diet that is usually empirically based (six-food elimination diet; SFED), oral fluticasone as well as other systemic anti-allergic agents. Continued surveillance, including endoscopy is encouraged because of concerns regarding long term sequelae including scarring.

Celiac Disease

Although not following the classic paradigm for a food hypersensitivity or allergic disorder, celiac disease is an environmentally triggered autoimmune disorder which

shares several features with intestinal allergies. An in-depth discussion of celiac disease is beyond the scope of this review but it is worth reiterating that several reviews have highlighted the significant burden of undiagnosed celiac disease in our society. A recent review of the literature suggests that in several Mediterranean countries, amongst the low-risk and general population the prevalence of celiac disease identified through serologic screening ranges from 0.14% - 1.3%.¹⁷ The increasing incidence of celiac disease appears to parallel the presentation of more atypical clinical presentations of the disease. It is reasonable to consider and discuss serologic celiac screening (total serum IgA, anti-tTG IgA, IgG) in a broad gamut of clinical scenarios including apparent food hypersensitivity.



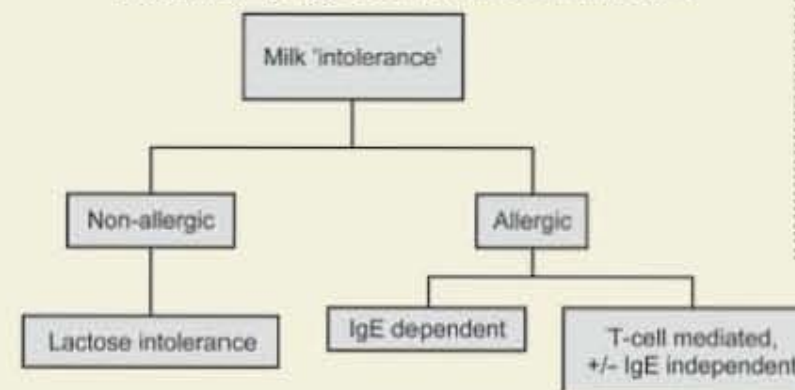
Figure 1 Endoscopic findings in eosinophilic esophagitis. A. Mucosal rings. B. Longitudinal furrows and nodular mucosa.

Milk Allergy or Lactose Intolerance?

Lactose intolerance is often confused with milk allergy, or more confusingly the two are hybridized as milk intolerance (Figure 2). Lactose intolerance refers to a condition of relative or absolute intestinal lactase deficiency; this brings about maldigestion of foods containing lactose, notably dairy. Undigested lactose is osmotically active and is fermented by endogenous bacterial flora resulting in diarrhea, gas and typically spasmodic abdominal cramps. Symptoms usually follow half an hour to several hours of exposure. Although lactose intolerance can be diagnosed through breath hydrogen testing a clinical diagnosis is usually sufficient. Sometimes lactose intolerance is clinically evident, in most cases it is primary or genetic (hypolactasia adult type) and starts at around 3 to 5 years of age. Lactose intolerance can be a component IBS but it may also complicate several illnesses (secondary lactose intolerance) which result in small intestinal mucosal injury, including Celiac Disease, Crohn's Disease and bacterial overgrowth. Indeed, hematochezia and other systemic manifestations such as weight loss and fever are not consistent with a diagnosis of primary lactose intolerance.

In conclusion, allergic diseases are increasingly prevalent in our population including children. Specific food hypersensitivity disorders are age-dependent and overlap with functional disorders such as infant colic and recurrent abdominal pain in the older child. Clinicians need to have a clear understanding of the basic pathophysiology in order to effectively diagnose and treat this spectrum of illnesses.

Figure 2. Patterns of milk intolerance by mechanism



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Focus on

The Diabetic Foot

How to save a limb – Part II

by Kevin Cassar

The age standardized incidence rate of lower limb amputations in diabetics is 13.1 times (95% CI 9-17.2) greater than for the general population. The incidence of diabetes related lower limb amputations is 475 per 100,000 patient years or 10.2 per 100,000 patients per year.¹ Extrapolating this to our own population, we would expect to have no more than 50 major amputations per year. If we take into account the higher prevalence of diabetes in our country we should not have more than 80 major amputations per year. As can be seen from figure 1, the number of major amputations per year in our country has been static at around 120 per year. Figure 2 shows that there is also a considerable number of minor amputations carried out per year; the numbers of which have again remained relatively stable in the past 5 years. Clearly the numbers performed locally are far in excess of those recorded in other countries. This begs the question of why our amputation rates are so high and what can we do to try and reduce this avoidable tragedy?

Foot screening

At present there is no national foot screening programme for diabetics. However the department of podiatry is working hard with the Health Care Services Division and Primary Health to develop a national foot screening programme in the near future. This is crucial in our local context where the number of patients registered with a general practitioner or a general practice is a very small minority. Routine health checks and visits are also uncommon. Any investment in the development of such a programme would be well spent and would lead to a considerable reduction in amputations and probably overall costs.

Structured Foot Care

A multidisciplinary diabetic foot clinic operates from Mater Dei Hospital once weekly. This was set up in the last 2 years and provides a comprehensive service including education, podiatry, diabetes care, wound care and vascular surgery. There is also a daily diabetic podiatry service run by highly dedicated diabetic podiatrists who have direct access both to the diabetologists who work at the same clinic and to vascular surgery. Diabetic podiatrists regularly refer patients as emergencies as indicated.

Footwear, orthoses and total contact casting

Unfortunately there is only one orthotist to provide footwear and orthoses to the large number of diabetic patients, who is based at St Luke's Hospital and



Figure 1: Major amputations in Malta 2002-2007 (total number, above knee amputations and below knee amputations)

therefore off-site. The number of patients requiring this service is high making it impossible for one person to provide an adequate service. Attempts are being made to develop this service and to make it more efficient and less reliant on overseas support. A service of total contact casting and off loading is also being developed within Mater Dei to provide adequate and effective off loading for patients immediately after debridement or minor amputations to ensure that these patients who are all high risk for further ulceration do not go on to develop further ulceration or gangrene in other toes of the same foot or the contralateral foot.

Arterial reconstruction

Recent improvements in imaging techniques and new equipment and personnel at Mater Dei Hospital has made the investigation of arterial disease more thorough and efficient. The advent of high quality CT angiography together with the acquisition of a high specification vascular ultrasound scanner has enabled increasingly more diabetic patients with arterial disease to be diagnosed and treated. Indeed there have been significant changes in the proportions of amputations and revascularisations done between 2006 and the present (Figure 3). The number of infrainguinal bypass procedures has also increased dramatically and in particular the number of femoro-distal bypasses has also increased. This indicates that increasingly more patients with diabetes are benefiting from revascularisation which hopefully will translate into a reduction in the number of patients requiring major amputations.

How to save a limb

The family physician has a key role to play in this crusade to save limbs. Family physicians should themselves take the initiative to screen patients under their care with diabetes and categorise them into

"The family physician has a key role to play in this crusade to save limbs."

Vector borne diseases



by Tanya Melillo Fenech

A vector-borne disease is one in which the pathogenic microorganism is transmitted from an infected individual to another individual by an arthropod or other agent. The transmission depends upon the attributes and requirements of at least three different living organisms: the pathologic agent which is either a virus, protozoa, bacteria or helminth (worm); the vector, which is commonly an arthropod such as ticks or mosquitoes; and the human host.

A vector-borne risk assessment was organised by the Infectious Disease Prevention and Control Unit in April 2009 with the help of experts sent by the ECDC. The aim was to identify the main vector borne diseases with public health relevance occurring on the Maltese islands and identify tools to detect and respond to vector-borne diseases related to health threats.

During this risk assessment, a total of 11 mosquito species were recorded from Malta. The main conclusion was that one of the mosquitoes, *Culis pipiens*, found in abundance locally, is the vector for West Nile Fever. Surveillance continued throughout Summer and in September 2009, Dr Paul Gatt discovered the *Aedes Albopictus* mosquito or Asian Tiger mosquito on the island.

It comes from the mosquito family Culicidae and is characterized by its black and white striped legs, and small black and white body. The Asian tiger mosquito has a rapid bite that allows it to escape most attempts by people to swat it.

The female lays her eggs near water; not directly into it as other mosquitoes do, but typically near a stagnant

How to Minimise getting bitten

- Minimize outdoor activities during day light hours when it tends to bite;
- Minimise areas of exposed skin if possible;
- Aerosol Insecticides, vaporizing mats and mosquito coils can help to clear rooms of mosquitoes;
- Optimum protection can be obtained by using repellents on exposed skin (Products containing DEET);
- Have secure screens on windows and doors;
- Use fans as affects their flying abilities.

pool. However, any open container containing water will suffice for larvae development, even with less than an ounce of water.

Adult females are aggressive daytime biters and prefer to bite outdoors. It is of public health importance because it is known to be a competent vector of at least 22 arboviruses. The most important ones are: Dengue, Chikungunya, Yellow fever, Japanese encephalitis and West Nile Fever. These diseases are characterised with sudden onset of febrile illness lasting one week. No specific treatment is available.

Chikungunya is characterised by sudden onset of high fever and severe joint pain. Other symptoms include rash, headache, fatigue, nausea, vomiting and myalgia.

Dengue fever is characterised by sudden onset of fever, intense headache, myalgia, arthralgia, rash, nausea, vomiting and minor bleeding phenomena.

West Nile Fever is characterised by fever, headache, myalgia, nausea, vomiting, rash on chest, back and stomach and swollen lymph glands. 80% of those infected with WNF are usually asymptomatic. Possible increase in vector-borne disease transmission or introduction of new species due to climate change is a concern.



Measures to take to control mosquitoes

- Remove any water-filled containers like old tires, food containers and buckets from your yard;
- Keep mosquitoes from breeding in bird baths, pet water dishes and paddling pools by emptying them at least every 2-3 days;
- Locate puddles that last more than three days, inlets to sewers and drainage systems holding stagnant water and drain them;
- Roof gutters should be kept clean of fallen leaves and other debris so that water does not collect in them;
- Flower pots, standing flower vases, knotholes and other crevices that can collect water should be filled with sand or fine gravel to prevent mosquitoes from laying eggs in them;
- Any standing water in pools, catchment basins, etc, that cannot be drained or dumped can be periodically treated with properly labelled insecticides; Do not leave fish ponds without fish.



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Levitra®, the only PDE5 inhibitor producing a statistically superior duration of erection, even in men who have underlying medical conditions, restoring the patient's duration of erection to within the range observed in normal, healthy men^{3,4,5}.

¹Mear M et al. J Sex Med 2008; 5 (6): 1455-57. ²Rosenberg MT et al. Int J Clin Pract 2009; 83 (1): 27-34. ³Patrick DL et al. J Sex Med 2005; 2(3): 355-67. ⁴Guiliano F et al. Eur Urol. 2008; 53 (5): 1046-57. ⁵Curly EW and Guenters JM. J Sex Med 2008; 5: 1261-1266



NAME OF THE MEDICAL PRODUCT: Levitra 5mg film-coated tablets. **QUALITATIVE AND QUANTITATIVE COMPOSITION:** Each tablet contains 5 mg of vardenafil (as hydrochloride salt). **PHARMACEUTICAL FORM:** Film-coated tablet. **Other parts:** Tablets are marked with the Bayer cross on one side and "V" on the other side. **CLINICAL PARTICULARS:** **Indication:** Treatment of erectile dysfunction in adult men. Erectile dysfunction is the inability to achieve or maintain a penis erection sufficient for satisfactory sexual performance. Levitra is indicated for the treatment of erectile dysfunction in adult men. **Contraindications:** Levitra is contraindicated in patients who are taking nitrates (such as nitroglycerin or isosorbide dinitrate) or who are taking other PDE5 inhibitors (such as tadalafil or sildenafil). **Warnings and precautions for use:** Prior to initiating any treatment for erectile dysfunction, physicians should consider the cardiovascular status of their patients. **Side effects:** The most common side effects are headache, flushing, nasal congestion, indigestion, back pain, and dizziness. **Use in special populations:** Levitra is not recommended for use in patients with severe renal or hepatic impairment. **Pharmacological properties:** Levitra is a PDE5 inhibitor that acts by increasing the levels of cyclic guanosine monophosphate (cGMP) in the penis, which leads to an erection. **Pharmacokinetics:** Levitra is rapidly absorbed and reaches its maximum concentration in the blood within 30 minutes. **Pharmacodynamics:** Levitra acts by inhibiting the enzyme phosphodiesterase type 5 (PDE5), which normally breaks down cGMP. **Preclinical safety data:** Levitra was found to be safe and effective in studies conducted in rats and dogs. **References:** 1. Rosen I, et al. N Engl J Med. 2004; 350: 473-83. 2. Rosen I, et al. N Engl J Med. 2004; 350: 473-83. 3. Rosen I, et al. N Engl J Med. 2004; 350: 473-83. 4. Rosen I, et al. N Engl J Med. 2004; 350: 473-83. 5. Rosen I, et al. N Engl J Med. 2004; 350: 473-83.

INDICATION: Treatment of erectile dysfunction in adult men. **Contraindications:** Levitra is contraindicated in patients who are taking nitrates (such as nitroglycerin or isosorbide dinitrate) or who are taking other PDE5 inhibitors (such as tadalafil or sildenafil). **Warnings and precautions for use:** Prior to initiating any treatment for erectile dysfunction, physicians should consider the cardiovascular status of their patients. **Side effects:** The most common side effects are headache, flushing, nasal congestion, indigestion, back pain, and dizziness. **Use in special populations:** Levitra is not recommended for use in patients with severe renal or hepatic impairment. **Pharmacological properties:** Levitra is a PDE5 inhibitor that acts by increasing the levels of cyclic guanosine monophosphate (cGMP) in the penis, which leads to an erection. **Pharmacokinetics:** Levitra is rapidly absorbed and reaches its maximum concentration in the blood within 30 minutes. **Pharmacodynamics:** Levitra acts by inhibiting the enzyme phosphodiesterase type 5 (PDE5), which normally breaks down cGMP. **Preclinical safety data:** Levitra was found to be safe and effective in studies conducted in rats and dogs. **References:** 1. Rosen I, et al. N Engl J Med. 2004; 350: 473-83. 2. Rosen I, et al. N Engl J Med. 2004; 350: 473-83. 3. Rosen I, et al. N Engl J Med. 2004; 350: 473-83. 4. Rosen I, et al. N Engl J Med. 2004; 350: 473-83. 5. Rosen I, et al. N Engl J Med. 2004; 350: 473-83.

Radio opportunity for Family Doctor

Opportunity for a Family Doctor to take part in a bi-monthly slot on RTK circa 1 hour a month (2 half hour sessions).

Anyone Interested call Sonya Young at RTK syoung@rtk.org or 99483761

Locum Pharmacist Required

Locum Pharmacist required to work two afternoons on a regular basis for St Joseph Pharmacy in Mosta. Any enquiries can be made by phoning 79417593.

Errata Corriga to last issue's Interview: 'An Individual Story of Art' (page 24 & 25)

The last sentence should read "... I am still beaming from the meeting with the Pope, which memory I cherish with joy." The printing error is regretted.

This could be your space.

Contact us on 21453673 or mp@thesynapse.net

1st Maltese Gastroenterology Conference

The Gastroenterology Department, supported by the European Social Fund, has the honour to welcome you to the first Maltese Gastroenterology Conference. This conference shall be held on the 8th & 9th October 2010 at the Mater Dei Central Auditorium and is free of charge. We will surely promise you a professional, highly stimulating, interactive, guidelines-based gastroenterology knowledge 2010 update. The main target audience are doctors from all specialties especially general practitioners, consultants in internal medicine, resident specialists, HSTs, BSTs, as well as 5th year medical students. A limited number of places are available to nurses, pharmacists and other medical professionals with an interest in gastroenterology.

Topics to be discussed include GORD, H.pylori, coeliac disease, inflammatory bowel disease, irritable bowel syndrome, colorectal cancer screening, iron deficiency anaemia, hepatitis B and many more. Speakers from USA, UK and Italy will enrich us with their experience. There will also be an interactive session with the use of keypads for the participants.

Registration is a must. This will be in the form of an 'Online Registration' through the MAM website. Certificate of attendance including CPD points will be distributed to each person attending. We hope to see you all in this conference, and keep watching this space for more updates.

For further details access <http://www.thesynapse.net/events/view.asp?eventID=107> or <http://sites.google.com/site/gastroenterologydepartment/home>

Equipment for sale

Following closure of Marina Court Clinic the following equipment is for sale: Diathermy machine, theatre trolley, examination couch, hospital bed, Laerdal portable sucker, instruments trolley. Interested parties may contact by e-mail on swah.charles@gmail.com or on mobile number 99482205.

Pharmacist Assistant Available

Pharmacist assistant available for employment in the evenings and weekends. Has been in full time employment for the past two years in the pharmaceutical field (finance & administration). Also has previous experience in sales & customer service. Please contact 79460295.

Dental Surgeon Required

Savina Dental Clinic in Gozo is looking for a dental surgeon to join the practice full time with immediate effect. Part time considered. Conditions negotiable depending on experience. Please send CV in confidence to drjuxereb@savinadental.com or call 7942732

Clinic Available

A new clinic served with all amenities is available at Saf Pharmacy (near St Benedit's school & Housing Estate), which may serve as a central hub to cover the population needs of Saf, Zurrieq, Msabba, Qrendi & Kirkop. Registrars / consultants may phone 79080903 for more details.

Master of Science in Reproductive Health

The Department of Obstetrics & Gynaecology will provide a comprehensive theory-based course of studies to enable the medical doctor to upgrade key aspects of knowledge relating to reproductive health. The course will facilitate learning within a structured framework covering relevant aspects within the basic sciences, the speciality of reproductive health in females and males, and those aspects of medicine, surgery and paediatrics relevant to the practice of the speciality. The ethos of the course is to ensure that future graduates will be in a position to make significant contributions not only towards clinical care, but also towards promoting the academic aspects of the speciality in teaching and research. The course will be run as an evening course over five semesters. The Course shall be open to applicants in possession of:

- (a) the degree of Doctor of Medicine and Surgery, as defined by Part 1a of the Second Schedule of the Health Care Professions Act together with a minimum of one year including a three-month clinical experience in the field as a medical practitioner post attainment of said degree; or
 - (b) a qualification deemed by Senate, on the recommendation of the Board, to be equivalent to the qualification listed in (a).
- For more information contact Prof. Charles Savona-Ventura, Head of the Department of Obstetrics & Gynaecology on charles.savona-ventura@um.edu.mt

COMPETITION CORNER - ISSUE 3/10

This month's Challenge answers

1. Arum italicum (the plant featured in the front cover) has been used in the past to remove freckles? True
2. Mention the name of the contributor from Turkey? Dr Nezan Karaoglu
3. Where are the Grapes Expectations Wine Events planned to be held? Petillant Restaurant

The winners are:

- 1st prize - **Ms. Graziella Grevino** (2 tickets to the Wintermoods concert)
- 2nd prize - **Dr. Michael Refalo** (1 day membership to the Corinthia Athenaeum Spa, Attard)
- 3rd prize - **Dr. David Muscat** (1 day membership to the Corinthia Athenaeum Spa, Attard)

Update your details winners

The winners are:

- 1st prize - **Ms. Daniele Giordimaina Fernandez** (2 tickets to the Elton John concert)
 - 2nd prize - **Dr. Anne Marie Bonello** (1 month membership to the Corinthia Athenaeum Spa, Attard)
- Runner ups (1 day membership to the Corinthia Athenaeum Spa, Attard)

Dr. Joe Pace, Dr. Joseph Xuereb, Dr. Petramay Cortis, Ms. Lisa Galea, Ms. Linda Galea Debono, Mr. Michael Rosal, Mr. James Vassallo, Mrs. Alison Attard, Ms. Ambra Cauchi, Mrs. Noemi Attard, Mr. Tonio Cassar, Mr. Daniel Micallef, Dr. Rodianne Bonnici, Mr Michel Grech, Ms Giselle Mallia

TheSynapse team would like to congratulate the winners and thank the sponsors of these competitions.



THIS MONTH'S CHALLENGE



The answers to all questions can be found in Issue 3/10. Those who get a correct answer will participate in a draw where the first two drawn names will each win a 1 day membership to the Corinthia Athenaeum Spa, Attard.

1. What was the biblical name which featured in the Wine Expectations article's quote?
2. The prize given to the first drawn name of the Update and Win quizz was 2 tickets to the Elton John concert? Yes / No _____

Kindly submit the answers by mail by filling the form on this page addressed to The Professional Services Centre, 3 Guzi Cutajar Street, Dingli, DGL 1201 or submit your answers on-line on www.thesynapse.net/quizz. All submissions will participate in a draw. You have up to the 27 September 2010 to submit your answers.

Fill in your details

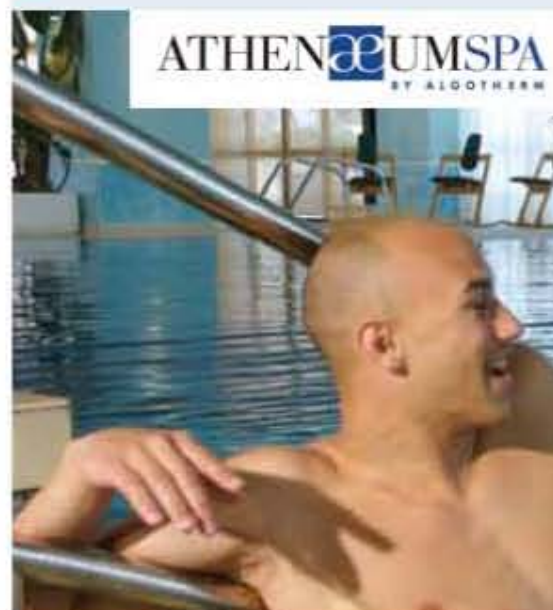
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The professionals at the Athenaeum MediSpa are focused on helping you take care of your individual skin care and beauty needs. Our internationally qualified physicians and trained aestheticians will consult with you on your beauty and skin-care goals, and recommend products and treatments to help you get the most out of your visits to the MediSpa. ISpa.

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Catafast®
 Presentation: Catafast powder for oral solution in sachets of 50 mg diclofenac potassium. **Indications:** Short-term treatment in the following acute conditions: post-traumatic pain, inflammation and swelling, e.g. due to sprains, post-operative pain, inflammation and swelling, e.g. following dental or orthopaedic surgery, painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis, migraine attacks, painful syndromes of the vertebral column, non-articular rheumatism, as an adjuvant in severe painful inflammatory infections of the ear, nose or throat. **Dosage:** Dose to be individually adjusted, lowest effective dose to be given for the shortest duration. **Adults:** 50 to 150 mg daily in divided doses. For dysmenorrhoea and migraine attacks: up to 200 mg daily. **Adolescents aged 14 and over:** 50 to 100 mg daily in divided doses up to 150mg daily. **Children and adolescents below 14 years of age:** not recommended. **Contraindications:** Active gastric or intestinal ulcer, bleeding or perforation; known hypersensitivity to diclofenac or to any of the excipients, to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs); Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs; last trimester of pregnancy; severe hepatic, renal or cardiac failure. **Precautions/warnings:** Avoid use with other systemic NSAIDs including COX-2 inhibitors. Risk of gastrointestinal (GI) bleeding, perforation or serious allergic reactions, persistent abnormal liver and renal function tests; to be discontinued if these conditions occur. Risk of allergic reactions. May mask signs and symptoms of infection. Caution recommended in patients with symptoms/history of GI disease, asthma, seasonal allergic rhinitis, chronic pulmonary diseases, chronic infections of the respiratory tract, elderly or impaired hepatic function (including porphyria), ulcerative colitis or Crohn's disease. Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelets agents or SSRIs. Caution while driving or using machines. Combined use with protective agents to be considered in patients with history of ulcers, elderly, and those requiring low dose aspirin. Monitoring of liver function and blood counts recommended during prolonged treatment. Monitoring of renal function recommended in patients with history of hypertension, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. Monitoring recommended in patients with defects of haemostasis. As Catafast contains a source of phenylalanine, may be harmful for patients with phenylketonuria. Beware of severe fluid retention and oedema. Very rarely reported serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis. Discontinue at the first appearance. May be associated with a small increased risk of arterial thrombotic events. Before treatment consider carefully patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease, and before initiating longer-term treatment of patients with risk factors for cardiovascular disease. **Pregnancy and lactation:** Should not be used in the first and second trimester of pregnancy and by breast-feeding mothers. Not recommended to use in women attempting to conceive as it may impair female fertility. Should not be administered during breast feeding in order to avoid undesirable effects in the infant. **Interactions:** Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs. Monitoring recommended for patients receiving anticoagulants, anti-platelet agents as well as blood glucose level if used concomitantly with antidiabetics. Monitoring of serum lithium and digoxin levels recommended if used concomitantly. Dose of diclofenac to be reduced in patients receiving ciclosporin. Interactions with concomitant use of quinolones antibacterials. **Adverse reactions: Common undesirable effects are:** Headache, dizziness, vertigo, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia, transaminases increased, rash. **Rare undesirable effects are:** Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnoea), gastritis, gastrointestinal haemorrhage, haematemesis, melaena, diarrhoea haemorrhagic, gastrointestinal ulcer (with or without bleeding or perforation), hepatitis, jaundice, liver disorder, urticaria, oedema. **Very rare undesirable effects are:** Thrombocytopenia, leucopenia, anaemia (including haemolytic anaemia and aplastic anaemia), agranulocytosis, angioneurotic oedema (including face oedema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident, visual disturbance, vision blurred, diplopia, tinnitus, hearing impaired, palpitations, chest pain, cardiac failure, myocardial infarction, hypertension, vasculitis, pneumonitis, colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, oesophageal disorder, diaphragm-like intestinal strictures, pancreatitis, fulminant hepatitis, bulous eruptions, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura, allergic purpura, pruritus, acute renal failure, haematuria, proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis. **Marketing Authorisation number:** MA 088/00303. **Marketing Authorisation Holder:** Novartis Pharmaceuticals UK Ltd., Frimley Business Park, Frimley, Camberley, Surrey GU16 7 SR, UK. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available on request from Novartis Pharma, P.O. Box 124, Valletta, VLT 1000, Malta. Tel: +356 22983217. 2009-MT-01-Catafast

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- **Onset of action within 5 minutes¹**
- **Significant pain relief within 13.5 minutes²**
- **Placebo-like tolerability³**

References

1. Novartis Pharmaceuticals UK Ltd. Catafast Summary of Product Characteristics.
2. Marzo A et al. Pharmacokinetics of diclofenac after oral administration of its potassium salt in sachet and tablet formulations. *ArzneimForsch / Drug Res* 2000; 50(1):43-47.
3. Diener HC, Montagna P et al. Efficacy and tolerability of diclofenac potassium sachets in migraine: a randomized, double-blind, cross-over study in comparison with diclofenac potassium tablets and placebo. *Cephalalgia* 2006;26(5):537-47.

Get Informed for your patients

Health Promotion and Disease Prevention Directorate

What is on for summer in health promotion?

The Directorate is responsible for preventing illness and promoting health in order to improve the health and well-being of the Maltese population and for providing leadership for health promotion to reduce/delay the onset of illness. We encourage the promotion of healthy lifestyles amongst the population and work in partnership with other Ministries, external stakeholders and health care workers to tackle the determinants of illness, particularly to reduce the disease burden caused by non-communicable and communicable diseases.

Throughout the year we focus on various aspects which all build up to encourage a healthier lifestyle. Summer is with us and so does the rise in the UV Index. The rise in the incidence of skin cancers over the past decades is strongly related to increasingly popular outdoor activities and recreational exposure. Overexposure to sunlight is widely accepted as the underlying cause for harmful effects on the skin, eye and immune system. So since May and throughout summer we will be encouraging people to stay out of the sun and take protection.

Advice includes:

Do not burn

Sunburns significantly increase one's lifetime risk of developing skin cancer, especially for children

Avoid Sun Tanning and Tanning Beds

UV light from tanning beds and the sun causes skin cancer and wrinkling

Generously Apply Sunscreen

Generously apply sunscreen. Choose one with a high SPF and which provides protection from both ultraviolet A (UVA) and ultraviolet B (UVB) rays. Reapply every two hours, even on cloudy days, and after swimming or sweating

Wear Protective Clothing

Wear protective clothing, such as a long-sleeved shirt, pants, a wide-brimmed hat, and sunglasses, when possible

Seek Shade

Seek shade when possible and remember that the sun's UV rays are strongest between 11 am and 4 pm.

Another problem is obesity. Malta is reported to have one of the highest overweight problems in Europe. The Health Behaviour In School-Aged Children study in 2008 found a high proportion of Maltese children to be overweight. In fact around 15% of 13-year olds are above the 95th weight centile. The European Health Interview survey of 2008 reports 36.3% of adults being overweight and a further 22.3% being obese. Hence obesity is one of the priorities we are working on and hence we will continue with our campaign on obesity focusing on **four main messages:**

1. Getting involved in healthy food preparation
2. Healthy choices in food
3. Limit food portions
4. Include more physical activity

We are also offering free weight management classes in health centers and aerobics in local councils for people who have BMI over 25 to encourage them to loose weight and stay healthy. A strategy is being drafted to tackle the obesity issue including the enabling of the environment which will encourage the update of healthy activities.

Copies of material related to these campaigns will soon be obtainable from TheSynapse online library or by calling the directorate on 23266000.

Health Promotion Quizz

When was the fifth European Immunisation Week held?

The answer can be found in Issue 3/10. The first drawn name will get a 3 month membership for a Parent and Kid at Spinach Fitness Club, Malta's first kids' gym – Melita Training Grounds, Pembroke. The gym may be contacted at www.spinachfitness.com or 2179383740.

Kindly submit the answers by mail by filling the form on this page addressed to The Professional Services Centre, 3 Guzi Cutajar Street, Dingli, DGL 1201 or submit your answers on-line on www.thesynapse.net/quizz. All submissions will participate in a draw. You have up to the 27 September 2010 to submit your answers

Fill in your details

Name

Address

Email

Mobile



A short review of the evidence base for Dead Sea Salt topical treatment and balneotherapy for skin and joint pathologies

by David Grech

The beneficial influence of the Dead Sea and the clinical benefits of its mineral salts in different illnesses were first documented by the ancient historian Josephus Flavius about 2000 years ago. In recent years, scientific studies have confirmed a clinical evidence base for the lasting improvement of dermatological and rheumatological conditions following balneotherapy and topical treatments with Dead Sea salts and their commercial derivatives. Balneotherapy is properly defined as the use of bathing of the whole or parts of the body in mineralized water at a temperature of at least 20°C and with a mineral content of at least 1 g/l.¹ More so, it is more common that the temperature of the thermal water is approximately 34°C. The chemical composition of Dead Sea salts is unique: high levels of magnesium (34%) and potassium (28%) cations and a significant concentration of bromide (0.4%) anions render it different from other mineral wells. The sodium content is comparatively much lower, at 18%. The chemical effects of the Dead Sea salt treatment in psoriasis were first demonstrated in a series of studies

between 1985 and 1995 by Shari et al by in vitro and in vivo human and animal studies.² The studies demonstrated that Dead Sea minerals, applied through bathing or topical derivative products, penetrate psoriatic skin more than healthy skin, with psoriatic keratinocytes revealing elevated mineral content while retaining normal structure. Furthermore, it was shown that the high levels of magnesium and potassium ions have a specific inhibitory capacity on the uncontrolled proliferation and differentiation of psoriatic dermis grown in tissue culture.

A double blind controlled study conducted by Halevy et al³ in patients with psoriasis vulgaris also revealed a beneficial effect of balneotherapy with Dead Sea bath salts as compared to common salt. The percent reduction in the Psoriasis Area Severity Index (PASI) score following balneotherapy with Dead Sea bath salt at the end of treatment (3 weeks) and 1 month later (34% and 43%, respectively) was higher than that recorded following balneotherapy with sodium chloride (27% and 24% respectively). Immunohistochemical staining also showed a decrease in the normally high

expression of TNF-α and IL-6 on psoriatic keratinocytes. The authors further suggested that balneotherapy with Dead Sea bath salts serves as an adjuvant anti-proliferative and anti-inflammatory therapy in psoriasis vulgaris.

In a multicentre study of 280 patients, Schiffner et al⁴ assessed synchronous balneophototherapy with narrow band UV-B and bathing in Dead Sea Salt solution to be, based on investigator and patient feedback, superior to previous treatments undergone by the patients, with no severe side effects and positive perceptions by the patients of the treatment as being pleasant and comfortable. Mean PASI improvement of 71% compared favourably to oral PUVA treatment (81%). This appears significant in patients with chronic diseases where multiple lifetime treatment courses may be necessary, because quality of life may be impaired not only by the disease but also by the treatment modalities. Dead Sea salts, particularly the magnesium salt component, are also shown to be effective for atopic

skin.⁵ Bathing in Dead Sea salt solution significantly improved skin barrier function compared with the tap water-treated controls in eczema patient cohorts with elevated basal transepidermal water loss (TEWL). Skin hydration was enhanced and skin roughness and redness as markers for inflammation were significantly reduced after bathing in the salt solution. A positive influence on joint pain was also noted in the Schiffner study. This has been validated in randomized controlled trials of the therapeutic rheumatological effect of Dead Sea Salt balneotherapy.⁶ Once again balneotherapy was shown to decrease the levels of inflammatory mediators such as prostaglandin E2 as well as interleukin-1 and leukotriene B4. An interesting finding is that balneotherapy reduces the levels of catalase, superoxide dismutase, malondialdehyde protein and glutathione peroxidase. Balneotherapy is associated with clinical improvement in rheumatological disease affecting mainly the vertebral spine and shoulder-neck area such as osteoarthritis, fibromyalgia, ankylosing spondylitis, rheumatoid arthritis and in chronic low back pain.

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- 2 - Shari J, Eisen-Paz Z, Avraham WW, Rubinstain M, Ushin R, Justesen NPS, Hufnagel W. Topical replacement therapy of psoriasis by dead sea salts, evaluated by scanning electron microscopy and X-ray fluorescence. *Dermatosen* 1991;28:49-55.
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- 6 - Fregoe M, E, Zeridatou E, Refshals P. The Therapeutic Effect of Balneotherapy: Evaluation of the Evidence from Randomized Controlled Trials. *Int J Clin Pract* 2008;68(7):1088-1094.

Focus on

Continues from page 13

different risk groups and follow international guidelines as to diabetic foot care. Early referral to podiatry and diabetic podiatry according to the level of risk will have a determining effect on prevention of ulceration and limb loss. Most importantly however those patients with ulcerated feet or gangrene should be referred to the appropriate specialist as early as possible and those cases with features of critical ischaemia or severe infection should be referred as emergencies and seen within 24 hours. Risk factor control in those patients with diabetes and arterial disease will also contribute significantly to a reduction in morbidity and mortality in this group. Sadly we are still seeing considerable number of patients who are only referred once the limb is unsalvageable either through delayed presentation by the patient to the GP, or through misguided delay by the GP in an attempt to treat patients with ischaemic ulceration with local applications or dressings. It is also important for doctors working within accident

and emergency departments to recognize the features of critical ischaemia and severe infection which warrant immediate hospital admission and treatment. Discharging these patients home on oral antibiotics without a proper vascular assessment and management plan is inadequate care. Finally we are all responsible for contributing to patient education. Intensive education has been shown to reduce amputations and recurrent ulceration in patients who have had previous diabetic foot disease.

Major amputations are associated with a 30 day mortality as high as 30%. The disability and reduction in quality of life associated with these procedures is considerable. Relatively small investments in education and prevention will mean not only less major amputations, but also less unnecessary deaths, improved quality of life for these individuals and dramatic reductions in health care costs.

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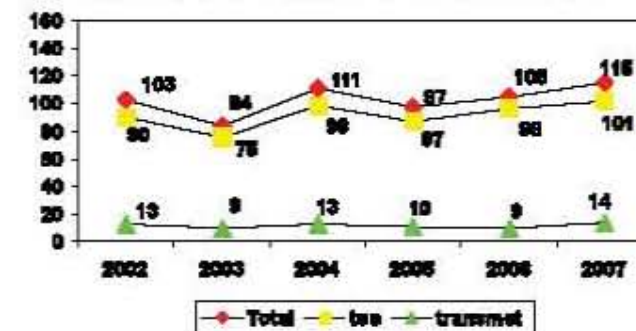


Figure 2: Minor amputations in Malta 2002-2007 (toe, toe end transmetatarsal amputations)

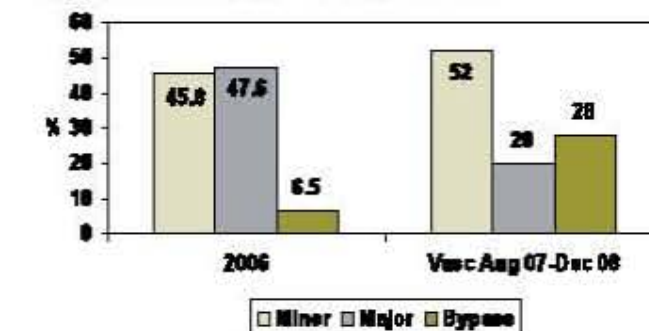


Figure 3: Proportion of Major/minor amputations/infragaingial bypass surgery: comparison between 2006 and 2008

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1. New JP, McDowell D, Burns E, Young RJ. Problem of amputations in patients with newly diagnosed diabetes mellitus. *Diabetes Medicine* 1988; 15:760-4

Microwave (MW) ablation offers many of the advantages of RF ablation while possibly overcoming some of the limitations. Since MW ablation does not rely on conduction of electricity into tissue, it is not limited by charring and does not require grounding. Therefore, temperatures greater than 100°C are readily achieved, which potentially results in a larger zone of ablation, faster treatment time, and more complete tumor kill. Because the cooling effect of blood flow is most pronounced within the zone of conductive rather than active heating, a larger power field may also enhance treatment of perivascular tissue. Thus there is some evidence that microwaves tend to suffer less from "heat-sink effects" than RF.

Liver tumors are particularly suited to RF or microwave ablation. Primary liver lesions (particularly hepatocellular carcinomas) and metastases may be treated effectively with this technique (Figures 4 & 5).

Palliative tumor ablation in a 62-year-old man with a painful 7-cm hepatocellular carcinoma in his liver.

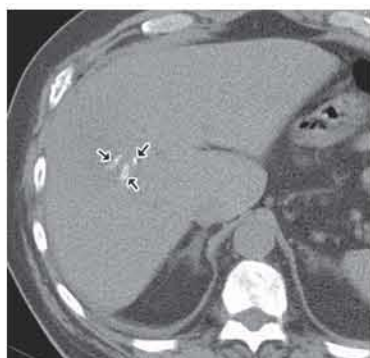


Figure 4(a) CT scan obtained before ablation shows internal calcifications (arrows).

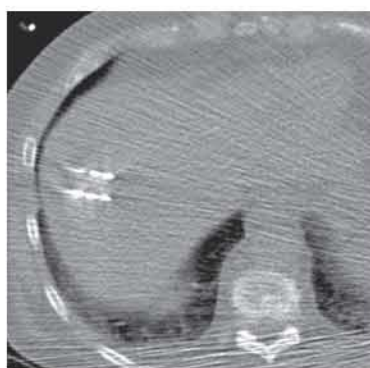


Figure 4(b) CT scan shows microwave antennae in the center of the lesion.



Figure 4(c) Post-procedural CT scan obtained with contrast material enhancement shows a large area of thermo-coagulation (arrows).

Microwave ablation of a hepatic metastasis in an 82-year-old woman with metastatic colon cancer to both lung and liver. She had responded well to chemotherapy and had only one hepatic lesion left, measuring approximately 4.3 cm in segment 7



Figure 5(a) CT-guided Microwave ablation

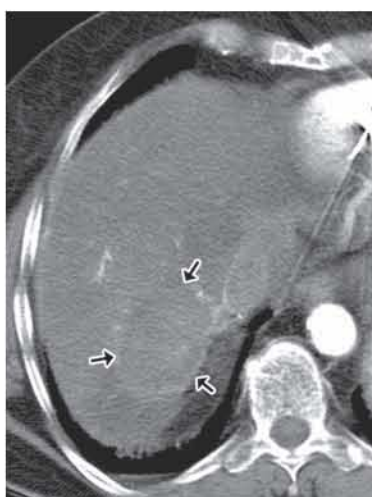


Figure 5(b) - : Contrast enhanced CT scan post ablation showing an area of necrosis (arrows).

The number of lesions and their location would determine approach and suitability for thermo-ablation. Lung lesions (both primary and metastatic) have also been successfully treated with RF and microwave ablation (Figure 6). Both experimental and now fairly extensive clinical work illustrates the potential clinical applications and advantages of RF and microwave ablation. The technique requires considerable experience with imaging guided lesion localisation and is time-consuming and expensive. It requires an interventional operating theatre with facilities for general anaesthesia, expensive probes and imaging equipment and a full team of specialised staff. The full potential of this technology is still under evaluation and further clinical implementation will help improve experience and contribute to both curative and palliative care of patients with cancer.

Microwave ablation of primary lung cancer in an 86-year-old man.



Figure 6(a) CT scan shows a microwave antenna in the mass along its superior portion.

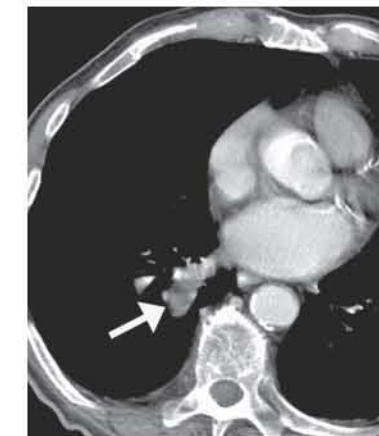


Figure 6(b) On a post-procedural contrast-enhanced CT scan shows no enhancement within the lesion.

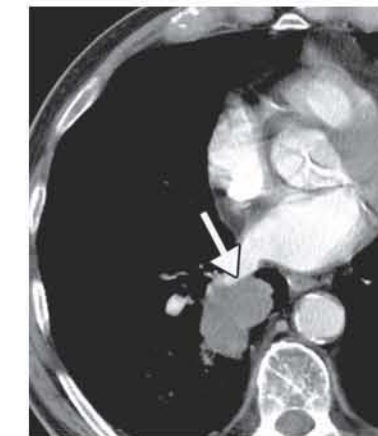


Figure 6(c) CT scan obtained at 9-month follow-up shows interval shrinkage and no enhancement of the mass (arrow).

Dermatology

Looking for Melanoma

by Joseph L. Pace

Melanoma is increasing worldwide and UK death rates from melanoma have more than doubled from 1.2 per 100,000 in 1971 to 2.6 per 100,000 in 2007. Cancer Research UK predicts that by 2024, rates of malignant melanoma in people aged 60 to 79 will rise by a third. Genetic factors are the most important of the known risk factors, including the familial tendency to develop melanoma, prominent moles, and atypical moles. Overexposure to ultraviolet radiation in sunlight is believed to be a contributing factor to some cases of melanoma; short periods of intense exposure, such as sunbathing is associated with a 2-fold increase in melanoma risk. Indeed, both cheaper package holidays to sunny destinations and the excessive use of sunbeds from the 1970's are said to be related to increased melanoma risk. Malta has not been spared and in the decade between 1998 and 2008 reported cases trebled from just under 20 to 60 per annum. Some of these will be due to increased awareness among both doctors and public and many will be curable melanomas in situ, but nevertheless this increase is

in keeping with the experience of other countries. The outcome in each case depends on the extent of the lesion in particular the depth of skin affected. When melanoma is detected at its early stage, simple surgical removal cures the disease in most cases, but when spread to lymph nodes, the 5-year survival rate is 30-40%, falling to a dismal 12% with spread to distant organs. Thin melanomas therefore have an excellent prognosis, unlike thicker lesions. With the realisation that for cases with metastases there is relatively little available in the way of consistently successful therapy, the onus is on the dermatologist to make a crucial early diagnosis when cure becomes the rule and not the exception. According to The Melanoma Letter, a publication of the Skin Cancer Foundation, a dermatologist using a quality hand lens will only make a correct diagnosis in 65% of cases. The arrival of the dermoscopy technique (surface microscopy) which utilises a microscope to identify characteristic melanoma patterns not otherwise visible was a major landmark enabling the experienced dermatologist to



diagnose melanoma earlier and thus make it more amenable to curative treatment. In addition, the number of innocent moles removed "just in case" was expected to diminish resulting in less morbidity and more cost effectiveness. It was however realised early on that Dermoscopy (also known as Epiluminescence Microscopy, ELM) would enable a trained dermatologist to achieve >80% correct diagnosis but that casual dermoscopy can degrade diagnostic accuracy.

Amid rising melanoma rates and with less than 20% of US dermatologists confident with dermoscopy, attention was turned to the possible use of computerised systems to make the benefits of dermoscopy even better and available to dermatologists who are not experienced dermoscopists.

The technology has evolved rapidly in recent years with major research centres such as the renowned Sydney Melanoma Diagnostic Centre placing Automated diagnosis of melanoma on the skin in the forefront of their current major research programmes.

The approach developed is an image-analysis system of computerised (digital) dermoscopy images. These are displayed so that analysis of a 'mole-like lesion' can be compared with a large database of previously analysed melanomas and benign moles. This approach, initially conceived to help dermatologists not fully expert in dermoscopy, has now been repeatedly demonstrated to achieve a comparable or superior diagnosis to that of a range of clinician groups, including the acknowledged experts in the field.

There are a number of different computerised digital dermoscopy applications, all successful in their own way. One of the more advanced systems is the DB-Dermo MIPS developed in Siena by Deleva and Burroni, the latter holding a Chair at the University of Siena, dedicated solely to the computerised diagnosis of melanoma. Publications have confirmed that the inspection of pigmented skin lesions by digital epiluminescence has a better diagnostic accuracy than that of a trained dermatologist using the epiluminescence technique only, and that this computerized system can play an essential role in the detection of early melanomas.¹ The same research group later showed that computerized analysis of digital images obtained by epiluminescence light microscopy evaluated 48 objective parameters used to train an artificial neural network (compared to 5-7 parameters analysed by the dermatoscope alone) and obtained a maximum accuracy in distinguishing

melanoma from benign lesions of about 93%. It was also independently confirmed that a diagnostic algorithm for digital image analysis of melanocytic lesions can achieve the same range of diagnostic accuracy as the application of dermoscopic classification rules by experts.² Differentiation of small melanomas from small benign pigmented lesions challenges even expert physicians. Computer-vision systems can facilitate early detection of small melanomas and may limit the number of biopsies to rule out melanoma performed on benign lesions.³

Computerised digital dermoscopy is now increasingly being utilised to supplement the dermatologist's clinical acumen and improve outcomes for patients with melanoma by providing an early diagnosis. A secondary beneficial effect is reduction of need of excision and pathological examination of benign lesions. The technology available

it was however realised early on that Dermoscopy ... would enable a trained dermatologist to achieve >80% correct diagnosis but that casual dermoscopy can degrade diagnostic accuracy.

In Malta is the DB-Dermo MIPS and this highly efficient system is set at a sensitivity level that will also give a warning result (and hence notice to excise) to a small number of benign lesions that do not satisfy all or almost all of the 48 parameters examined.

This system has been in use in a number of countries for some years with excellent results. Computerised digital dermoscopy like all sophisticated diagnostic systems in other fields of medicine, is NOT for mass screening purposes but rather to help the dermatologist look for melanoma in persons considered to be at higher risk, as well as to support the clinical ELM diagnosis in individual cases. These higher risk cases which merit at least 2-yearly examinations

include: (1) when there is a personal / family history of melanoma (annually for this group); (2) when there are numerous dysplastic (atypical) naevi; (3) when the skin is light-colored and heavily freckled due to excessive sun exposure and/or Ultraviolet radiation from sunlamps and sunbeds; and (4) Post organ transplant patients. In addition, a one-time total-body skin exam to hunt for melanoma in patients who are older than 50 is considered as cost-effective as other widely accepted cancer screenings such as mammograms and Pap smears⁴ while the American Cancer Society recommends having a complete skin exam every year if you're older than 40. These screening exams involve a head-to-toe inspection of your skin by a dermatologist.

Single lesions that exhibit recent changes will ordinarily be removed and examined unless clinical examination and ELM confirms a benign condition such as a pigmented seborrheic keratosis. Digital dermoscopy can help to confirm a diagnosis which may not yet be totally clear.

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NOTE-This digitalised dermoscopy computer system has been up and running for some time with highly satisfying results. To strongly support and complement the initiative of the The Maltese Association of Dermatology and Venereology in the sphere of melanoma prevention with the annual Melanoma Monday campaign, it has been decided to emphasise this important health message on a continuing basis by offering a number of free DB-Dermo MIPS examinations, where indicated on one day each month throughout 2010. Patients will be referred by their family doctors as explained above and should be limited to those at higher risk. It is important that only those in these risk groups are referred since slots are of course limited. This programme is being held with the generous support of the Chemimat Group, owners of the DB-Dermo MIPS system in Malta, and of a number of dermatologists who will give their time gratuitously. Colleagues are of course welcome to visit and see DB-MIPS - please email us on mpi@

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LOOKing at Cancer up close

by Marika Azzopardi

A nuclear physician specialising in the imaging of tumours, Dr Mark Anthony Aquilina recently returned back to Malta after a stint of specialising and working up north in Milan's prestigious San Raffaele Hospital. From his north Italian posting he went into depths in his field of nuclear medicine, becoming an expert at PET-CT scanning, a sub-specialty of this imaging technique. With the introduction of this imaging method in Malta, Dr Aquilina has brought to fruition his long-term intention of returning to island living, carrying on practicing his specialisation here and serving the Maltese people.

He speaks openly of his experience in Italy. "I graduated from the University of Malta in 2001 and finished housemanship in 2003. Malta was still not an EU member and the post-graduate exams to get into specialisation in Italy were extremely difficult. In fact many years had passed since the last Maltese doctor specialised in Italy. But I was determined to specialise in Italy and at age 25 I had to take a bank loan to do what I had set my heart on doing, and I also had to rely on my family for financial support. Then I suddenly found myself at the largest Nuclear Medicine centre in Europe with great exposure and the best tutors around. The fact that I graduated with distinction when I finished specialisation allowed me the luxury of choosing between a consultant post in San Raffaele, another hospital in Milan, Bergamo, and later on another important hospital in London. However I immediately opted to take up an opportunity to work at the San Raffaele."

His first boss was Italy's famous politician Prof. Ferruccio Fazio, now Italian Minister for Health. As director at the San Raffaele Nuclear Medicine Department, Fazio voiced an instant gut feeling that the Maltese doctor would stay on once a specialist post was opened purposely for him. And Dr Aquilina did ... stay on and learn that with today's high technology methods, some cases of cancer have become more like a chronic disease rather than a fatal one.

The going was not easy. In Italy he had few connections initially, had to relinquish some of his sporting activities and could not keep a pet nor really live comfortably in his 40-metre-square of apartment space. "My social network changed but I still found that Milan is an easy place to integrate in and make buddy pals. However, it was an uphill struggle, breaking into a system that required for instance, writing reports in perfect Italian, and working in a system somewhat alien to the British



President Abela's visit in February 2010 at St James Hospital. Source: DOI

methods used here in Malta. Each and every report had to be on the dot because our assessors would take random samples of our writings and expect them to be perfect every time. So there was no chance of skiving. After all, San Raffaele is considered a centre of excellence in the field (Nuclear Medicine), and a top notch product is expected from the specialists working there."

He also learnt more about dealing with people, as opposed to dealing with patients. People who arrive at hospital are generally very scared with many misgivings as to the outcome of their tests, whether they already have a diagnosis or merely a suspicion of one. "Many a-time, people from Malta would arrive at San Raffaele and link immediately with me because they feel more attached to a fellow national than to a foreign Italian one even because of the language barrier which, where medical terms are concerned, can be quite non-plussing to foreigners. You learn to interact with people and address their fears rather than merely scan and test 'cases'. Patients bring with them a fear of the unknown and it is our responsibility to help them rather than just give them a pill to tranquillise them."

Dr Aquilina states the fact that as medical doctors most are very good at diagnosing and managing illnesses, and there are absolutely no problems with standards. But he bemoans how one limitation stands out particularly... very much like a sore thumb... "We are not trained to give out bad news".

"PET/CT is an essential tool to the oncologist, but a person who reads a scan is also the one facing the patient when a high level of tension is palpable. Besides reporting thousands of conventional nuclear medicine scans and seeing to hundreds of patients undergoing radionuclide therapies, I have done on average some 1000 PET/CT scans a year for more than five years in



Dr Aquilina together with the Italian Minister of Health, Ferruccio Fazio (photo taken in 2004; before Prof. Fazio became Minister, he was Dr Aquilina's director at San Raffaele Hospital)

a centre where 10,000 PET/CT scans are performed annually, but I am never prepared enough to deal with people's fears. It is never easy telling somebody about their terminal illness, nor telling somebody that their child or loved one has something of the sort."

He feels that PET-CT scanning positively alters the picture of cancer and a considerable percentage of patients have their management changed or optimised. Through PET-CT, most cancers can be imaged. This new method offers essential complementary information to the stand-alone CT scan since functional data is added to structural imaging and the physician can also see all organs within an extensive field of view.

"For example we know that in many instances a PET-CT can remove the necessity of a biopsy completely; by characterising lesions the scan helps one to make a better and sharper decision during diagnosis, and optimise management thereafter. It is also essential in evaluating a response to therapy appropriately and in the follow-up of patients. Many Maltese patients came to Milan for PET-CT scans because this extremely expensive apparatus was not previously available in Malta. Scans do not come cheap however as is the case with all new applied technology; the tracer is also bought from abroad."

For the moment, Dr Aquilina is relishing his time back in Malta, helping establish the new scanning system together with San Raffaele Hospital and returning to a life here. He plans to return to scouting and to playing football with his Maltese buddies, something which he never stopped doing in Italy, even going so far as fracturing his cheekbone on the field. "I also play table tennis when the opportunity arises and did judo in the past Am looking forward to having a pet again.... I can never get over the loss of the dog which I had from age five months till 18 years."



Dr Aquilina with his family

ILTS Grape Expectations

Britain to us

Bordeaux & London

by Albert Cilia-Vincenti

This the first of a two part series on how the 18th and 19th century British middle classes shaped the wine industry

The emergence of the cult of fine wine may be traced back to 10th April 1663, when Samuel Pepys, diarist and man-about-London, wrote how much he liked "a sort of French wine called Ho Bryan that hath a good and most particular taste that I never met with". What he had experienced was Château Haut Brion of Bordeaux, and he tasted it at the Royal Oak Tavern in the heart of London. This was one of many such establishments that had sprung up after the return of exiled King Charles II three years earlier, and which offered such new delicacies as tea, coffee and fine wines.

The hedonistic atmosphere of those days was responsible for introducing not only "Ho Bryan" and other great wines from Bordeaux, but also port from Portugal's Douro Valley, the sparkling wines from the Champagne region and a brandy from a small town north of Bordeaux, called Cognac.

As Pepys was introduced to "Ho Bryan", big economic shifts were under way, with London beginning to replace Amsterdam as the world's trade hub. Its merchants were growing in power, wealth and appetite for luxuries, including claret (as the British call red Bordeaux wine). By the 18th century Londoners were the world's biggest consumers of good claret.

Previously royal connections had made drinks famous and popular. The Court of France's King Louis XIV, who himself drank Burgundy wines, was the arbiter of alcoholic taste. Now, for the first time, a wider social group, including aristocrats and commoners, such as Pepys, with fashionable aspirations, were setting the tone.

The English had been drinking claret for five centuries before Pepys's time, but it was poor stuff that was drunk very young before it turned to vinegar within months. Up to the end of 17th century it continued to be drunk mainly by those using "claret to cool their port", according to one observer. Fake wine was already well established and, someone calling himself "Satirical Dick", wrote how a "jolly wine-cooper" could blend a "pint of old port" with some rough Spanish wine and thus "could counterfeit claret the best of the sort".

"Wine... offers a greater range for enjoyment and appreciation than possibly any other purely sensory thing which may be purchased"

Ernest Hemingway (1899-1961)

The owners of Ho Bryan were the Pontacs, the top winemaking family of their day, and they opened a fashionable restaurant, called Pontack's Head, in London in 1663. John Locke, the philosopher whose theory of the social contract inspired America's revolutionaries, but who also had worldly interests, identified the reasons for Ho Bryan's superiority on a visit to the vineyard in 1667. He noted "a little rise of ground...white sand mixed with a little gravel; scarce fit to bear anything". He added that "they say the wine in the next vineyard to it, tho' seeming equal to me, is not so good". Today that vineyard is still rated just below its neighbour.

Locke had discovered the concept of terroir, the combination of soil and subsoil types, drainage and microclimate which largely determine wine quality. Another connoisseur, the 18th century economist Adam Smith, noted that "the vine is more affected by the difference of soils than any other fruit tree. From some it derives a flavour which no culture or management can equal".

Claret was getting better and more popular. By the early 18th century, it was designed to be kept for years not months, notably by being carefully stored in oak casks, better corks allowed longer safe storage, and bottles were produced that could be laid down on their sides to mature. By Smith's time the industry's shape was established. Advertisements in the London Gazette noted wines for sale from four châteaux – Haut Brion, Latour, Lafite and Margaux, all on the gravel banks above the Gironde estuary in the Médoc, the peninsula north of Bordeaux. These four estates remain the greatest brands in wine. Their main competitors, then as now, are a handful of tiny vineyards in Burgundy.

British appetite for their produce was growing but, so too, the obstacles to getting hold of it. Britain, Portugal and their allies were at war with France and Spain. Portugal's port was therefore considered the patriotic drink. Vendors in the 1707 sales, and many others, claimed (an unlikely story) that their supplies were captured by British ships in the fighting. Drinking claret in the 18th century distinguished the rich from England's port-sodden squirearchy. Port was not only the more traditional drink, it also was far cheaper.

Hyperhidrosis - 'Virtually non-invasive' management

by Peter Apap

Hyperhidrosis is a disease characterized by perspiration in excess of the physiologic amount necessary to maintain thermal homeostasis.¹ Primary or idiopathic hyperhidrosis and secondary hyperhidrosis are the two main categories. Patients can have excessive sweating either in a localized area (focal) or over the entire body (generalized).² Primary disease is usually focal, affecting the soles, palms, and axillae in various combinations and with varying degrees of severity. Secondary hyperhidrosis can be generalized or focal.³ In secondary hyperhidrosis the symptoms are a consequence of certain medical conditions, example diabetes, or the use of certain drugs, example nortriptyline.⁴

Hyperhidrosis can have very significant effects on patients' lives, causing physical discomfort, social embarrassment and impacting negatively occupational and daily activities. Skin maceration from constant wetness can lead to bacterial and fungal overgrowth, and subsequent axillary intertrigo and bromhidrosis (foul-smelling sweat).

Pathophysiology and epidemiology

Sweat glands in patients with hyperhidrosis are not histopathologically different from those in normal patients, nor is there an increase in the number or size of glands. The condition is caused by hyperfunction of the sweat glands rather than hypertrophy.⁴ A recent representative survey of 150,000 households in the US showed a prevalence of 2.8%. Of those with hyperhidrosis, only 38% consulted their physician about their excessive sweating.⁵

The main treatment options available to patients with primary hyperhidrosis can be categorized as non-surgical (topical antiperspirants, iontophoresis) or surgical (endoscopic thoracic sympathectomy, excision of axillary tissue).¹ 'Minimally Invasive' Botulinum toxin injections are another option for axillary hyperhidrosis.

Topical Treatments

OTC Anti-perspirants containing aluminium chloride can control underarm sweating and odour. However patients with moderate-to-severe hyperhidrosis need stronger therapies.⁶ Iontophoresis is defined as the passing of an ionized substance through intact skin by the application of a direct electrical current (DC).⁷ Tap water iontophoresis is considered by many dermatologists to be the first line of treatment for hyperhidrosis of the palms and soles.^{7,8}

Although the mechanism of action in hyperhidrosis is currently not understood, there have been several theories.⁹ Iontophoresis can be performed with a professional device in a clinic setting, or at home using portable devices. Hands and feet can be treated simultaneously, using separate trays. Treatment with a professional device⁸ requires fewer initial treatment sessions (5-8 sessions of 20 minutes each for palmo-plantar treatments) and more spaced out maintenance sessions (on average, once a month). It is essential that maintenance sessions are carried out as soon as the first signs of hyperhidrosis are noticed. Newer 'pulsed' professional devices⁸ also offer enhanced tolerance for patients sensitive to a DC current. However pregnant patients or those with pacemakers

or arrhythmias should not be treated.^{7,10} Caution must also be exerted with metallic implants such as orthopedic prostheses. In a recent study, 112 patients had palmar iontophoresis.¹¹ Sweat production was measured at baseline and 20 days after all of the 8 treatments. The final sweat production was significantly reduced compared to baseline (P<0.001) for 81.2% of the patients. The mean time for patients to become asymptomatic again was 35 days. Longer periods of remission were seen after a second period of treatment. A few side effects are commonly reported with iontophoresis. Vesiculation is usually transient.¹² Redness of the skin, often along the water line,¹² and skin dryness are also commonly reported.¹³

Botulinum Toxin Injections (Botox®)

Botulinum toxin A injection has been used successfully to reduce excessive sweating in all of the body areas affected in primary hyperhidrosis: axillary, palmo-plantar and facial. However it is most commonly used for treatment of axillary hyperhidrosis. It works by inhibiting release of acetylcholine from the presynaptic terminal of the cholinergic nerve junctions with striated muscle and eccrine glands.^{13,14} Treatment takes less than 30 minutes and must be repeated anytime between 4 - 18 months after to maintain results. Side effects are generally related to pain, tenderness and bruising after injection, as well as to paresis of adjacent muscles, seen primarily with facial and palmar treatments.¹⁴⁻¹⁷

Smartlipo™ Laser

Smartlipo™ Laser with the same 1,064-nm Nd-YAG laser used successfully to liquify (and subsequently aspirate) excess fat from localized areas of the body, has recently gained popularity as a safe and effective option for axillary hyperhidrosis. In a 2008 study^{17,18} patients with axillary hyperhidrosis were treated, using subdermal 1,064-nm Nd-YAG laser (Smartlipo™). The patients' global assessment showed an excellent result in 12 cases (70.6%), a good result in 3 cases (17.6%), and 2 patients reported fair results (11.8%). No patient reported poor results. The physicians' global assessment was excellent in 10 patients (58.8%), good in 4 patients (23.5%), and fair in 3 patients (17.8%) resulting in 82.3% of good or better outcome. Adverse effects were limited, transient and mild. The postoperative period was well tolerated in all patients, without significant discomfort or pain.

Of the 17 patients treated, all but 1 subject remained asymptomatic during the follow-up period which ranged from 12 to 43 months. 1 relapsed with axillary hyperhidrosis and required an additional laser treatment to the same area. Postoperative scarring was inconspicuous. No nerve injuries, bruises or other major skin complications were reported. It is clear that hyperhidrosis is a disease that has a profound impact on patients' lives. The impact on quality of life compares to that of other chronic dermatologic and systemic diseases. Patients with excessive sweating need to be identified first and offered the most suitable virtually non-invasive treatment options in order to lessen the physical, psychosocial, and occupational impact of their condition.

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