

The Synapse

The Medical Professionals' Network

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Reinventing Star Trek

As I observe the Maltese Ministry of Health battling with the ongoing out-of-stock saga of medicines within the Pharmacy of Your Choice scheme, my neuronal long-term potentiation recalls my childhood experience of Star Trek. I wonder why ...

Essentially, I grew up watching Star Trek. To put it very mildly, the series has influenced the way we think today, even if we do not realise this.

Mobile phones have been invented this way. This has been claimed during an interview by none other than Martin Cooper, who invented the first mobile phone, way back in 1973 (www.youtube.com/watch?feature=player_embedded&v=wN-_VA5HFwM). Another medical advance heralded by the TV series is hyposprays, whereby Dr McCoy, more commonly known as Bones, administered injections which didn't involve needles. Yet another example is aptly demonstrated by Geordi La Forge, the blind Lieutenant on the Enterprise-D, who was able to see because of a visor, which consisted of a small strip of metal that went across his eyes like a pair of glasses. Scientists today refer to this technology as the bionic eye and although challenging, its application for blind people may be closer to us

than one may think. Monash University in Melbourne is one of its champions (www.monash.edu.au/bioniceye/technology.html).

Interestingly, a recent technology which is also reminiscent of the American science fiction series, is the MR-guided focused ultrasound surgery. InSightec, which is headquartered in Israel, is marketing this innovation as ExAblate®. This personalized, non-invasive, real-time treatment works by using a transducer to transmit ultrasound waves. Its applications may include various conditions including uterine fibroids, breast cancer, prostate cancer, liver cancer and pain palliation of bone metastases. It seems to be particularly promising for Parkinson's disease and neuropathic pain. In fact videographic footage has evidenced patients suffering from essential tremor leaving the room post-treatment with no tremors (www.youtube.com/watch?v=Ze54lQXtUxo&list=TLmVURADr-4PM)

Its advantages include a short recovery time, the fact that no hospitalization is needed and that it is drug-sparing. Furthermore, no incisions are needed and there is a low frequency of adverse events. Nevertheless there are various challenges for each clinical scenario.

One example is the non-uniformity of skulls which needs to be factored in during the treatment of brain tumours.

Innovative applications of this focused ultrasound sonification process include haemorrhagic stroke where it can be used to liquefy clots, and targeted drug delivery, where it can be used to deliver medicines in a reproducible manner through the blood-brain barrier. As reported by Etame et al in *The Journal of Neurosurgery* in January 2012 (PubMed: 22208896), this targeted drug delivery is achieved by increasing the permeability of the blood-brain barrier. Last April, *Nanoscale* has also published an article by Zha et al who detailed the adaptation of this technology for image-guided microbubble destruction of cancer cells. This is done by incorporating CuS nanoparticles (PubMed: 23467503).

Hopefully we will hear more of similar technologies soon enough. S

Ian C Ellul

Ian C Ellul

A JOKE A DAY KEEPS THE DOCTOR AWAY

Final doctor's trip

A cardiac surgeon died and at his funeral the coffin was placed in front of a huge heart made of flowers. When the priest finished with the sermon, and after everyone said their good-byes, the heart opened, the coffin rolled inside and the heart closed.

Just then, one of the mourners burst into laughter.

The guy next to him asked: "Why are you laughing?"

"I was thinking about my own funeral!" the man replied.

"What's so funny about that?"

"I'm a gynecologist."



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EUCREAS® is indicated as triple oral therapy in combination with an SU²
GALVUS® and **EUCREAS**® indicated for use in conjunction with insulin^{1,2}

Galvus® (vildagliptin) tablets

PRESENTATION: Each tablet contains 50 mg of vildagliptin. **INDICATIONS:** For the treatment of type 2 diabetes mellitus in adults. As monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. As dual oral therapy in combination with metformin in patients with insufficient glycaemic control despite maximal tolerated doses of monotherapy with metformin, a sulphonylurea in patients with insufficient glycaemic control despite maximal tolerated doses of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance, a thiazolidinedione in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate. As triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control. **DOSEAGE:** When used as monotherapy in combination with thiazolidinedione, in combination with metformin and a sulphonylurea or in combination with insulin (with or without metformin), the recommended daily dose of vildagliptin is 100mg, administered as one dose of 50 mg in the morning and one dose of 50 mg in the evening. When used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. Galvus can be administered with or without a meal. Doses greater than 100 mg are not recommended. Galvus is not recommended for use in children and adolescents (< 18 years). The safety and efficacy of Galvus in children and adolescents (< 18 years) have not been established. No data are available. The recommended dose for patients with moderate-to-severe renal impairment is 50mg once daily. If a dose of Galvus is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day. No dose adjustments are necessary in elderly patients (≥ 65 years). The safety and efficacy of vildagliptin as triple oral therapy in combination with metformin and a thiazolidinedione have not been established. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. **WARNINGS / PRECAUTIONS:** Galvus should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. There is limited experience in patients with ESRD on haemodialysis. Therefore Galvus should be used with caution in these patients. Galvus is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST > 2x the ULN. Liver function tests should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3xULN or greater persist, withdrawal of Galvus therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Galvus. Clinical experience in patients with NYHA functional class III treated with vildagliptin is still limited and results are inconclusive. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. Patients with rare hereditary forms of glucose intolerance, the long latency deficiency or glucose intolerance misdiagnosis should not take this medicine. Galvus should not be administered during pregnancy or breast-feeding since no studies on the effect on human fertility have been conducted for Galvus. It should be used with caution in patients with renal impairment. Sulphonylureas are known to cause hypoglycaemia. Patients receiving vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetic (glitazones, meglitinides, meglitinol, ameglitin, dipeptidyl, nateglin, nivaloglitin, sitagliptin, vildagliptin) or warfarin were observed after co-administration with vildagliptin. As with other oral antidiabetic medicines, the hypoglycaemic effect of vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics. **ADVERSE REACTIONS:** Rare cases (1/10,000 to <1/1,000): angioedema, abnormal liver function tests, hepatic dysfunction (including hepatitis). **Massotherapy Common (≥1/100 to <1/10):** dizziness, Uncommon (≥1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. **Very rare (<1/10,000):** URTI, nasopharyngitis. **Combination with metformin Common:** nausea, headache, dizziness, nausea, hypoglycaemia, hyperlipidaemia, asthenia. **Combination with sulphonylurea Common:** tremor, headache, dizziness, nausea, hypoglycaemia. **Uncommon:** constipation. **Very rare nasopharyngitis.** **Combination with Thiazolidinedione Common:** weight increase, oedema peripheral. **Uncommon:** headache, asthenia, hypoglycaemia. **Combination with insulin:** Common: decreased blood glucose, headache, chills, nausea, gastro-intestinal reflux disease. **Uncommon:** Dizziness, fatigue/weakness, hypoglycaemia, hypokalaemia, hypotension, and abnormal liver function tests (reversible upon discontinuation of the medicinal product), blurred or exfoliative skin lesions. **LEGAL CATEGORY:** POM. **PACK SIZES:** 7, 28 tablets. **MARKETING AUTHORISATION HOLDER:** Novartis European Limited, Welwyn Hatfield, Herts, UK. **Novartis, PH12 5AB, United Kingdom. MARKETING AUTHORISATION NUMBERS:** LU/02/14/001, 003. Please refer to Summary of Product Characteristics (SPC) before prescribing. Full prescribing information is available at www.novartis-pharma.com. © 2013 Novartis Pharma Services Inc, Representative Office India, Plot B, Cross 4, Marla, MIDC, Malvi, Tel: +91 206 22563117 / +91 206 2122872. 2013-MT-GAL-07-AUG-2013

Eucreas® (vildagliptin/metformin hydrochloride) film-coated tablets

PRESENTATION: Each 50 mg/850 mg film-coated tablet contains 50 mg of vildagliptin and 850 mg metformin hydrochloride. Each 50 mg/1000 mg film-coated tablet contains 50 mg of vildagliptin and 1000 mg metformin hydrochloride. **INDICATIONS:** Eucreas is indicated in the treatment of type 2 diabetes mellitus patients, indicated as the treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of one metformin tablet or who are already treated with the combination of vildagliptin and metformin as separate tablets. Eucreas is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled with metformin and a sulphonylurea. Eucreas is indicated in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. **DOSEAGE:** The dose of antihyperglycaemic therapy with Eucreas should be individualised on the basis of the patient's current regimen, effectiveness and tolerability while not exceeding the maximum recommended daily dose of 100 mg vildagliptin. Eucreas may be initiated at either the 50 mg/850 mg or 50 mg/1000 mg tablet strength twice daily, one tablet in the morning and the other in the evening. For patients inadequately controlled at their maximal tolerated dose of metformin monotherapy. The starting dose of Eucreas should provide vildagliptin at 50 mg twice daily (100 mg total daily dose) plus the dose of metformin already being taken. For patients switching from co-administration of vildagliptin and metformin as separate tablets, Eucreas should be initiated at the dose of vildagliptin and metformin already being taken. For patients inadequately controlled on dual combination with metformin and a sulphonylurea. The doses of Eucreas should provide vildagliptin at 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken. When Eucreas is used in triple combination therapy with insulin and the maximal tolerated dose of metformin, the dose of Eucreas should provide vildagliptin at 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken. Eucreas should be taken with or just after food to reduce gastrointestinal symptoms associated with metformin. Patients > 65 Years Eucreas should have their renal function monitored regularly. Eucreas is not recommended for use in patients less than 18 years old. For use in renal or hepatic impairment, see contraindications and precautions below or refer to the SPC for more information. The safety and efficacy of vildagliptin and metformin as triple oral therapy in combination with a thiazolidinedione have not been established. **CONTRAINDICATIONS:** Hypersensitivity to vildagliptin or metformin hydrochloride or to any of the excipients. Diabetic ketoacidosis or diabetic pre-coma. Renal failure or renal dysfunction defined as creatinine clearance < 30 ml/min. Acute conditions with the potential to alter renal function e.g. dehydration, severe infection, shock or intravascular administration of osmolar contrast agents. Acute or chronic disease which may cause tissue hypoxia e.g. cardiac or respiratory failure, recent myocardial infarction, shock, hepatic impairment, acute alcohol intoxication, alcoholism, lactation. **WARNINGS / PRECAUTIONS:** Eucreas is not a substitute for insulin in insulin-requiring patients and should not be used in patients with type 1 diabetes. Due to the risk of lactic acidosis, renal function should be monitored at least once yearly in patients with normal renal function and at least two to four times yearly in patients with serum creatinine at the upper limit of normal and in elderly patients. Eucreas is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST > 2x the ULN. LFTs should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3x ULN or greater persist, withdrawal of Eucreas therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Eucreas. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. As Eucreas contains metformin, treatment should be discontinued 48 hours before elective surgery with general anaesthesia and not usually resumed earlier than 48 hours afterwards. The IV administration of osmolar contrast agents can lead to renal failure. Therefore due to metformin's active ingredient, Eucreas should be discontinued prior to or at the time of the test and not resumed until 48 hours afterwards and only after renal function has been re-evaluated and found to be normal. Eucreas should not be administered during pregnancy or lactation. Sulphonylureas are known to cause hypoglycaemia. Patients receiving vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetic (glitazones, meglitinides, meglitinol, ameglitin, dipeptidyl, nateglin, nivaloglitin, sitagliptin, vildagliptin) or warfarin were observed after co-administration with vildagliptin. Interactions with metformin hydrochloride that are not recommended include alcohol, systemic sodium bicarbonate, e.g. immediate and intravenous administration of osmolar contrast media. Combinations requiring caution include metformin hydrochloride with medicines tending to produce hypoglycaemic activity e.g. glucocorticoids, beta agonists and diuretics. The dose of antihyperglycaemic medicinal products may need to be adjusted in combination with ACE inhibitors. **ADVERSE REACTIONS:** See cases (1/10,000 to <1/1,000): angioedema, hepatic dysfunction (including hepatitis) have been reported with vildagliptin. **Vildagliptin Monotherapy Common (≥1/100 to <1/10):** dizziness, Uncommon (≥1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. **Very rare (<1/10,000):** URTI, nasopharyngitis. **Metformin monotherapy Very common (≥1/10):** Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. **Combination with metformin and sulphonylurea Common:** hypoglycaemia, dizziness, tremor, hyperkalaemia, asthenia, decreased blood glucose, headache, chills, nausea. **Combination with insulin:** Decreased blood glucose, headache, chills, nausea, gastro-intestinal reflux disease, dizziness, asthenia. **Combination with metformin and thiazolidinedione Common:** weight increase, oedema peripheral. **Uncommon:** headache, asthenia, hypoglycaemia. **Combination with insulin:** Common: decreased blood glucose, headache, chills, nausea, gastro-intestinal reflux disease, dizziness, asthenia. **LEGAL CATEGORY:** POM. **PACK SIZES:** 7, 28 film-coated tablets. **MARKETING AUTHORISATION HOLDER:** Novartis European Limited, Welwyn Hatfield, Herts, UK. **Novartis, PH12 5AB, United Kingdom. MARKETING AUTHORISATION NUMBERS:** EU/01/02/001-003, EU/01/02/008-006. Please refer to Summary of Product Characteristics (SPC) before prescribing. Full prescribing information is available upon request from: Novartis Pharma Services Inc, Representative Office India, Plot B, Cross 4, Marla, MIDC, Malvi, Tel: +91 206 22563117 / +91 206 2122872. 2013-MT-EUC-01-JUL-2012



1. Novartis European Ltd. Galvus®. Summary of Product Characteristics
2. Novartis European Ltd. Eucreas®. Summary of Product Characteristics



Dr Charles A. Gauci MD FRCA FIPP FFFMRCA RAMC (Retd) is a consultant in Pain Medicine recently retired to Malta, having run the Pain Clinic at Whipps Cross University Hospital, London for over 20 years; prior to that he served in the RAMC, retiring in 1992 in the rank of Lt. Colonel. He was, until recently, visiting Consultant at MDH. He was an expert witness in the UK Courts and has been involved in medico-legal work for over 30 years.



Jakov Cordina B.Pharm graduated from the UOM in 2004 and is currently reading an M.Pharm degree under the supervision of Dr Claire Shoemake. He works in the Pharmaceutical Industry as a Supply Chain and Launch Manager for Malta, Cyprus and Africa. The co-authors are Dr Claire Shoemake and Prof Lilian Azzopardi.



Professor Maurice Cauchi MD MSc PhD DPH FRCPA FRCPath was Professor of Pathology and Director of Pathology in Malta. He has published several monographs, including Health, Bioethics and the Law. For his services to the Maltese community in Australia he was made Member of the Order of Australia (AM), and given the Medalja għall-Qadi tar-Repubblika by the Maltese Government.

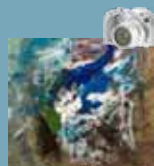


Dr Pierre Vassallo MD PhD FACA Artz fur Radiologie specialised in radiology at the Institute of Clinical Radiology at the University of Muenster, Germany and the Memorial Sloan-Kettering Cancer Center, New York, US. He is currently Consultant Radiologist and Managing Director at DaVinci Hospital, Malta.

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COVER:



Crucible of Fire | Acrylic on hardboard
Anna Miggiani started painting after she graduated in Pharmacy under the tuition of the late Joseph Bellia, who was also a pharmacist. Her preferred subject is abstracts, where she likes to use the contrast of colours and texture to create vivid abstract images. Most of her work is executed in acrylics. She has had several solo exhibitions over the years and many of her works are found in private collections.

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Onbrez Breezhaler (indacaterol) inhalation powder, hard capsules

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. If a dose is missed, the next dose should be taken at the usual time the next day. **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. Hypertglycaemia: 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. 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. Immediate hypersensitivity reactions have been reported after administration of Onbrez Breezhaler. If signs suggesting allergic reactions (in particular, difficulties in breathing or swallowing, swelling of tongue, lips and face, urticaria, skin rash) occur, Onbrez Breezhaler should be discontinued immediately and alternative therapy instituted. **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 known to cause interactions with co-medications. **ADVERSE REACTIONS:** The most common adverse reactions with Onbrez Breezhaler are: dizziness, nasopharyngitis, upper respiratory tract infection, sinusitis, headache, cough, rhinorrhoea, respiratory tract congestion, muscle spasm, peripheral oedema. Common: Chest Pain, Oropharyngeal pain including throat irritation. Uncommon: Myalgia, Musculoskeletal pain, Pruritis/rash, Paradoxical bronchospasm, tachycardia, palpitations, hypersensitivity, diabetes mellitus and hyperglycaemia, paraesthesia, atrial fibrillation and non-cardiac chest pain, ischaemic heart disease. Please refer to SmPC for a full list of adverse events for Onbrez Breezhaler. **LEGAL CATEGORIES:** 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, Wimborne Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/05/593/001, 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 Malta P.O. Box 124, Valletta, VLT 1000 Malta. Tel: +356 229832117/+35621222672 - 2012-MT-ONB-02-Aug-2012.

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1. Gao Y, Ma Y, Wang H, et al. Inhaled long-acting beta2-agonists for COPD and asthma. Br J Pharm. 2008;153(7):1289.
2. Review: European Union Onbrez Breezhaler Summary of Product Characteristics.

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Reversing the road to malignancy

The aim of cancer chemotherapy is to destroy the maximum number of tumour cells with the minimum number of normal body cells in order to achieve a maximal therapeutic ratio. Nevertheless it is a therapy which is often ineffectual and quite frequently associated with severe complications.

It is therefore with considerable interest that one reads that other methods of therapy, which do not involve cell killing, is surprisingly showing promise in what is one of the most lethal forms of leukaemia, namely acute pro-myelocytic leukaemia (APL), a disease which often has a 100% mortality within weeks.

There is no question about the fact that cancer cells behave in their characteristic aggressive way as a result of changes in the DNA which controls all cell metabolic activity. It is also well established that a DNA change might take several years to become established as clinical cancer, often requiring other ancillary stimulations, genetic or environmental, to activate and promote this irreversible

result. In other words, a genetic change in the cell DNA is necessary but not sufficient to produce clinical cancer.

For a long time it was thought that once a genetic change has occurred there is little that the environment can do to reverse the action of this blueprint. However, it is now clear that several factors can modify the activity of genes, to either stimulate or suppress their activity.

At the recent meeting of the American Society of Hematology, considerable evidence was provided that the course of APL could be arrested and reversed by drugs which, while not cytotoxic, can somehow stop the malignant mechanism and set the cell back to its normal developmental pathway.

Current treatment for APL consists of a combination of ATRA (all-trans retinoic acid) and chemotherapy. The new therapy consists of ATRA plus arsenic trioxide (ATO). Dr Francesco Lo-Coco, professor of hematology at the University of Tor Vergata

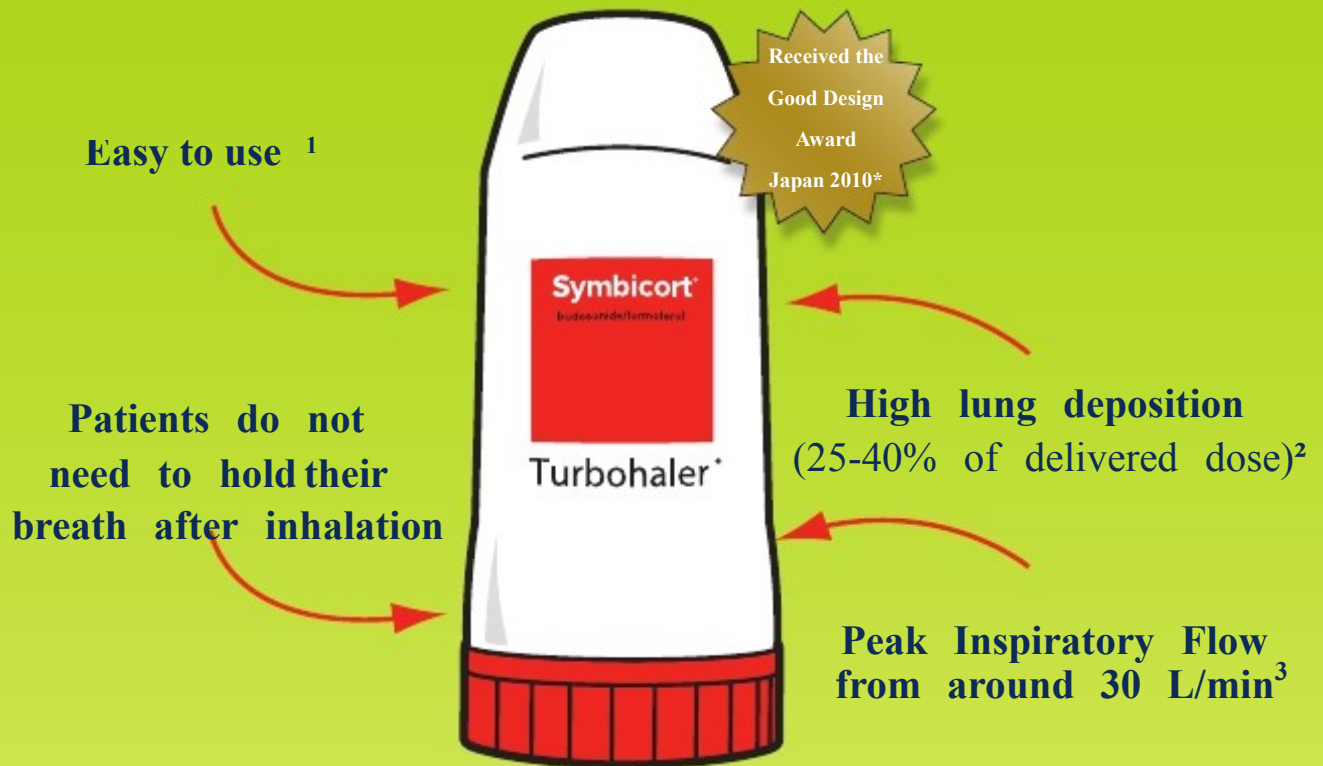
in Rome, one of the authors of the study, is convinced that this modality of treatment shows that this finding upturns the standard dogma and provides evidence that malignant cells can be transformed back into their normal, non-malignant form. In the opinion of the authors, this combination is "really quite impressive". In effect, Lo-Coco says, "cancer is not an irreversible condition."

The mode of action of this combination therapy is currently under intensive investigation. A recent article in the top hematology journal, *Blood*, indicates that ATO inhibits the formation of pro-myelocytic leukemia protein and stabilises cytoplasmic precursor compartments (PubMed: 22692509).

Whether the action of this combination will be found effective in reversing other more common malignancies remains to be seen. It is, however, encouraging to see that a first step has been made in upsetting the standard thinking about treatment of cancer, which raises hope for a more physiological way of controlling it. S

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Turbohaler

PRESCRIBING INFORMATION. Refer to full Summary of Product Characteristics (SmPC) before prescribing Symbicort® Turbohaler®100/6; 200/6; 400/12; Inhalation Powder (budesonide/formoterol fumarate dihydrate)

Presentations: Inhalation powder. **Symbicort Turbohaler 100/6** Each metered dose contains 100mcg budesonide/inhalation and 6mcg formoterol fumarate dihydrate/inhalation. **Symbicort Turbohaler 200/6** Each metered dose contains 200mcg budesonide/inhalation and 6mcg formoterol fumarate dihydrate/inhalation. **Symbicort Turbohaler 400/12** Each metered dose contains 400mcg budesonide/inhalation and 12mcg formoterol fumarate dihydrate/inhalation. **Uses: Asthma:** Treatment of asthma where the use of a combination (inhaled corticosteroid and long acting β_2 adrenoceptor agonist) is appropriate. Symbicort 100/6 is not appropriate for patients with severe asthma. **COPD**

(**Symbicort 200/6; 400/12**): Symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. **Dosage and Administration: Asthma (Symbicort maintenance treatment with a separate rescue medication): Adults (including elderly)100/6 and 200/6:** 1-2 inhalations twice daily. Some patients may require up to a maximum of 4 inhalations twice daily. **400/12:** 1 inhalation twice daily. Some patients may require up to a maximum of 2 inhalations twice daily. **Adolescents (12-17 years)100/6 and 200/6:** 1-2 inhalations twice daily; **400/12:** 1 inhalation twice daily. **Children 6 years and older100/6 only:** 2 inhalations twice daily. **Symbicort is not recommended for children under 6 years. Symbicort 400/12 is not recommended for children under 12 years.** Not intended for the initial management of asthma. Dose should be individualised. If an individual patient requires dosages outside recommended regimen, appropriate doses of β_2 adrenoceptor agonist and/or corticosteroid should be prescribed. When long-term symptoms are controlled, titrate to the lowest effective dose, which could include a once daily dosage. **Asthma (Symbicort maintenance and reliever therapy - regular maintenance treatment and as needed in response to symptoms) for Symbicort 100/6 and 200/6 only (NOT recommended with 400/12 strength):** especially consider for (i) patients with inadequate asthma control and in frequent need of reliever medication (ii) patients with asthma exacerbations in the past requiring medical intervention. Close monitoring for dose-related adverse effects is needed in patients who frequently take high numbers of Symbicort as-needed inhalations. **Adults (including elderly)100/6 & 200/6:** 1 inhalation twice daily or as 2 inhalations once daily. For some patients a dose of 2 inhalations twice daily may be appropriate (200/6 strength only). Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. A total daily dose of more than 8 inhalations is not normally needed; however, up to 12 inhalations a day could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice and should be reassessed; their maintenance therapy should be reconsidered. Patients should be advised to always have Symbicort for reliever use. **Children and adolescents under 18 years of age:** not recommended. **COPD (200/6): Adults:** 2 inhalations twice daily. **(400/12):** 1 inhalation twice daily. **Contraindications, Warnings and Precautions etc. Contraindications:** Hypersensitivity (allergy) to budesonide, formoterol or lactose (which contains small amounts of milk proteins). **Warnings and Precautions:** If treatment is ineffective, or there is a worsening of the underlying condition, therapy should be reassessed. Sudden and progressive deterioration in control requires urgent medical assessment. Patients should have their appropriate rescue medication available at all times. i.e. either Symbicort or a separate reliever. If needed for prophylactic use (e.g. before exercise) a separate reliever should be used. Therapy should not be initiated during an exacerbation. Serious asthma-related adverse events and exacerbations may occur and patients should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of Symbicort. Paradoxical bronchospasm may occur, with an immediate increase in wheezing and shortness of breath after dosing. This responds to a rapid-acting inhaled bronchodilator and should be treated straightaway. As with any inhaled corticosteroid, systemic effects may occur, particularly at high doses prescribed for long periods. These may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract and glaucoma and more rarely a range of psychological or behavioral effects. Potential effects on bone should be considered especially in patients on high doses for prolonged periods that have co-existing risk factors for osteoporosis. Prolonged treatment with high doses of inhaled corticosteroids, particularly higher than recommended doses, may also result in clinically significant adrenal suppression. Therefore additional systemic corticosteroid cover should be considered during periods of stress such as severe infections or elective surgery. Treatment with supplementary systemic steroids or inhaled budesonide should not be stopped abruptly. During transfer from oral steroid therapy to Symbicort, a generally lower systemic steroid action will be experienced which may result in the appearance of allergic or arthritic symptoms which will need treatment. In rare cases, symptoms such as tiredness, headache, nausea and vomiting can occur due to insufficient glucocorticosteroid effect and temporary increase in the dose of oral glucocorticosteroids is sometimes necessary. Observe caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, or severe cardiovascular disorders. As with other β_2 adrenoceptor agonists, hypokalaemia may occur at high doses. Particular caution recommended in unstable or acute severe asthma as this effect may be potentiated by xanthine-derivatives, steroids, diuretics and hypoxia. Monitor serum potassium levels. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. In diabetic patients, consider additional blood glucose monitoring. Symbicort contains lactose monohydrate, as with other lactose containing products the small amounts of milk proteins present may cause allergic reactions. **Interactions:** Concomitant treatment with potent CYP3A4 inhibitors should be avoided. If this is not possible the time interval between administration should be as long as possible. Symbicort maintenance and reliever therapy is not recommended in patients using potent CYP3A4 inhibitors. Not to be given with beta adrenergic blockers (including eye drops) unless there are compelling reasons. Concomitant administration with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine), MAOIs and TCAs can prolong the QTc-interval and increase the risk of ventricular arrhythmias. L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance. Concomitant administration with MAOIs, including agents with similar properties such as furazolidone and procarbazine, may precipitate hypertension. Risk of arrhythmias in patients receiving anaesthesia with halogenated hydrocarbons. Concomitant use of other beta adrenergic drugs or anticholinergic drugs can have a potentially additive bronchodilating effect. **Pregnancy and Lactation:** Should only be used when the benefits outweigh the potential risks. Budesonide is excreted in breast milk, however at therapeutic doses no effects on the child are anticipated. **Undesirable effects:** **Common:** headache, palpitations, tremor, candida infections in the oropharynx, coughing, mild irritation in the throat, hoarseness. **Uncommon:** tachycardia, nausea, dizziness, bruises, aggression, psychomotor hyperactivity, anxiety, sleep disorders. **Rare:** hypokalaemia, cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles, bronchospasm and immediate and

delayed hypersensitivity reactions including exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction. **Very Rare:** psychiatric disorders including depression, behavioural changes (predominantly in children), angina pectoris, prolongation of QTc-interval, hyperglycaemia, taste disturbance, Cushing's syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, cataract and glaucoma and variations in blood pressure. As with other inhalation therapy, paradoxical bronchospasm may occur in very rare cases. **Package Quantities:** Each Symbicort Turbohaler 100/6 or 200/6 contains 120 inhalations. Each Symbicort Turbohaler 400/12 contains 60 inhalations. **Legal Category:** Prescription Only Medicine (POM). **Marketing Authorisation Number(s):** MA046/00901-3. **Marketing Authorisation Holder (MAH):** AstraZeneca AB, Gartnavagen, S-151 85 Sodertalje, Sweden. **Further product information available on request from:** Associated Drug Co. Ltd., Triq L-Esportartur, Mriehel, Birkirkara, BKR 3000, Malta. Telephone: (+356) 22778000. Fax (+356) 22778120. **Abridged Prescribing Information prepared:** 04/12. Symbicort and Turbohaler are Trade Marks of the AstraZeneca group of companies. URN: 12/0447 **Date of Preparation:** October 2012.

Reference: 1. Adelphi Respiratory Disease Specific Programme 2009. 2. Olof Selroos et al. *Treat Respir Med* 2006; 5 (5): 305-315. 3. Engel et al. *Br J Clin Pharmacol* 1992; 33(4): 439-44.

*JIDPO (Japan Industrial Design Promotion Organisation) Good Design Award Japan 2010: <http://www.g-mark.org/award/detail.html?id=36687&sheet=outline&lang=en>



AstraZeneca
Respiratory

Labelling and testing of foods designated as suitable for diabetic and low calorie diets

Abstract

The aim of this project was to assess whether consumers, especially those following a diabetic or low calorie diet, would benefit from newly designed food labels denoting glycaemic load and whether these labels would help them make a faster food selection.

Introduction

Over 30,000 patients in Malta have been diagnosed with diabetes, with statistics indicating that there are thousands of other undiagnosed patients who are still not aware that they are suffering from this condition.¹ The first line treatment for such patients includes regular exercise and dietary changes, which calls for a moderate consumption of carbohydrates and proteins, whilst increasing the consumption of low sugar-containing fruit, vegetables and fibre, and decreasing the intake of oils and fats.² The World Health Organization (WHO), whilst advocating dietary changes in diabetes, does not provide guidelines by which patients can be helped to distinguish what food is right for them. Indeed in 1987³, the WHO and the FAO (Food and Agriculture Organization of the United Nations), agreed that foods require better labeling to guide diabetic patients, but adjourned the meeting, noting that due to the advancements being made at the time, a decision on the matter should be taken at a later date. This has, to date, never been re-discussed.

This study aimed to increase the patients' knowledge regarding how foods affect blood glucose levels (BGL) and empower these patients to make optimal decisions about which foods could help maintain their BGL as stable as possible, thus consequently improving treatment outcomes.

Methods

The study focused on the production of new glycaemic load (GL)-based labels, and on the evaluation of their efficacy in imparting the necessary information to people hailing from all educational backgrounds, using pre-validated standardized questionnaires. Face and content validation of the questionnaire was conducted with a pilot group consisting of six pharmacists, a doctor, two diabetic patients and a house-wife. Most of the suggested changes related to the wording of the actual questionnaire.

The questionnaire was compiled by customers visiting four main supermarkets in Naxxar, Sliema, Zabbar and Gudja over a period of one month. The data collected was subsequently evaluated and analysed using gender, education and dietary habits as baselines.

The labels were produced following the guidelines issued by the UK Coronary Prevention Group

Glycemic Load	High	24
Glycemic Load	Medium	15
Glycemic Load	Low	7

Figure 1: Glycaemic load label section, developed in this study that can be added to any standard food label

Analysis	Per 100g	Per pcs
Energy	1650KJ	141KJ
Protein	12g	1.0g
Carbohydrates	72g	6.2g
Carbohydrates of which Fructose	10g	0.9g
Fat of which saturated fatty acids	2.8g	0.2g
Dietary Fibres	4g	0.3g
Glycemic Load	MEDIUM	15

Figure 2: A mock-up of how the new GL section, developed in this study, could be integrated into a generic food product label

whose study showed that graphical representations were found to be better interpreted, on the basis of attractiveness and simplicity.⁴

A traffic light colour combination was chosen to denote danger, alertness and safety using Red, Orange and Green respectively to represent High, Medium and Low GL brackets – ensuring readability by patients, who in most cases were already accustomed to the meaning of these 3 colours (Figure 1). Figure 2 shows how a GL label, developed in this study, would look like.

A questionnaire was formulated in order to establish demographics of respondents, whether or not they were diabetic or were following a low calorie diet (to establish whether the respondents understood the relationship between GL and absorbance of sugars) and to identify whether or not the new labels prepared in this study would help patients make a faster selection of food products at the point of purchase. Before working through the questionnaire with the respondent, a verbal explanation of how GL could help a patient understand the blood sugar level (BSL) and the absorption of sugars in the body was given. These results were analyzed using frequency studies owing to the fact that these were considered to be more pertinent to the types of questions asked.

Results

In total, 102 respondents participated in the study, out of which 65 were female and 37 were male. The average age of the respondents was 31.8 years (ranging between 18 and 80 years).

Figure 3 illustrates the difference in responses between sexes. Sixty-two percent (62%) vs 61% of male and female respondents respectively, stated that they were following a diabetic or low calorie diet. Seventy percent (70%) of female respondents buy products for these diets, compared with 54% of males. Ninety-one percent (91%) vs 92% of females and males respectively, thought that learning what GL represents and what GL a specific product has, would aid them make a faster selection of foods for these diets.

In figure 4, the relationship between educational level and the respondents' understanding of what GL represents is illustrated. None of the respondents who had a primary level of education understood what GL meant and how this affected BSL. Eighty Percent (80%), 86% and 100% of secondary, post-secondary and tertiary education levels respectively understood what the term GL really meant.

Out of all the respondents, 61% stated that they were following a diabetic or low calorie diet (Figure 5). Ninety-five percent (95%) of these respondents answered that the new labels helped them make a faster selection, while only 5% said that this does not affect the speed of the selection process (Figure 6).

Figure 7 shows that although a higher percentage (14%) of respondents who do not follow a diabetic or low calorie diet were not affected by the new labels, a high percentage (86%) noted that these would enable them to select their food faster.

The overall visual rating of the labels, as well as the ease with which respondents were able to identify the information given by the GL section (new labels) were found to be either good (36%) or very good (64%) (Figure 8)

Discussion

While an equal amount of men (62%) and women (61%) were following a diabetic or low calorie diet, only 54% of males, compared to 70% of females

Figure 3: Male vs Female trends (n-102)

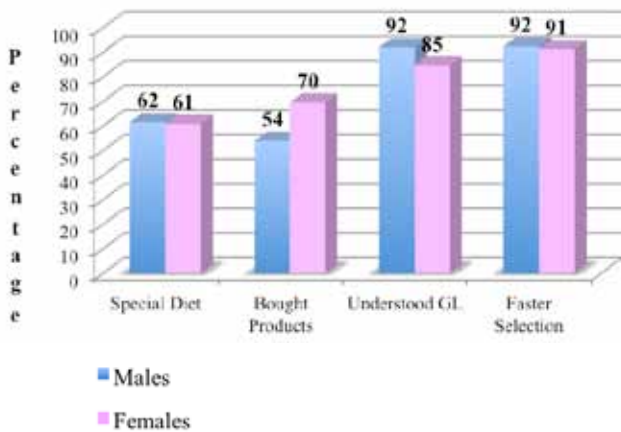


Figure 5: Total Respondents following a diabetic or low calorific diet vs those not following a diabetic or low calorific diet (n-102)

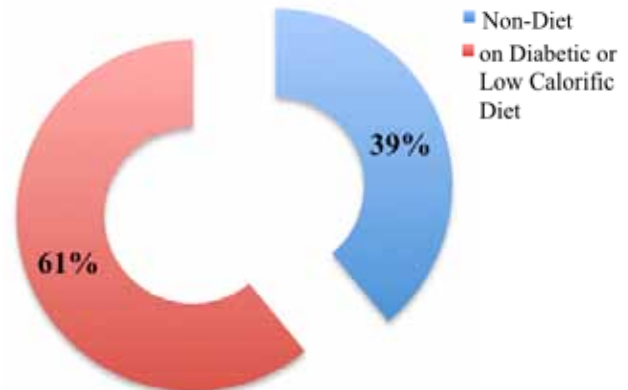


Figure 4: Understanding by education level (n-102)

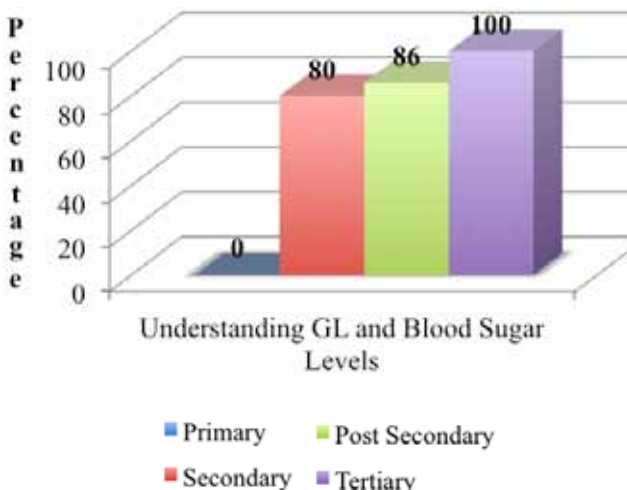


Figure 6: Percentage of patients who are following a specific diet, stating whether the mock-ups affected the speed in selecting which foods to buy (n=102)

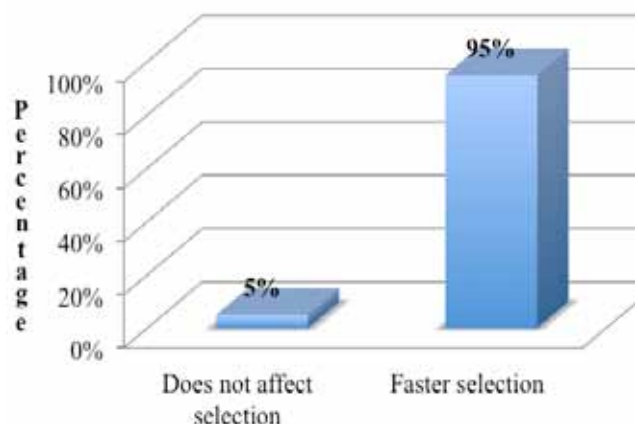


Figure 7: Percentage of patients who are not following a specific diet, stating whether the mock-ups affected them in choosing what foods to buy (n=102)

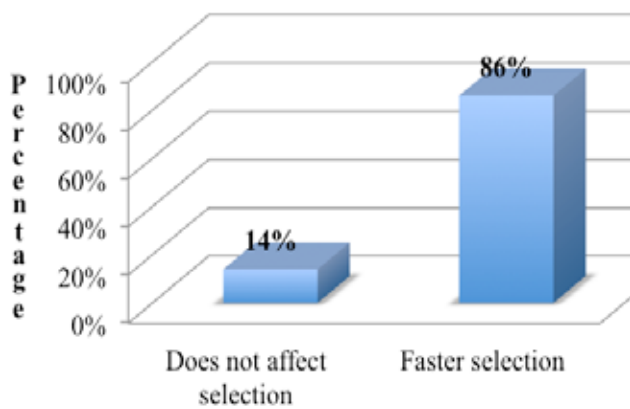
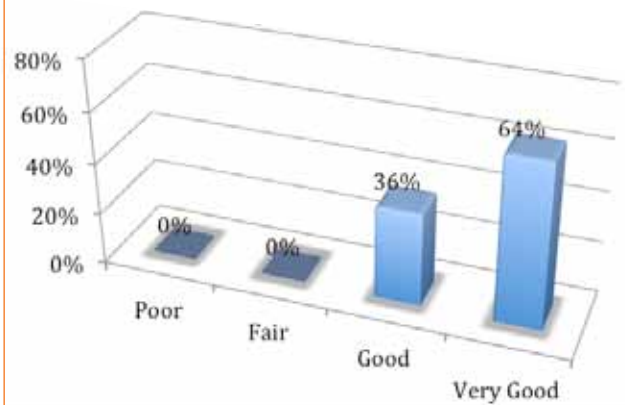


Figure 8: Rating of the GL section on the food label (n=102)



interviewed, actually bought products for these diets – suggesting that women are more likely to be the food buyers in the household. Ninety-two percent (92%) of the men vs 85% of the women interviewed stated that they understood the meaning of GL and how this can be used to indicate how the food affects BSLs. Both men and women (92% of men and 91% of women) confirmed that the new labels would help them make a faster selection of food, should these be included on packages.

The findings of this study have shown that respondents coming from a secondary (80%), post-secondary (86%) or tertiary (100%) educational background, understood the relationship between GL and BSLs. Further education campaigns on the GL and BSL explanation should be undertaken so as to make this easily understood by respondents coming from a primary (0%) background.

Sixty-one percent (61%) of the total respondents claimed to be following a diabetic or low calorie diet, which suggests that a high number of Maltese people are actively following these diets – an indication of the high demand for low GL foods in the community. The implication is that there would be an increased awareness among this population cohort of the importance of reading the labels of the foods that they purchase, which could explain why a higher percentage of the participants claimed that the designed labels

would help them make a faster food selection. While being a significant conclusion, this should not be taken to mean that the designed labels appeal exclusively to dieters and diabetics, as evidenced by the fact that all respondents, irrespective of their diet or diabetic status rated the labels as good (36%) or very good (64%).

The GL was selected as being the best value to work for the new labels. The other option of the Glycaemic Index (GI) was discarded owing to the fact the latter does not take into consideration the amount of carbohydrates (CHO) per serving; the GL is the GI multiplied by the CHO amount per serving of the food.⁵⁻⁷

Patient education remains a priority, in that the consumption of a large amount of low GI foods should still

be avoided. However, empowering patients to distinguish between food types definitely constitutes a step in the right direction. §

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45th Annual Meeting of the Diabetes in Pregnancy

8TH OCTOBER | Location: Malta

**7th Biennial Primary Health Care Department Conference:
Optimising the delivery of primary healthcare in Malta**

10 – 12TH OCTOBER | Location: Malta

**23rd Alzheimer Europe conference:
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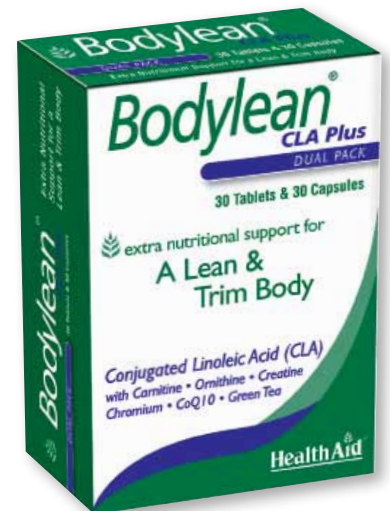
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Science in the City 2013: Malta's science and art festival in Valletta

Researchers' Night - Science in the City, Malta's science and art festival, is back again on the 27th September in Valletta from 6pm onwards. Science will be exposed through art and entertainment including street art installations, graffiti art exhibitions, music concerts, children's shows, live experiments, talks, tech areas, and much more ... a memorable night which is fun, interactive and free.

As part of the pan-European event known as Researchers' Night, Science in the City is organising over 25 events for all the family. Live experiments will be run in different areas around Valletta and a kids area will keep children hooked on science for hours. The public will be able to do some of these themselves, highlighting the fun and spread of science in our everyday life.

Families, young people, and adults can learn about insects surrounded by a 10-foot tall butterfly. Or they can make their own cup of coffee using pedal power, or better still, see the latest technology in making things work around a house without lifting a finger. A tech area will see robots and art installations coming to life.

The activities will occupy Valletta, running from the Upper Barrakka and St James Cavalier, down both Merchant's Street and Republic Street till St George's Square (Palace Square) and the Old Market area.


The festival opens the doors of Valletta for everyone to meet researchers from the University of Malta as well as artists, and participate in the interactive demonstrations, discussions, workshops and children's activities.

Researchers will be present at different venues to talk about the science behind the activities. A special event will be held at the King's Own band club where anyone can pop over for a drink and chat with researchers about the science of food, our universe, or some unique facts about Maltese blood.

A day before the big night, the Science in the House event will bring together researchers and politicians. Several researchers are presenting broad research themes to MPs, ranging from medical genetics to material science. Engaging politicians helps raise awareness about the important of research in Malta and why it needs more support. This Science in the House event will also be held as a public event during Notte Bianca, Saturday, October 5.

The event is coordinated by The University of Malta's Research, Innovation and Development Trust, in partnership with the Malta Chamber of Scientists. The University's Research, Innovation and Development Trust (RIDT; www.ridt.org.mt) is supporting the 2nd edition of the Researchers' Night - Science in the City festival since it manifests the best in research and researchers

in their efforts to advance knowledge and benefit society in Malta and elsewhere. The event will highlight the appeal of pursuing a career in research. Investment in scientific research is a guarantee of the successful future of our country. The RIDT actively seeks funds and support from private and corporate bodies, private individuals, and University alumni to expand the University's research studies. The Malta Chamber of Scientists (www.mcs.org.mt) is one of the principal members of the organizing consortium. The Chamber is a professional organisation of science professionals, academics, teachers and students from broad areas of science and the social and economic sectors. Apart from the Science in the House event, it will also run a special Malta Café Scientifique at the La Vallette band club with the title '*Protons, Proteins and Particle Accelerators.*'

The Researchers' Night - Science in the City festival is also supported by the EU FP7 Programme and the Malta Arts Fund. The organizing committee also includes the Valletta Local Council, MEUSAC, Malta Council for Science and Technology, Malta Council for Culture and the Arts, The Public Broadcasting Service, Where's Everybody, Valletta 2018 Foundation, Notte Bianca, iCreatemotion, Microsoft and St James Cavalier. 

The Science in the City website www.scienceinthecity.org.mt is updated with a full program
The festival may also be followed on Facebook: www.facebook.com/ScienceInTheCityMalta

A medico-legal problem

Pain can be either acute or chronic. *Acute pain*, while deeply unpleasant, is vital to our survival; when it is no longer necessary, acute pain goes away. *Chronic pain*, on the other hand, serves no useful function, except to demoralise the sufferer, put a strain on the family and burden the nation's health resources.

Chronic pain is not just a symptom: it is a disease in its own right and one which demands treatment. Chronic pain is bad enough, but it can also trigger psychological problems, including depression and anxiety, producing a most unpleasant state of affairs for both the sufferer and his/her family and friends. On the other hand, chronic pain can also appear as a result of mental illness such as depression.

Pain is not just an unpleasant sensation; it is also an emotional experience (*suffering*), which often generates altered behaviour. Thus it is not just the chronic pain that needs to be dealt with, but also all the other unpleasant effects that it generates.

Chronic pain and the many physical and psychosocial changes and complications associated with it constitute a major healthcare problem. It also constitutes, at least in the

UK, a major medico-legal problem, since British Courts award claimants compensation for pain resulting from personal injuries.

Pain, especially chronic pain, is very much a personal experience. The same condition may cause different types of pain in different individuals – and what's more, what one person considers to be severe pain may be quite moderate to another. How someone feels pain is influenced by psychological, emotional and cultural factors – even by their own personality.

It is virtually impossible to prove the presence of pain or to measure it objectively. Hence the problem which pain creates in medico-legal cases.

Measuring pain

There is no direct, objective way of measuring pain; indeed one of the main problems in medico-legal

work is that, to a large extent, you are relying on what the claimant tells you.

Some individuals may, intentionally or otherwise, mislead the expert. One, therefore, needs to be very attentive when questioning claimants; one also needs to make a detailed examination of previous clinical records.

The Visual Analogue Scale (VAS) is a very simple way of quantifying or measuring pain; however, it is very limited, for it only measures one dimension, i.e. pain, without taking anything else, such as the emotional trauma inflicted by the pain, into account.

Many pain clinics use a variety of questionnaires in their bid to log the whole of the unpleasant experience i.e. pain, more accurately.

Quite apart from the difficulty of putting a numerical value, pain does not always appear at the spot where the problem occurs i.e. *referred pain*.

Types of Pain

There are three categories of pain, namely:

- Nociceptive pain;
- Neuropathic pain;
- Non-organic (or psychological) pain.

Nociceptive pain is essentially pain caused by damage to body tissues in the presence of a totally normal nervous system. There can be damage to the body framework – *somatic* – or it can be due to damage to the body organs – *visceral*.

Neuropathic pain (*'Nerve Pain'*) is pain “which arises as a direct consequence of a lesion or disease affecting the somatosensory system.”¹¹ Neuropathic pain refers to pain which is due more to a sensitisation of the nervous system. The damaged nerve(s) and sometimes even nearby undamaged nerves become oversensitive and can then be ‘set off’ by various stimuli, sometimes as innocuous as light touch.

Continual bombardment of the spinal cord by repeated barrages of nerve impulses coming from these affected nerves can make the spinal cord very sensitive so that it starts to magnify the intensity of the pain impulses it transmits to the brain (*windup*); as seen, it can also distort innocuous sensations, converting them into pain.

It is important to remember that even if the damage, which triggered off the nerve problem in the first place has healed, one of the sequelae can be that the nerve(s) remains in this hyper excitable state. In neuropathic pain, therefore, the pain is being caused by the damaged nerve and not by the original injury.

According to Dr Alan Basbaum (a leading American pain specialist), “*The nervous system after injury, with respect to the processing of pain, is a very different nervous system to that which existed before it was injured.*”¹²

Non-organic (psychological) pain happens due to alterations in the normal function of the nervous system as a result of non-organic (psychological) causes. On the whole, most people can handle physical pain more than they can handle psychological pain. It is this latter kind of pain which often causes the most controversy in medico-legal cases.

An individual under severe emotional pressure, for whatever reason, may readily convert his/her stress into pain and project this pain to a specific part of the body e.g. the back, by a process called *somatisation*. A person who converts ‘emotional pain’ into physical pain is called a *somatizer*. In these cases, the patient may feel severe pain in some part of his/her body without any identifiable cause in that part. A patient already suffering from chronic physical pain in a part of his/her body e.g. the back, can more easily become a somatizer, as the pre-existing physically painful locus presents a ready focus for somatisation. Thus, a pre-existing low back pain may get worse if the patient finds him/her self under stress.

A patient may have chronic pain in one area of the body due to an organic cause and this can then trigger non-organic pains at other sites. Thus a patient may start off with a back problem and after some time start complaining of pain in many other areas of the body – so called *global pain* or *total body pain*. Fibromyalgia is a condition classically associated with total body pain.

In some cases, there may be no physical cure available for a painful problem and in such cases, the patient must be taught how to live with and cope with his/her pain.

This is done by means of specialised multidisciplinary ‘*Pain Management Programmes.*’

A Pain Management Programme is a psychologically-based rehabilitative programme for people with chronic pain which has remained unresolved by currently available methods of therapy. Its main aim is to reduce the disability and distress caused by chronic pain by teaching sufferers physical, psychological and practical techniques to improve their quality of life.

A Pain Management Programme differs from standard pain clinic therapy in that pain relief is not the primary goal, thus the patient is taught that his/her pain is never going to go away; having accepted this basic premise, he/she is then taught how best to cope with the pain.

A Pain Management Programme tackles various factors, namely, exercise/physical fitness, activity planning,

cognitive therapy, reduction of medication and relaxation.

I now wish to highlight a few topics of specific interest to medico-legal practitioners:

1. Chronic pain and psychological factors;
2. MRI scan changes in spinal pain;
3. Waddell’s signs in low back pain.

1. Chronic pain and psychological factors

In medico-legal work, we often come across the interplay between chronic pain and psychological factors. Thus, it is not at all uncommon for a claimant to suffer a relatively minor injury and yet to complain of persistent pain for an inordinately long period of time. A number of whiplash cases fall into this category.

The defendant’s legal team will inevitably maintain that the claimant is ‘making it all up’ in order to embellish his/her case, i.e. that he/she is malingering; in a number of cases, the defendant may very well be proven right by independent surveillance evidence. However things are not always as simple or as clear cut as that.

Thus,

1. The claimant may have suffered a major trauma and have an undisputed, non-controversial reason for his/her chronic pain. All the experts in the case are in agreement; end of problem!
2. The claimant may have suffered trauma, which generated a genuine physical cause for continuing pain; the physical cause persists, but the pain is totally out of proportion to the said physical cause.
3. The claimant may have suffered trauma which generated a genuine physical cause which produced ‘physical pain’; the physical component, although still present to some extent, has decreased substantially, but the level of pain it produces is out of proportion to that physical component. In this case, the psychological component, although not *creating* the pain, is maintaining it.
4. The claimant may have suffered trauma which generated a genuine physical cause which, however, has produced pain for an inordinately long period of time, long after the said physical cause has disappeared; thus, in the absence of a *continuing* physical

cause, psychological factors are now both *creating* and *maintaining* this pain.

So, we now need to look more closely at these 'psychological problems.' In some cases, there may undoubtedly be an element of deliberate profit-seeking exaggeration, but in others, the psychological factors may be quite genuine.

The expert has to look closely at the pre-accident state of the claimant; for example, does he/she have a long track-record of repeated visits to the GP with a host of (often) trivial complaints? Is there a history of psychological problems e.g. self-harm, marital strife, substance abuse? Has the claimant seen a psychiatrist or psychologist before? Has he/she received counselling for whatever cause? Such individuals are regarded as having *vulnerable* personalities and are prone to blowing things out of all proportion, a process called *catastrophization*.

These individuals are also more likely to convert psychological problems into physical problems; this process, as discussed, is called *somatisation*.

It is also possible that the claimant develops a *Pain Disorder*. There is some confusion on what constitutes a '*Chronic Pain Syndrome*' and a '*Pain Disorder*.'

Chronic Pain Syndrome

Chronic pain is pain that is unlikely to resolve, or pain that lasts longer than the usual healing time; pain is generally accepted as 'chronic' if it has been present for at least three months.

Although there are no generally accepted criteria for diagnosing a chronic pain syndrome, Rice et al³ specify the criteria which are required for the diagnosis of a chronic pain syndrome.

These include the following:

- Persistent pain of longer than two to four weeks' duration;
- Pain behaviours, both verbal and non-verbal;
- Vague, inconsistent and inaccurate reporting of pain, indicating non-specific pain;
- Substance abuse and/or dependence;
- Depression;
- Muscular dysfunction and de-conditioning, resulting in secondary pain of musculo-skeletal origin;
- Withdrawal from work, recreational and family endeavors;
- Dependence on physicians, spouses and families.

Thus, co-existing physical or mental disease can be modified or, indeed, amplified by the presence of chronic pain, further complicating the picture. In addition, perceptions of pain may be altered by anticipation, age, medications, environment and physical status. Culture and belief also alter the way chronic pain co-morbidities manifest themselves.

Pain Disorder

In some cases, the psychological component of the patient's problem becomes very prominent and sometimes overwhelming. Psychiatrists then speak of a "*Pain Disorder*". A pain disorder is a response with definite psychological features and *possibly*, also some physical features to ongoing pain. It can only be formally diagnosed by a psychiatrist, with specific reference (at least in the UK) to the *Diagnostic and Statistical Manual of Mental Disorders* (the 'DSM').⁴

The perception of pain, for a variety of reasons, becomes exaggerated in the patient's mind; he/she becomes increasingly depressed and despondent.

This further worsens the perception of the pain so that a vicious cycle is set up. If one component of this vicious cycle - either physical or psychological - can be broken, then the other component tends to improve *pari passu*.

Two things should be pointed out with reference to a pain disorder. Firstly, it is generally (although not universally), accepted that a pain disorder is a genuine medical condition. It is as much psychological (if not more so) in origin as physical but it is, nonetheless, a specific medical condition. Secondly, it is a condition distinct from malingering, in that the patient with a pain disorder really does *perceive* the pain in his/her own mind and consequently *suffers* the disability. The patient behaves in just the same way whether he/she is being observed or not.

Of course, it can be sometimes very difficult to decide between a patient who is a genuine victim of a pain disorder and someone who is malingering. This is, ultimately, a matter for the court to decide. We might in fact, be witnessing a *Conversion Disorder* or a *Factitious Disorder*.

A **Conversion Disorder** implies somatization, i.e. the patient converting his/her psychological issues into pain. During my Army days, I saw a few cases of this when dealing with Far Eastern Prisoners of War (*FEPOW*), who suffered unimaginable horrors at the hands of their Japanese captors; guilt from survival was a powerful somatizer. One individual, who, I remember vividly, suffered chronic pain as a form of atonement to make up for surviving; previously, his mate, was made to kneel next to him and was decapitated with a sword. But for the fortunes of war, that victim might well have been him. He felt intense guilt at his survival and somatized his guilt into total body pain. Such somatized pain is based upon unconscious motives and emotional conflicts.

In some cases the cause of the pain is obvious and in others it is not so obvious; in other words, there is a split in the psychological processes between what is known and what is unknown, i.e. between the symptoms and the conflict



Perceptions of pain may be altered by anticipation, age, medications, environment and physical status

that has caused it. It is an *Extreme Behavioural Response*, by which the patient expresses any stress, tension or unhappiness in life by focusing on physical symptoms.

In some cases, somatization can become an illness in itself; we then have a *Somatization Disorder*. A *Somatization Disorder*, previously called *Briquet Syndrome*, or *St Louis Hysteria* is a psychosomatic disorder where mental turbulence expresses itself in physical symptoms, rather than psychiatric complaints; this leads to abnormal illness behaviour and a pattern of multiple, unexplained, symptoms, including pain.

A **Factitious Disorder** implies that the patient is feigning the symptoms or simulating an illness. This behavior is at a *conscious* level and is often motivated by psychological conflict.

An individual might be motivated to perpetrate factitious disorders in order to gain a variety of benefits including attention and sympathy that are unobtainable in any other way. All the above is in contrast to malingering, in which the patient deliberately and consciously feigns his/her symptoms in order to obtain an obvious material gain, which may include compensation following an accident.

Factitious disorder and malingering cannot be diagnosed in the same patient, and the diagnosis of factitious disorder depends on the absence of any other psychiatric disorder. Sometimes the medical court expert is very surprised when an apparent chronic pain sufferer is shown, in covert surveillance evidence, to be doing considerably more than he/she claims to be capable of. Only the court can decide if a Claimant is actually malingering.

2. MRI scan changes

A common bone of contention between medical experts is often the presence of MRI scan changes in cases of neck and back pain. In simple terms, the defendant's legal team will maintain that "... this claimant has pre-existing MRI scan spinal changes, he/she now has pain in that area, ergo his/her pain is not really due to the index accident, it would have happened anyway."

A simple extrapolation of MRI spinal scan changes to pain is rather dangerous! It is by no means as straight-forward as it would, at first, appear to be. A large proportion of totally asymptomatic patients can have significant changes in their MRI scans, including prolapsed intervertebral discs, so one cannot simply ascribe post-trauma pain to these 'pre-existing' changes. This being said, degenerative arthritis, as evinced by MRI scan changes, could eventually cause the patient some trouble.

The sooner after the index accident the MRI scan is carried out, the better; an early scan would be good evidence of pre-existing degenerative change. One could argue that, in the absence of the index accident, the claimant would, eventually, still have had some symptoms in the spine; thus, in these cases, one could opine that the index accident *accelerated* the onset of the pain. Factors to bear in mind when considering acceleration include any pre-existing injuries, the nature of accident, the *extent* of MRI scan degenerative changes (mild to severe), and whether the claimant is a smoker, together with his/her life-style.

Another thing to bear in mind is that as an individual grows older and degenerative processes appear and progress, due to the slow process involved, the individual may adapt and cope and thus experience minimal or no pain. A traumatic event, however, upsets the applecart and can then precipitate severe pain, which would otherwise, perhaps not have appeared or become a problem.

3. Waddell's signs in low back pain

Much is made of *Waddell's signs* in cases of low back pain by defendants' medical experts, in an effort to destroy a claimant's credibility. Waddell et al⁵ described five categories of signs, namely, tenderness tests, simulation tests, distraction tests, regional disturbances and overreaction. Although Waddell's signs can detect a non-organic component to pain, they do not, *per se*, exclude an organic cause.

Clinically-significant Waddell scores are considered indicative only of symptom magnification or pain behavior but they are not considered a *de facto* indicator of deception for the purpose of financial gain. In fact, in a 2004 review, Fishbain et al concluded that "*there was little evidence for the claims of an association between Waddell signs and secondary gain and malingering. The preponderance of the evidence points to the opposite: no association.*"⁶

Conclusion

In this day and age, no one should be told to 'go and live with their pain' until and unless everything possible has been done to reduce the level of their pain.

The pain specialist is an expert in understanding and managing pain, and all the emotional baggage that pain brings with it. A number of chronic pain consultants in the UK are involved in medico-legal work and compile reports on receiving solicitors' instructions, on behalf of both claimants and defendants, since UK Courts award compensation for pain arising from personal injuries; the situation in Maltese Courts, is, I believe, totally different.

In my opinion, the time has come for our legal colleagues to look at this. Compensation following a personal injury should not just be awarded for physical disability but also for genuine pain. S

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‘Lost in Translation’ the Maltese way

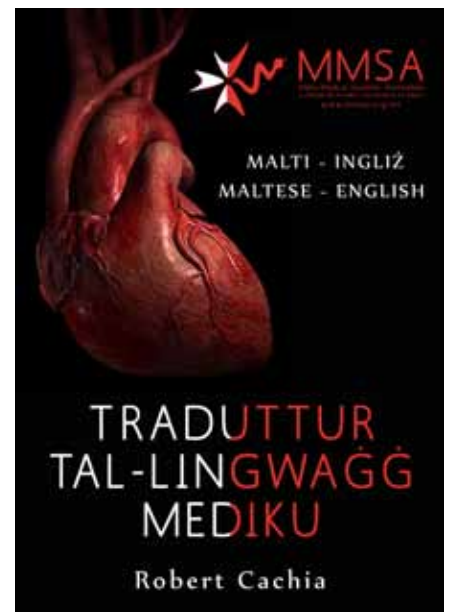
For one so young, Robert Cachia is a highly dynamic person. Entering his fifth year as a medical student at the University of Malta, he is intensely involved in the Malta Medical Students’ Association (MMSA) and has held a position in the executive board twice, once as the Medical Education Officer and currently as the President of the association.

“One of my responsibilities as the Medical Education Officer was to create opportunities for medical students in order to fill in any gaps existing within the medical curriculum. One such opportunity was a suturing workshop which attracted a good number of students with great enthusiasm.”

Robert recently turned an idea into a tangible reality when he thought of creating a pocket-size medical translator – The MMSA Medical Language Translator | Traduttur tal-Lingwaġġ Mediku. The publication,

issued last April by the MMSA is a 1000+ word book that translates medical terms from Maltese to English and vice versa. Why was it created?

“As a clinical student I started experiencing situations where doctors and patients were having communication problems due to a language barrier. I personally speak Maltese at home but many Maltese students at University are English-speaking and have difficulty keeping up a conversation in proper Maltese. Moreover we now have many foreign students who come to Malta and have to deal with the Maltese/English dual terminology situation. Difficulties arise when speaking to Maltese people who do not understand or speak English or use old Maltese terms and phrases, especially the elderly who make up a great majority of the hospital population. For instance, what would you call a ‘leak’ in Maltese? Or how would you correctly translate the



The publication, issued last April by the MMSA is a 1000+ word book that translates medical terms from Maltese to English and vice versa

With friends at the Taj Mahal



word into English? Then again, how do you differentiate between ‘minfes’ and ‘minhar’? In fact you don’t, if you know that they both refer to ‘nostril’.”

Together with fellow students, he started working spontaneously on the project by forming a quick list of basic words which turn up to be difficult to translate in everyday medical practice. The quick list started from around 100 words and quickly expanded as he researched a contemporary Maltese dictionary in tandem with a contemporary English dictionary. The end result was a total of over one thousand translated words. Each translation is presented in two ways where possible, in order to facilitate communication in different scenarios i.e. it provides layman’s terms when communicating with patients and also provides scientific terms when writing scientific articles and journals.

During the process of this dictionary’s creation, Robert found invaluable help from Professor Manwel Mifsud, Dr Michael Spagnol and Mr Josef Trapani from the Department of Maltese of the University of Malta. “We had plenty of support from the Department of Maltese with great enthusiasm for the finished product which will also be of assistance to Maltese language students, translators and interpreters.” Yes of course, the *Medical Language Translator* promises to be handy mostly to doctors (including foreign trainees), pharmacists, as well as students of these professions and other healthcare professionals, who sometimes have to struggle for that one unique word which makes things that much clearer especially for patients.

Robert is now awaiting the coming academic year to further promote this translator book. He explains how he has experienced varied situations where medical translation is vital. This has been especially so in his travels during which he attended various student exchanges experienced in Poland, Netherlands and Austria as well as several international conferences experienced in Denmark,

India, Ghana and Chile. “I attend these International Federation of Medical Students’ Associations (IFMSA) conferences with great enthusiasm because I learn so much. During the most recent one in Chile there were 118 member organisations from 110 different countries gathering a total of some 1000 delegates. It is obvious

that language differences exist in such a diverse accumulation of people; however finding strident language differences on such a tiny island as Malta is thoroughly fascinating. Discovering so many Maltese words of which I had never known the existence of was also a learning experience for me.”



Each translation is presented in two ways where possible, in order to facilitate communication in different scenarios



MR imaging of early Rheumatoid Arthritis and Spondyloarthropathy – Part I

PIERRE VASSALLO

Rheumatoid arthritis (RA) and spondyloarthropathy are two groups of inflammatory joint disease. Detection of early inflammatory joint disease is not possible with clinical examination or plain radiography, which have been the main diagnostic methods in the past. Changes detected on plain radiography are those of chronic damage caused by these conditions rather than acute inflammation, which results in delay in diagnosis and often suboptimal outcomes in these patients.

RA is the most common inflammatory arthritis, affecting approximately 1% of the world's population. In 25% of cases, non-articular soft tissues are also involved in the inflammatory process. RA results from inflammation of the synovial membrane (synovitis), with joints becoming swollen, tender and warm and stiff. Most commonly involved are the small joints of

the hands, feet and cervical spine, but larger joints like the shoulder and knee may be affected. Multiple joint involvement (polyarthritis) is common and is typically symmetrical in distribution although not in early disease. Over the last two decades, significant improvement in its prognosis has been achieved owing to new strategies for disease management, the emergence of new biologic therapies (including tumor necrosis factor–blocking agents such as rituximab, abatacept, and tocilizumab) and better utilization of the conventional disease-modifying antirheumatic drugs. Furthermore the generalized use of standardized criteria for the evaluation of disease activity such as the American College of Rheumatology (ACR) improvement criteria and European League Against Rheumatism response criteria have proved useful for monitoring the disease course in daily clinical practice.

In contrast, spondyloarthropathy comprises a group of chronic inflammatory rheumatic diseases, including ankylosing spondylitis, reactive arthritis (Reiter syndrome), arthritis or spondylitis associated with inflammatory bowel disease, and psoriatic arthritis, as well as undifferentiated spondyloarthritis. These afflictions predominantly affect the axial skeleton, causing pain and stiffness; are seronegative for rheumatoid factor; and are often associated with the presence of human lymphocyte antigen (HLA)–B27. They are largely differentiated on the basis of clinical information and the distribution of radiographic abnormalities. Spondylarthropathy tends to have an asymmetric distribution when multiple joints are affected.

MR imaging has demonstrated greater sensitivity for the detection

of synovitis and erosions than either clinical examination or conventional radiography and can help establish an early diagnosis of RA and spondyloarthropathy. It also allows the detection of bone marrow oedema, which is thought to be a precursor for the development of erosions in early RA and spondyloarthropathy as well as a marker of active inflammation. In addition, MR imaging can help differentiate RA from some clinical subsets of peripheral spondyloarthropathies by allowing identification of inflammation at the insertions of ligaments and tendons (enthesitis).

Magnetic resonance (MR) imaging has become the most recent innovation and the important change with respect to the previously established classification criteria. MR imaging can serve as a biomarker of disease activity, allows monitoring, and can provide guidance for the treatment of affected patients, and has become even more central to the care of these patients. Familiarity with the anatomy, anatomic variants, and physiologic joint changes is important for correctly interpreting findings and avoiding misdiagnosis.

The term *early RA* is not defined precisely in the literature. Most authors use the term to describe only disease duration of less than 1 year from the first episode of clinically detectable joint inflammation, although the duration of early RA varies widely between publications (up to 2–3 years in some series). Erosions, periarticular osteopenia, and cartilage loss are all known to occur within 2 years of the onset of RA in the absence of effective therapy. Radiography is not helpful for establishing an early diagnosis of RA, since fewer than 20–25% of patients initially present with erosions. Up to 30% of patients test negative for serum rheumatoid factor, and other pathognomonic features such as rheumatoid nodules usually appear late in the disease process. In addition, RA may start in atypical fashion. It can have a very sudden onset with marked systemic features such as fatigue, fever, and weight loss, or can manifest as polymyalgia rheumatica syndrome

(pain and morning stiffness in the hip and shoulder girdles), oligo- or even mono-arthritis, or bilateral carpal tunnel syndrome. The extent of irreversible joint damage and disability will depend primarily on how much time has elapsed before satisfactory treatment is achieved. The effectiveness of management strategies designed to disrupt the development of RA and prevent the long-term effects of this disease depends largely on early initiation of treatment.

When imaging for RA, the hands are the most likely to be involved and usually symmetrically. However it is best to image the more painful hand since this is likely to produce more florid findings. Imaging should include coronal and axial T1-weighted, STIR or fat-saturated T2-weighted images and pre- and post IV contrast (Gadolinium DTPA) Fat-Saturated T1-weighted

images using a high resolution flexible coil and covering all the wrist joints as well as the MCP and PIP joints since this is the most common pattern of distribution in RA.

Synovitis is the earliest abnormality to appear in RA. Normal synovial tissue that lines joint cavities, bursae, and tendinous sheaths is usually too thin to be visible on MR images. MR imaging signs of synovitis include synovial thickening, increased water content, contrast enhancement, or a combination thereof (Fig 1). Contrast enhanced T1-w MR images allow distinction between synovial hypertrophy and joint effusion. Fibrotic pannus, which is usually present in end-stage rheumatoid arthritis, may show poor or limited enhancement after the intravenous administration of gadolinium-based contrast material. S

(to be continued)



Figure 1: Synovitis in early RA of the wrist (6 months duration); patient had normal radiographic findings. **(A)** Coronal T1-w MR image shows extensive synovitis (arrows). On STIR **(B)** and axial fat saturated T2-w **(C)** MR images, the synovitis has high signal intensity (arrows). * indicate bone marrow oedema at the bases of the second metacarpal, capitate, and hamate bones. **(D)** Sagittal contrast-enhanced fat-saturated T1-w MR image shows intense enhancement of the periscaphoid synovitis (arrows), in the area of bone marrow oedema in the scaphoid bone and in the base of the second metacarpal bone (*).



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References: 1 Terpstra JJ, Acne treatment with 4% erythromycin and 1.2% zinc acetate. Cardiff 1988; 255-259. 2 Stainforth J et al. Dermatol Treat 1993 4: 119-122. 3 Schachner L et al. J Am Acad Dermatol 1990; 22(3): 489-495.

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Malta Medical Students Association Alumni



Robert Cachia

Throughout its 60 years of existence, the Malta Medical Students' Association (MMSA) has always been driven by great visionaries who aimed to develop the MMSA into what it is today. Hard-working Executive Boards and past dedicated members have given their precious time to the association in order to help build it into one of the strongest student organisations on campus.

Last year, the MMSA initiated a pilot project to bring together all its esteemed alumni into one database. It would be a privilege for us if you could form part of this database. If interested please send an email on alumni@mmsa.org.mt so that we can

add you to our database and keep you up-to-date with the progress of the association and the variety of events we organise under the different standing committees. §

Medical language translator

Traduttur tal-lingwaġġ mediku

The Medical Language Translator is a book which has a collection of over 1000 words and phrases used in the health care setting on a daily basis, translated from Maltese to English and vice versa. The aim of this book is to serve as an aide to all health care professionals in order to improve their level of communication with the patient, which in turn results in a higher quality of care. The publication has also been proofread by members of the UoM Department of Maltese so as to ensure that it is of a high calibre.

If you would like more information or are interested in acquiring a copy please do not hesitate to contact us on medicaltranslator@mmsa.org.mt.



The Malta Pharmaceutical Students' Association

The Malta Pharmaceutical Students' Association (MPSA) has been running since 1966 but was officially recognised by the senate in 1985. It is a students' association working in collaboration with the Department of Pharmacy within the Faculty of Medicine and Surgery. MPSA represents students both locally and on an international level and eligible students participate in various events being organised by MPSA itself such as the annual live-in and symposium gala dinner. We are also members of the European Pharmaceutical Student Association (EPSA) and the International Pharmaceutical Student Federation (IPSF) which work on an international level by organising student assemblies. The next event is EPSA's 10th Autumn assembly being held in Valencia, Spain to which a good number of students have already decided to participate.

We would like to officially introduce our Health Campaigns Team which is

responsible for educating the general public on ways how to improve their quality of life through exercise, diet and other lifestyle modifications. Different modes of communication will be used to ensure that these awareness campaigns are easily understood and followed by the public at large. We have also set up a page in Facebook, where snippets of health-related information are shared with the public on a weekly basis. This can be easily accessed on www.facebook.com/MpsaHealthCampaigns

We currently have a number of events coming up including the *World Pharmacists Day* which will be celebrated on 25 September. This is being held in collaboration with the Department of Pharmacy, the Malta Pharmaceutical Association and Actavis. A public outreach spread over 23-27 September will be highlighting the pharmacist's



Althea Marie Xuereb

important contribution towards the safe use of medicines. The theme for this year's *World Pharmacists Day* as identified by the International Pharmaceutical Federation (FIP) is 'Pharmacists - Simplifying your medicines use, no matter how complex'. Another activity which most students would be looking forward to is Freshers' Week on Campus. MPSA meets the new students and introduces them to the beginning of a new chapter in their lives. For the older students, this marks the start of a new academic year, a great excuse to call for a small party for all to get to know each other, mingle and catch up! §

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