

The Synapse

The Medical Professionals Network

Exclusive

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Foundation
Programme**

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Healthcare – Part II P 10**

Shoulder Ultrasound

Update on Celiac Disease

**Herbal Medicinal Products –
The Two Sides of the Coin**

Sandra Gauci article

A Case of Thyroid Cancer

Meeting Lawrence Scerri



When I came to write this editorial I considered several topics. The projected influx of immigrants on this rocky island, with their baggage of possibly forgotten & not-so-treatable medical conditions which could further stifle our stretched medical resources, or possibly the oocyte vitrification debate which is being discussed ... to mention just a few. But in this issue I will simply resort to penning a personal event which occasionally resurfaces every now and then much to the detriment of my serotonin levels ...

When I graduated (8 years ago) I joined a couple of friends for a go-karting session to celebrate the home coming of a friend who was studying veterinary medicine in Italy. I ended up with a bimalleolar ankle fracture. This has made me heavier with 6 pins & a metal plate, costing 3 operations and the equivalent of €4000. To add to all this no-one of my course-mates called to ask how I was or how I was recovering. The reasons could be manifold ... being abroad, being busy gearing up to the first employment, and so on ... However thankfully many other friends called on me to help out ... which more than compensated the shortcomings of human nature.

At this point many of you are querying whether I have mistakenly included a guest editorial for Flimkien for this magazine's editorial. However I can assure you that I have not mistaken any submission. I have written this simply as a testimonial of how us fragile human beings depend

on others. Being a healthcare professional does not mean that we are immune to life's events. And that is why when I remember this event I re-commit my allegiance for the various patient support groups which are formed from time to time (I am fortunate in this respect because this is perfectly in line with The Synapse's Editorial Board's position). We pledge free advertising for any patient support group which contacts us.

With the risk of sounding rhetorical, I have a dream, that one day a support group for healthcare professionals will be formed to precisely support those healthcare professionals who are in need, who are suffering from some serious illness, formed by healthcare professionals who are intent to do this job seriously without falling victim to social loafing or nepotism, and without being individuals who are jack of all trades but master of none (which incidentally I know a few).

And not forming this support group simply for the sake of forming it so that we can proudly say that we head a support group and that we can get EU funding.

I will conclude this editorial by the following reflection. In philosophy there is a paradox known as the Ship of Theseus.

If, over time, all the ship's planks are replaced, does it remain the same ship? How many times have we seen such mirror images in our life with people changing headship hats but still implementing the same ideas

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over and over again? God help us steer away from all this if we were to form the aforementioned support group ...

Ian C Ellul
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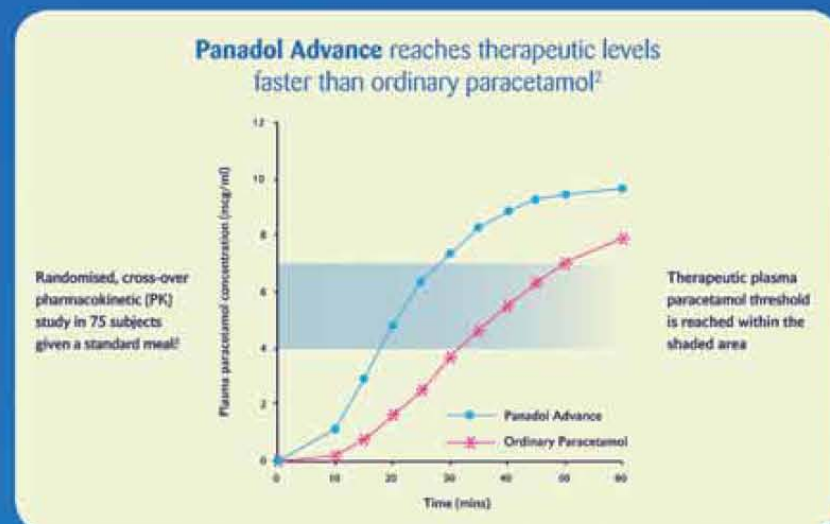
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Issue Guide

Contributors



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Front Page cover

Anacamptis pyramidalis (Orkida pyramidal; Pyramidal orchid)

A wild species complex of grasses that have been boiled and used medicinally for leg swelling, as a tranquiliser and tonic, as a diuretic and to combat diarrhoeal illnesses. More recently, oatmeal has been found to reduce levels of cholesterol in the blood, and colloidal oatmeal is the basis of some proprietary emollients.

Reference: Lanfranco G. Hxejjex Medicinali u oħrajn fil-gzejjer Maltin. Media Centre Print; Malta. 1993.

Photography: Guido Bonett ARPS AMPS



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The Malta Foundation Programme: one year on Pt.1

by Kevin Cassar & Tonio Piscopo



The Malta Foundation programme was launched in July 2009. In July 2010 the first group of foundation doctors were awarded their Foundation Achievement of Competence Document allowing them to proceed to the next step of their career, basic specialist training. The programme was set up with two main objectives:

A. to improve the first two years of postgraduate training of doctors and to ensure that doctors achieved a level of competence enabling provision of safe patient care; and

B. to reverse the exodus of Maltese medical graduates and retain an adequate proportion of doctors to allow the local health service to provide a good quality service. We present the results of the introduction of the Foundation programme to Malta and ask whether the main objectives have been achieved.

1. Educational and Clinical Supervision

One of the main changes introduced with the foundation programme was the implementation of a curriculum developed by the Academy of Medical Royal Colleges and the various departments of health in the UK. This curriculum outlines the knowledge trainees need to acquire but also the skills, attitudes and behaviours they will need to develop by different stages of the programme. The curriculum allows trainees to direct their own learning and link their work-based experience and educational activities against the curriculum. Trainees are encouraged to take responsibility for their own learning but are fully supported in this through the allocation of an educational supervisor.

110 consultants and resident specialists volunteered and were trained as **educational supervisors**. Educational supervisor training lasts one and a half days. Training started in February 2009 initially by trainers from the United Kingdom and later by Maltese trainers. The response by hospital consultants, general practitioners and resident specialists was very encouraging and the numbers recruited have allowed allocation of one educational supervisor to each trainee. The same educational supervisor follows the trainee for the whole year and then hands over to a different educational supervisor for the trainee's second year. Assessment and appraisal of the trainee is also conducted by the educational supervisor. This role is facilitated by the use of an online e-portfolio which has been developed by NHS Education Scotland

and which is used by foundation schools throughout the UK. All work-based assessments, educational activities, personal development plans and supervisor reports are recorded on the e-portfolio. This allows the educational supervisor to monitor the trainee's progress, performance on work-based assessments and overall engagement in the educational process. The meetings between the educational supervisor and the trainee are also recorded on the e-portfolio.

Trainees are allocated a balanced programme consisting of 8 three-month assignments in various specialties. During these assignments each trainee is allocated a clinical supervisor who is a Consultant or GP. The clinical supervisor is responsible for the day-to-day clinical supervision of the trainee. Each clinical supervisor completes a clinical supervisor's report at the end of the trainee's assignment which is recorded on the e-portfolio and to which the educational supervisor has access. 312 clinical supervisor reports were completed between July 2009 and July 2010.

2. Training and Educational Activities

i. One hour **lectures** are held every Friday afternoon for both first (FY1) and second year (FY2) trainees. The lectures cover important parts of the curriculum and trainees are obliged to attend at least 70% of the lectures to obtain a completion certificate. After the first year of lectures, a trainee committee was set up to provide feedback on the lecture programme. The lecture programme for this year (2010-2011) has been altered based on the feedback provided by trainees. There are now separate lecture programmes for FY1 and FY2 trainees. In an attempt to improve the interactive nature of these lectures an electronic keypad system has been adopted. This allows trainees to answer questions and express their views during the lectures.

ii. **Training days** in Family Practice as well as in Accident and Emergency were organised for trainees taking up posts in these specialties.

iii. Trainees are also provided with **clinical skills training** which involves use of models for acquisition of practical skills such as venepuncture, intravenous cannulation, arterial blood gas sampling, central venous catheterisation, urinary catheterisation, nasogastric tube insertion, blood cultures, spirometry, peak flow rate measurement, skin suturing, pleural fluid and air aspiration, joint aspiration and lumbar puncture.

Furthermore a high fidelity advanced patient simulator (SimMan) has been acquired and trainees both at F1 and F2 attend clinical simulation training sessions. Dr Josef Micallef has been responsible for the development of Clinical skills and simulation training for foundation doctors. Clinical skills and simulation trainers have themselves received training in the United Kingdom in the delivery of these sessions.

iv. In FY2 advanced life support (ALS) training is mandatory and all FY2s attended ALS last year. As of this year F1s will also be provided with intermediate life support training (ILS) and FY2s with ALS. Efforts are being made to provide ILS as early as possible in the foundation programme.

v. In conjunction with the Synapse, e-learning modules have been specifically developed for foundation doctors in various subjects. These include amongst others a module on Safe Prescribing and another on Nutrition. Further e-modules are being developed.

Trainees are also given free access to BMJ Learning through the postgraduate training centre. This is a very useful resource with modules on practical clinical scenarios and clinical situations.

vi. Programmes for taster weeks have been developed

across various specialties. Trainees are allowed to take one week of study leave to spend in a specialty of their choice. This gives trainees the opportunity of "tasting" a specialty that they might be interested in as a future career and which they might not have the opportunity to experience as part of their rotations. Timetables have been developed for these taster weeks that expose the trainee to what working in the specialty entails and what the training in the specialty involves. 87% of trainees attending taster weeks have reported that they were satisfied or very satisfied with the experience.

vii. An **induction and shadowing week** has been introduced as part of the foundation programme. New recruits now spend the first week of their employment on induction and shadowing. During this week trainees are given important information about practical issues such as use of electronic systems, administrative issues relating to study, vacation and sick leave and are also able to shadow the foundation doctor of the team they will be working with. This allows for a smoother transition and gives the new doctor time to start working under direct supervision of the previous foundation doctor. The feedback from trainees on the induction and shadowing week has been positive but on the whole trainees felt that this was too short. As of next year the period of induction and shadowing will be increased to 2 weeks.



The Synapse MedClub is proposing to start dining and blind wine tasting sessions in the very near future. There will be no embarrassing pressure on participants to guess wine type, and the scope is to learn how to taste wine, assess its quality and determine personal wine style preferences. The learning process will also endeavour to demystify the complexities of the wine world.

The pattern of the sessions will be based on the experience gained at "Il-Qatra" Wine Club, which started 10 years ago with 12 members and now has 70. Wine was invented to compliment meals, and therefore should be assessed and enjoyed with a proper meal and not just cheese and biscuits. The sessions will be planned and tutored by colleague Albert Cilia-Vincenti,

one of the founding committee members of "Il-Qatra". The format will be a quality dinner accompanied by blind tasting of four wines.

The dinners will be held at the Radisson Blu in St Julians, in the same restaurant that the Qatra Wine Club holds its sessions, and where the level of service for such a function is well established. The cost will be €65 per member (€110 for member & partner) to include everything. Negotiations are also ongoing with ITS with a view of enjoying a similar quality dinner at a cheaper cost. Before going ahead with these sessions, the TheSynapse MedClub needs to know whether any members are actually interested. If you are interested kindly send an email on mpl@thesynapse.net or phone 21453973.

The ABC of genital warts

by Philip Carabot

Genital warts are amongst the commonest sexually transmitted infections with a lifetime risk of acquisition of 10%. In spite of this there is still widespread misinformation on the subject which causes unnecessary anxiety, (sometimes bordering on the pathological), amongst patients. This is more marked in females who are given the impression that they are sitting, (quite literally in some cases) on a time-bomb regarding the development of cancer. This alarmist misinformation is obtained from friends, the dreaded internet, but also, sometimes, from us health professionals. It is estimated that 50-80% of sexually active men and women will acquire a genital HPV (both high and low risk) in their lives.

This article will attempt to answer patients' most frequently asked questions.

1. What causes genital warts?

Human Papilloma virus (HPV) types 6 and 11 (low-oncogenic-risk (LR) types, cause 90% of genital warts. However multiple HPV types are found in 56% of genital warts. In 11% these are the high-risk (HR) types 16 and 18. HR infections usually cause sub-clinical or latent infection.

2. Are genital warts always sexually transmitted?

The short answer is yes, in the majority of cases, and this includes oral sex. There is little evidence for auto-inoculation, although it may occur. There is no evidence of transmission via fomites. Although we do not have enough evidence to help establish the age when vertical transmission can be excluded, sexual abuse must be considered in any child presenting with anogenital warts.

3. Does the virus cause cancer?

The LR HPV types do not cause cancer, with the exception of the exceedingly rare Buschke-Lowenstein tumours. On the other hand the HR HPV types responsible for genital carcinomas do not cause warts. However studies from Scandinavia have shown an increase risk of carcinoma in situ but not of invasive cancer. Therefore women with genital warts can be reassured that they do not need more frequent smear tests.

4. How long does it take for warts to go?

The choice of appropriate treatment at presentation has improved response rate, but all treatment options have significant failure rates, with recurrence rates ranging between 10 and 90%. The choice of therapy depends on the number, type and site of warts, always keeping in mind that no treatment is always an option. Soft warts respond better to podophyllotoxin while keratinized warts are better treated with physical ablation. Imiquimod may be suitable for both. Small volume warts are best treated with ablative therapy from the outset. Appropriate therapy should clear most warts in three months.

5. Will the virus stay with me for ever?

It is generally accepted that the vast majority of people with HPV do not develop clinically apparent warts but 60% of women with types 6/11 will develop lesions within 2 years of infection. Most people will clear the virus within 18 months of infection, but between 10-20% will not, and remain DNA positive. These are the individuals who are at risk of developing intra-epithelial neoplasia and invasive cancer. Although the HPV DNA viral load does increase from the latent to the sub-clinical to the clinically overt state, the exact

Acknowledgements

Most facts and figures have been taken from the excellent review paper by P. Goon and C. Sonnex: "Frequently asked questions about genital warts in the genitourinary medicine clinic: an update and review of recent literature". (Sex. Transm. Inf. 2008; 84; 3-7). Additional material was taken from "HPV-immune response to infection and vaccination" by Margaret Stanley (Infectious Agents and Cancer 2010; 5:19). The treatment section follows the guidelines of the British Association of Sexual Health and HIV (www.basbh.com)

infectivity of each state is unclear. The effect of treatment on viral load is also not clear, and there is no evidence as yet that this reduces the risk of transmission, although it is assumed that it probably does. Atopic patients with genital warts have a more protracted clinical course and a greater probability of recurrences.

6. Warts and pregnancy

Genital warts may become first apparent or increase during pregnancy. Vertical transmission in utero is extremely rare but it can be passed during vaginal delivery in between 1:80 and 1:1500. The most important manifestation is juvenile laryngeal papillomatosis, an important disease with significant morbidity. The option of caesarean section will need to be discussed but it is not generally recommended unless the warts cause vaginal obstruction or in the presence of extensive cervical disease.

7. Do condoms help?

Data are conflicting, but it should be stressed that condoms may protect against HPV acquisition when used consistently and also have a therapeutic effect when both partners are infected, possibly by preventing continued re-exposure to the virus. However protection can never be complete since most HPV disease is sub-clinical and multi-centric. The incubation period (median 3 months) can be much longer thus allowing transmission. Moreover as already mentioned, transmission can still occur from sub-clinical disease.

8. Should I take the HPV vaccine?

The use of the HPV vaccine is an evolving subject with many grey areas. However what is agreed is that is prophylactic and not therapeutic. For ideal use it should be given to girls, and possibly also boys, aged 12-13 years before they start having sex. Giving the vaccine to patients with previous warts could boost type specific antibodies to types 6 and 11 and may provide protection against re-infection. However it is unlikely to prevent recurrences since these depend on a host cell mediated response.

9. Should I and my partner do an HPV test?

Routine HPV testing is currently not recommended in view of the transient nature of the majority of infection, and the potential of a HR positive result causing undue anxiety, without any viable treatment to offer. There is not as yet a commercially available HPV DNA test for men.

10. How can I prevent recurrence?

There is limited evidence to suggest one's lifestyle can affect the natural history of HPV disease. Excess alcohol and chronic stress and depression seem to increase the risk of developing warts. The role of smoking remains controversial with conflicting data. However it does appear that women smokers with cervical HPV have an increased chance of developing low-grade SIL than non-smokers.

Finally, common and mundane as genital warts may be, we must always keep in mind they are STIs and are associated with other hidden infections in 28% of cases. It is all too tempting to simply treat and dismiss. Therefore all first-presentation cases must have a full GU screen to exclude all other STIs. In spite of this warts are not a reason for an "urgent" referral and patients can be reassured that there warts will not suddenly multiply if they have to wait a couple of weeks for an appointment.

External Genital Warts treatment

A gentle genital approach with low recurrence rate



Cream, 5%
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Stimulating immunity where needed

MEDA

PRESCRIBING HUMOUR IN HEALTHCARE - PART I

by Joseph Agius

With regards to the effects of humour and laughter on immunity, research is not so conclusive. While some studies have reported that IgA, T-Cells and Natural Killer Cells increase with laughter, methodical problems question these conclusions. According to Sultanoff¹, it is also not yet clarified whether laughter reduces blood pressure. One study found no overall correlation when scores were separated by gender. In women, high humour scores were correlated with lower blood pressure and for men high humour scores were correlated with higher blood pressure. Sultanoff also notes that 'diabetic patients, on a day when watching a humour video, had lower glucose levels (after eating) compared to a day when they attended a bland lecture'. While the first wave of research data in the 1980's focused mainly on the relation of humour and laughter with pain reduction and the immune system, there is exciting new research, mainly in Japan, examining the impact of humour on specific disease conditions (McGhee²). During the course, current research evidence on the potential health benefits of humour and laughter was reviewed.



Therapeutic Use of Humour
According to the Association for Applied and Therapeutic Humour, Therapeutic Humour is 'any intervention that promotes health and wellness by stimulating a playful discovery, expression, or appreciation of the absurdity or incongruity of life's situations. This intervention may enhance health or be used as a complementary treatment of illness to facilitate healing or coping, whether physical, emotional, cognitive, social or spiritual'. Thus, humour therapy is a therapeutic process claiming beneficial effects from the use of positive emotions associated with laughter. The benefits of humour makes an appearance in the Bible itself. The Book of Proverbs 17.22 states 'A merry heart doeth good like a medicine: but a broken spirit make one sick'. The earliest historical reference to humour therapy comes from the fourteenth century, when French surgeon Henri de Mondeville used humour therapy to aid recovery from surgery. He wrote 'Let the surgeon take care to regulate the whole regimen of the patient's life for joy and happiness, allowing his relatives and special friends to cheer him and by having someone tell him jokes'. In the sixteenth century, Robert Burton, an English parson and scholar used humour as a cure for melancholy. Also in the sixteenth century, Martin Luther used a form of humour therapy as part of his pastoral

counselling of depressed people. He advised them not to isolate themselves but to surround themselves with friends who could joke and make them laugh. In the seventeenth century Herbert Spencer, sociologist, used humour as a way to release excess tension while educator Richard Mulcaiter recommended laughter for those suffering from head colds.

Modern humour therapy dates from the 1930's when clowns were brought into hospitals to cheer up children hospitalised with polio. However it was author Norman Cousins who brought humour therapy to the attention of the medical community in 1979 with the book 'Anatomy of an illness'. Cousins detailed his experiences in overcoming ankylosing spondylitis by laughing at favourite comedy shows such as 'Candid Camera' and 'Marx Brothers' films. He claimed that ten minutes of laughing gave him two hours of drug-free pain relief. In 1998 there was renewed interest in the uses of therapy thanks to the release of the film 'Patch Adams' starring Robin Williams. The movie is based on the real Hunter 'Patch' Adams treating the poor in rural West Virginia while bringing 'fun, friendship, and the joy of service back into health care'.³

More than a hundred American hospitals now have either humour rooms or a smaller version which is called a comedy cart - funny books, DVDs and cartoons. A software package has also been developed in order to help hospitals provide personalised humour prescription to patients. Although humour therapy has been widely accepted, not everyone will appreciate it. Some people may consider humour in these situations as inappropriate. Therefore, it is very important to know and be able to identify risks of humour in therapy.

The Course

The purpose of this course was to help participants understand how to use humour in the health setting in order to enhance communication, as well as diagnostic and treatment skills. It also activates one of the most powerful means available to us for dealing with daily life stress - our sense of humour! ... quoting Oscar Wilde, he used to say 'Life is too important to take seriously - so laugh!'

Dr Patch Adams argues that caring is not a business transaction but a loving, creative, positive human interchange. The course was merely the first step. It did not make participants a comedy writer or a stand-up comedian - but it did show how to build up

the basic skills needed to use one's sense of humour with clients. During the course, current research about humour and laughter was presented and the use of humour as a clinical tool was explored and the theory and rationale for its application in health care discussed. The course focused on how humour can be used as a mechanism to enhance communication and build a healthy therapeutic relationship.

The aims of the course were to enhance the participant's ability to:

- Understand the experience of humour and the experience of laughter;
 - Identify the core therapeutic impacts of humour;
 - Distinguish between the physical, emotional, and cognitive benefits of humour;
 - Understand the different types of laughter;
 - Attempt using the Humour Training Program;
 - Understand what triggers a humorous experience and discuss humour styles and theories on humour;
 - Outline the philosophical literature on humour throughout history;
 - Understand the development of humour in children;
 - Understand humour and gender;
 - Describe linguistic humour and language play: Irony, Paradox, Parody and, Satire;
 - Identify risks of humour in therapy;
 - Develop a sense of humour and increase one's 'humour quotient';
 - Identify how humour can be used as a treatment tool;
 - Understand how to develop and expand one's humour interventions;
- Integrate a model of therapeutic humour at work.

The Humour Training Programme

During the course, participants were also introduced and went through the humour training programme developed by Dr Paul McGhee 'The 7 Humour Habits (7HH) Programme'. The effectiveness of this programme is documented on three continents and is presented in the book 'Humor as Survival Training for a Stressed-Out World - The 7 Humor Habits Program'.⁴

Participant feedback

Following the delivery of the course, in-depth participant

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evaluations were employed to fine-tune future course organization and course content. All scores averaged 'very good' to 'excellent'. 'As a family doctor I feel I that the course has improved my communication skills and has enriched me personally as well' 'I am in a better position to use humour as a communication tool in practice' 'Good course because it made a difference of how I tackle stress and look at problems' 'Got more knowledge and skills to use them in my personal life and in my medical career. Well done and keep it up' 'I feel more confident that a humpristic approach does not mean being unprofessional as long as it is applied adequately. Humor takes away the rough edges of reality, creates positive stimulation; if adequately applied provides a common platform for individuals to communicate and makes life worthwhile'. 'It opened new opportunities to understand myself and where to look for research.'

'It met my objectives fully ... and much more.'

'Would like to see a laughter club set up. Please contact me if available as I am going to miss these lectures terribly.'

'I believe that this course will be beneficial to me at present and in everyday life situations, especially when working with patients and meeting others socially.'

Conclusion

This course was merely the first step. It did not turn participants into a comedy writer or a stand-up comedian - but it did show them how to build up the basic skills needed to use their sense of humour with their clients. Hopefully, they will take many more steps that will lead to confidence in themselves as positive and fun people. Confidence comes with experience, and experience comes with time and effort. Participants must have the proper attitude, motivation, and desire to be the best at what they do. I strongly believe that passion and determination are the keys to their success.



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WITH EVEN GREATER BP EFFICACY^{1,2}**

RASILEZ® (aliskiren) film-coated tablets
PRESENTATION: Each film-coated tablet contains 150mg or 300mg of aliskiren. **INDICATIONS:** Treatment of essential hypertension. **DOSAGE:** 150mg to 300mg once daily with a light meal, alone or in combination with other anti-hypertensive agents. No adjustment of initial dose required in elderly (>65 years), renal and liver impairment. Not recommended in patients under 18 years of age. Grapefruit juice should not be taken together with Rasilez. **CONTRAINDICATIONS:** • Hypersensitivity to the active substance or excipients. • Second and third trimesters of pregnancy. • Concomitant use with ciclosporin, itraconazole, quinidine and verapamil (highly potent P-gp inhibitors). • History of angioedema with aliskiren. • Hereditary or idiopathic angioedema. **WARNINGS/PRECAUTIONS:** • Increased risk of hyperkalaemia in patients receiving other RAS agents, and/or those with reduced kidney function and/or diabetes mellitus • Caution in patients with serious congestive heart failure and patients with a history of angioedema. • Treatment should be discontinued, if angioedema or symptoms suggestive of a hypersensitivity reaction/angioedema occur and appropriate therapy and monitoring provided until resolution of signs and symptoms. • Close medical supervision in patients with marked volume- and/or salt-depletion due to risk of hypotension. • Caution in patients with severe renal dysfunction or pre-disposing conditions, renal artery stenosis, a history of dialysis, nephrotic syndrome, or renovascular hypertension. • Not recommended during pregnancy or when planning to become pregnant, to be discontinued if pregnancy occurs. • Should not be used during the first trimester of pregnancy. • Not recommended in breastfeeding women. • In event of severe and persistent diarrhoea, Rasilez should be stopped. • Caution with moderate P-gp inhibitors such as ketoconazole. • Caution in driving or operating machinery. • Not recommended in patients below 18 years of age. **INTERACTIONS:** • Monitoring when used concomitantly with furosemide • Concomitant treatment with drugs that may increase serum potassium levels • Possible interaction with digoxin, irbesartan, St. John's wort, and rifampicin • Meals with high fat content substantially reduce absorption. • Caution should be exercised on concomitant treatment with P-gp potent inhibitors (eg. Ciclosporin). • Caution should be exercised on concomitant use with ketoconazole or other moderate P-gp inhibitors (itraconazole, clarithromycin, erythromycin, amiodarone, telithromycin). • Caution in the combination with NSAIDs especially in the elderly. • Caution with potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium or other substances that may increase serum potassium levels. • Grapefruit juice. **UNDESIRABLE EFFECTS:** • Common: diarrhoea • Uncommon: Rash, hyperkalaemia, acute renal failure, renal impairment, oedema peripheral • Rare: Angioedema, haemoglobin decreased, haematocrit decreased, blood creatinine increased. • Laboratory values: decrease in haemoglobin and haematocrit, increase in serum potassium. Frequency not known: peripheral oedema. **LEGAL CATEGORY:** POM. **PACK SIZES:** 7, 28 film-coated tablets. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBER:** EU/1/07/405/001 - 020. 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 22983217. (van 2011-MT-03-RAS Feb2011)

References: 1. Palatini P, Jung W, Shiyakho E, et al. *J Hum Hypertens* 2010; 24:93-103; published online 21 May 2009. 2. Villani A, Chrysant SG, Calhoun D, et al. *J Hypertens* 2007; 25:217-226

Case study

A Case of Thyroid Cancer

by Barbara Ioni & Francesco Carelli

Diagnosis and timely therapeutic intervention permitted a correct surgical approach in a case of papillary carcinoma with lymph nodes metastases.

A 40 year old normal weight patient presented to the practice complaining of a loss of eight kilograms over the previous six months without any change in lifestyle or diet. With negative medical history and without any objective findings on examination, we decided to proceed with further investigations.

Complete blood count and ultrasound abdomen were normal however an ultrasound of the thyroid showed a 10x12 mms mixed echogenic nodule at the left lobe and a 15x13x12 mms one at the isthmus, with a partially exophytic development.

After thyroidectomy with left paratracheal and pretracheal lymphadenectomy, the histology confirmed the diagnosis of about a 3 cm left lobe papillary carcinoma extending from the isthmus, to the pyramidal lobe and the third superior right lobe, infiltrating the soft coatings of the perithyroid and locally the striated muscle at third medium left lobe. Furthermore metastases were spotted in 7/14. TNM was: pT3; N1a

The post operative course was uneventful except for an asymptomatic hypocalcemia. The patient was discharged on the second postoperative day on treatment with L-thyroxin 100mg, 1 tablet per day, Calcium carbonate 1g twice a day and Calcitriol 0.50mcg three times per day. While on therapy with sodium levothyroxine 150x5+100x2mcg per week and calcium carbonate 300mg once daily, three months later the patient was submitted to metabolic radiotherapy: 1850MBq of I-131 after thyrotropin alpha. The total body post dose scintigraphy pointed out two uptake areas: a cervical one and a sub-jugular one.

Following endocrinological inspection found a constant decrease of TSH (from 104 to 2.9), Ab-Tg 1254 U/ml, and lymph nodes with internal spots at echographic neck investigation. Our patient follow up continues with regular controls about every two months, and contemplates FT4,TSH,Tg, Ab-Tg, ionized Ca dosage, neck echographic test with clinic evaluation and therapy management.

Reflections

Every year twenty six thousand new cases of thyroid carcinoma are diagnosed in Europe, most of them of epithelial origin.¹

References

1. Borget I, Coroneo C et al. Sick leave for follow-up control in thyroid cancer patients: comparison between stimulation with thyrogen and thyroid hormone withdrawal. *European Journal of Endocrinology* (2007) 156, 531-538
2. Cappelli C, Castellano M, Piola L, Gandossi E, De Martino E, Cumetti D, Agosti B, Agabiti Rossi E. Thyroid nodule shape suggests malignancy. *European Journal of Endocrinology* (2008) 155, 27-31

More than 80% are represented by differentiated forms and, among these, papillary adenocarcinoma is the most frequent and the most detected incidentally by imaging studies.

Although thyroid cancer remains relatively rare, its incidence has been increasing progressively over the last decades.

Thyroid nodules are very common, in particular among the young generation or, in any case, among the working generation, therefore one is always in search of ultrasound characteristics that can identify most of the lesions that hold the highest risk of malignancy, especially in not palpable nodules.

Cappelli and his colleagues² have been demonstrating how, with ultrasound confirmation, a long shaped nodule with a ratio of anteroposterior/transverse diameter more than or equal to 1, can be a good predictor of malignancy, independently of its dimension, but always associated to at least 2 more ultrasound characteristics such as micro calcification (most suspected are of the splash type), blurred margins, solid hypo-echoic appearance of nodule and its central hypervascularity.

The diagnostic criteria for thyroid nodules were also discussed at the last Congress of Italian Thyroid Association (AIT), with the introduction of two new tests: the elastography and the molecular diagnosis. Elastography is a special echography that indicates the nature of the nodule evaluating its resiliency, based upon the fact that the malignant coating is more rigid than the healthy one; the second one, to help the Fine needle aspiration cytology (FNAC) classic and enables it to increase its diagnostic precision up to 90%, is based upon a new rapid test for the screening of gene B-Raf mutation V600E that resulted in change in 40% of papillary carcinomas and protooncogene Ret/Ptc.

Among the new instruments utilized for this surgery, we have the bipolar coagulator and the ultrasound scalpel that stops micro haemorrhages during the operation, safeguarding nervous structures and thus reducing risks. Among the new techniques there is the MIVAT (mini invasive video-assisted thyroidectomy), developed in Italy. By using a camera, it ensures major precision and more restrained cuttings, but it cannot be used if the organ that has to be removed is too swollen or if there are adhesences among coatings.

Feeling free from symptoms



Seretide maintenance therapy achieves and maintains GINA guideline-defined asthma control, giving patients the opportunity to live life to the full.^{1,3}

Seretide™ (salmeterol xinafoate and fluticasone propionate)
Abridged prescribing information (see SPC for full prescribing information). **Presentations:** Seretide Diskus – Each dose provides 50 microgram salmeterol xinafoate and 100 microgram, 250 microgram or 500 microgram respectively of fluticasone propionate. **Therapeutic Indications:** Seretide is indicated in the regular treatment of asthma where use of a combination (long-acting beta-2-agonist and inhaled corticosteroid) is appropriate. Seretide Diskus is indicated for the symptomatic treatment of patients with COPD with a FEV1 <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. **Dosage and administration:** Adults and adolescents 12 years and over: Seretide Diskus is for inhalation use only. Asthma: Seretide Diskus – one puff b.d. of Seretide 100 or Seretide 250 or Seretide 500. Children 4-11 years: Seretide 100 Diskus (50 mcg salmeterol and 100 mcg fluticasone propionate) – one puff b.d. COPD: Seretide 500 Diskus (50 mcg salmeterol xinafoate and 500 mcg fluticasone propionate) – one puff b.d. **Contra-indications:** Hypersensitivity. **Warnings and Precautions:** Seretide should not be used to treat acute asthma symptoms for which a fast- and short-acting bronchodilator is required. Patients should not be initiated on Seretide during an exacerbation, or if they have significantly worsening or acutely deteriorating asthma. Serious asthma-related events and exacerbations can occur during Seretide therapy, sudden and progressive deterioration in control or increased use of bronchodilator therapy warrants urgent medical assessment especially in patients of African-American origin (SMART). Administer with caution in patients with pulmonary tuberculosis, severe cardiovascular disorders, including heart rhythm abnormalities, diabetes mellitus, untreated hypokalaemia/patients predisposed to hypokalaemia or thyrotoxicosis. In case of paradoxical bronchospasm discontinue Seretide, assess patient and give alternative therapy if necessary. Systemic effects may occur particularly at high doses prescribed for long periods, but are less likely than with oral steroids.

Prolonged treatment high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crises. Monitor height of children on prolonged inhaled steroid therapy. Transfer from oral steroids: special care needed. Monitor adrenal function. Consider appropriate steroid therapy during periods of stress or elective surgery. Ritonavir can greatly increase the concentration of fluticasone propionate in plasma, therefore avoid concomitant use. Increased risk of systemic side effects with other potent CYP3A4 inhibitors. Increased reporting of lower respiratory tract infections (particularly pneumonia and bronchitis) in the TORCH study in patients with COPD receiving Seretide compared with placebo. Avoid concomitant treatment with ketoconazole or other potent CYP3A4 inhibitors. **Drug Interactions:** Avoid beta-blockers. Concomitant use with other beta-adrenergic containing drugs can have a potentially additive effect. Potent CYP3A4 inhibitors: The concomitant administration of ketoconazole should be avoided, unless the benefits outweigh the potentially increased risk of systemic side effects of salmeterol treatment. There is likely to be a similar risk of interaction with other potent CYP3A4 inhibitors (e.g. itraconazole, telithromycin, ritonavir). **Pregnancy and Lactation:** Experience limited. Balance risks against benefits. Side effects: Very Common/Common – candidiasis of mouth and throat, pneumonia, bronchitis, hypokalaemia, headache, tremor, palpitations, hoarseness/dysphonia, throat irritation, nasopharyngitis, sinusitis, contusions, muscle cramps and traumatic fractures. See full prescribing information for other possible side effects. Overdose: due to Salmeterol – tremor, headache, tachycardia; due to Fluticasone propionate – temporary adrenal suppression. MA Holder: GlaxoSmithKline (Ireland) Ltd. Trading as: Allen & Hanbury's Ltd. MA Numbers: MA 192/00901-3. **Drug classification:** POM. Pack size: Seretide Diskus is available as a 60 dose Diskus. **Date of revision of text:** November 2010. For further information contact: GlaxoSmithKline (Malta) Ltd. on 21 238131

References: 1. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2007. 2. Bateman ED et al. *Am J Resp Crit Care Med* 2004; 170: 836-844. 3. Bateman ED et al. *Eur Respir J* 2007; 29: 56-63.

Herbal Medicine: Two sides of the coin

by Everaldo Attard

Introduction

A Herbal Medicinal Product (HMP) may be classified either as a herbal with a Well-Established Use/s (WEU) or a Traditional Herbal Medicinal Product (THMP). Its status primarily depends on the toxico-pharmacological profile and the way the product is presented on the market.

Although scientific research on quality, safety and efficacy may be essentially the same for both categories, the manufacturer may present the HMP in either category as long as the product conforms to one of the two main Council Directives.^{1,2} The main differences between these two categories are outlined in table 1.

	THMPs	Herbals with WEU
Discovery of product	Long History of Usage (30 years)	Discovered recently or use proven recently (10 years)
Proof of Efficacy	No proof. Bibliographic traditional information	Proof of efficacy by bibliographic clinical data
Proof of Safety	In vitro testing for genotoxicity and support by bibliographic data	In vitro and in vivo testing of product
Proof of Quality	Processed under pharmaceutical manufacturing procedures or as stated by an official European or Community Monograph	Processed under pharmaceutical manufacturing procedures. Reference to a Community Monograph can be made
Registration	Simplified Registration (registered HMPs)	WEU Marketing Authorisation (licensed HMPs)
Regulated by Council Directive	2004/24/EC ³	2001/83/EC ⁴

Table 1: The main differences and similarities for THMPs and herbals with WEU.

Proof of efficacy for HMPs

If the product efficacy has been proven scientifically, the HMP is probably a herbal with WEU. Scientific proof should be well-founded with appropriate in vitro and in vivo clinical trials, and with the relevant statistical backing. If no scientific efficacy is proven, the product may be a THMP. However, to qualify under this category the medicinal product should cover a traditional use for more than 30 years, with at least 15 years within the European Union. If this is fulfilled the product may proceed along the THMP line. Otherwise, additional information is required for the product to reach the market, either as a THMP with more bibliographical data, or as a herbal with WEU with more clinical data.

Routes of administration for HMPs

The route of administration has also an important implication on the categorisation of a HMP. A THMP should be administered orally, topically or by inhalation. In the case of herbals with WEU, these can be administered through any route of administration. This is because THMPs, intended to control or treat minor medical conditions, may

References

1. Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use. *Official Journal L* 135; 85-80. 2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. *Official Journal L* 311; 67-128. 3. Legal Notice 239 of 2003. FOOD SAFETY ACT, 2002. Food Supplements Regulations, 2003. 22p.
4. Decision tree for the classification of traditional herbal medicinal products and herbal medicines with a well-established use at <http://staffum.edu.mt/ea/tt/THMPs/>

be presented as over-the-counter (OTC) products for self treatment, while herbals with WEU are usually intended to control or treat more serious medical conditions and therefore require medical supervision. The latter are the prescription-only medicines (POM).

Doses and dosage regimens for HMPs

In spite of their medical intent, HMPs should contain specific herbal preparations or herbal substances with a specific dose range and frequency of administration. This is mandatory as a guide to the general public and healthcare professionals such as physicians and pharmacists. If the doses and dosing regimen are not included within the package leaflet (PL) and the HMP packaging, the product will fail to reach the market. Since these HMPs are usually extracts, the extracts are adjusted according to a valuable reference substance. These substances may be active markers, i.e. compounds that exhibit the pharmacological activity stated, or analytical markers, i.e. compounds that indicate the strong presence of a class of compounds but do not necessarily contribute to the pharmacological activity. These categorise HMPs into standardised and quantified extracts, respectively. However, there are other HMPs that cannot be standardised or quantified, and in most cases, such extracts are not granted a marketing authorisation. Further classification of HMPs within these categories, is beyond the scope of this article.

Additional active constituents to HMPs

If there are no additional active constituents then the product is likely to be classified as either a THMP or a herbal with a WEU. However, additional active constituents that are allowed in herbal preparations are vitamins and minerals. If these do not have a pharmacological role, vitamins and minerals may be omitted from the herbal medicinal product. On the other hand, if these are retained in the product, the quantities should be according to or less than the daily maximum requirements, depending on the frequency of daily administration.³ If there are other active constituents other than vitamins and minerals, the product may be either modified to eliminate these constituents, particularly if the constituents are toxic, or else considered as a herbal combination product. Combination products that are not supported by a traditional use may only be considered as herbals with WEU as long as there is bibliographic proof of clinical efficacy.⁴

Conclusion

The distinctive characteristics of HMPs guide healthcare professionals towards rational use of plant-derived natural products. This facilitates the integration of green medicine, with an optimum quality-safety profile, within modern prescribing and dispensing practices.



ANKLE GUARD SERIES



ANKLE BRACE WITH CRYO-GEL PADS



HIP PROTECTORS



GUARDIAN KNEE BRACE



WALKER SERIES



WRIST/THUMB SUPPORT



MOTION CONTROL KNEE SPLINT



GRIP BUDDY

COMPETITION CORNER - ISSUE 1/11

Last issues' challenge answers

1. Mention the name of the interviewee: Rinderpest
2. What is the estimated sum needed to implement a local National Sexual Health Policy? The European Society of Cardiology

The winner is:

Lrraine (SURNAME) (2 One-day membership at Athenæum Spa)

The Synapse team would like to congratulate the winner and thank the sponsors of these competitions.



THIS MONTH'S CHALLENGE

The answers to all questions can be found in issue 6/10. 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 Athenæum Spa, Attard.

1. Explain shortly why one should join the TheSynapse MedClub's dining and blind wine tasting sessions?

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/quiz. All submissions will participate in a draw. You have up to the 15th March 2011 to submit your answers.

Fill in your details

Name

Address

Email

Mobile

Health Promotion Quiz

Which National Plan has recently been launched by the Ministry for Health, the Elderly and Community?

Fill in your details

Name

Address

Email

Mobile

The answer can be found in Issue 1/11. 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 21/79383740.

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/hpdquiz. All submissions will participate in a draw.

You have up to the 15th May 2011 to submit your answers

Pharmacy Student Available for Summer job

First year pharmacy student, very friendly and with a flair for sales and customer service, currently looking for a job in the pharmacy field for the summer months and possibly also for some hours a week during the academic year. Can speak Maltese and English very fluently as well as some basic German. Please send your proposals to mpl@thesynapse.net.

Clinic Space

New clinic space in pharmacy available for Gynaecologist/Doctor with special interest in Gynaecology. If interested, please contact owner on 9947 2781 or by e-mail attbon@orvol.net

Update your details and win competition

The following medical students each won a Euro20 book voucher courtesy of Actavis. All they had to do was join The Synapse Web Portal by end December 2010 (and win, of course!).

Gabriela Camilleri
Rosemarie Vella Baldacchino
Caroline Attard
Mary Louise Camilleri
Matthew Attard



We thank Actavis for their continuous support to education through TheSynapse.



GALVUS and EUCREAS COMPREHENSIVE POWER TO ADVANCE TYPE 2 DIABETES TREATMENT

INSULIN INCREASE

GLUCAGON DOWN

GALVUS is a DPP-4 inhibitor that improves glycemic control through powerful islet enhancement¹
EUCREAS is the combination of a DPP-4 inhibitor, GALVUS, and metformin²

Galvus® 50mg (vildagliptin) tablets
PRESENTATION: Each tablet contains 50 mg of vildagliptin. **INDICATIONS:** For the treatment of type 2 diabetes mellitus. As dual oral therapy in combination with - metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin, - a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose 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. **DOSAGE AND ADMINISTRATION:** In combination with metformin or thiazolidinedione 100mg daily, administered in two divided doses of one 50 mg in the morning and one 50 mg in the evening. In combination with sulphonylurea, 50 mg once daily in the morning. Galvus can be administered with or without a meal. Doses greater than 150 mg are not recommended. Galvus is not recommended for use in patients less than 18 years old. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. **PRECAUTIONS/WARNINGS:** Galvus should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Galvus is not recommended in patients with moderate or severe renal impairment or in haemodialysis patients with end-stage renal disease. Galvus is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x 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. Vildagliptin should be used with caution in patients with congestive heart failure of New York Heart Association (NYHA) functional class I-II and is not recommended in patients with NYHA functional class III-IV. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **PREGNANCY AND LACTATION:** Galvus should not be administered during pregnancy or lactation. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, gliclazide, metformin), amiodipine, digoxin, simvastatin, valsartan 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. **UNDESIRABLE EFFECTS:** Rare cases (>1/10,000 to <1/1,000) angioedema, hepatic dysfunction (including hepatitis). **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. **Combination with metformin:** Common: tremor, headache, dizziness, nausea, hypoglycaemia. Uncommon: fatigue. **Combination with sulphonylurea:** Common: tremor, headache, dizziness, asthenia, hypoglycaemia. Uncommon: constipation. Very rare: nasopharyngitis. **Combination with Thiazolidinedione:** Common: weight increase, oedema peripheral. Uncommon: headache, asthenia, hypoglycaemia. **PACK SIZES:** 7, 28 tablets. **MARKETING AUTHORISATION NUMBERS:** EU/107/14/001, 003. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimborne Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **LEGAL CATEGORY:** POM. Before prescribing please refer to Summary of Product Characteristics (SPC). 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 22883217. 2011-MT-01 GAL JAN 2011

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 who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets. **DOSAGE AND ADMINISTRATION:** The recommended daily dose should be based on the patient's current regimen of vildagliptin and for metformin hydrochloride. The usual dose is 50 mg/850 mg or 50 mg/1000 mg twice daily one tablet in the morning and the other in the evening. Eucreas should be taken with or just after food. Doses of vildagliptin greater than 100 mg are not recommended. Patients > 65 taking 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. **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 < 60 ml/min. Acute conditions with the potential to alter renal function e.g. dehydration, severe infection, shock or intravascular administration of iodinated 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.** **PRECAUTIONS/WARNINGS:** Eucreas 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 >3x the ULN. LFT's 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. Vildagliptin should be used with caution in patients with congestive heart failure of New York Heart Association (NYHA) functional class I-II and is not recommended in patients with NYHA functional class III-IV. Metformin is contraindicated in patients with heart failure, therefore Eucreas is contraindicated in this population. 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 iodinated contrast agents can lead to renal failure. Therefore due to metformin active ingredient, Eucreas should be discontinued prior to or at the time of the test and not reinstituted until 48 hours afterwards and only after renal function has been re-evaluated and found to be normal. **PREGNANCY AND LACTATION:** Eucreas should not be administered during pregnancy or lactation. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, gliclazide, metformin), amiodipine, digoxin, simvastatin, valsartan or warfarin were observed after co-administration with vildagliptin. Interactions with metformin hydrochloride that are not recommended include alcohol, cationic active substances e.g. cimetidine and intravascular administration of iodinated contrast media. Combinations requiring caution include metformin hydrochloride with medicines tending to produce hyperglycaemic activity e.g. glucocorticoids, beta agonists and diuretics. The dose of antihyperglycaemic medicinal products may need to be adjusted in combination with ACE inhibitors. **UNDESIRABLE EFFECTS:** Rare cases (>1/10,000 to <1/1,000) angioedema, hepatic dysfunction (including hepatitis) have been reported with 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. Common: metallic taste. **Combination vildagliptin with metformin:** Common: tremor, headache, dizziness, nausea, hypoglycaemia. Uncommon: fatigue. For a full list of Adverse reactions, please refer to the SPC. **PACK SIZES:** 30, 60 film-coated tablets. **MARKETING AUTHORISATION NUMBER:** EU/107/14/002-003, EU/107/14/008-009. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimborne Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **LEGAL CATEGORY:** POM. Consult full Summary of Product Characteristics (SPC) 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 22883217. 2011-MT-01 EUC JAN 2011

Nutritional Medicine

Healing & The Series Disease Is Reversed

by Albert Cilia Vincenti

Abstract

Anxiety is a universal human experience. It is an unpleasant mood and is often accompanied by the physical symptoms of autonomic arousal and fearful cognitions. Its duration, intensity and impact on daily function determine whether it is a disorder or an appropriate response which prepares the individual to successfully manage risk. Maladaptive thought processing underpins a range of anxiety disorders. Cognitive Behavioural Therapy, anxiolytic and antidepressant medications are the mainstay of treatment.

When whole-wheat flour is processed into white flour, or brown rice into white rice, the fibre and bran are removed, turning a "good carbohydrate" into a "bad carbohydrate". Removing fibre and bran results in four unhealthy consequences:

1. Large amounts of "bad carbohydrates" can be eaten without feeling full. Removing fibre allows consumption of virtually unlimited calories without feeling full.
2. "Bad carbohydrates" are absorbed quickly raising blood glucose rapidly. When blood glucose rises too much, the pancreas secretes insulin to bring it back down. It may go down too much, and the resulting hypoglycaemia produces lethargy and a craving for more "bad carbohydrates". A vicious cycle is created and "bad carbohydrates" become addictive.
3. Too much insulin accelerates conversion of calories into triglycerides, which is how the body stores fat. As explained, eating a lot of "bad carbohydrates" leads to excessive consumption of calories without feeling full, and these extra calories are converted to body fat. Insulin may also encourage more lipoprotein lipase production, increasing fat uptake into cells, leading to weight gain. High triglyceride level in blood lipid profile tests is therefore a surrogate marker for hyperinsulinaemia.

4. Chronic secretion of too much insulin may lead to insulin resistance and even diabetes. Repeated surges of insulin in response to too many "bad carbohydrates" may make insulin receptors on cells less sensitive, leading to insulin resistance, which in turn induces more insulin production just to maintain the same effect on blood glucose. With time, this may lead to type 2 diabetes. Insulin is a growth factor, and chronic hyperinsulinaemia enhances arterial smooth muscle proliferation and promotion of atherosclerosis. High triglycerides, combined with low high density lipoprotein levels in blood lipid profile tests, is one of the best risk indicators for atherosclerosis and its complications. Being a growth factor, hyperinsulinaemia also increases risk for a number of cancers.

Never eating bad carbohydrates is too restrictive and unrealistic. In moderation they may be safely consumed

along with good carbohydrates and other high fibre foods. The fibre in good carbohydrates will slow the absorption of bad carbohydrates. What matters is the glycaemic index (or load) of the whole meal, not just individual foods. Some people may need to limit their bad carbohydrate intake more than others, depending on their overall state of health.

Trying to lose weight may eventually generate guilt feelings due to presumed lack of motivation or discipline. However, individual variations in biology, not just willpower, may play a role in weight loss. A study published in The Journal of the American Medical Association showed that individual variations in biology may cause some to have a harder time losing weight and keeping it off than others. In the study, 73 obese young adults were assigned to either a conventional low-fat, high-glycaemic-load diet or a low-glycaemic-load diet. The people found to secrete insulin slowly lost the same amount of weight on both diets. Those who secreted insulin rapidly and were on the low-glycaemic-load diet lost five times more weight, and they kept all the weight off throughout the 18 months of the study.

The study above concludes that when it comes to healthy eating, one size may not fit all. It may be unwise to recommend decreasing dietary fat without adequate attention to the carbohydrates that replace them, and vice versa. It's not low-fat versus low-carbohydrate – both are important. An optimal approach may be a diet containing high-quality, unprocessed low-glycaemic carbohydrates, plant-based proteins, and fats.

This study found that people who secrete insulin too quickly lose more weight when they eat low-glycaemic-index foods (which don't provoke an excessive insulin response). A glucose tolerance test will tell whether an individual secretes insulin rapidly or slowly, but this is not usually necessary to perform. If one eats predominantly low-glycaemic-index foods, whether he/she secretes insulin fast or slowly doesn't matter very much, as these foods won't provoke a rapid insulin response even if genetically predisposed to rapid insulin secretion.

In summary, there is corresponding benefit to the degree of substitution of good carbohydrates for refined bad carbohydrates, but it's not an all-or-nothing effect.

« I cannot concentrate,
I cannot sleep,
I feel overwhelmed »



Marc, 50 years old - Accountant
He has just lost his job

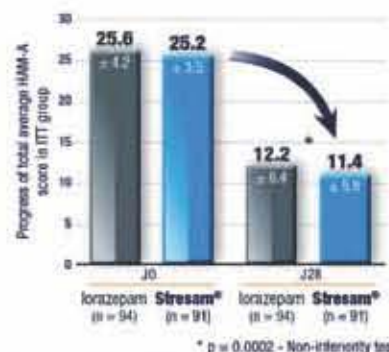
« I feel nervous,
I have palpitations,
I have knots in
my stomach »



Anna, 35 years old - Sales assistant
Her son is suffering from a serious illness

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first-line treatment



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depending on the intensity of the
patient's anxiety, for several days to
several weeks

Maximum duration of prescription
= 12 weeks

1. Houten R, Kohn E, Pochet C et al. Efficacy of etifoxine compared to escitalopram monotherapy in the treatment of patients with anxiety disorders with comorbid depression: a double-blind, randomised study. *Hum Psychopharmacol* 2006; 21: 101-104.
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3. Stresam® (etifoxine) capsules.

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Reacting & Adjusting

by Anothony Dimech

Abstract:

Anxiety is a universal human experience. It is an unpleasant mood and is often accompanied by the physical symptoms of autonomic arousal and fearful cognitions. Its duration, intensity and impact on daily function determine whether it is a disorder or an appropriate response which prepares the individual to successfully manage risk. Maladaptive thought processing underpins a range of anxiety disorders. Cognitive Behavioural Therapy, anxiolytic and antidepressant medications are the mainstay of treatment.

Article:

The experience of anxiety in the context of real adverse circumstances is neither necessarily abnormal nor indicative of even mild mental illness. As long as there is no marked discrepancy between the stressful stimulus and the elicited anxious response, both in intensity and duration, and there is no resulting gross impairment in the different domains of daily functioning, anxiety is not only normal, but can become an instrumental component of sound adjustment to calamity. Anxiety is a mood that is universal in human nature. It is usually accompanied by the release of adrenaline and other catecholamines, resulting in unpleasant physical symptoms affecting most of the physiological systems of the body, such as palpitations, breathlessness, nausea, frequency of urination, trembling, muscle tension, dizziness and headaches. It is frequently revived by fear-laden thoughts, the content of which depends on current circumstances, past memories and experiences. It is a natural alarm that danger is imminent and serves to prepare the individual to minimise risk and maximise safety.

So when does anxiety become a disorder? Problems start to arise as the intensity and duration of anxiety grow out of proportion to the actual threat that provoked it. Executive functions such as judgement, decision making and problem solving are affected to a certain extent, though symptoms remain reality-based and insight is not lost. In essence, anxiety is maintained and amplified through biased thought processing resulting in overrating of threat and underestimation of personal capability to deal with and contain the risk.²

On Saturday night, Paul, a 53 year old married man with 2 children is watching his favourite TV show. His 19 year old son Julian went out with his friends at 11 pm and promised to come back before three. He knows his son usually sticks to his time plus or minus one hour. Paul experiences thoughts that Julian or his friends might have too much to drink or smoke a bit of weed but reminds himself that he can do very little to prevent this. At times he gets brain images of his son being arrested by the police or getting involved in a traffic accident. These thoughts provoke short-lived palpitations and a bit of chest tightness. Overall, the father has a good relationship with his son, and though he got into some trouble in the past after getting drunk during a barbeque, Paul believes that Julian is likely to act sensibly and steer away from danger in the majority of occasions. This helps to ease his anxiety and he continues to enjoy his TV programme until he dozes off on the settee. He later manages to go to sleep in his bedroom but does wake up 3 hours down the line to check that his son returned home safely. He then manages to

go back in the hands of Morpheus for the rest of the night. On the other hand, Katya, Paul's wife, feels increasingly anxious as the weekend approaches. Her appetite and sleep are affected and she complains of headaches and palpitations which are usually worse from Thursday onwards. Julian is annoyed by her repetitive advice to stay away from drink and drugs, to come home early and to avoid all situations that can possibly lead to danger. Katya knows he is completely against her driving him to his friends and back on Saturday nights but she keeps forcing him to accept. She resorts to diazepam on Fridays and Saturdays but she still feels anxious all day. She spends Saturday nights in the balcony smoking cigarettes and counting the minutes. Lately, she started holding a picture of her son in her hands as soon as he is picked up by his friends. Though Katya is fully aware that there is little sense in this, she feels obliged to kiss it three times repetitively to ensure her son's safety.

The above two reactions to the same situation distinguish between anxiety and anxiety disorder. There is a range of anxiety disorders and most people experience symptoms from different disorders in the course of their condition. In almost all anxiety conditions, symptoms of autonomic arousal are prominent and comorbidity with other disorders such as depression, substance use and personality disorder is frequent.³

Generalised anxiety disorder is characterised by persistent uncontrollable worry about different topics whilst episodic paroxysmal anxiety attacks which follow catastrophic misinterpretation of internal events occur in panic. Situational anxiety is the highlight of phobias. In obsessive compulsive disorder anxiety originates from the experience of recurrent intrusive thoughts or mental images with absurd content and urges to perform repetitive and time-consuming rituals intended to neutralise the feared events. Adjustment disorders describe abnormal reactions to stress. There is a delayed and prolonged response to a real and very threatening event in post traumatic stress disorder.

Cognitive behavioural therapy has gained a prime position in the treatment of anxiety problems and is considered as the state of the art psychological approach.⁴ In the acute phase benzodiazepines can generally be prescribed in low doses for short periods whilst selective serotonin reuptake inhibitors and triptolite antidepressants produce relief in the medium and long terms. Other medications such as venlafaxine, pregabalin, hydroxyzine, buspirone and antipsychotics in low doses also induce anxiolysis. Etifoxine has anxiolytic and anticonvulsant properties and may be used in the short term as an alternative to benzodiazepines or for longer periods, given it lacks tolerance or withdrawal symptoms.

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The sun, the sea, good wine and more besides...

by Marika Azzopardi

Rewind to last summer. Remember the health promotion efforts made to remind us all of the risks of excessive sun exposure? Meet a key person behind it all – Dr Lawrence Scerri, who has been Chairman of the Department of Dermatology & Venereology since 2000. Meeting him in his office at Boffa Hospital, we get talking of the long route that led him to this post.



"I specialised in Dermatology in Nottingham and Southampton University Hospitals in the UK, following which I took up an NHS consultant job in Derby UK for one year. I must say that working in the UK was pretty gratifying as the work conditions and the job experience were both excellent. But I couldn't wait to return to my roots. Mostly I missed our great Maltese weather and the laid-back island style of living." Today he is one of some 12 specialists in dermatology practising in Malta and Gozo and whilst this number might seem minimal, he claims that the current specialist to patient ratio is adequate to cater for the dermatological needs of the 400,000 odd people living here.

Dr Scerri is not only involved in clinical work but is also kept busy academically as a Senior Lecturer in Dermatology at undergraduate and post-graduate levels at the University of Malta. This apart from being Vice President of the MADV – Maltese Association of Dermatology & Venereology. He also held the position of board director of the largest European scientific dermato-venereological organisation, the European Academy of Dermatology and Venereology – EADV, as well as being chairman of the membership committee of this same academy. He currently chairs the CME/CPD committee of the EADV. Dr. Scerri has been one of Malta's delegates on the UEMS Dermatology/Venereology section, which is responsible for harmonising dermato-venereology training in Europe, for the past 12 years. He is also regular journal reviewer of several international and local scientific journals. His main areas of special interest include skin cancer

and acne, and he has to date accumulated over 40 publications in peer-reviewed scientific journals, and presented and chaired at numerous international congresses.

We move on to speak of the other branch of his activities, and one which he holds very much at heart – health promotion about skin cancer. "I have been a key local coordinator of the European Melanoma Campaign since its inception in 2000. The main responsibilities circle around the issue of raising awareness about skin cancer."

My journalistic nose is twitching – has the campaign succeeded in its intent of educating the general public about the dangers of too much sun on our bodies? "The level of public awareness has definitely increased and we can confirm this through a progressive increase in requests for consultations to check moles and a variety of lumps and bumps on the skin. We have been much supported in our efforts by the attention of the media which punctually publishes information and promotes our initiatives each and every year. The campaign has also produced much feedback, mostly from the visual impact of billboards and widely circulated health promotional flyers. Over the past 10 years, I feel our work regarding sun damage caused to the skin has certainly been beneficial. People have slowly come to realise that besides the increased risk of skin cancer there are also cosmetic repercussions, namely premature skin ageing that comes about thanks to excessive sun exposure. This does not mean however that the sun-tan culture has disappeared."



Some people tend to believe that a healthy dose of sunshine is actually good for the body and is essential for the skin to build adequate amounts of Vitamin D. How true is this? "There is some truth and some myth involved. Indeed a good dose of Vitamin D is essential for maintaining healthy bones, but sun exposure is not a justifiable excuse. It has been scientifically worked out that just 10 to 15 minutes of daily sun exposure is enough to provide the necessary dose of Vitamin D for one day, not to mention that most vitamin D supplementation can be acquired from a healthy balanced diet. You don't have to religiously roast in the sun at peak time to get your fair share of your 'D' requirements."

Ironically enough, Dr Scerri loves one very sunny activity – boating. He admits, "I adore spending free time boating with my family and friends. I do however take all the necessary precautions to minimise sun damage by covering up and applying generous amounts of sunscreen. I might not come across as the type of person who loves the exhilaration of speed, but I do. Indeed, that is why I have opted to own a sport cabin cruiser rather than a sailing boat. Boating round the Islands is an incomparable experience and a great opportunity to enjoy dips in the clean sea around isolated bays. Fishing was another pastime which I enjoyed especially with my previous smaller boat. Today boating is also an excellent way to socialise with friends and bond with my children, Chiara 17 (first year sixth form, dreaming of becoming a vet), Alex 18 (first year Law student) and Justine 20 (second year Law student)." From talking of boats we move on to talk of tennis and

I find that Lawrence Scerri is a dedicated tennis player and has been since he was 10. "I was a student at De La Salle College and one day I saw this racquet on sale in the school tuck-shop. I bought it on the spur of the moment and taught myself to play tennis, and have developed and improved my game ever since through practice, and trial and error." Playing friendly's and taking part in tournaments is a regular activity and in 2010 he landed the runner-up in the Men's Doubles Tournament of the Malta Medical Tennis Association.

Amazingly Dr Scerri also finds time for another great socialising activity – wine tasting. Being an active member of the local wine club "Dielja" has allowed him the luxury of learning more about wines. "I sometimes travel to wine tasting events abroad as well – France and Italy as well as California. In recent years I have learnt to appreciate a good wine, and have become reasonably familiar with the world wine ranging from grape variety, microclimates, region, flavours, complexity, to wine ageing. My favourite wines are the St Emilion Gran Cru wines, Barolos, and Brunello di Montalcino"

Is there more? "Oh yes, I think I have not as yet mentioned that I am a great Manchester United fan following on my father's footsteps and enticing also my son to follow suit. I'm an avid supporter of this great team and have on several occasions visited the magical Old Trafford Stadium also known as the "Theatre of Dreams" to watch the Red Devils. Luckily every time I watched them "live" they won. When I'm with my son and father, we often end up discussing football and the progress of Manchester United ... all three of us – it's a great way to bridge the generation gap!"

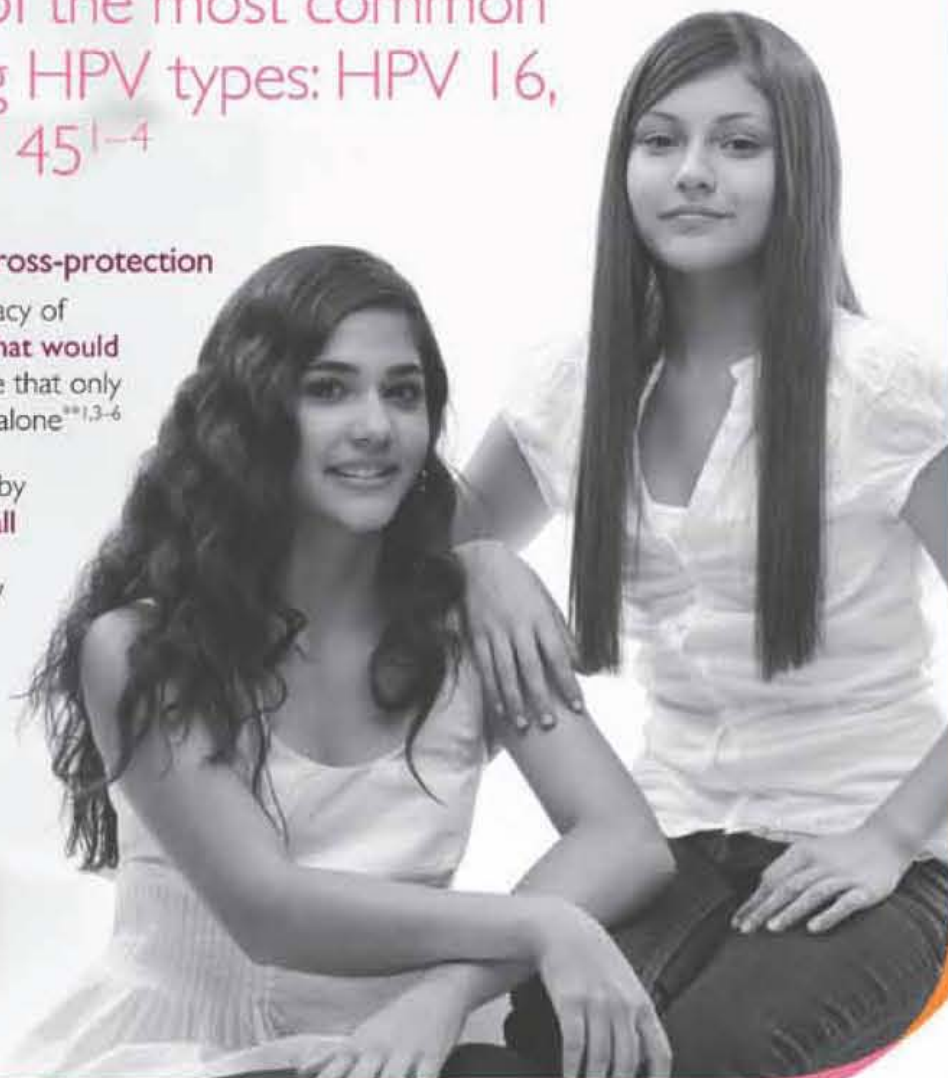


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**Comparison based on worldwide epidemiology data, which can vary in different regions.⁶

†Vaccine efficacy against CIN3+ irrespective of HPV type in lesions was 87.0% (54.9-97.7) in the TVC-naïve cohort.^{1,2}

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hepatitis B (rDNA) vaccine (Twinrix) or with hepatitis B (rDNA) vaccine (Engerix B). If Cervarix is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites. There is no evidence that the use of hormonal contraceptives has an impact on the efficacy of Cervarix. In patients receiving immunosuppressive treatment, an adequate response may not be elicited. **PREGNANCY AND LACTATION:** Vaccination should be postponed until after completion of pregnancy. Cervarix should only be used during breast-feeding when the possible advantages outweigh the possible risks. **ADVERSE EVENTS:** Common and very common: headache; gastrointestinal symptoms including nausea, vomiting, diarrhoea and abdominal pain; itching/pruritus; rash, urticaria; myalgia and arthralgia; injection site reactions including pain, redness, swelling; fatigue; fever (≥38°C); Uncommon: dizziness, upper respiratory tract infection, other injection site reactions such as induration, local paraesthesia. Post marketing surveillance: lymphadenopathy, allergic reactions, angioedema, syncope or vasovagal responses to injection, sometimes accompanied by tonic-clonic movements. **PRESENTATION:** Pack of 1 pre-filled syringe with a plunger stopper containing 0.5ml of suspension + 1 needle (refer to full SPC for information on disposal). **LEGAL CATEGORY:** POM. **M.A.HOLDER:** GlaxoSmithKline Biologicals S.A. Belgium. **M.A. NUMBER:** EU1/07/419/004. For further information and full prescribing information contact GlaxoSmithKline (Malta) Ltd. Tel: 21 238 131. Date of revision of text: March 2011.

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BIO/006/10. Date of preparation: August 2010.
GlaxoSmithKline Biologicals, Wavre, Belgium.
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Update on Celiac Disease

by Thomas M Attard

Celiac Disease is a chronic autoimmune process that is modulated by an environmental trigger, namely gliadin; a part of gluten which is present in wheat, barley and rye. Celiac disease is clearly increasing in prevalence worldwide and with easier access to screening tools the notion that it is a disease of Western society is increasingly being challenged. We have also seen a broader gamut of symptoms and disease conditions that are associated with celiac disease to the extent that the nomenclature of classic and non-classic manifestations seems redundant. The increased recognition in prevalence is poorly understood but seems to also reflect a true increase in incidence. These observations supported by constantly improving diagnostic techniques; including serologic, genetic testing and endoscopic modalities has frustratingly not been paralleled in any measure by any breakthrough in management.

The current prevalence of celiac disease in the Maltese population, based on the provision of gluten-free diet items through the government health service is 1.9 per 1,000 general population. This compares fairly well with similar, clinically diagnosed population based studies in Southern Europe and the Mediterranean Basin.^{1,2} Case recognition based on population screening programs however places the prevalence figures much higher; from 4 - 10 per 1,000 in most populations studied.

Amongst the commonest pitfalls facing the general practitioner is the selection of the appropriate, at-risk patient population who require investigation. These individuals include those presenting with both typical and atypical intestinal (constipation, vomiting) and extraintestinal manifestations (Table 1).

Dermatitis Herpetiformis	Iron-deficient anemia resistant to oral Fe
Dental enamel hypoplasia of permanent teeth	
Osteopenia/Osteoporosis	Hepatitis
Short Stature	Arthritis
Delayed Puberty	Epilepsy with occipital calcifications

Table 1: Extraintestinal Manifestations / Presenting Symptoms of Celiac Disease

Also at increased risk are first and second degree relatives of affected individuals, individuals with other autoimmune disorders (IDDM, autoimmune thyroiditis, hepatitis, arthritis) and patients with genetic syndromes (Down, Turner, Williams Syndrome). In relatives, as in individuals at risk because of associated autoimmune or genetic syndromes it is important to stress with the family that serologic surveillance, if negative, needs to be repeated on a regular, usually every two year, basis.

The serologic testing available for the diagnosis of celiac disease has evolved over the last decade (Table 2). Anti-tissue transglutaminase (tTG) and antiendomysial (EMA) IgA serology offer the highest sensitivity and specificity albeit are not reliable in individuals with IgA deficiency. These individuals are, in turn, more susceptible to develop Celiac Disease and may be picked up by IgG based testing (EMA-IgG & tTG-IgG). Therefore, total serum IgA testing is indicated in all symptomatic individuals being investigated for possible celiac disease.³

	Sensitivity %	Specificity %
AGA-IgG	69 - 85	73 - 90
AGA-IgA*	75 - 90	82 - 95
EMA (IgA)*	85 - 98	97 - 100
TTG (IgA)*	90 - 98	94 - 97

Table 2: Serologic Testing in Celiac Disease. * Limited in patients with IgA deficiency

An exciting aspect of diagnostic testing has been the evolution of genetic testing. What is most clinically relevant at this point is the observation that either HLA haplotype HLA-DQ2 or DQ8 need to be present if an individual is at risk of developing celiac disease. The converse however, does not hold true given the high incidence of these haplotypes in the general, unaffected population. This offers a useful adjunct in screening at risk individuals and suspected cases with an atypical presentation.⁴

Although the mainstay of diagnosis remains duodenal biopsy, there is on the one hand a trend toward forgoing biopsy in symptomatic individuals with very high antibody serologic titres (anti-tTG IgA > 200). Although this strategy is attractive, it is as yet unsupported as standard of care. There is, on the other hand evidence that diagnostic sensitivity of biopsy is better with multiple, including duodenal bulb, biopsies. In cases where biopsy is negative in the context of positive serology or with atypical histology, wireless capsule endoscopy may be a useful adjunct in diagnosis. Capsule endoscopy is also indicated in individuals with suspected small bowel lymphoma complicating celiac or individuals unable to undergo traditional diagnostic endoscopy with biopsy⁵ (Figure 1).



Figure 1: Scalloping of the mucosa in Celiac Disease on Wireless Capsule Endoscopy.

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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. **Hyperglycaemia:** • 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. **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, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/09/593/001, 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 P.O. Box 124, Valletta, VLT 1000 Malta. Tel: +356 22983217 2010-MT-01-ONB-16-Jun-2010

Once Daily
onbrez®
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indacaterol inhalation powder

References:
1. Cazzola M, Matera MG. Novel long-acting bronchodilators for COPD and asthma. *Drugs* 2008; 155:291-299.
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Pediatrics

A central tenet of celiac management is patient education and compliance. It is important that celiac is understood to be a lifelong condition, that gluten is completely excluded and not allowing for any form of 'diet holiday', and that, in itself, a gluten-free diet is healthy, even for non-celiacs and with imagination and perseverance, can be palatable.

There are many barriers to compliance and it is best to gradually implement steps towards a strict gluten-free diet over a short period so as not to overwhelm caregivers. Compliance can be limited by lack of education or the availability of gluten-free foods, foods may be mislabelled and ingredients may change so that items that were 'safe' may come to include gluten over time. Compliance can also be challenged if the patient, especially if a child, receives mixed messages, if there is peer pressure or the need not to feel or act different in the case of a teenager. Time and food preparation constraints as well as eating out or travel abroad tend to be problematic in adults. It is important to provide adequate support and locally, we are fortunate to have provision of gluten-free food items through the government pharmacy service and to have an especially proactive and effective patient association (<http://www.oeliacmalta.org/>).

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What's on for Health promotion for May 2011?

by Charmaine Gauci

The prevalence of overweight and obesity continues to increase globally and also in Malta. The long-term consequences include increased risk of developing hypertension and stroke, coronary heart disease, diabetes, osteoarthritis and certain cancers. In fact, overweight and obesity may soon cause as much preventable disease and death as tobacco does.

It's estimated that over half of the European population is overweight or obese. Whilst it is often seen as something that affects body image and confidence, being overweight has health consequences. In fact, losing 5-10% of overall body weight can:

- Reduce the incidence of diabetes by 58%;
- Reduce the risk of developing hypertension;
- Decrease total cholesterol;
- Reduce the risk of coronary heart disease by 48% in men and 40% in women;
- Reduce risk of osteoarthritis.

Furthermore a decrease in the BMI (Body Mass Index) of 2 points reduces the odds of developing osteoarthritis in the knee by more than 50%.

To reach this goal, people should limit energy intake from total fats and shift fat consumption from saturated fats to unsaturated fats; increase consumption of fruit and vegetables, as well as legumes, whole grains and nuts; and limit their intake of sugars. To increase the calorie expenditure, people can boost their levels of physical activity to at least 30 minutes of regular, moderate-intensity activity on most days.

The Health Promotion and Disease Prevention Directorate will be joining other European countries on the 21st May on a 'STOP YO-YO' campaign. The main messages are:

- Obesity is a chronic disease.
- Some overweight and obese patients use ineffective solutions to manage their weight;
- Overweight and obese patients should be encouraged to consult their health care professionals to find the best sustainable solutions for them;
- Such sustainable solutions are likely to require a multidisciplinary approach, bringing in a range of healthcare professionals;



Shoulder Ultrasound

by Pierre Vassallo

Ultrasound (US) has been shown to be an effective imaging modality in the evaluation of both rotator cuff and non-rotator cuff disorders. Magnetic resonance imaging has taken on a secondary role in shoulder imaging for assessing sonographically inaccessible structures such as bone, labral cartilage, deep parts of various ligaments, capsule, and areas obscured by bone.

Ultrasound has several advantages over MRI for shoulder imaging. Ultrasound is a quick and inexpensive technique that is more widely and readily available. Ultrasound also has a higher spatial resolution than MRI and therefore has the potential of demonstrating smaller details (MRI has a higher contrast resolution). Ultrasound allows dynamic assessment of moving structures and can better assess problems such as tendon impingement and tendon subluxation (particularly of the long head of biceps tendon). Ultrasound allows the examiner to go directly to the site of pain as indicated by the patient so that the structure and often the pathological process causing the symptoms can be immediately identified. Ultrasound is also very effective for guiding interventions such as steroid infiltrations, fluid aspirations and aspiration of liquid calcific deposits. Tendon calcifications are best seen with ultrasound (they are not visible on MRI). Ultrasound may be the only option in patients with metallic implants in the shoulder and pacemakers as well as in claustrophobic patients who will not tolerate an MRI scan. The following paragraphs will outline the most common types of pathology affecting rotator cuff and non-rotator cuff structures and their appearances on ultrasound.

The rotator cuff is composed of four tendons that are fused together to form a supporting sleeve to stabilise the humeral head within the shallow glenoid fossa. The

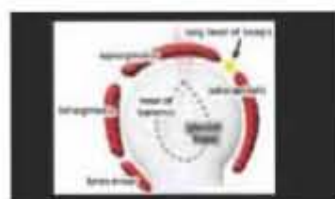


Figure 1. The rotator cuff tendons encircle the humeral head to retain it in the glenoid fossa. The long head of biceps tendon passes between the subscapularis and supraspinatus tendons.

tendons include from posterior to anterior; the teres minor; the infraspinatus; the supraspinatus and the subscapularis tendons (Figure 1).

A small gap between the subscapularis and supraspinatus tendons allows the passage of the long head of biceps tendon; this is called the rotator cuff interval.

The supraspinatus tendon is the tendon most commonly involved in rotator cuff disease. Since the supraspinatus runs above the humeral head and below the acromion of the scapula, it is prone to impingement in this restricted location. Also it is the most superiorly located tendon of the cuff and therefore takes most of the load particularly during arm abduction. The supraspinatus tendon is seen on ultrasound as an echogenic band exiting below the acromion and tapering towards its attachment into the greater humeral tuberosity. It frequently shows a fibrillar pattern (fine longitudinal lines within it) and close to attachment (due to reflection of sound waves by the parallel running fibers) a dark area may be seen which is called anisotropy and is normal (Figure 2).



Figure 2. Supraspinatus tendon in longitudinal view is seen as an echogenic band superior to the humeral head, with a convex upper surface that tapers toward the greater tuberosity. The arrow indicates a hypoechoic area due to tendon anisotropy (arrow).

Supraspinatus tendon degeneration also known as supraspinatus tendonosis is the result of repeated strain injury and impingement of the supraspinatus tendon. A longitudinal scan through the tendon shows thickening of the tendon and hyperechogenicity due to deposits of myxomatous tissue (Figure 3). Supraspinatus tendonopathy may also present with calcifications within the tendon (Figure 4).

Calcific tendinitis is a common disorder caused by deposition of calcium hydroxyapatite crystals. The

cause is considered to be dystrophic, and all tendons can be affected, although the most common site is within the supraspinatus tendon near its insertion. A partial-thickness supraspinatus tendon tear extends either to the articular or bursal surface of the

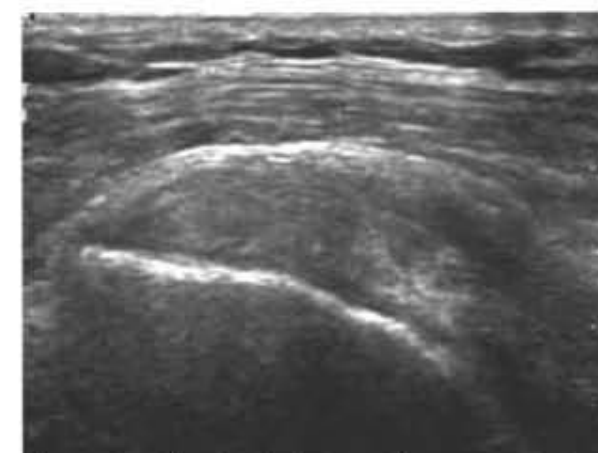


Figure 3. A longitudinal view of the supraspinatus tendon demonstrates a heterogeneous echogenicity in the tendon without any tendon gap. This pattern may be compatible with tendinosis.



Figure 4. A longitudinal view showing two dense calcifications (c) with posterior shadowing near the insertion of the supraspinatus tendon.

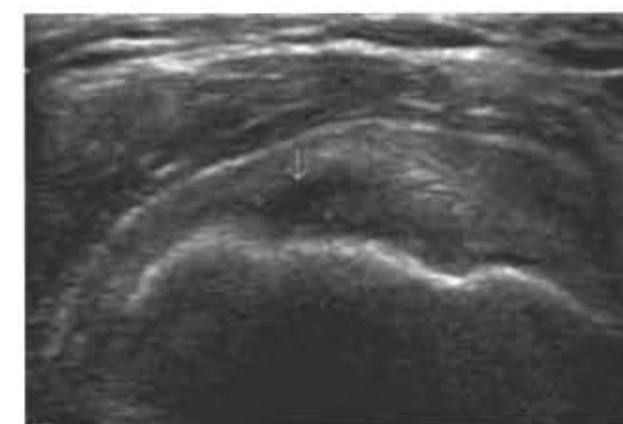


Figure 5. A longitudinal view of the supraspinatus tendon shows a partial-thickness tear as a distinct hypoechoic defect (arrow) at the tendon's articular side.

tendon. An articular-side partial-thickness tear appears as a distinct hypoechoic or mixed hyper-hypoechoic defect of the articular surface (Figure 5). A bursal-side partial-thickness tear produces flattening of the bursal surface, with loss of the superior convexity of the tendon (Figure 6).

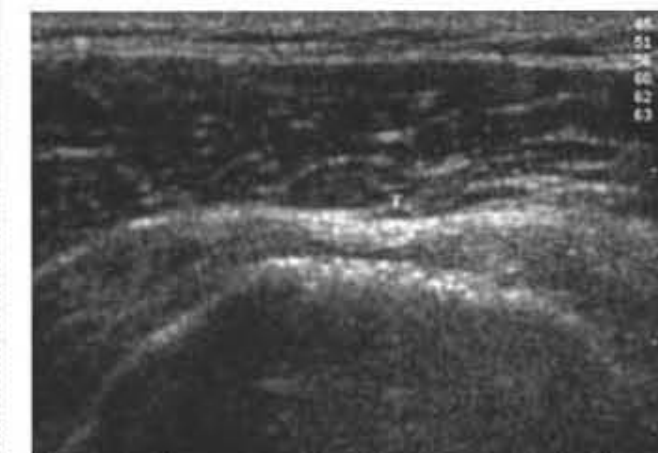


Figure 6. A transverse view of the supraspinatus tendon showing a partial-thickness bursal side tear; note the flattening (T) of the normally convex superior margin of the supraspinatus tendon.



Figure 7. A longitudinal view of the supraspinatus tendon showing a full-thickness tear (T) filled with anechoic joint fluid.



Figure 8. A longitudinal view of the supraspinatus tendon shows a complete tear of the tendon; the tendon absent and the deltoid muscle (D) is now in contact with the humeral head (H).

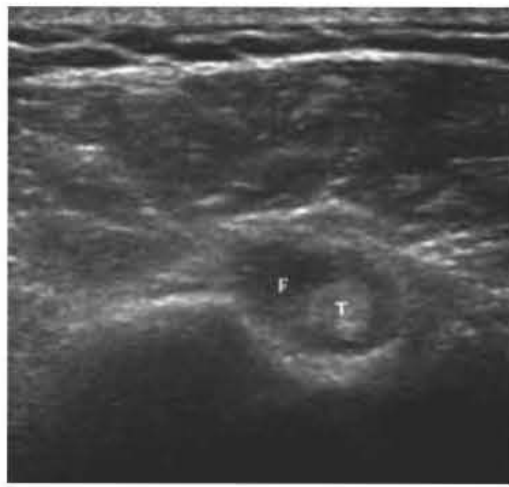


Figure 9. Transverse view of the biceps tendon (T) showing hypoechoic fluid collection within the tendon sheath (F).

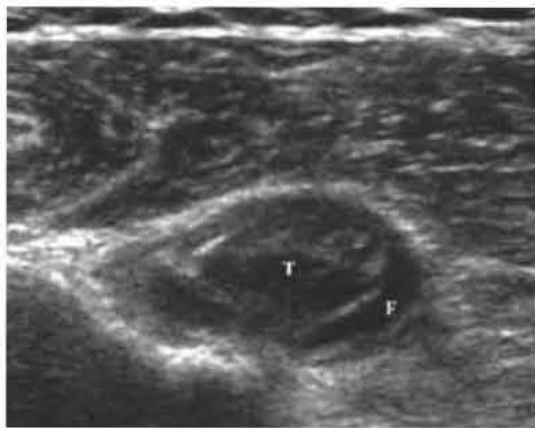


Figure 10. A transverse view of the LHBT shows an enlarged tendon (T) with an inhomogeneous echotexture and associated fluid in the sheath (F) that are features of tendinosis.

A full-thickness tear of the supraspinatus tendon presents with a gap involving the full thickness of the tendon that is filled with fluid or debris (Figure 7).

A complete tear of the supraspinatus tendon presents with absence of the tendon below the deltoid muscle (Figure 8).

Due to the complete tear, the supraspinatus tendon has retracted medially and as a result, the deltoid muscle is now in contact with the humeral head.

The long head of biceps tendon is also commonly involved in acute or chronic shoulder injuries. The most common finding is rotator cuff tenosynovitis that presents with fluid in the tendon sheath (Figure 9).

Long head of biceps tendonitis may also occur and present with a thickened, heterogeneous and hypoechoic tendon (Figure 10). Long head of biceps subluxation out of the bicipital groove may result from trauma and is readily diagnosed by ultrasound

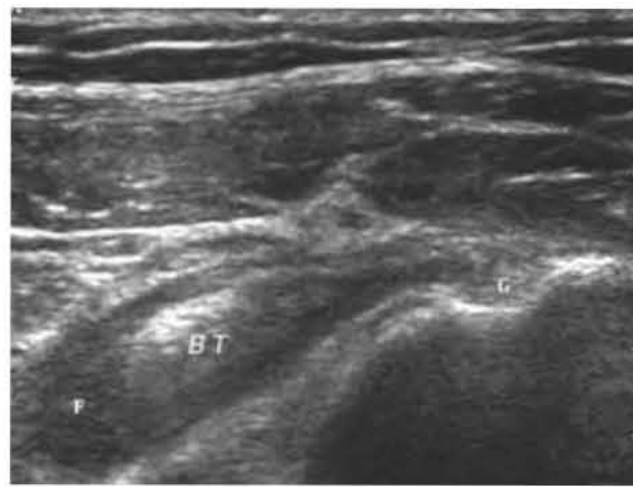


Figure 11. Transverse view through the bicipital groove shows a subluxed LHBT (BT) is surrounded by a hypoechoic fluid.

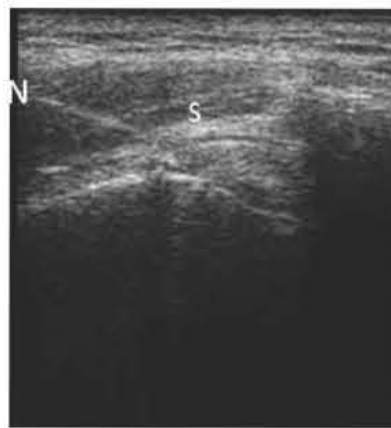


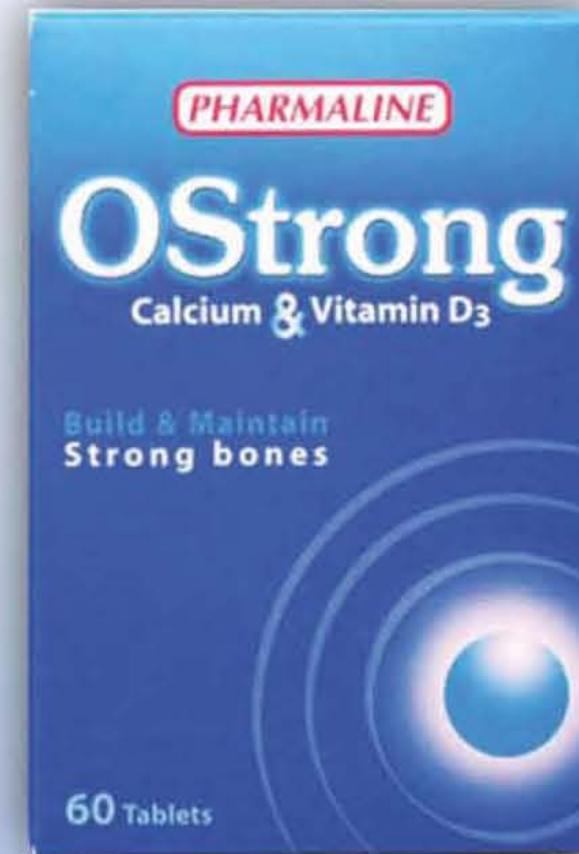
Figure 12. Steroid infiltration of the subdeltoid bursa with realtime control of needle (N) entering the subdeltoid bursa (S) from the left.

particularly during dynamic internal and external rotation of the arm (Figure 11).

Finally, ultrasound is also used to guide interventional procedures, particularly steroid infiltrations and aspiration of fluid collections. The real-time monitoring of these procedures with ultrasound ensures accurate delivery of medication and confirmation of completeness of fluid aspiration (Figure 12).

High-resolution US has proved to be an efficient imaging modality for the assessment of a wide spectrum of rotator cuff and non-rotator cuff disorders, the more common of which have been described above. It is fast and inexpensive and allows dynamic assessment of the joint. A direct correlation of the imaging findings with the patient symptoms can be easily obtained and interventional procedures can be guided.

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1. Bischoff-Ferrari JA et al. (2008). Effect of calcium supplementation on fracture risk: a double-blind Randomized controlled trial. American Journal of Clinical Nutrition. 87 (6), 1945-1951

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¹ Summary of Product Characteristics. 2 PD Delmas et al., Bone 2003, 33.

Evista® Prescribing Information. Refer to the Summary of Product Characteristics before prescribing. **Qualitative and quantitative composition:** each tablet contains 60 mg raloxifene hydrochloride, equivalent to 50mg raloxifene free base. The tablets contain lactose. **Therapeutic indication:** treatment and prevention of osteoporosis in postmenopausal women. A significant reduction in the incidence of vertebral, but not hip, fractures has been demonstrated. When determining the choice of Evista or other therapies, including oestrogens, for an individual postmenopausal woman, consideration should be given to menopausal symptoms, effects on uterine and breast tissues, and cardiovascular risks and benefits. **Dosage and Administration:** one 60mg tablet daily by oral administration, which may be taken at any time of the day without regard to meals. No dose adjustment is necessary for the elderly. Due to the nature of this disease process, Evista is intended for long-term use. Generally, calcium and vitamin D supplements are advised in women with a low dietary intake. Evista should not be used in patients with severe renal impairment. In patients with moderate and mild renal impairment, Evista should be used with caution. Evista should not be used in patients with hepatic impairment. **Contra-indications:** must not be used in women with childbearing potential. Active or past history of venous thrombo-embolic events (VTE), including deep vein thrombosis, pulmonary embolism, and retinal vein thrombosis. Hypersensitivity to raloxifene or to any of the excipients in the tablets. **Warnings and Special Precautions:** raloxifene is associated with an increased risk for venous thrombo-embolic events that is similar to the reported risk associated with current use of hormone replacement therapy. The risk-benefit balance should be considered in patients at risk of venous thrombo-embolic events of any aetiology. Evista should be discontinued in the event of an illness or a condition leading to a prolonged period of immobilisation. Discontinuation should happen as soon as possible in case of the illness, or from three days before the immobilisation occurs. Therapy should not be restarted until the initiating condition has resolved and the patient is fully mobile. In a study of postmenopausal women with documented coronary heart disease or at increased risk for coronary events, raloxifene did not affect the incidence of myocardial infarction, hospitalized acute coronary syndrome, overall mortality, including cardiovascular mortality, or stroke, compared to placebo. However there was an increase in death due to stroke in women assigned to raloxifene. The incidence of stroke mortality was 1.5 per 1000 women per year for placebo versus 2.2 per 1000 women per year for raloxifene. This finding should be considered when prescribing raloxifene for postmenopausal women with a history of stroke or other significant stroke risk factors such as transient ischaemic attack or atrial fibrillation. There is no evidence of endometrial proliferation. Any uterine bleeding during Evista therapy is unexpected and should be fully investigated by a specialist. The two most frequent diagnosis associated with uterine bleeding during raloxifene treatment were endometrial atrophy and benign endometrial polyps. In postmenopausal women who received raloxifene treatment for 4 years, benign endometrial polyps were reported in 0.9% compared to 0.3% in women who received placebo treatment. Raloxifene is metabolised primarily in the liver. Single doses of raloxifene given to patients with cirrhosis and mild hepatic impairment (Child-Pugh class A) produced plasma concentrations of raloxifene which were approximately 2.5-times the controls. The increase correlated with total bilirubin concentrations. Until safety and efficacy have been evaluated further in patients with hepatic insufficiency, the use of Evista is not recommended in this patient population. Serum total bilirubin, gamma-glutamyl transferase, alkaline phosphatase, ALT, and AST should be closely monitored during treatment if elevated values are observed. Limited clinical data suggest that in patients with a history of oral oestrogen-induced hypertriglyceridaemia (≥ 6 mmol/L), raloxifene may be associated with a marked increase in serum triglycerides. Patients with this medical history should have serum triglycerides monitored when taking raloxifene. The safety of Evista in breast cancer patients has not been adequately studied. No data are available on the concomitant use of Evista and agents used in the treatment of early or advanced breast cancer. Therefore, Evista should be used for osteoporosis treatment and prevention only after the treatment of breast cancer, including adjuvant therapy, has been completed. As safety information regarding co-administration of raloxifene with systemic oestrogens is limited, such use is not recommended. Evista is not effective in reducing vasodilatation (hot flashes), or other symptoms of the menopause associated with oestrogen deficiency. Evista contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, should not take this medicine. **Pregnancy and Lactation:** Evista is only for use in postmenopausal women and must not be taken by women of child bearing potential. Raloxifene may cause foetal harm when administered to a pregnant woman. If this medicinal product is used mistakenly during pregnancy or the patient becomes pregnant while taking it, the patient should be informed of the potential hazard to the foetus. It is not known whether raloxifene is excreted in human milk. Its clinical use cannot be recommended in lactating women. Evista may affect the development of the baby. **Undesirable Effects:** the undesirable effects associated with the use of raloxifene in clinical trials are summarised below: Vascular disorders Very common ($>10\%$): Vasodilation (hot flushes). Uncommon (0.1-1%): Venous thrombo-embolic events, including deep vein thrombosis, pulmonary embolism, retinal vein thrombosis, and superficial vein thrombophlebitis. Musculoskeletal disorders Common (1-10%): Leg cramps. General Very common ($>10\%$): Flu syndrome. Common (1-10%): Peripheral oedema. The following events have been reported in post-marketing experience: Blood and Lymphatic System Disorders Very rare ($<0.01\%$): thrombocytopenia. Gastro-intestinal disorders Very rare ($<0.01\%$): Gastro-intestinal symptoms, such as nausea, vomiting, abdominal pain, and dyspepsia. General Disorders and Administration Site Conditions Rare ($<0.1\%$): peripheral oedema. Investigations Very rare ($<0.01\%$): Increased blood pressure. Nervous system disorders Very rare ($<0.01\%$): Headache, including migraine. Skin and subcutaneous tissue disorders Very rare ($<0.01\%$): Rash. Reproductive system and breast disorders Very rare ($<0.01\%$): Mild breast symptoms, such as pain, enlargement, and tenderness. Vascular Disorders Rare ($<0.1\%$): venous thromboembolic reaction. Very rare ($<0.01\%$): arterial thromboembolic reaction.

Legal Category: POM **Date of Preparation:** January 2009 **Marketing Authorisation Holder:** Daiichi Sankyo Europe GmbH, Ziefeltstrasse 40 D-81379