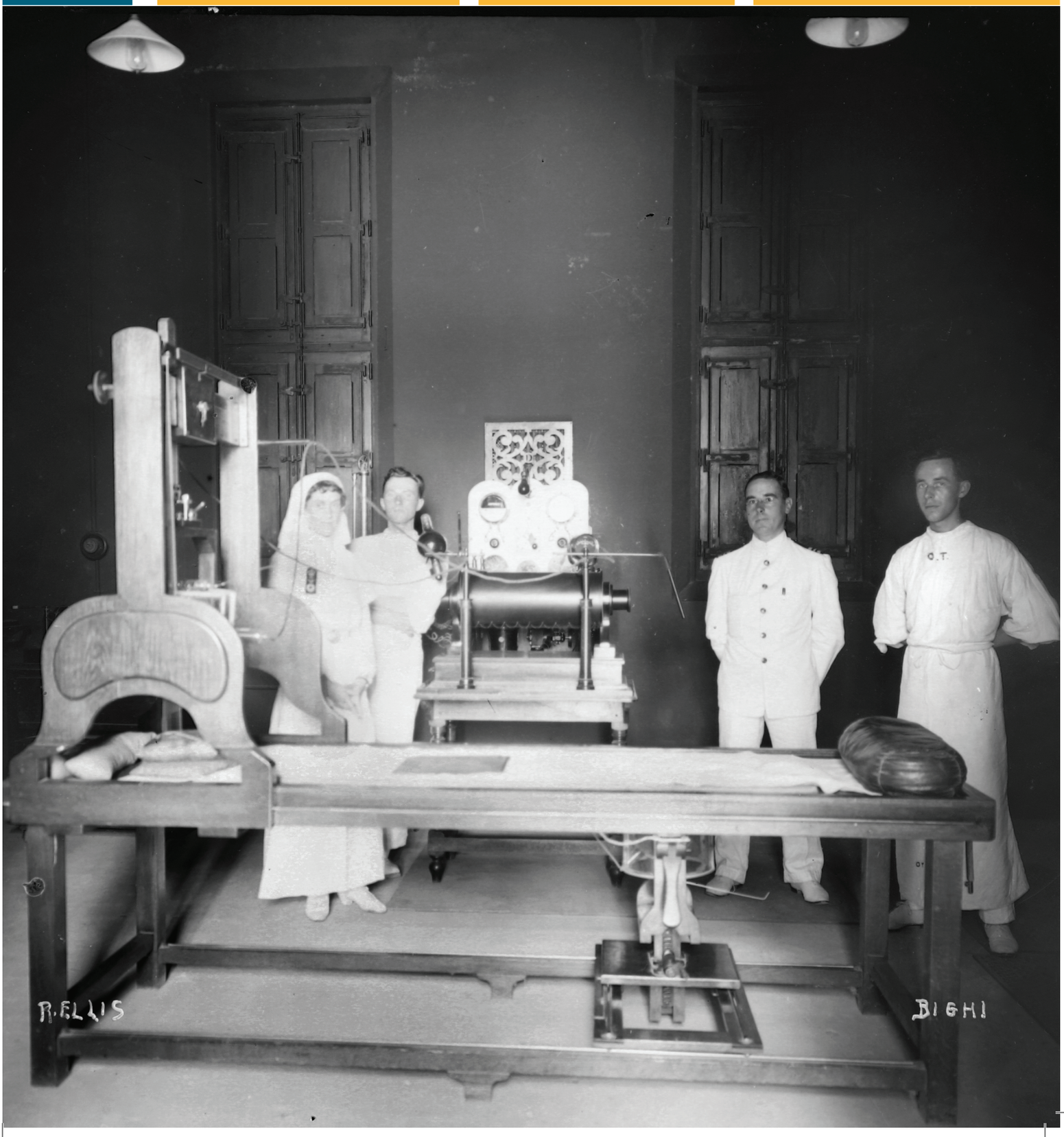
NEWSPAPERPOST

TheSynapse

The Medical Professionals' Network

Issue 03/12



Change by design

Imagination. This represents the bunch of keys with which humankind can attempt to open nature's locks and unravel its secrets. This being just a personal point of view - after attending the EuroMold fair in Frankfurt last November – it has now become a justified way of thinking.

Additive manufacturing (including stereolithography) is precisely one of these keys. At this stage please forgo economies of scale being hammered onto us during management studies and forget as well the scare being instilled in blue chip interim reports that their business positioning will be negatively affected due to technical migration to poorer counties (namely due to cheap labour). But what is this seemingly tongue twister? To put is simply it is 3D printing.

In 3D printing a software takes a series of digital slices through a computer-aided design (similarly to a CT scan) and sends descriptions of those scans to a 3D printer, which adds successive thin layers until a solid object emerges. 3D printers can employ diverse technologies. *Objet*, an Israeli company, uses an inkjet head to spray an ultra-thin layer of liquid plastic onto a build tray. The layer is cured by exposure to ultraviolet light. The tray is then lowered fractionally and the next layer added. Another method is fused-deposition modelling, a system used by *Stratasys,* a US company. This involves melting plastic in an extrusion head to deposit a thin filament of material to build the layers.

Other systems use powders as the print medium. The powder can be spread as a thin layer onto the build tray and solidified with a squirt of liquid binder. It can also be melted into the required pattern with a laser in a process called laser sintering, a technology which *EOS,* a German firm uses. On the other hand, *Arcam,* a Swedish company, fuses the powder in its printers with an electron beam operating in a vacuum.

Indeed, the variations are endless. And that is why there has been a gradual paradigm shift from simply creating prototypes to producing the finished goods. Actually we are now seeing machines building parts to build more machines like themselves. Reminiscent of the *Terminator* movie series, right?

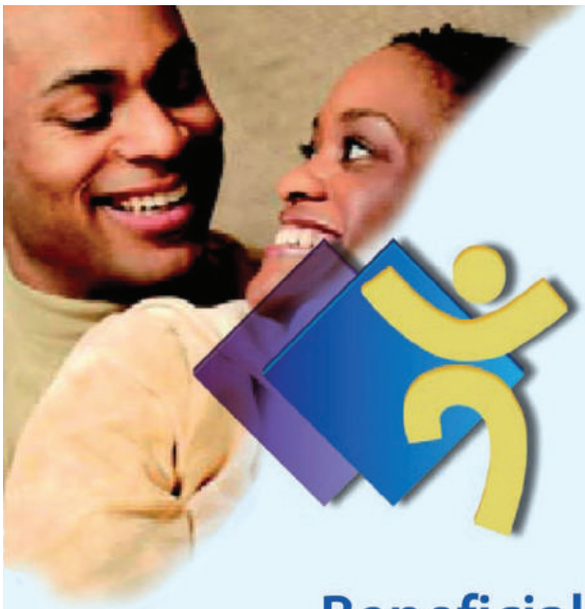
This technology is very versatile and has numerous advantages. One of the most important advantages is that manufacturing objects through a 3D printer is becoming comparatively cheap to produce, simply because the software which is used can be tweaked endlessly. Different objects can be produced by the same printer. Remember also that the fixed cost of making a 3D printer, similarly to a normal home printer, is the same whether you print one object, or thousands of them (excluding maintenance costs, of course). Besides, as opposed to traditional manufacturing, it is possible to use just enough material to make the finished product thus contributing to considerable weight savings. Needless to say this drives down the production costs. Also since the number of people involved in the manufacturing decreases this will push further down the costs. This means that some of the manufacturing would eventually return to the richer countries, this being catalysed by the fact that such technology is handled more efficiently by richer countries since it is they that fund the bulk of the R&D investment.

Where does medicine come into this? The link could not have been more aptly evidenced than by an 83 year old woman who was suffering from osteomyelitis hailing from Netherlands. Last year a new titanium lower jaw has been fitted in her skull. The link is a 3D printer. An MRI scan was fed to the printer which in turn made the titanium jaw. A computer controlled high-precision laser was used to fuse titanium powder particles in layers (it took 33 layers to build just one millimeter). Later, the jaw was coated in a biocompatible ceramic layer. In the end, the jaw weighed 107 grams, which was only one-third heavier than her previous jaw.

Furthermore, replacing the jawbone through artificial implantation took only 4 hours, but if the operation was done in classical micro-surgical reconstructive method, then it would take 20 hours. As the 3D-printed jaw fitted the patient perfectly, the woman was able to speak and swallow normally.

And this example is just the tip of the iceberg.

Ian C Ellul



Proven in depression

Beneficial in :

- Treating depression with co-morbid anxiety[1,2]
- Reducing the recurrence of new episodes of depression[3]
- Patients who are concerned about weight gain[4]
- Treating depression in sexually active patients as it is associated with low incidence of sexual dysfunction[5]

FAVERIN

A quality and affordable antidepressant

Abbott
A Promise for Life

Faverin® 50, 100mg: white, film-coated tablets. **Therapeutic Indications:** Major Depressive Episide, Obsessive Compulsive Disorder (OCD). **Dosage**: *Depression:* The recommended starting dose is 50 or 100mg, given as a single dose in the evening. It is recommended to increase the dose gradually until an effective dose is reached. The maximum dose is 300mg. Dosages above 150mg should be given in divided doses. OCD:The recommended starting dose is 50mg per dau for 3-4days. The effective dosage usually lies between 100mg and 300mg per day. The dosage should be increased gradually until the effective dosage is achieved, with a maximum of 300mg per day for aduits and 200mg per day for children from 8 years on. **Contra-indications:** Fluvoxamin tablets are contraindicated in combination with tizanidine, agomelatine and monoamine oxidase inhibitors. **Special warnings and precautions for use:** Depression and OCD is associated with an increased risk of suicidal thoughts, suicidal attempts and suicide. The risk persists until significant remission occurs. It is general clinical experience that the risk of suicide-related behaviour is highest shortly after presentation and may increase again in the early stages of recovery. Therefore patients should be monitored carefully until improvement is noticed. Fluxoxamine should not be used in the treatment of children and adolescents under the age of 18 years except for patients with OCD. Patients suffering from hepatic or renal insufficiency should start on a low dose and be carefully monitored. Treatment with fluvoxamine has rarely been associated with an increase in hepatic enzymes, generally accompanied by clinical symptoms. In such cases, treatment should be discontinued. Glycaemic control may be disturbed, especially in the early stages of treatment. Caution is recommended when the drug is administered to patients with a history of convulisve disorders, even though animal studies in fluvoxamine showed no pro-convulsive properties. Fluvoxamine should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. Treatment with fluvoxamine should be discontinued if seizures occur or if seizure frequency increases. On rare occasions serotonin syndrome or neuroleptic malignant syndrome-like events have been reported in association with treatment of fluvoxamine, particularly when given in combination with other serotonergic and/or neuroleptic drugs. Treatment with fluvoxamine should be discontinued if such events occur. When combined with fluvoxamine; plasma concentrations of terfenadine, astemizole or cisparide may be increased resulting in an increased risk for QT-prolongation/Torsade de Pointes. Fluvoxamine may cause an insignificant decrease in heartbeat. **Interactions**: Fluvoxamine should not be used in combination with MAOIs. Fluvoxamine is a potent inhibitor of CYP1A2, and to a lesser extent CYP2C and CYP4A4. *CYP1A2* When given with fluvoxamine, warfarin plasma concentrations were significantly increased and prothrombin times prolonged. Isolated cases of cardiac toxicity have been reported when fluvoxamine was combined with thioridazine. As plasma concentrations of propranolol are increased in combination with fluvoxamine, the propranolol dose may need to be lowered. Caffeine plasma levels are likely to be increased during co-administration with fluvoxamine. As plasma concentrations of ropinirol may be increased in combination with fluvoxamine thus increasing the risk of overdose, surveillance and reduction in the posology of ropinirol during fluvoxamine treatment and after its withdrawal may be required. CYP2C Patients co-administered fluvoxamine and CYP2C metabolised drugs with a narrow therapeutic index (such as phenytoin) should be carefully monitored and if necessary, dose adjustment of these drugs is recommended. CYP3A4 Patients co-administered fluvoxamine and CYP3A4 metabolised drugs with a narrow therapeutic index (such as carbemazepine, ciclosporin) should be carefully monitored and, if necessary, dose adjustment of these drugs is recommended. The plasma levels of oxidated metabolised benzodiazepines (e.g. triazolam, midazolam, alprazolam, and diazepam) are likely to be increased when co-administered with fluvoxamine. *Glucuronidation* Fluvoxamine does not influence plasma concentrations of digoxin. *Renal excretion* Fluvoxamine does not influence plasma concentrations of atenolol. **Pregnancy and lactation**: Data on a limited number of exposed pregnancies indicate no adverse effects of fluvoxamine on pregnancy. To date, no other relevant epidemiological data are available. **Undesirable effects**: Nausea, sometimes accompanied by vomiting. Common undesirable effects include: *Metabolism and nutrition disorders* Anorexia; *Nervous system* agitation, anxiety dizziness, headache, insomnia, nervousness, somnolence, tremor; *Cardiac disorders* Palpitations/tachycardia; *Gastrointestinal disorders* Abdominal pain, constipation, diarrhoea, dry mouth, dyspepsia; *Skin and subcutaneous disorders* sweating; *General disorders and administration site conditions* Asthenia, malaise. **Overdose:** *Symptoms* These include gastro-intestinal complaints (nausea, vomiting and diarrhoea), somnolence and dizziness; Cardiac events (tachycardia, bradycardia, hypotension), liver function disturbances, convulsions and coma have also been reported. Fluvoxamine has a wide margin of safety in overdose. *Treatment* There is no specific antidote to fluvoxamine. In case of overdose the stomach should be emptied as soon as possible after tablet ingestion and symptomatic treatment should be given. The repeated use of medicinal charcoal, if necessary accompanied by an osmotic laxative, is also recommended. **Instruction for use/handling:** None. **MA Holder**: Solvay Pharmaceuticals B.V. **MA Number:** MA030/00301-02

GALVUS and EUCREAS

COMPREHENSIVE POWER TO ADVANCE TYPE 2 DIABETES TREATMENT

GALVUS is a DPP-4 inhibitor that improves glycemic control through powerful islet enhancement[1]

EUCREAS is the combination of a DPP-4 inhibitor, GALVUS, and metformin[2]

Galvus® 50mg (vildagliptin) tablets

PRESENTATION: Each tablet contains 50 mg of vildagliptin **INDICATIONS:** For the treatment of type 2 diabetes mellitus: As monotherapy ♦ in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. As dual oral therapy in combination with ♦ metformin, in patients with insufficient glycaemic control despite maximal tolerated 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:** When used as monotherapy or in combination with metformin or thiazolidinedione the recommended daily dose of vildagliptin is 100mg, 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 100 mg are not recommended. Galvus is not recommended for use in patients less than 18 years old. The recommended dose for patients with moderate/severe renal impairment is 50mg once daily. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients **WARNINGS / PRECAUTIONS:** ♦ Galvus should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. ♦ 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. ♦ There is no experience of vildagliptin use in clinical trials in patients with NYHA functional class III-IV and therefore use is not recommended in these patients. 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. Galvus should not be administered during pregnancy or lactation. ♦ Should be used with caution in patients with renal impairment. **INTERACTIONS:** ♦ Vildagliptin has a low potential for drug interactions. ♦ No clinically relevant interactions with other antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, 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. **ADVERSE REACTIONS:** Rare cases (>1/10,000 to <1/1,000) angioedema, abnormal liver function tests, 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: nasopharnyngitis. Combination with Thiazolidinedione: Common: weight increase, oedema peripheral, Uncommon: headache, asthenia, hypoglycaemia. Frequency not known: urticaria, pancreatitis **LEGAL CATEGORY:** POM **PACK SIZES:** 7, 28 tablets **MARKETING AUTHORISATION** HOLDER: Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/07/414/001, 003. **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. 2012-MT- GAL-03-Feb- 2012

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:** The recommended daily dose should be based on the patient's current regimen of vildagliptin and /or 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 SmPC 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 **WARNINGS / PRECAUTIONS:** Eucreas should not be used in patients with type 1 diabetes. Due to the risk of lactic acidosis, renal function could be monitored at least once yearly in patients with normal renal function and at least two to four times/year 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 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, pioglitazone, metformin), amlodipine, digoxin, ramipril, 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. **ADVERSE REACTIONS:** Rare cases (>1/10,000 to <1/1,000) angiodema abnormal liver function tests, hepatic dysfunction (including hepatitis) have been reported with vildagliptin. Vildagliptin Monotherapy: Common (>1/100 to <1/10): dizziness, Uncommon (>1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. Very rare (<1/10,000): URTI, nasopharyngitis. Metformin monotherapy: Very common (>1/10) Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. Common: metallic taste. Combination vildagliptin with metformin: Common: tremor, headache, dizziness, nausea, hypoglycaemia. Uncommon: fatigue. Frequency not known: urticaria, pancreatitis For a full list of Adverse reactions, please refer to the SmPC. **LEGAL CATEGORY:** POM **PACK SIZES:** 30, 60 film-coated tablets **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBER:** EU/1/07/425/002–003, EU/1/07/425/008-009. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available upon request from: Novartis Pharma Services Inc, Representative Office Malta, P.O. Box 124, Valletta VLT 1000, Malta. Tel +356 22983217 - 2011-MT- EUC-07 Dec- 2011

GAL Ad1 06/12 MT

NOVARTIS

Galvus® vildagliptin

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

Eucreas® vildagliptin/metformin

Dr Clare Holt MD
is Foundation Programme Year 2 Doctor at the Foundation Programme, East Anglian Deanery. The other interviewee is Dr Sophie Butler and the interviewer is Dr Mark Agius, consultant psychiatrist at the Department of Psychiatry, University of Cambridge, UK and the South Essex Partnership University Foundation Trust, UK.

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is a private surgical pathologist. He is a former pathology teacher at London and Malta Universities, and pathology services director to the British and Maltese health services. He trained at London's Royal Marsden, Royal Free, St George's, Charing Cross and The Middlesex hospitals.

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paediatrician, graduated in 1990 and is a Resident Specialist at Mater Dei. He practices paediatrics in the community and authored several papers on child health. The co-author of the paper is Dr Valerie Zammit, paediatrician.

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contents

COVER:
Cottonera Military Hospital

Experimental X Ray Machine installed at Bighi Hospital in early 1900s. X Rays were discovered by William Konrad Roentgen in 1895. In a very short period of time, X Ray technology arrived in Malta and Dr Temi Zammit experimented using the new technology together with John Ellis. By 1908 X rays were being used in Hospitals on a regular basis in Malta

Photography: Richard Ellis

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Current weaning practices in a group of Maltese parents

JOSEPH MIZZI
VALERIE ZAMMIT

Abstract

Background Certain weaning practices are known to increase the risk of problems such as allergies, fussy eaters and childhood obesity.

Aim To assess the variations in weaning practices, including the time of introduction of food and of lumpy/finger foods in a group of Maltese parents.

Methods Email questionnaire-based survey of the weaning practices of 300 parents.

Results There were 130 respondents. One-third of infants were exclusively breast fed. Two-thirds of parents started weaning between 4 and 6 months. Lumpy foods were introduced after eight months in 74% of cases.

Conclusions Significant deviations from the recommended weaning advice were identified which potentially increases the risk of problems in these children.

MESH terms:

weaning, questionnaire, obesity

Introduction

Correct weaning practices are important to reduce the risk of allergies, the development of fussy eaters later on in life, and childhood obesity. Weaning practices in different countries vary greatly, but some principles are well established, namely, (a) exclusive breastfeeding till around 6 months of age, (b) the introduction of simple foods such as rice cereal, fruit and vegetables, followed later on by meat, eggs and dairy products, and (c) the introduction of lumpy foods and finger foods at around 8 months of age.

Objectives

The aim of this study is to assess the variations in weaning practices, including the time of introduction of food, and lumpy or finger foods, and thus to compare the results to the official recommendations by the Maltese Department of Health and other health authorities.

Methods

A deliberately simple and short questionnaire (Appendix 1) was sent by email to a cohort of 300 parents in March 2010, who were asked to return the completed questionnaire by email. It included questions on the timing of weaning, the types of food used, the introduction of solid and finger foods, and feeding habits. The email addresses were obtained over the previous two years from the parents of young infants in the private practice of one of the authors (JM), and they were all included in the study. Of the 340 parents asked to give their email address, forty did not have an email account.

Results

Of the three hundred questionnaires sent out, 130 (43%) were returned, most of the respondents were mothers (79%), aged between 31 and 40 (63%). The results are summarized in Table 1.

Thirty-four percent of infants were exclusively breast fed. Most parents (61%) started weaning between 4 and 6 months; a few started before four months (Figure 1). Baby rice cereal was the first weaning food in the majority of babies (81%). Lumpy foods were introduced after eight months in 74% (Figure 2). Meat, chicken or fish were introduced at six to eight months in 59%, with 30% starting after 8 months. A number of parents (16 out of 130) sometimes added a biscuit to the bottle feed. Forty-three percent of babies were never or rarely fed during family meals.

Parents obtained information about weaning from various sources, including their doctor, printed literature, internet, the midwife and the grandparents. Slightly more than half of the parents found weaning a pleasant experience, with the other half saying it was a challenging one. All the respondents were aware of the importance of appropriate hygiene practices when preparing feeds.

Discussion

This study has shown that there are clinical significant variations in the timing and other important aspects of weaning in a limited number of Maltese families.

The number of exclusively breast-fed babies was low (34%, compared to about 70.3% in Sweden in 2003)[1] in spite of a national policy promoting

breast feeding and the establishment of a Breast Feeding Clinic, which to date is still hospital-based and is limited by the number of personnel. The health benefits of breastfeeding include reduced risk of infectious diarrhoea and acute otitis media.[2] Population-based studies have confirmed an association between breastfeeding and lower risk of obesity of the baby in later life; this association is stronger if the infant was exclusively breast-fed.[3,4]

Overall weaning was started according to current recommendations, which is around six months of age, with a tendency of many mothers to start as early as four months. This is acceptable. The WHO guidelines recommend 'exclusive breastfeeding from birth to 6 months of age, and [to] introduce complementary foods at 6 months of age while continuing to breastfeed.'[5] However, according to a recent re-evaluation of the current evidence by the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN), exclusive or full breast-feeding for about 6 months remains a desirable goal, but they clarify that complementary feeding should not be introduced before 17 weeks and not later than 26 weeks.[6] The American Academy of Pediatrics also advices starting weaning between 4 and 6 months.[7]

The most common introductory food was rice cereal. Animal protein was introduced appropriately at around 6 months of age. There is no convincing scientific evidence that avoidance or delayed introduction of potentially allergenic foods, such as fish and eggs, reduces allergies, either in infants considered at increased risk for the development of allergy or in those not considered to be at increased risk.[5] There is also no scientific basis for preferring one type of food to another as the initial weaning food – one may start a plain rice cereal, vegetable puree or fruit. Well-cooked eggs,[8] fish[9] and orange juice[10] may be safely included in the infant's diet from six months of age. Breast milk or formula milk should be the main milk source until 12 months of age, however small amounts of pasteurized cow's milk may be added to the complementary food. Moreover, dairy products such as cheese and yogurt should be included in the infant's diet.[5]

It is interesting to note that a number of parents added biscuits or cereals to milk in bottles despite the recommendation to use biscuits only as finger foods at an older age. A third of babies were not fed with the family, thus depriving the baby and other

Table 1: Summary of participants' data

- **Parent's sex:** Mother 103 (79%); Father 27 (21%).
- **Parent's age:** 20-30 42 (32%); 31-40 81 (63%); 41-50 7 (5%).
- **Milk before weaning:** Breast milk 44 (34%); Formula milk 33 (25%); Both 53 (41%).
- **Biscuit added to milk in bottle:** Yes 0 (0%); No 114 (88%); Sometimes 16 (12%).
- **Information on weaning:** Midwife 42 (32%); Doctor 80 (62%); Grandparents 20 (15%); Books/Magazines/Internet 68 (52%).*
- **Age at first solid food:** Less than 4 months 4 (3%); 4-6 months 79 (61%); More than 6 months 47 (36%).
- **First weaning food:** Baby rice cereal 105 (81%); Pureed vegetables 17 (13%); Pureed fruit 8 (6%); Other (0%).
- **Introduction of meat/chicken/fish:** Less than 6 months 14 (11%); 6-8 months 77 (59%); More than 8 months 39 (30%).
- **Introduction of finger foods or lumpy foods:** Less than 6 months 1 (1%); 6-8 months 32 (25%); More than 8 months 97 (74%).
- **Baby fed during family meal times:** Yes 74 (57%); No 25 (19%); Rarely 31 (24%).
- **Weaning experience:** Enjoyable 73 (56%); Challenging 57 (44%).
- **Hygiene awareness:** Yes 130 (100%); No 0 (0%).

** adds to 210 since information could have been obtained from multiple sources*

Figure 1: Age at introduction of solid foods

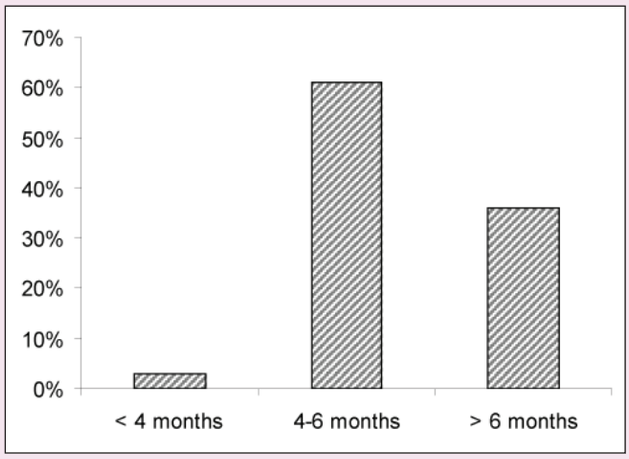
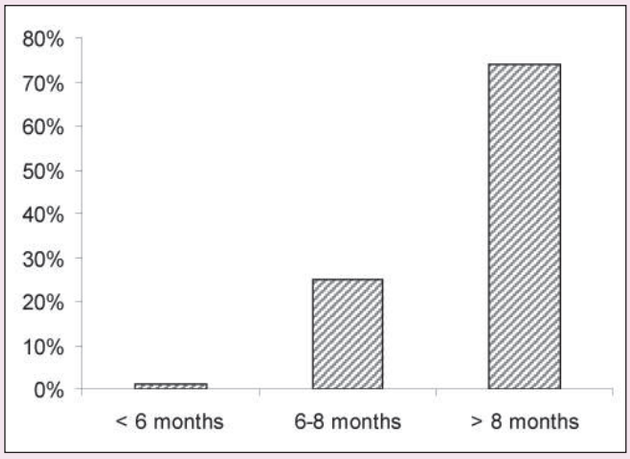


Figure 2: Age at introduction of lumpy food



family members of the beneficial social interactions associated with sitting together at table.

Only 25% introduced lumpy food and finger food between 6 and 8 months of age. The late introduction of lumpy food or finger foods may result in feeding problems later on. Reduced consumption of important food groups such as fruits and vegetables, as well as feeding difficulties are more likely to occur when lumpy foods are introduced at or after 10 months of age.[11,12]

Parents obtain information from a variety of sources which are not always consistent and correct. The Department of Health has published a guide on weaning in English. To our knowledge there is no information on weaning available in Maltese, or any information about the subject on the Health Promotion website.

Weaning proved to be a challenging experience to a relatively high proportion of parents, perhaps reflecting on parental expectations and inexperience of those participants who were first-time parents. This observation would merit further evaluation in order to identify the greatest source of difficulty in handling this phase of parenthood.

The main limitations of the study are the small size and bias of the study population. The participants came mainly from the South Harbour and East regions of Malta. No attempt was made to classify them according to social class. Moreover their feeding and weaning practices were influenced by a single paediatrician. Therefore the results cannot be extrapolated to the entire Maltese population. This study has demonstrated a great variability of the weaning practices which differ from established recommendations and which are know to influence children's health. This suggests a need for improving parental education which can be achieved by using a variety of media. Further research on a more representative sample of the Maltese population is suggested.

Appendix 1

Questionnaire: Introducing Solid Foods to Infants

Please answer all questions and mark with an X as appropriate.

1. Mother ☐ Father ☐
2. What is your age?
   20-30 ☐ 31-40 ☐ 41-50 ☐
3. What kind of milk did you give your baby from birth until weaning?
   Breast milk ☐ Formula milk ☐ Both ☐
4. Did you add a biscuit or cereal with the milk in the bottle?
   Yes ☐ No ☐ Sometimes ☐
5. Where did you learn about weaning? (choose one or more)
   Midwife ☐ Doctor ☐ Grandparents ☐ Books/magazines/Internet ☐
6. At what age did you introduce solid food to your baby?
   Less than 4 months ☐ 4-6 months ☐ More than 6 months ☐
7. What type of food did you first introduce in your baby's diet?
   Rice cereal ☐ Pureed vegetables ☐ Pureed fruit ☐ Other ☐
8. At what age did you start meat/chicken/fish?
   Less than 6 months ☐ 6-8 months ☐ More than 8 months ☐
9. At what age did you start finger foods or lumpy foods?
   Less than 6 months ☐ 6-8 months ☐ More than 8 months ☐
10. Did you feed your baby during family meal times?
    Yes ☐ No ☐ Rarely ☐
11. How was the weaning experience?
    Enjoyable ☐ Challenging ☐
12. Were you aware of the importance of hygiene in the preparation of baby food?
    Yes ☐ No ☐ Sometimes ☐

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Becoming a young doctor –
Meeting Sophie Butler and Clare Holt

MARK AGIUS

Becoming a doctor is a major life changing event for any medical student. Students grow into their new role over the first 'foundation' years. Here, a year after their graduation, a senior doctor talks with two junior doctors, who are his friends and colleagues, about their experiences over the first year of their career.

My name is Dr Mark Agius, a Psychiatrist in Bedford and Cambridge, England and I am working with a couple of FY2 Doctors, or rather, they have just become FY2 Doctors, a year ago they were still medical students. Their names are Sophie Butler and Clare Holt. What I would like to talk to them about is what it felt like to stop being medical students and become Doctors and how it has felt over this last year.

Sophie and Clare are planning to become psychiatrists so the other thing I want to talk to them about is how they are organising themselves so that eventually they will go into psychiatry.

MA - "I have known you for about four years now since you were medical students. I have seen you graduate and I have seen you for a whole year as a FY1 and now that you are about to start your FY2 jobs I just wondered whether you could you tell me about what it felt like to change from being a medical student to being a doctor".

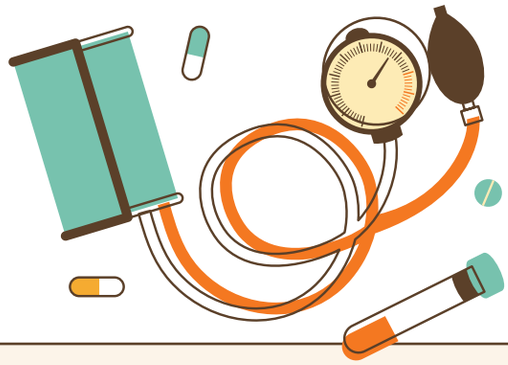
SB – "At first it was really very scary, but after the initial shock of having lots of responsibility wore off, it became very enjoyable. It was good to change from being a medical student who was always in the way to having a job to do and contributing towards the team".

CH – "Definitely quite daunting at first, suddenly feeling quite a weight of responsibilities that you just don't have to the same degree as a medical student. In fact, probably feeling like you have more responsibility that you actually do have as a FY1 Doctor! It was definitely rewarding to feel that finally we were managing to do what we had been planning to do for 6 years and, as Sophie said, feeling like we actually had a role within the hospital benefiting other people rather than a role that mostly only involved furthering our own learning."

"I think I definitely gained quite a lot of confidence on actually acting as a Doctor and I think part of that is that patients respond to you differently when you say you are a doctor compared to being a student. There is also an element of sometimes it is only you around so you have to take responsibility and just get on with it in a way that you don't have to do as a student. Once you have done that successfully a few times then you realise that you really do know what you are doing!"

MA – "Clare, did you find that because you were feeling so responsible, you were perhaps spending more time on the wards than in the office. I know that when you and I meet you tend to be very late owing to your busy schedule, is this because you have found that really you need to spend more time with people?"

CH – "Definitely the office hours are minimal and the reality is that we junior doctors work longer hours than we are officially supposed to. I think



that medicine is a career in which it is difficult just to walk out at the end of the day if you haven't finished absolutely everything that needs to be done. It is not something where you can easily say "it can wait until tomorrow". If a job needs to be done than you need to continue and do it."

MA – "It sounds as though you feel ready to work until the job is done, and I wonder Sophie, is that because this is important since you are dealing with people who somehow seem to depend on you?"

SB – "I think that as a FY1 a lot of the day-to-day jobs do fall down to you; if you don't do them, nobody else will. You have to be the one who makes sure that all the small individual jobs are done, so that the overall patient's management works out. In fact, in my first job, I was living in hospital accommodation and I would go back to my room and think of a very little thing which I had missed during the day, so I would end up either bleeping the on-call from my bedroom or go in to the hospital again to finish things off."

MA – "Does having to do that feel good?"

SB – "Well obviously I would rather spend my own time enjoying myself but when I first started working it was difficult to stop thinking about work. At the end of the day, I would rather take 10 minutes out of my free time to ensure a job was done properly."

MA – "Is that what it was like with you too Clare?"

CH – "Yes, and especially at first; you find that those small things which you have missed during the day play on your mind. I think that it is more so than other jobs because there is actually a human being at the other side of it, so it is quite easy to convince yourself that that small thing which you have missed will have a massive effect on that individual."

"As I progressed through FY1 I have become more realistic about the importance of time management and the importance of not unduly ruminating on the small things. I still do ring up the ward if I feel I have missed something but only if I actually have rationally decided that it is going to have an impact on the patients care"

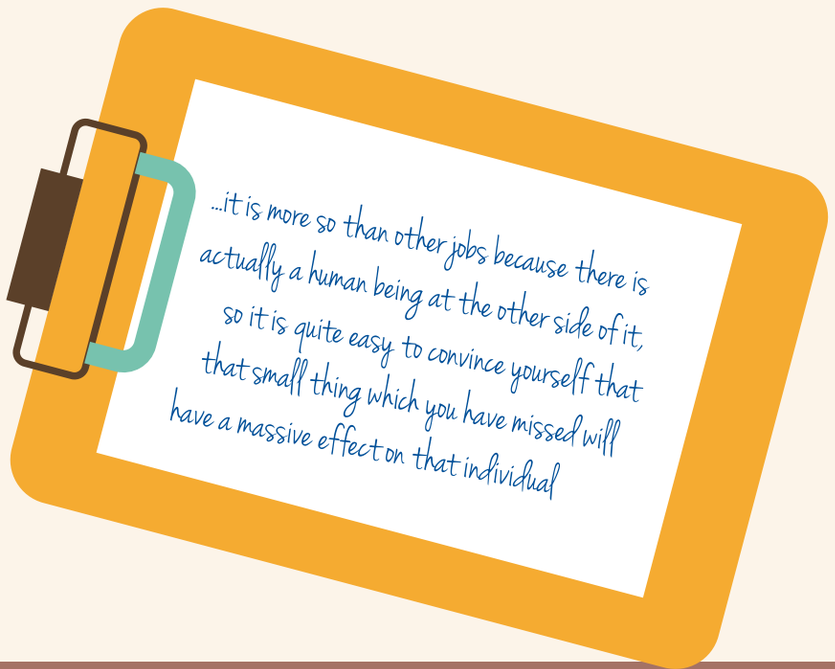
MA – "I want to talk about something else. I know that both of you are planning to become psychiatrists. The problem is that there are no psychiatric jobs or really very few psychiatric jobs in the rotations for the FY Doctors in Cambridge, so how are you organising yourself in order to develop a CV which would help you get a psychiatric job next year".

SB – "Basically I have had to do most of my psychiatry in my free time. Thanks to the opportunity given to me by yourself, I already have some ongoing projects on which I work after work. It is also important to remember that actually in the day-to-day work on the wards there are lots of people with psychiatric issues who are very interesting and from whom you can learn a lot about psychiatry".

MA - "Clare, I know that you have been doing the same as Sophie and in fact it is worth saying that Sophie, Clare and myself collaborate together in a number of research projects. Maybe you would also like to tell us what else you are planning to do."

CH – "I have been working with yourself on various psychiatry projects and I also want to reiterate what Sophie was saying about there actually being quite a lot of psychiatry within general medicine. Actually sometimes general psychiatric patients do not interest general medics as much, which means that if you do have an interest in psychiatry then there is even more opportunity to actually get involved in it."

MA – "So really medicine is all about integration; it's knowing a lot of different specialities and using each one of them when and as necessary. I think I ought to close this by saying that actually Sophie, Clare and myself share a lot of experiences. We travel a lot, attend international conferences and present papers and, as we are doing today, catch up on each other during a good meal, to make future plans!"



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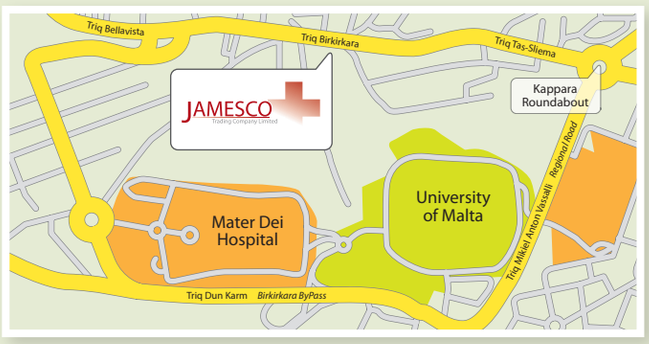

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The Local Organising Committee has been able to confirm the presence of the President of Malta at the event as official Patron and the Welcome Reception is to be held in the Palace of the President in Valletta, a historic building housing Parliament built by the Knights of St. John in the 16th century.

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The aim of this new online course is to give a practical overview of smoking cessation techniques and practices to health care workers who deal with smokers on a daily basis.

These online courses are available to all Foundation Students and also to TheSynapse online members. If you wish to participate and you are not yet a registered online member of TheSynapse, please visit TheSynapse Website – www.thesynapse.net and click on the register button which is located at the top right-hand corner. If you need any support, please send an e-mail to mpl@thesynapse.net or contact the Administration on telephone number 21453973/4.

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Teacher Philip Dingli
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Informed Consent to Medical Treatment
Teacher Pierre Ellul
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Nutritional Care
Teacher: Geoffrey Axiak
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Teacher: Mark Zammit
Enrolment key "prescribing"

Gastrointestinal cancer screening and surveillance programmes: a worldwide perspective – Part I

JURGEN GERADA

Abstract

Cancer is a leading cause of death worldwide and such deaths are projected to continue to rise, creating significant morbidity and mortality. Devising programmes to detect early cancer, aiming to achieve complete cure, has been high on the agenda of various professional bodies. This paper focuses on the various screening and surveillance programmes around the world, aiming at detecting early gastrointestinal malignancies. Starting with Barretts' oesophagus, we shall see the different surveillance programmes across countries to detect premalignant stages of oesophageal cancer, while at the same time reviewing the only country in the world, China, which has an oesophageal cancer mass screening programme. Moving to gastric cancer, we shall review Japan's screening programme, followed by other countries' measures in surveilling premalignant gastric conditions. Colorectal cancer is the only gastrointestinal cancer where mass screening has been employed in various countries. This will be discussed in detail, with particular emphasis on the British and American systems. We shall also be discussing the surveillance programmes for moderate and high risk patients of colorectal cancer. Finally, we shall also review the different recommendations with regards to screening for hepatocellular carcinoma.

Keywords

Screening programmes, gastrointestinal cancer, surveillance programmes

Introduction

Cancer is a leading cause of death worldwide and such deaths are projected to continue to rise. WHO is estimating cancer-related deaths worldwide to increase to 12 million in 2030[1]. Such figures create significant concerns among policy makers, as such conditions result in significant morbidity and mortality, causing huge financial burden on national health care systems. It is a well documented fact that when a cancer is detected in its early stages, complete cure is possible. For this reason, devising methods and programmes to detect early cancer were always high on the agenda of professional bodies in the past century and will continue to be in the years to come. Various countries have now a 5-10 year experience with various screening programmes such as breast, cervical and bowel, all proving to be successful. In the following text, we will be looking at various screening programmes involving diseases of the gastrointestinal tract and how these vary across different countries. While screening is the terminology used to describe testing healthy asymptomatic large population groups, surveillance is the terminology used to describe periodic testing of individual patients known to suffer from conditions which are premalignant[2]. Such surveillance programmes will be discussed as well.

Oesophagus

Barrett's oesophagus is a premalignant precursor for oesophageal adenocarcinoma. This type of cancer is rising alarmingly[3] and a surveillance programme is recommended by all professional bodies in patients with Barrett's oesophagus, aiming at detecting dysplasia and treating premalignant lesions. On the other hand, the only place where mass screening for oesophageal cancer is carried out is in China.

Although surveillance in Barrett's oesophagus is widely practiced worldwide, as indirect evidence suggests benefit, this remains controversial because of lack of randomized trials supporting its value. The appropriate surveillance interval in patients with Barrett's oesophagus depends on the grade of dysplasia. The American guidelines, issued in 2008, suggest that patients with no evidence of dysplasia should have 2 OGDs within the first year, and every 3 years thereafter. Patients with evidence of LGD should have a repeat OGD within 6 months of diagnosis and if no signs of HGD are present, yearly OGD should be carried out until no dysplasia is found on 2 consecutive annual endoscopies. Lastly, since patients with HGD progress to adenocarcinoma in more than 30% of cases within 5 years, such patients require a repeat OGD after 3 months from diagnosis, confirming HGD on both set of biopsies by an expert gastrointestinal pathologist. They should be counseled regarding their therapeutic options including intensive monitoring, local ablative therapies by endoscopic means or oesophagectomy. Four quadrant biopsies at 2cm intervals of Barrett's mucosa are recommended at every OGD, however using histological evidence of dysplasia as a marker for the frequency of surveillance remains problematic as there are issues with sampling, interpretation and concomitant presence of oesophagitis from reflux disease precluding accurate identification and confusing the reading of dysplasia [3].

The above guidelines differ slightly from the British. In 2005, BSG stated that Barrett's oesophagus without evidence of dysplasia should be surveilled every 2 years, using the same biopsy protocol as the Americans. Patients with low grade dysplasia should be screened every 6 months for as long as it remains stable and the interval can be increased to 2-3 yearly if regression on 2 consecutive

examinations is apparent. Moreover, patients with high grade dysplasia, despite acid suppression, should be considered for oesophagectomy if the patient is fit for surgery, or endoscopic ablation if surgery is contraindicated[4].

In China, oesophageal cancer is ranked second after gastric cancer as the leading cause of cancer death, with the predominant factor being related probably to diet, mainly micronutrient deficiencies, low levels of protective factors that occur in fresh fruit and vegetables, and consumption of food containing high levels of initiating carcinogens such as nitrosamines. Being highly prevalent, public mass screening in adults over 35 years, using balloon cytology or gastric occult blood bead tests, was initiated in 1974. Those with dysplasia or cancer went on to have an upper endoscopy and treatment. Those with normal mucosa were screened every 1-2 years. Having screened over 160 million participants between 1973 and 1999, this cohort's 5 year survival rate has increased from 10% to 90%, thereby reducing mortality in this high-risk population using inexpensive, simple and effective methods[5]. *(to be continued)*

Abbreviations

AASLD: American Association for the Study of Liver Diseases
ACG: American College of Gastroenterology
AFP: Alphafetoprotein
ASGE: American Society for Gastrointestinal Endoscopy
BSG: British Society of Gastroenterology
CRC: Colorectal cancer
DCBE: Double contrast barium enema
FAP: Familial Adenomatous Polyposis
FH: Family history
FOBT: Faecal occult blood test
HCC: Hepatocellular carcinoma
HGD: High grade dysplasia
HNPCC: Hereditary non-polyposis colorectal cancer
LGD: Low grade dysplasia
OGD: Oesophagogastroduodenoscopy
PSC: Primary sclerosing cholangitis
WGO: World Gastroenterology Organization
WHO: World Health Organisation

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Cervical Cancer Screening – An Update

ALBERT CILIA-VINCENTI

In many countries cervical cancer is the commonest gynaecological cancer. In Malta and in the United States, it is the third most common gynaecological cancer. Countries which introduced organised cervical screening programmes saw a dramatic decrease in incidence and mortality from this cancer.[1] In Malta however, its incidence and mortality has remained relatively constant in the last few decades, in keeping with the fact that we lack a national organised call and re-call cervical screening programme.[2] Our cervical screening is largely opportunistic and most of it is carried out in the private sector. Although incidence and mortality has not decreased, our present imperfect screening must however have prevented a significant rise in incidence and mortality, because the detection (and treatment) of premalignant cervical lesions has risen over recent decades, in keeping with increased sexual promiscuity.

Infection with high-risk strains of human papillomavirus (HPV) has been identified as the underlying cause of cervical cancer.[3] However, HPV infection is usually transient and quite common in the general population, with a lifetime cumulative risk of at least 80%.[4,5] Persistent infection by high-risk HPV (most commonly subtypes 16, 18, 31 and 45) is a prerequisite for development of cervical intraepithelial neoplasia (CIN – premalignant lesion), and subsequent malignant transformation to invasive cervical cancer. HPV is a necessary precursor of CIN but does not act alone – host factors such as age, immune status,[6] history of other sexually transmitted diseases[7] and smoking[8] are cofactors.

CIN lesions are usually diagnosed in women younger than 40 years, which is 10 to 15 years earlier than in women diagnosed with invasive cervical cancer, this age gap indicating a long latency period for malignant transformation. Low-grade CIN is usually diagnosed in women in their 20s, whereas high-grade CIN is usually diagnosed in women aged 25 to 35 years, and invasive cancer is most often diagnosed in women older than 40 years.

About 70% of cervical cancer is caused by HPV types 16 and 18. Vaccines have been developed against both HPV 16 and 18 and against low-risk HPV 6 and 11, the latter two being responsible for the majority of genital warts.

Although it is not clear how long immunity will last after vaccination, the

data suggest at least 5 to 6 years.[9,10] Nevertheless vaccinated women are still at risk for cervical cancer related to other less common high-risk HPV types, and it is imperative that vaccinated women should continue screening.

An understanding of the natural history of low-grade and high-grade CIN lesions is central to clinical management of abnormal cervical cytology. Low-grade CIN lesions have poor reproducibility between pathologists, some not even making a distinction between uncomplicated HPV infection changes and low-grade CIN. Unfortunately this is encouraged by the Bethesda System whose low-grade squamous intraepithelial lesion (LSIL) category does not distinguish between pure HPV changes and CIN 1. The cellular abnormalities in teenage girls and women in their early 20s are practically always due to simple HPV infection uncomplicated by CIN, and invasive cervical cancer in this age-group is as rare as hen's teeth. Cytological diagnoses of LSIL in teenage girls may lead to colposcopy, which would amount to over-investigation that is difficult to justify – if this leads to cone biopsy, it would mean even worse management.

Pathology consultation reports should communicate diagnostic opinion to clinicians in clear clinical language and not in laboratory jargon. It is the author's experience that, if clinicians want to know whether their patient has simple HPV infection, low-grade or high-grade CIN, the smear report should use these terms, rather than koilocytosis, dyskaryosis, LSIL, HSIL, etc., to avoid any possible misunderstanding as to the exact pathology the cytology report is suggesting. If the pathologist is uncertain whether the cellular abnormalities are due to non-specific inflammatory reactive hyperplasia, HPV infection or CIN, this uncertainty should be stated in plain English – to the author, Bethesda System diagnostic categories such as "atypical cells of uncertain significance" suggest an inexperienced beginner is issuing the cytology consultation reports.

Clear laboratory reporting should be complimented by adequate clinical information on smear request forms – why? The smears which should be examined most carefully are those from women in their 30s and 40s without a history of regular normal smears, in an effort to cut down, as much as possible, the ever-present risk of the dreaded false-negative smear in a patient with invasive cervical cancer. The cervical cytology request form should therefore, ideally, be designed to prompt the clinician to offer some basic clinical information about the patient, namely, age and whether or not she has a history of regular normal smears. Information about parity is irrelevant because this is not related to risk of cervical cancer, as believed several decades ago.

The screening methods available are the conventional smear, liquid-based cytology (LBC) and HPV DNA (high-risk, not type specific) plus cytology. The reported sensitivity of a single conventional smear varies from 32 to 92%,[11] which prompted the early guidelines for annual smear screening.

LBC has a similar performance record to the conventional smear, and meta-analysis of eight studies demonstrated similar sensitivity and specificity between the two technologies.[12] Thus, either method is an acceptable screening test, and raises the question whether the significantly increased cost of LBC is justified. Furthermore, from the author's experience, the LBC technique leads to under-diagnosis of bacterial vaginosis – a not insignificant condition as it may require antibiotic treatment.[13]

HPV DNA testing, in combination with cytology, is useful in identifying patients with difficult-to-interpret cytological abnormalities who are at increased risk for neoplasia.[14] In this patient category, the negative predictive value of the HPV DNA (high-risk, not type specific) for CIN 2 and CIN 3, or worse, as confirmed by colposcopy, is 99%.[15] Women testing negative on both cytology and HPV DNA can increase their screening interval to 3 years.[16]

A biomarker that distinguishes between low-risk transient HPV infections from high-risk persistent infection might prove more accurate than HPV DNA testing in the above category of women with equivocal cytology. The tumour suppressor gene *p16* is upregulated in high-risk HPV-transformed cells, and 95% sensitivity and 84% specificity in detecting high-grade CIN has been reported.[17] S

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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 56mg 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 tablet. Hepatic impairment, including cholestasis. Severe renal impairment. Unexplained uterine bleeding. Evista should not be used in patients with signs or symptoms of endometrial cancer, as safety in this patient group has not been adequately studied. **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 (›5.6 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 flushes), 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.

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CHARMAINE GAUCI

Update from the Health Promotion and Disease Prevention Directorate

The Directorate is responsible for preventing illness and promoting health in order to improve the health and well-being of the Maltese population and for providing leadership for health promotion to reduce/delay the onset of illness. Throughout the year we focus on various aspects which all build up to encourage a healthier lifestyle. Throughout summer we encourage people to avoid sun exposure as this is widely accepted as the underlying cause for harmful effects on the skin, eye and immune system.

It is important to avoid sun exposure:

- As a general rule, whenever someone's shadow is shorter than their height, care should be taken: the shorter the shadow the more likely it is that sunburn will occur.
- Solar UV is most damaging in the 3-5 hours around noon when approximately 50% of daily UV is received in summer, so avoidance of bright sunshine from 11:00 to 16:00 is desirable. If this is not possible, one should try to seek shade or cover up with clothing, a hat and sunglasses.
- Sunburn can occur on cloudy days as well as clear days, although heavy, overcast skies do offer some protection. It is the UV and not the heat rays of the sun that are harmful, thus one can still burn on a cool, windy day in summer.
- Care should be exercised in and around water and open spaces because of the extensive contribution of UV exposure from the sky (direct and atmospherically scattered UV). Many people are sunburnt when they are swimming, boating or playing on a beach.
- The best form of protection is to wear loose-fitting, closely woven fabrics that cast a dense shadow when held up against the light. Most types of textiles, both natural and synthetic, provide good protection against UV.

Topical sunscreens act by absorbing, scattering or reflecting UV. The sun protection factor (SPF) gives an indication of the effectiveness of the sunscreens. For example, a sunscreen with SPF 4 means that the UV exposure received after spending a given time in the sun is one-quarter that received in the absence of any protection.

For those people who want good UV protection, a high factor, broad-spectrum (blocking UVB and UVA) sunscreen should be used over those parts of the body that are not covered by clothing. An even thickness should be applied liberally to clean, dry skin and allowed to dry for 15 minutes or so before going outside. Sunscreens applied too thinly or too infrequently will not provide adequate protection. They should be reapplied every 2 hours.

Occupational exposure to UV should be kept to a minimum. The risk from solar UV exposure to outdoor workers such as agricultural workers, labourers, construction workers and fishermen can be minimized by wearing appropriate tightly woven clothing and, most importantly, a brimmed hat to reduce face and neck exposure. Sunscreens can be applied to exposed skin to reduce UV exposure further.

Copies of material related to a healthy lifestyle can be obtained from the directorate on 2326 6000.

MARIKA AZZOPARDI

The pharmacist who went PHYSICAL

Why would a pharmacist up and leave her apothecary practice after so many years of learning and serving medicinals out to the public? Finding out the valid reason behind this was my mission when I set out to meet 28-year-old Jessica Ghigo about whom I knew uniquely two facts – she is a pharmacist and she is a body-builder.

NABBA Nationals, 2009

There was no doubting the body-builder physique and so I started to discover the pharmacist behind it. Jessica seems to be used to this inquisitiveness from people as she takes to my questions nicely. "I graduated in 2007 and worked in pharmacies since then... up until approximately one year ago when I changed direction."

The lady from Zurrieq has a long story of body work behind her, starting at age 10 when she discovered gymnastics and practised the disciplining sport for some nine years. "The time I spent training in and eventually coaching gymnastics gave me plenty of important lessons and qualities – flexibility, physical strength, endurance, balance, agility, stamina and not least of course, discipline. I was on the national gymnastics team for a while and also on the school team, both of which provided me with the experience of adding a competitive edge to my sport." Jessica eventually had to stop the sport due to a series of injuries which coincided with her experience at Junior College and the demands of academy.

"I had also grown to an age when I knew that gymnastics was now beyond me. However I did not stop physical activity and took the time out of my studies to try jazz dance and probe into personal fitness and learn how my own body was dealing with it." Meanwhile her studies in pharmacy were leading her to discover more about how the body functions, the chemistry behind it, the nutritional factor and how it effected the whole set-up of the physique. A chance re-meet with an old friend whilst holidaying in London led her to succumb to the temptation of delving deeper in fitness and they trained together to take their individual physiques on to another newer level.

Jessica explains, "As I look back on my move from pharmacy to personal training, I realise that pharmacy was a valuable stepping stone into this new profession which I feel was ready and waiting for me to discover. Having a medical background has helped me immensely as has my post-graduate study of nutrition and dietetics." And so, with much courage and a hard time making the ultimate decision, Jessica up and quit her work in the pharmacy and went solo, launching her career as a personal trainer.

Today, she works from her studio as a personal trainer and fitness coach. No machines are present – this is not a gym. She strongly believes in functional training, using one's own body to train. Resistance training is coupled with weights and biometrics and dietetic advice… and the ultimate result is holistic training that allows one to have a circular experience of getting the body back in shape.

In the meantime, Jessica has become one of Malta's leading body building beauties. She has competed in the body building category, choosing that over the figure, fitness, bikini or physique categories. Starting from 2007, she has been on stage practically every year, whether in a simple pose-down, a National Amateur Bodybuilders Association (NABBA) or an International Federation of Bodybuilders (IFBB) contest. "There are few of us in Malta, but having a strong body does not mean only having big muscles. Basic fitness is not limited to women nor is it limited to adults either. People who visit me include men and children – in fact I am about to start a basic fitness course for kids. People like myself and in this profession, have to work hard to remove so many misconceptions as to what constitutes a healthy lifestyle. It is a long process to teach people how the body works, and how the individual body demands vary according to age, state of the body and health levels. But everybody can have a great body and fitness is for everybody. It is not about pumping iron – it is about being strong and healthy for a better quality of life."

Having a medical background has helped me immensely as has my post-graduate study of nutrition and dietetics

CT Colonography (virtual colonoscopy)

PIERRE VASSALLO

Thin-section multi–detector row computed tomographic (CT) colonographyis a powerful tool for the detection and classification of colonic lesions.

Isotropic imaging (ie equal voxel size in all three planes) of the colon with thin collimation has become standard and provides high-quality multi-planar reformatted (MPR) images and three-dimensional (3D) assessment of the entire colon, while allowing excellent visualisation of all other intra-abdominal organs.

A relatively clean, dry, and well-distended colon can be achieved with careful patient preparation, thereby avoiding the problem of residual stool and fluid. Patients generally undergo cathartic cleansing with oral administration of laxatives. Better results are obtained if patients also follow a low-fiber diet for 2–3 days before the examination and a clear liquid diet on the day of the examination. We use a combination of both techniques.

CT colonography is particularly useful as an immediate follow-up after failed optical colonoscopy, as the patient's bowel is already prepped. Failed optical colonoscopies may be due to a long and tortuous colon (eg sigma elongatum), bowel kinking (eg due to adhesions) and due to bowel obstruction (egan obstructing colonic cancer). CT colonography is able to view the colon beyond these physical impediments.

Bowel distention is performed with the patient in the left decubitus or supine position. A thin, flexible rubber catheter (eg, a small-gauge Foley catheter) is placed in the rectum, followed by gentle insufflation (either automated or manual) of carbon dioxide (CO_2) or air to patient. Tagging of faecal material can be achieved with use of barium or iodinated contrast material given orally prior to scanning.

Thin-section CT is ideally performed with a multi–detector row CT scanner with the patient first in the supine and then in the prone position. An initial scout view obtained prior to scanning in each position helps ensure adequate distention of the colonic segments, with additional CO_2 or air being insufflated if required. Colonic lesions can be enhanced with the intravenous injection of iodinated contrast agent; this allows better delineation of the lesion from adjacent normal bowel and better visualisation of invasion of the mesentry and adjacent structures.

The full abdomen is imaged in one breath-hold (7-13 secs) with a 64-Slice CT scanner and image slice thicknesses down to 0.6mm can be generated allowing for artifact-free multiplanar (axial, sagittal and coronal) images of identical high resolution (Fig 1 a,b,c) and also 3D endoluminalimaging (Fig 1d).A fly-through 3D CT colonography can best appreciated on a video clip (Fig 1e). Simultaneously available 2D and 3D image displays allow rapid correlation for the evaluation of any suspected finding. A further display modality is the colonographic view, which is

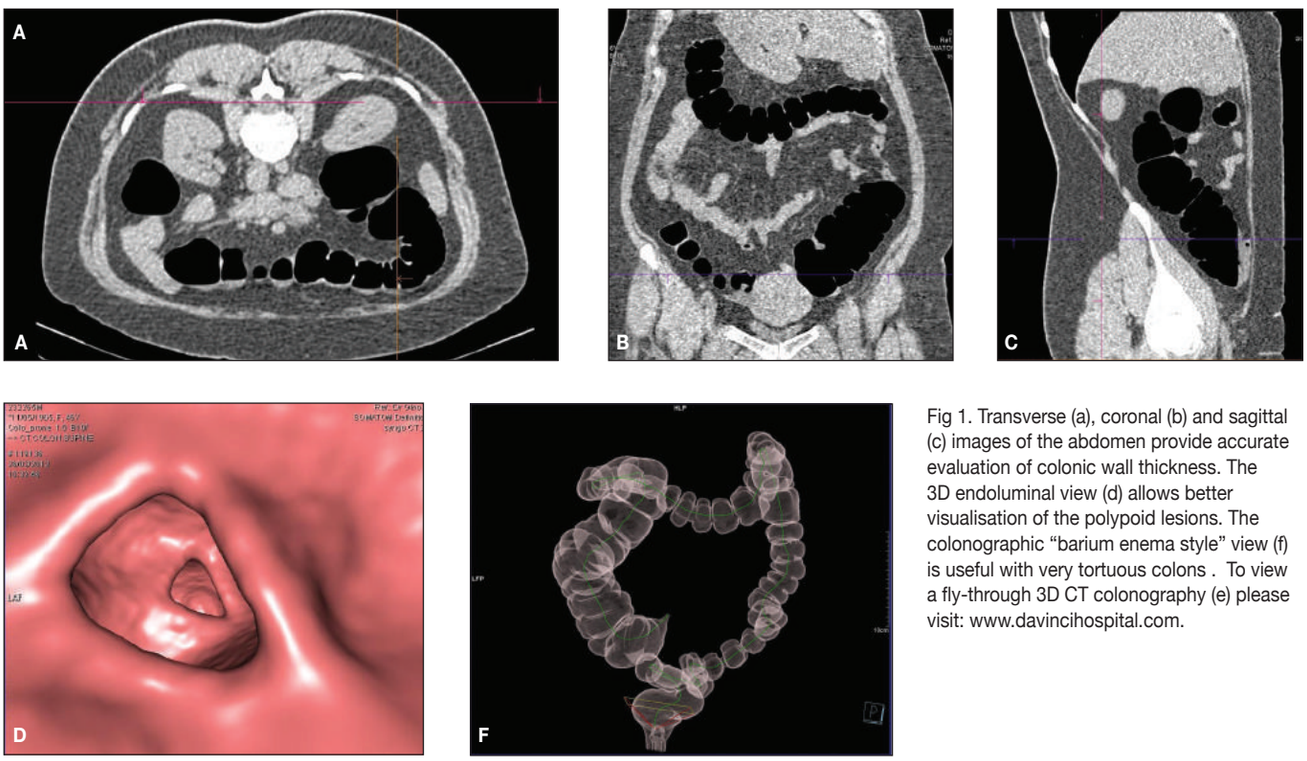
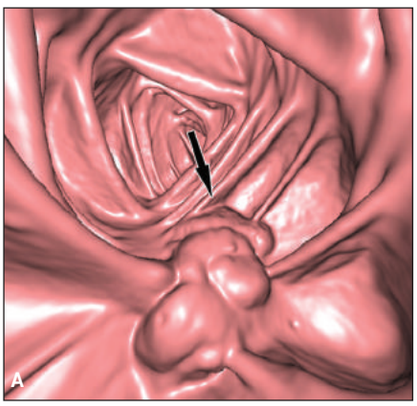
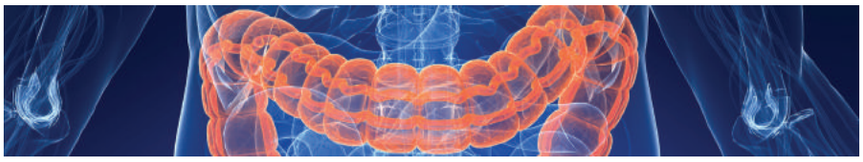


Fig 1. Transverse (a), coronal (b) and sagittal (c) images of the abdomen provide accurate evaluation of colonic wall thickness. The 3D endoluminal view (d) allows better visualisation of the polypoid lesions. The colonographic "barium enema style" view (f) is useful with very tortuous colons . To view a fly-through 3D CT colonography (e) please visit: www.davincihospital.com.



The use of CT colonography allows for significant health cost reduction and provides an accurate and detailed record of the patient's exam unlike optical colonoscopy



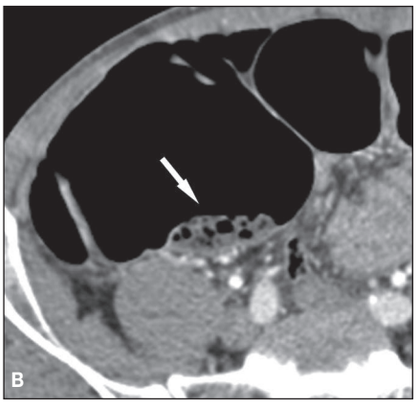


Fig 2. Residual stool appears as a broad-based, polypoid filling defect (arrow) on the 3D endoluminal image (a). The transverse image (b) no contrast enhancement, inhomogeneous texture and trapped gas in this pseudolesion (arrow).

reminescent of old barium enema examinations, however it does not suffer from the problems of overlapping bowel loops or kinks as it is a rotatable 3D image (Fig 1f).

The most common artifact that may cause some difficulty on CT colongraphy is the presence of stool. Here simultaneous evaluation of 3D and multiplanar thin slice images can resolve the problem (Fig 2) as faeces tends to contain gas bubbles and show inhomogeneous structure. Also faecal material will not enhance with intravenously administered contrast material, but will do so with orally administered contrast material.

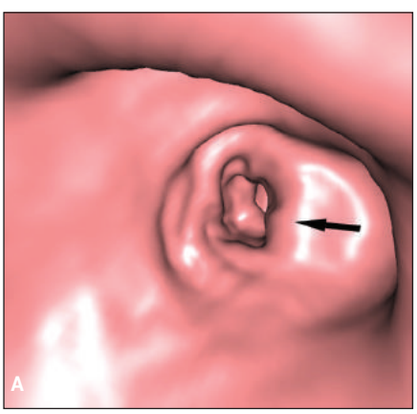
Colonoic spasm may be confused with a stenotic lesion, however evaluation of both prone and supine views in both 2D and 3D modalities will clarify the issue (Fig 3)

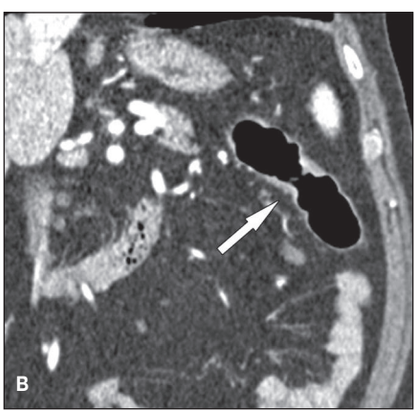
Residual fluid and inadequate gaseous distension of the colon may obscure polypoid lesion, however scanning in both the supine and prone positions results in movement of both fluid and gas due to gravity; those lesions obscured on the prone scan are exposed on the suprine scan (Fig 4).

Both polypoid and invasive colonic lesions are well visualised with CT colonography (Fig 5). CT colonography / Virtual Colonoscopy has been shown to have a sensitivity of 90-96% for polypoid lesions down to 6mm in diameter and a negative predictive value of 96% through numerous publications on the subject over the last 5 yrs when compared with optical colonoscopy. Virtual colonoscopy is now listed by the NCI (National Cancer Institute, of the NIH) as one of trecommended methods for colonic cancer screening.

Diverticula may be confused with polyps when 3D navigation is used for primary data evaluation. On 3D virtual endoscopic images, the diverticular orifice appears as a complete dark ring when seen en face, whereas a polyp shows incomplete ring shadowing (Fig 6).

CT colonography allows for distinction of intrinsic bowel wall lesions from extrinsic lesions impinging on the colon unlike optical colonoscopy or barium enema examinations. The latter examiniations only visualise mucosal contours of the colon, whereas CT colonography can assess wall thickness and all extracolonic organs (Fig 7).





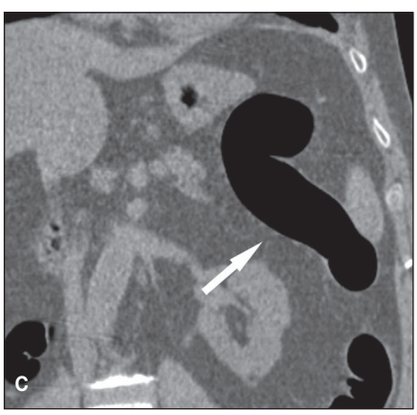


Fig 3. Segmental colonic spasm in the descending colon shows an irregular, circular narrowing of the colonic lumen (arrow) on the 3D endoluminal image (a) that simulates a stenosis. The transverse scan (b) shows focal, irregular circular wall thickening (arrow) with IV contrast enhancement. The prone scan (c) shows a normal smooth colonic wall without signs of stenosis or wall thickening (arrow) that indicate that the spasm has relaxed.

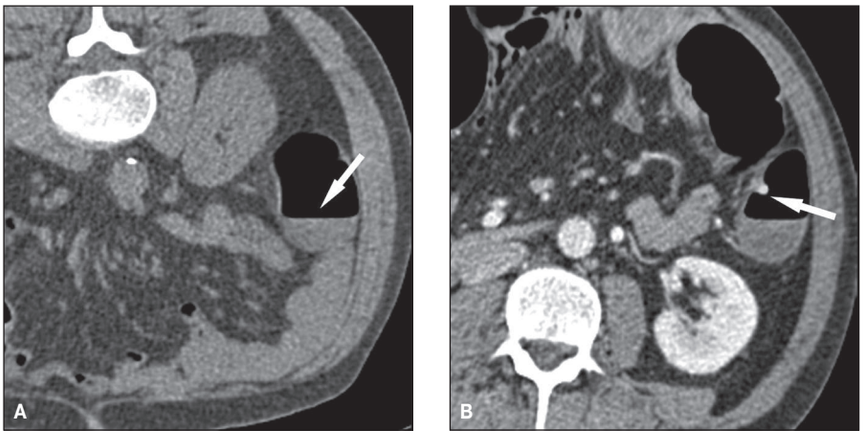


Fig 4.Fluid (arrow) obscures a descending colonic polyp in the supine position (a), but the polyp (arrow) is well seen in the prone position (b).

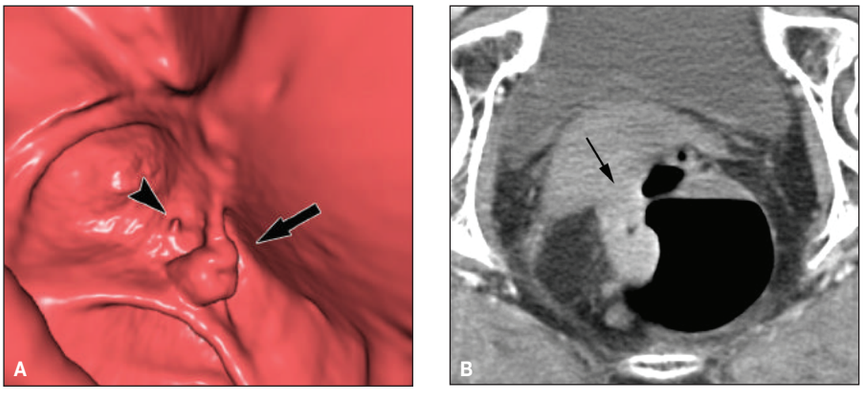


Fig 5. Sessile polypseen in the caecum (arrow) with adjacent appendiceal orifice (arrowhead) (a). Invasive rectal cancer (arrow) on 2D transverse image (b).

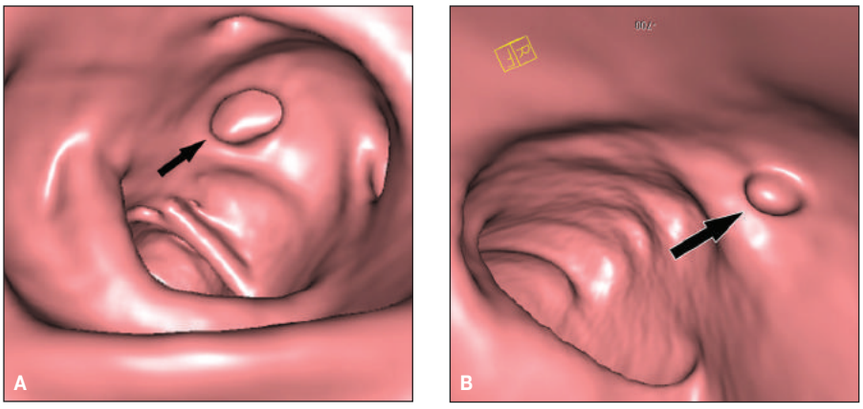


Fig 6. Full black ring seen with a diverticulum (a) but incomplete ring seen with a polyp (b) on 3D image.

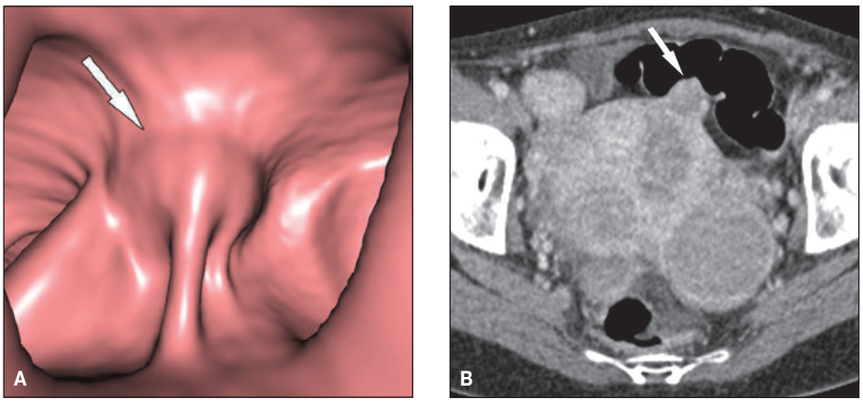


Fig 7.Extrinsic compression (arrow) noted on 3D image (a) confirmed to be due to a uterine fibroid (arrow) on the 2D image (b).

The only significant potential complication of CT colonography is bowel perforation (Fig 8). This is almost always related to the presence of inflammatory bowel disease or a constricting colonic lesion, but can also occur after snaring of colonic polyps. CT allows early detection of this complication unlike optical colonography. The likelihood of a performation with CT colonography is low (0.03%) particularly when compared to optical colonography (0.13%). Patient admission and observation are required in case of perforation. Surgerical intervention is rarely needed. After snare biopsies, CT colonography should be postponed by 4 weeks.

CT colonography can largely replace barium enema examinations. Optical colonoscopy can also be replaced by CT colonography, but not in the case of symptomatic patients where the requirement for biopsy is more likely. The use of CT colonography allows for significant health cost reduction and provides an accurate and detailed record of the patient's exam unlike optical colonoscopy, which provides a few photographic images at best. Availability of the full 3D data set for review and eventually for comparison with future exams is only possible with CT colonography.

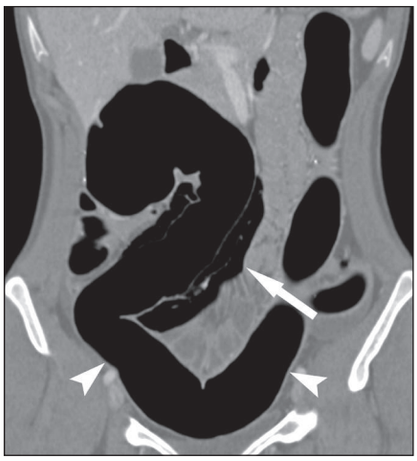
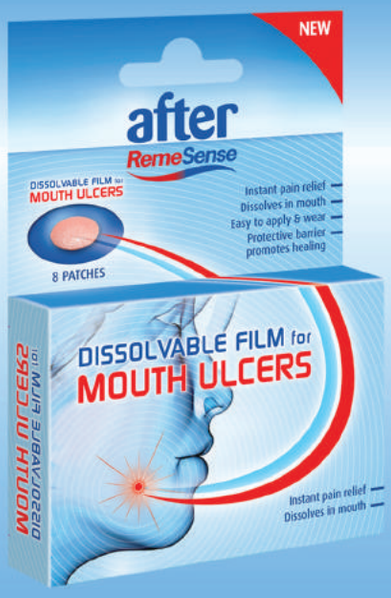


Fig 8. Colonic perforation seen on supine coronal CT scan shows pericolic air (arrow) around the transverse colon related to the perforation. Flattening and disappearance of the haustra is also seen (arrowheads) due to inflammatory bowel disease.



after RemeSense

PRODUCT:

After Remesense dissolvable film for mouth ulcers is a brand new,unique solution for immediate pain relief and treatment of mouth ulcers, cheek bites, abrasion from braces and denture irritation.
These slow dissolving buccal film patches have active properties that help to heal (recurrent) mouth ulcers and oral irritations. Apply the ultra thin, dissolvable patches to the affected area and the disc immediately forms a protective layer over the mouth ulcer while the triple action formula helps to speed up the natural healing. The pain is relieved instantly! The After Remesense patches are easy and hygienic to apply, stay firmly in place and slowly dissolve after hours.
This revolutionary product is a breakthrough in the treatment of mouth ulcers and works fast, easy and effective!

FEATURES:

- Instant pain relief for mouth ulcers and oral irritations
- Dissolves in mouth
- Easy and comfortable to apply and wear
- Protective barrier speeds up healing process
- Hygienic
- On the go packaging

TECHNOLOGY:

The After Remesense patch is based on the latest innovation in the pharmaceutical industry, the dissolving film technology. Sylphar has succeeded in charging this mucoadhesive film in a unique manner. The ingredients of the patch will be released slowly and sustained onto the affected area. Furthermore, the physical properties of the film will create a strong physical barrier between the ulcerated area and the oral cavity. This will isolate the mouth ulcer and will prevent painful stimuli (e.g. cold drinks, tongue, food,...) to reach the affected tissues.

This technology provides strong, fast, accurate dosing and increased patient compliance.

CONTENT:

8 dissolving patches.

PRODUCT:

Herpatch Remesense dissolvable film is the latest innovation for the treatment of fever blisters. The ultrathin, transparent patches can be used during the complete fever blister cycle from tingling to healing. Herpatch helps to speed up the healing process and reduce the pain, burning, itching and tingling by creating an excellent healing environment. Further, it seals the fever blister and helps to reduce the risk of contamination to other people and own body parts. Herpatch hides away the fever blister and even lipstick or sunscreen can be applied over the patch.
When used at first sign of an outbreak, Herpatch will help to reduce the symptoms and in certain cases may prevent the total outbreak of the fever blister.

TECHNOLOGY:

This second generation patch uses a dissolving technology, so there is no painful "ouch" effect or risk to tear open the wound when removing the patch. The patch dissolves over hours and if necessary can be removed with water.
The mucoadhesive Herpatch film creates an instant protective barrier which covers the fever blister and helps to relieve pain from external pain stimuli.

The active function of Herpatch is also supported by 3 ingredients:
First of all, beta-glucan is known to soothe, protect and hydrate the skin, which helps to improve wound healing.
Secondly, the sulfated polysaccharides from a red microalgae help to protect against sunlight exposure and also have protective moisturizing properties for the skin matrix.
Finally, zinc sulphate has an astringent action, which firms, tones and strenghtens the layers of the skin.

CONTENT:

8 dissolvable Herpatch Remesense patches

FEATURES:

- Dissolves automatically
- Painless removal
- With active properties
- Relieves pain & burning
- Helps to protect against sunlight exposure
- Fastens the healing process
- Hides instantly
- Reduces redness, swelling and blistering
- Helps to prevent itching & scabbing
- Helps to minimize contamination risk
- Firms, tones and strenghtens the skin
- Easy-to-use, invisible patch

Before prescribing please consult the summary of product characteristics

MSD

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