Volume 28, Issue 1, 2016

Malta Medical Journal

University of Malta
Medical School

UNIVERSITY OF MALTA
L-Università ta' Malta

http://www.um.edu.mt/umms/mmj

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Expanding student, shrinking paediatric cohorts . . .
Current challenges in undergraduate teaching in Paediatrics

Simon Attard Montalto

In the late 1990s, student cohorts in The Medical School, Malta, numbered 50 or thereabouts and admission was on an alternate year basis. Hence, for any one given year the Department of Paediatrics taught a single group of either fourth or Final year students. At the time, teaching responsibilities were shared amongst six appointed lecturers and/or consultants, and with half the cohort alternating with Obstetrics, this meant that just 4 students were allocated to each 'firm'at any one time. Fourth and final year examinations were held on alternate years, and Finals consisted of a traditional clinical format with short casesat the bedside, as well as assessments on clinical data/imaging/ECGs, etc. This setup required 'live' patients and up to 40 patients were invited to attend over three days. The change to an annual course with ever-increasing home-based student admissions, later compounded by intake from abroad (e.g. Kuwait and the EU) resulted in an exponential increase in students to 70/80 per year by 2008, >100 by 2011 and peaking at 185 for the group intake of 2014. These figures are further 'topped up' by approximately 25-30 elective students attached from 2-6 weeks per year. Presently, an average of 150 admissions for the course in Medicine and Surgery is expected for the foreseeable future.

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By 2004 it became impossible to trawl sufficiently appropriate clinical cases with 'examinable' clinical signs to guarantee a fair and objective examination, and the format for Paediatric Finals was changed to a 20-station Objective Structured Clinical Examination (OSCE) that included just two stations with 'live' patients. The OSCE was far more labour-intensive to prepare but could be run for the entire student cohort using just 18-20 clinical cases. More importantly, it was more objective for students and, given that they were tested on numerous conditions without negative marking, was more difficult to fail. However, the ever-expanding student groups and increasing difficulty in 'attracting' patients for examinations, meant that even this format could not be sustained and the clinical stations in the OSCE were eliminated altogether in 2011. These were replaced with simulated scenarios using actors (examiners) and short video clips.

The large number of students has not only forced the above changes in exam format, but has also led to practical issues relating to resources. Problems are now 'the norm' regarding the availability of suitably large rooms to run the projected part of the OSCE (with students placed at the back complaining of being disadvantaged), running consecutive sessions with problems quarantining large groups and preventing any 'cross fertilisation' of exam material from groups that have completed a session and others yet to begin, etc. Nevertheless, given this format, failure rates for the Final examination in Paediatrics remains extremely low (<5%), and include the weakest candidate(s) who invariably also fail one or several other subjects.

Over the same 20 year period bedside teaching has evolved (?devolved) with larger student groups essentially 'crowding out' the bedside approach, both metaphorically and physically – thirteen adults

simply do not fit around a newly born cot or incubator. Students are increasingly put off approaching sick children, and at times – with some justification – shooed off by nurses. This problem is compounded by decreasing inpatients with paediatric admissions plus day cases averaging 3,400 in 1999-2002 and 2,700 in 2002-13. The latter is partly due to a decreasing birth rate (from approximately 5,000 in 1986, 4,500 in 1996 to around 4,000 in 2004-14), a major contributor since ward admissions are positively skewed to younger age groups, also coupled with better community care. This has resulted from improvements at primary level (over the past 6 years or so, family practitioner trainees are required to rotate through a paediatric module), better and expanded community health centre-based services, and with the advent of at least 9 fully trained paediatricians working full time in private practice.

The changes in student cohorts necessitated a greater need for teaching staff resulting in additional lecturer appointments: 6 by 2002, 10 in 2010, 14 in 2013, and totalling 19 (plus 3 casuals) in 2016. There has been partly 'matched' by a steady increase in clinical consultant appointments within the Division of Health and greater subspecialisation from 5 generalists plus 1 community paediatrician in 1996, tojust 3 outright generalists in2016 plus 11 with an additional subspecialty interest including 4 community based consultants.These changes reflect, to some extent, the changing face of paediatrics and, therefore, the spectrum of paediatric curricula.[1-2] A decrease in malnutrition, deficiency states and gastrointestinal infections has been replaced with a concomitant increase in respiratory disorders, gastro-oesophageal reflux disease, enteropathies, allergies, late effects of cancer therapy, type I diabetes, perinatal problems and especially social, behavioural and psychosomatic issues including bullying.[3] Nevertheless, limitations in Paediatric consultant–led 'firms' in practice means that students are allocated to non-consultant lecturers with subsequent disruption in teaching schedules as these often have flexible working hours, generally centred around variable on-call duties. Commendable as it is, small group teaching with a push toward tutorials from lectures, in practice translates into lecturers delivering the same tutorial for up to 16 times per year, contributing to exasperation and lecturer burnout. Again, availability of teaching venues is becoming problematic with, on occasion, resorting to the use of 'open' outside-ward or Medical School foyers to conduct teaching sessions.

The problems associated with Paediatric undergraduate teaching are not unique to Malta,[4-5] and also apply to postgraduate Paediatrics in general.[6] Indeed, the specialty has been 'less popular' as a career prospect for a number of years.[7-8] In part, this has been due to intensity of placements, poor working hours, and poor remuneration in private practice, amongst others. Similarly, a relatively prolonged training programme of 6-9 years pre-accreditation and decreased academic placements has also made it difficult to recruit and retain paediatricians in academic fora.[9]

What do all these changes mean for undergraduate training in Malta in 2016? In a nutshell: the Department has reached near-saturation point with regard to the capacity of the teaching base (patients, lecturers and venue/facilities) versus the student cohorts that need to be accommodated. Any further significant addition in student numbers will invariably increase the strain at all levels and, in some respects, may simply become unsustainable. Some limitations particularly with regard to venues and teaching facilities are more easily addressed with an injection of resources, whilst increasing lecturer appointments are certainly possible – how to ensure all contribute effectively and within a complex but well-meshed timetable is less so. The use of simulation material, aids, manikins etc.[10-11] is useful to a point but cannot replace live patients with real (and therefore not 'squeaky-clean') signs, and the use of actors is particularly limited in Paediatrics. The greatest bottle neck remains patient numbers and suitability for teaching and these simply cannot be created. Ultimately, it is the limitation in paediatric patients that is dictating the current degree of saturation within this teaching module and defines Paediatrics as critical with regard to its capacity to expand. Hence, any proposals that will impose additional strain on this teaching resource, and especially any significant increase(s) in student numbers, may simply be untenable. Severely curtailing the Paediatric curriculum or eliminating this module altogether is not an option. Likewise, ignoring the problem and expanding student cohorts regardless, will result in a substandard module for

all and is equally unacceptable. In practice, the possibility of 'farming out' new additional students to other teaching hospitals overseas for the duration of this (and any other) critical placement needs to be considered seriously. For every given scenario, what is of paramount importance is effective communication with all key stakeholders whose primary interest (and expertise) is teaching students.

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Cover Picture:
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Original Article

Bisphosphonates: a cost benefit analysis patient

Sarah Cuschieri, Stephan Grech, Ray Gatt

Abstract

Introduction: Osteoporotic hip fractures are common in elderly. There is increased risk of sustaining other fractures that incur financial burden on the health system. Prescription of bisphosphonates after osteoporotic hip fracture surgery has been shown to reduce the overall incidence of re-fractures.

Methods**:** All osteoporotic hip fractures treated surgically in Mater Dei Hospital in the year 2011 were analysed in this observational retrospective study. The inclusion criteria were all primary osteoporotic hip fractures. The initiation, or not, of anti-osteoporotic treatment upon discharge from hospital was reviewed.

The mortality and re-fracture rate of this cohort was reviewed for a period of 3 years. The cost of hospitalization for hip fracture and re-fractures was calculated based on local health services costs and compared to the benefits of providing a free bisphosphonate medication to each patient.

Results: The osteoporotic hip fracture care pathway did not include initiation of anti-osteoporotic therapy after operations. A re-fracture rate of 11.7% over three years predominantly in female patients was observed. In the first year following hip fracture, an estimated direct medical health expenditure due to re-fractures was of €37,642.55 - €48,835.19.

Conclusion: Prescribing a bisphosphonate has been found to reduce both the re-fracture and mortality rates. In our study, a bisphosphonate prescription could have reduced the all cause mortality rate of 25.3% to 15.18% over the first year of hip fracture, as well as reduced the financial and social burden incurred due to a re-fracture.

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Keywords

Osteoporosis; Prevention & control; Femoral fractures; Osteoporotic fractures; Diphosphonates; Cost of illness; Health care costs; Health expenditures

Introduction

In an aging population, bone mass is progressively lost in a physiological process, resulting in an increased risk of a fracture following minor trauma. The commonest osteoporotic fractures are at the neck of the femur (hip), vertebral body and forearm.[1]

The most important osteoporosis-related fractures from a public health perspective are hip fractures.[2-3] In 2000, there were 0.89 million osteoporotic hip fractures in Europe. An estimated 179,000 men and 611,000 women are expected to sustain a hip fracture each year in European countries.[4-5] Hip-fractures due to osteoporosis were related to the highest medical costs incurred on the health services.[6] An estimated 820 million pounds Sterling per year was attributed to osteoporotic hip fractures in the United Kingdom.[7]

Hip fractures are associated with a high mortality of 10-20% as well as morbidity.[8-9] It is common knowledge that these elderly patients often lose a substantial amount of their daily independence after a hip fracture with 25 - 50% of them requiring residential help or nursing homes.[10-11]

Patients run a cumulative risk for further osteoporotic fractures after suffering a hip fracture.[12-13] Therefore osteoporosis-targeting treatment should be prescribed to all patients with previous history of osteoporotic fractures as stated by both the national institute for health and care (NICE) and the Scottish intercollegiate guideline network (SIGN).[14-15]

Bisphosphonates are considered to be the gold standard first line treatment in established osteoporosis.[16] They are also recommended in treating patients who have suffered an osteoporotic hip fracture. Calcium and Vitamin D may also serve as good supplements in elderly with hip fractures since vitamin D deficiency contributes to loss of bone in advanced age.[17] This is more prevalent than one would suspect even in countries like Malta where natural sunlight is in abundance. Yet, starting patients on anti-osteoporotic treatment prior to discharge is not part of the standard management plan in Malta.

Physicians need to be on the look out for factors that may lead to secondary osteoporosis and therefore resulting into fractures including thyroid disease, alcoholism, steroid therapy and malignancy.[20] There

have been mixed conclusions whether warfarin should also be considered as a predisposing factor to fractures.[22-23]

The aims of this study were to evaluate the current practice in Malta when it comes to prescribing anti-osteoporotic treatment following hip fracture surgery as well as:

1) Find the incidence of further osteoporotic fractures following a primary hip fracture;
2) Evaluate the costs involved in treating patients suffering an osteoporotic hip fracture.
3) Run a cost effectiveness comparison between the cost of prescribing anti-osteoporotic medication versus the cost of managing secondary fractures in the same patients suffering a primary osteoporotic hip fracture.

Permissions from Mater Dei Hospital chief executive officer and data protection office were obtained. Ethical approval was granted in accordance to the Declaration of Helsinki from the University of Malta Research and Ethics Committee.

Method

An observational retrospective study was performed analyzing all emergency osteoporotic hip fractures requiring surgery, presenting to Mater Dei Hospital, Malta, between January to December 2011. With the permission of the Chairman of the Department of Trauma and Orthopaedics as well as the Central Performance Unit (CPU), the operated hip fractures list was obtained. Mortality data was obtained from the Department of Health Information and Research.

The inclusion criteria for our study were patients over 60 years of age suffering a hip fracture following a low energy hip fracture. A low energy hip fracture was defined as a fracture suffered after minimal or low trauma. These were considered to be osteoporotic in nature. [21]

The exclusion criteria were those patients that were on long-term steroids, patients who consume large amounts of alcohol (over 3 units daily in males, over 2 units daily in females), had a history of malignancy, hypothyroidism or were on warfarin as well as those sustaining a high-energy trauma.

Using the 'Electronic Case Summary' software, which is a software used at Mater Dei Hospital on which discharge summaries are stored, each patient having undergone an osteoporotic hip surgery was analyzed as to the mechanism of injury and the management he/she was discharged on, with special attention to whether any anti-osteoporotic medication was prescribed. The picture archiving and communication system (PACS) was used to evaluate whether each patient re-presented to a state health care institution with another osteoporotic fracture over a period of 3 years following the primary hip fracture.

Data was stored in a spreadsheet and statistical analyses were performed using SPSS IBM v.11. An independent t-test evaluated the significance of age and gender in relation to hip fractures, while spearman's correlation co-efficient test was used to compare age and length of stay in hospital. The cost of hospitalization (including doctors, nurses, x-rays, bloods, electrocardiogram and physiotherapy) per night, major operation, intermediate operation costs and doctor consultation at outpatients at Mater Dei Hospital was obtained from the billing section of the hospital. Table 1 represents the itemized cost of each service.

Table 1: *Represents the itemized cost per service*

Service*	Cost
Hospitalisation**	€256.23/night
Intermediate Operation (Radial & humeral fractures)	€1048.22 / operation
Major Operation (Hip fracture)	€2329.37/ operation
Doctor consultation at outpatients	€36.94/visit

* Cost based on 2014 prices.

** Hospitalisation cost include in-patient doctors and nurses care, X-rays, Blood tests, ECG and Physiotherapy.

These costs were used to calculate the mean cost per patient who presented with a hip fracture as well as cost per re-fracture either requiring conservative management or an operation. The cost was calculated following the standard medical practice (as below) performed at the Department of Trauma and Orthopaedics, Mater Dei Hospital for each type of re-fracture.

The cost was calculated on the basis of an admission to hospital with a mean length of stay according to the type of fracture incurred and requiring an operation as follows; 11 days Hip fractures; one day Vertebral fractures; three days Humeral fracture; two days Radial fracture. The cost for radial and humeral re-fractures was calculated on the basis of either requiring an operation or just following a conservative management. Follow-up appointments were considered as follows: Conservative management of humeral and radial fractures requiring two follow-up appointments while one follow-up appointment after operative management. This is the standard protocol of follow up in our institution. Both humeral and radial fracture operations were considered as intermediate operations whilst hip fracture as major operations.

All costs excluded accident and emergency services and only considered direct medical costs.

Results

In 2011, there were 370 admissions (280 females and 90 males) to Mater Dei Hospital, Malta, between the ages of 60 and 99 years that required an orthopaedic hip operation. Out of which, 89 were excluded due to the presence of risk factors predisposing them to fractures. The remaining 281 (226 females and 55 males) were considered to have sustained an osteoporotic hip fracture, with most fractures occurring in females between the age of 79 and 87 years (p=0.0001).

The length of stay at hospital from day of admission to discharge ranged from three days to 51 days with a mean stay of 11 days. Figure 1 is a histogram that shows the length of stay of all patients with an osteoporotic hip fracture during the study period. The length of stay within hospital showed no co-relation with age (p=0.069); or with age and gender (females p=0.212; males p=0.793). The calculated mean bed cost, hip operation and follow-up (as discussed above) for an osteoporotic hip fracture was of €5,182.84.

None of the patients who sustained an osteoporotic hip fracture were started on a bisphosphonate or a calcium supplement by the responsible caring team. The only few patients, three in total, on anti-osteoporotic supplements had already been on this treatment prior to suffering the initial hip fracture.

Over three years, 11.7% (n=33) presented to a state health institute with a re-fracture with the majority being female (n=25) and the most common fracture being a fracture to the contralateral hip. Figure 2 shows the re-fracture presentation per year over three years according to gender. Figure 3 represents the cumulative re-fractures over three years post-hip fracture, while Figure 4 shows the types of re-fractures sustained over three years.

The re-fracture rate over a year from the index hip fracture surgery was of 6% (n=17). Table 2 represents the direct medical cost per re-fracture type and the cost sustained over the three years due to re-fractures in the population under study.

***Figure 1**: Histogram showing length of stay at hospital from admission to post-surgery discharge*

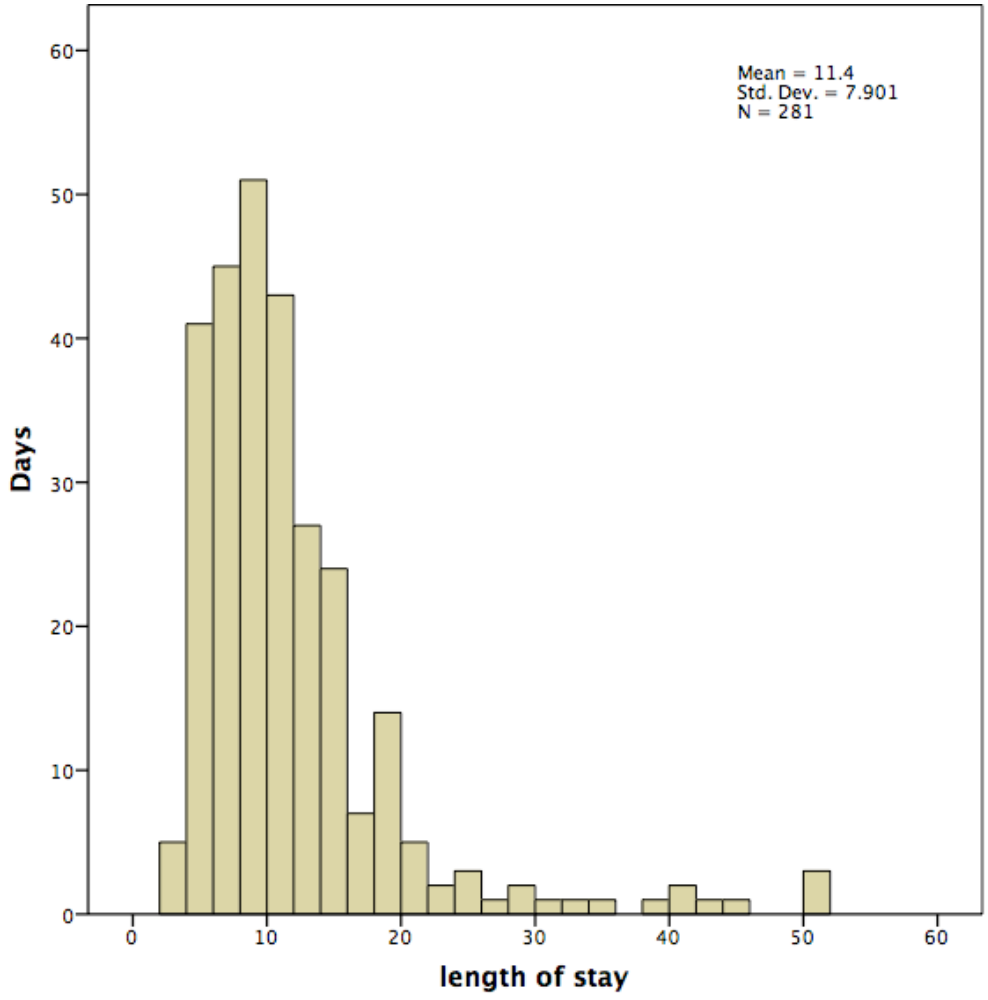

***Figure 2**: Presents the re-fractures per year over 3 years according to gender*

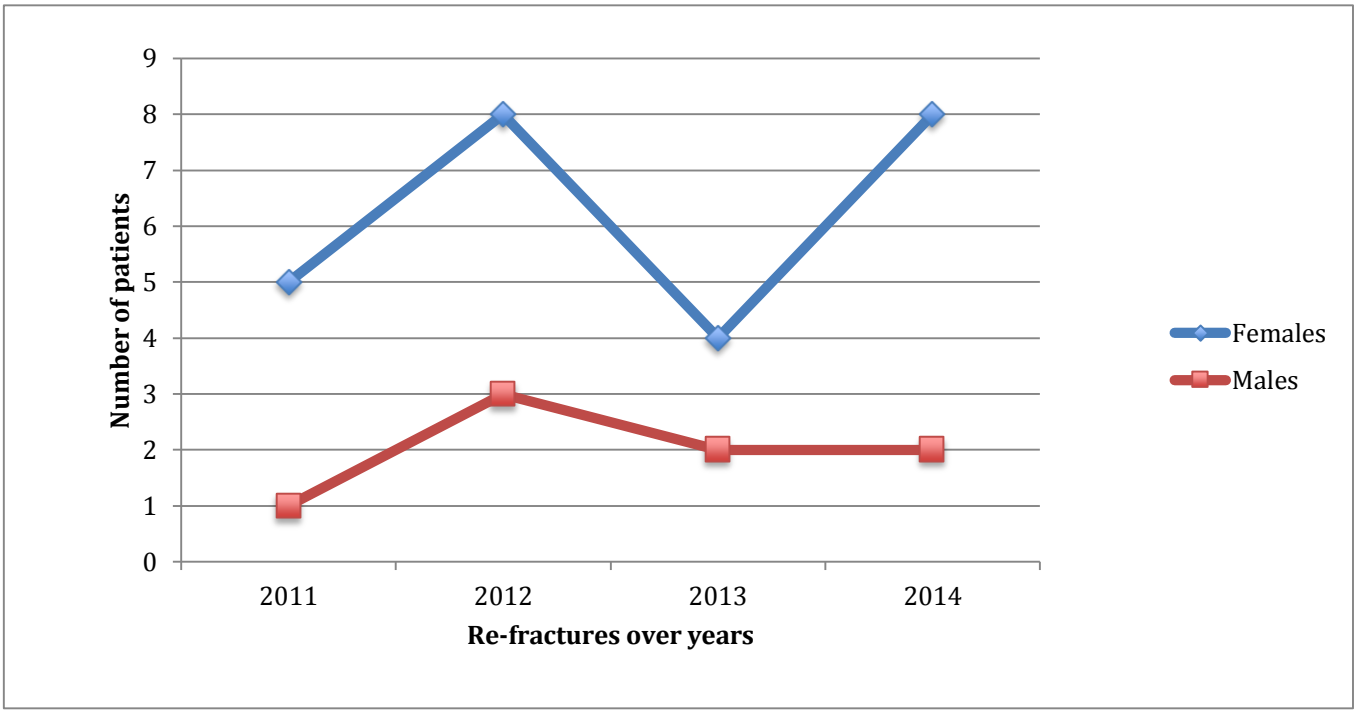

***Figure 3:** Cumulative re-fracture rate over 3 years*

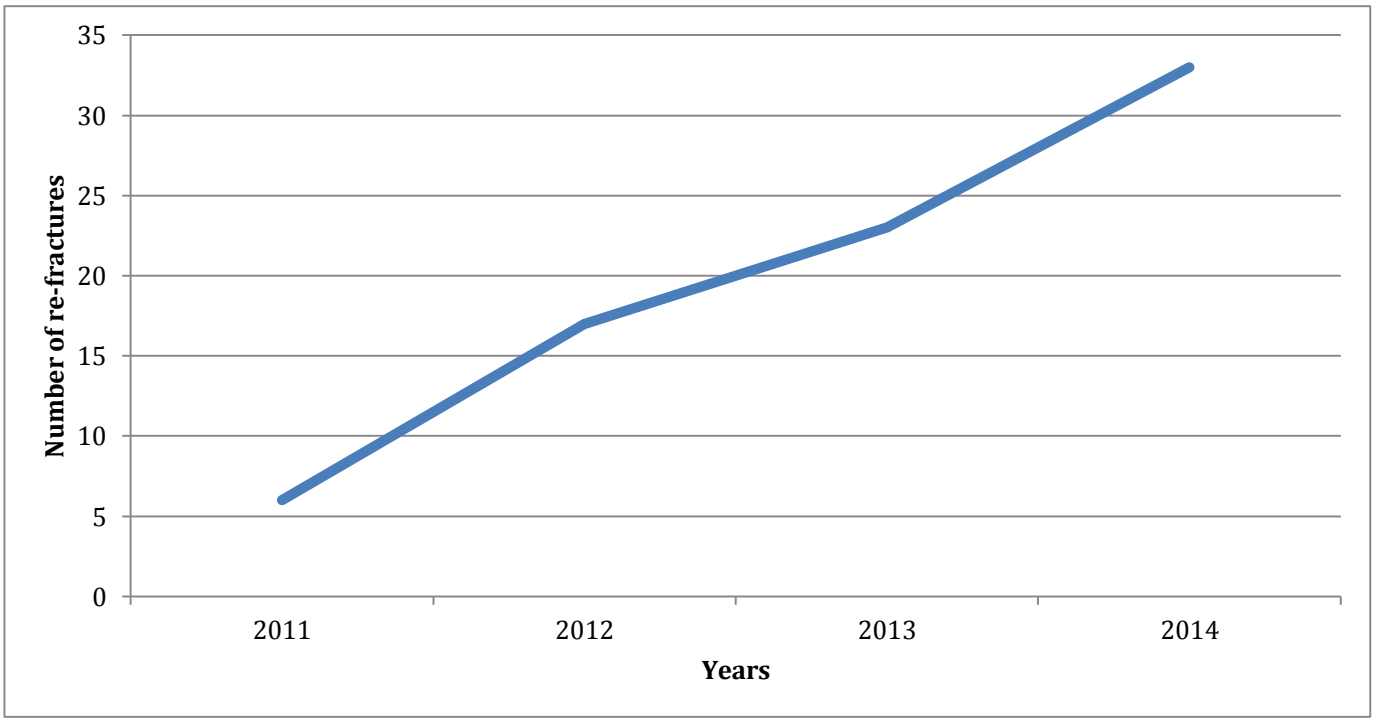

***Figure 4**: Different type of secondary fracture after the index hip fracture*

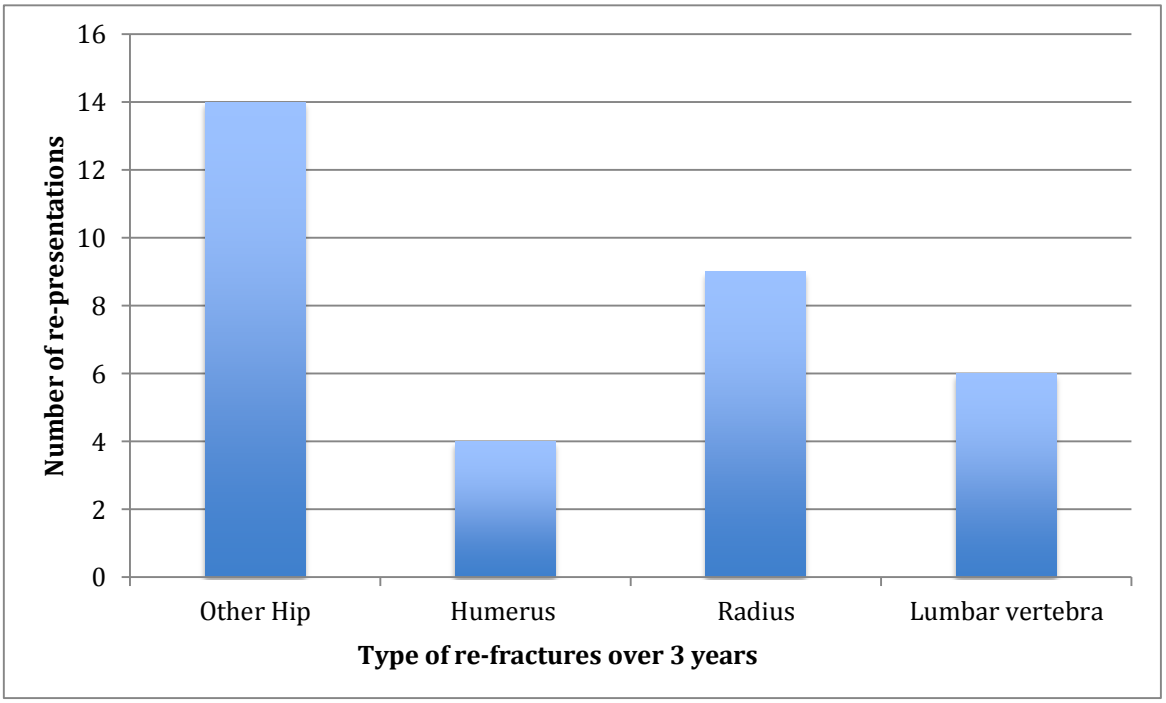

***Table 2**: Represents the direct medical cost per fracture management and the total cost incurred per fracture over the 3 years due to re-fractures*

Type of fracture	Cost per fracture in Euro		N	Direct medical cost incurred due to fractures over 3 years in Euro
Hip fracture	5,182.84		14	72,559.76
Vertebral fracture	291.17		6	1,747.02
Humeral fracture (Conservative)	69.88		4*	279.52
Humeral fracture (Operative)	1,851.85		4*	7,407.40
Distal radius fracture (Conservative)	69.88		9*	628.92
Distal radius fracture (Operative)	1,595.62		9*	14,360.58

* Cost for both conservative and operative management was calculated but in actual fact only one of the management plans was followed for these patients.

Discussion

Low-energy trauma causing a fracture in a major bone is a sign of bone fragility. Osteoporotic hip fractures are the most severe and serious results of osteoporosis. [22] The determining factors for osteoporotic fractures are a combination of bone strength and risk of falls. [23]

Our study evaluated low-energy traumatic hip fractures within the adult population of 60 years and over presenting to the only general hospital in the island.

Although private clinics are available, hip fractures are generally referred to Mater Dei hospital for management. Therefore this study can be considered as a population-based study over a period of one year. Since no patients were started on bisphosphonates post-osteoporotic hip fracture surgery, it was impossible to present a case-control study for possible re-fracture outcomes.

The majority of the patients presenting with an

osteoporotic hip fracture were female, which follows the findings of Couris CM et al. who stated that women aged 60 to 85 years, have increased risk of hip fractures. [24] Those elderly patients with a previous history of an osteoporotic hip fracture are at higher risk to develop other fractures later on. These elderly patients have a 2.5-fold increased risk of suffering vertebral fractures and 2.3-fold risk for further hip fractures.[25] This could be seen in our study where 11.7% (n=33) of the adult population under study experienced a re-fracture with 14 patients sustaining a fracture of the other hip, followed by nine patients exhibiting a distal radius fracture. Females showed a higher incidence of re-fractures when compared to males.

Once a hip fracture has been sustained, the quality of life decreases and the mortality increases by about 20%. [26] A hip fracture does not only have a negative impact on the quality of life of the patient but also on his/her family and society. It also implies an economic burden on the national health system (NHS), which in Malta amounts to a mean direct cost of €5,182.84 per osteoporotic hip fracture when there is a hospital stay of 11 days. Sustaining a re-fracture will further increase the negative impact on the patient as well as medical costs incurred by the NHS. A hip fracture has direct consequences on the patient himself apart from carrying a direct financial burden on the national health system. The study aimed to evaluate the direct costs incurred from the moment of hospitalization up to discharge from acute care. It is virtually impossible to calculate all the indirect costs including days off work (both by patients and relatives), rehabilitation costs, possible surgery related complications requiring further hospital readmissions, household alterations in order to render them more fall proof etc. All these hidden costs increase the overall expenditure dramatically.

Within a year the re-fracture rate was of 6% of the total population under study, with direct mean medical costs estimations ranging between €37,642.55 to €48,835.19, depending whether a conservative or an operative management plan was followed. In actual fact the total costs would be much greater due to indirect costs as well emergency services and rehabilitation, which were excluded. The estimated cost is based on whether the distal radial fractures and the vertebral fractures followed a conservative care pathway or a surgical pathway, in which case the cost would vary as discussed above. Only the financial aspect was taken into consideration. It is immediately obvious, that several patients and their relatives undergo a physically and psychologically painful experience. In fact, 24% (n=8) of the patients in the study, died after their re-fracture, within a three-year follow up period. Three patients passed away within three months of the second fracture.

The total all-cause mortality rate after one year of the index osteoporotic hip fracture was of 25.3%, with two of these patients having a re-fracture and dying within the first year. Therefore it is important to try to prevent such re-fractures from occurring by securing a number of measures. One simple way is prescribing anti-osteoporotic treatment. The aim of starting therapy is to prevent the re-fracture rate as well as improve the quality of life. Unfortunately a large amount of patients with hip fractures are not prescribed any anti-osteoporotic treatment.[22] This is the case in Mater Dei Hospital, Malta, where none of the osteoporotic hip fracture patients post-surgery were prescribed anti-osteoporotic treatment. Unfortunately there has not been any change in the management plan to date and no preventive policies or funding for osteoporotic drugs been implemented. It is hoped that this study will stimulate policy makers to implement this widely accepted international preventive management.

A study conducted in Belgium showed that only 6% of patients with hip fractures were discharged with anti-osteoporotic medication.[5] The same situation was found in the United States, where only 6.6% of the patients with hip fractures were prescribed calcium and vitamin D supplements and 7.3% were prescribed anti-osteoporotic agents.[27] This lack of anti-osteoporotic therapy prescription among the orthopedic community can be described as 'Clinical inertia' that is defined as "failure of healthcare providers to initiated or change treatment when the health status of the patient indicates such action is necessary".[28] This clinical inertia is having a negative impact both directly and indirectly to the economic situation in the country leading to a financial burden on the health and social services.

Different types of bisphosphonates have shown to decrease the incidence of hip fractures in women who are osteoporotic as well as increase bone density in the femoral neck and lumbar spine.[29, 30] Bisphosphonates both orally and intravenously have shown a reduction in mortality rate after an osteoporotic hip fracture. It was reported that oral bisphosphonates could lead to a relative reduction of 60% death per year.[31, 32] Although one must keep in mind the complications that may arise from their usage such as necrosis of the jaw and upper gastrointestinal side effects.[33]

Bisphosphonates for osteoporotic fractures are not part of the free medication scheme entitlement in Malta, so if prescribed by the orthopaedic team, the patient will have to incur the cost. Considering alendronic acid monthly tablets at retailed price from a pharmacy in Malta for a year supply would cost €117.12 per individual. If this was provided as part of the discharge requirements and entitlement to every patient leaving the NHS after sustaining an osteoporotic hip fracture during the study period (n = 281), the cost would have amounted to €49,770.72 per year. At retail price this would have cost the NHS €935.53 more than the re-

fracture management direct medical expense incurred. It is important to consider that the wholesale price of this drug to the NHS would be much cheaper. Also one needs to consider the fact that the indirect costs and rehabilitation costs were not included, so one can still suggest that providing a bisphosphonate to every patient sustaining an osteoporotic hip fracture is more economical and socially beneficial. Keeping in mind that following the osteoporotic hip fracture there was an all-cause mortality rate of 25.3%, prescribing of a bisphosphonate might have reduced this percentage by 60% [31-32], where 43 patients would have survived the first year post- hip fracture out of the 71 patients that died. The cost effectiveness of bisphosphonates is a well-established fact with multiple repeated studies published in the literature. The effectiveness takes between six to twelve months to be evident on bone mineral density measurement, and is effective up to ten years post continuous treatment. [34-36]

Study limitation

Our study investigated only patients that presented to the state health care institutes, where the national PACS is only available, so re-fractures presenting to private clinics or hospitals have been excluded in the study. The mechanism of injury, risk factors and treatment on discharge of each patient were based on case summaries that were written by doctors working in the orthopaedic department, therefore information could have been subject to human errors. The medical costs quoted are calculated according to the local NHS expenses at 2014 and does not represent the cost for different hospitals. All other anti-fragility hip fractures measures were not evaluated in this study as it is complex to put a cost to all these. They include steps taken to make homes safer such as attention to carpets and loose furniture.

Conclusion

Osteoporotic hip fractures are a common occurrence in the elderly population. These increase the overall morbidity and mortality in this sub population. Withstanding evidence based medicine; orthopaedic surgeons even nowadays still fail to prescribe anti-osteoporotic treatment post surgical fixation of an osteoporotic hip fracture. There should be an increased drive through the Mater Dei policy makers, to institute anti-osteoporotic treatment. Prevention is better than cure; prescribing a bisphosphonate post-surgery may be more beneficial both to the patient and to the national health services with a decrease incidence of osteoporotic fractures and related morbidity and cost to the health services.

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Original Article

Investing in the health of the 41-60 year old: Reaping the return in the 60+ population?

Antonella Sammut, Neville Calleja, John Cachia

Abstract

Introduction: Ageing brings an increased burden on healthcare systems. In Malta cardiovascular disease is the main cause of morbidity and mortality accounting for approximately 40% of all deaths. It is assumed that effective prevention strategies targeted at the middle-aged population would translate in better health outcomes in our elderly population.

Aim: To investigate how lack of awareness of conditions such as high blood pressure and high blood glucose level in the 41-60-year age group could influence the health status of future generations of elderly in our population.

Methodology: Two risk factors for cardiovascular disease namely raised blood pressure and raised blood glucose were identified for analysis: (i) The comparison of perception and measurement of the selected risk factors assessed in 2 cohorts aged 41-60 years at two different time points: (a) 1981/4 and (b) 2008/2010; (ii) The analysis of any changes in perception and measurement of these risk factors over time between the 1981/4 sample and a follow-up sample drawn from the first cohort 30 years later, now 60 plus years of age.

Results: Awareness for hypertension has increased in the 41-60-year olds over the 30-year period. However, awareness for diabetes has decreased in the same cohorts. Awareness for both hypertension and diabetes has increased as the 41-60-year olds reach 60+.

Conclusion: Improved perception for hypertension and diabetes in the 60+ group is not matched with better control of the condition. Medical intervention in the 41-60-age group in the 2008/2010 sample has resulted in better control of blood pressure, but not of blood glucose. These results highlight the need for stepping up awareness and screening for these conditions especially in the 41-60 group coupled with better control.

Keywords

Perception, awareness, awareness index, hypertension, diabetes

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Introduction

Demographic changes are affecting Europe and Malta is no exception. Locally individuals aged 65 years and over are projected to increase from 15.16% in 2010 to 31.7% by 2060. In fact, the population of persons aged 65 years and over is projected to reach 111,700 – an increase of 72% when compared to this segment of the population in 2010.[1] An ageing population presents challenges for our societies, economies and healthcare systems. The importance of healthy and active ageing cannot be over emphasized.

In this study the focus shall be on hypertension and diabetes, two contributory risk factors for diseases of the circulatory system which accounted for 46.7% of all deaths in Malta in 2012.[2] Of these diseases, ischaemic heart disease was responsible for 27.5% of deaths from all causes and was the most important cause of premature mortality, in those less than 65 years of age.[2] Although these figures may indicate the size of the problem, they do not reflect the impact of the actual burden of disease in middle age and beyond, both on the

individual and on the healthcare services. This necessitates the need to embark on increasing awareness, effective prevention strategies, opportunistic screening and lifestyle changes particularly targeted to delay the onset of diseases of the circulatory system.

A literature review was conducted of similar studies to be able to compare our findings. Awareness and actual presence of these conditions will be analysed in comparative local studies of 2 cohorts aged 41-60 years at two different time points (1981/84 and 2008/2010). A subgroup of the surveyed population, 41-60 year 1981/84 cohort was followed as it reached 60 plus age group. Evaluation of the public health strategies issued from time to time and their influence on health behaviour and outcomes on the population will be explored. Also, the paper will focus on areas of possible failure of health promotion in halting the rising prevalence of hypertension and diabetes through increased awareness and the introduction of healthy lifestyles from a young age thus reducing the associated morbidity and mortality from circulatory diseases.

Method

The study set out to measure the awareness index which is the proportion of percentage of individuals with perceived disease and the actual percentage of individuals with the condition. (Awareness Index = % perceived disease / % measured disease or ratio expressed as a proportion of perceived to measured disease). An awareness index of zero (0) is equivalent to no awareness, whereas an awareness index of one (1) denotes full awareness.

Data on self-reported perception and actual measurement of raised blood pressure and raised blood glucose was available from studies performed in Malta. These include the Diabetes survey performed in 1981, the Multinational MONitoring of Trends and Determinants in Cardiovascular Disease (MONICA Project) in 1984, the European Health Information Survey (EHIS)[3] in 2008 and the European Health Examination Survey (EHES) done in 2010.[4]

Each of these surveys was a separate cross sectional study based on a representative sample of the population. No attempt has been made to actively resample any of the previous studies' population.

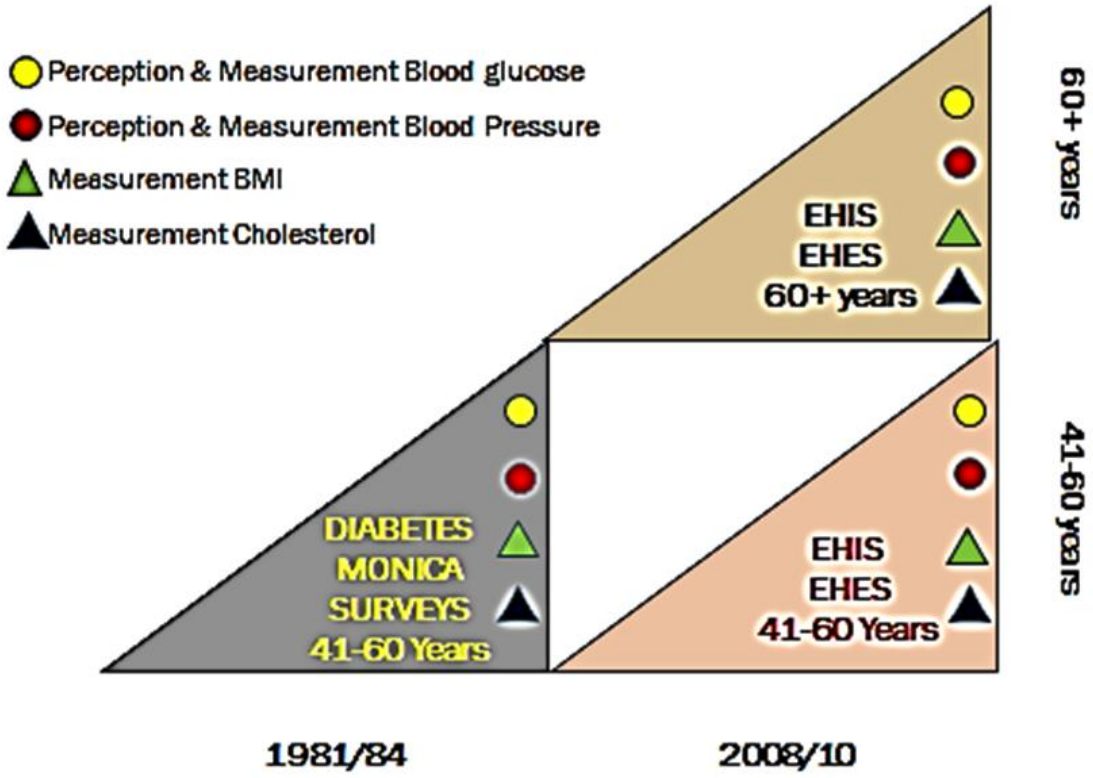
A problem in health surveys that use only questionnaires is that the individual's perception of having a disease may be different to whether that person is actually suffering from the condition or not. In medical surveys, there is a tendency of underreporting of the condition which may lead to serious bias in estimates of disease prevalence. This limitation is usually overcome by combining a questionnaire with a health examination. This has been the case in the Diabetes and MONICA surveys and the EHES whilst the European Health Information Survey (EHIS) only consisted of a questionnaire (Fig. 1).

A person was considered to be hypertensive or diabetic if a raised blood pressure or raised blood glucose (fasting or random) was found upon examination or if the individual was known to be hypertensive or diabetic but was found to have a normal blood pressure or a normal blood glucose on examination. Normal blood pressure was assumed to be when systolic blood pressure was <140mmHg and diastolic blood pressure was <90mmHg. Normal blood glucose level was taken to be ≤7.1mmol/l after fasting for 8 hours and ≤11.1mm0l/l for a random sample of blood glucose.

In the Diabetes survey, a representative sample of 1,100 households was contacted out of which 1,098 agreed to participate. All members of the household 15 years and older participated; giving a total sample of 2,945 individuals. Individuals interviewed were asked a variety of questions including whether they had been ever diagnosed as diabetic. The purpose of this question was to avoid giving a glucose tolerance test to known diabetics because of the deleterious effect such a high dose of glucose can have on them. Unfortunately, the survey does not identify non-diabetics who said that they had been diagnosed with diabetes as the latter were not given a glucose challenge as this could have had a deleterious effect on the perceived condition.[5]

The MONICA survey assessed risk factors for heart disease through a questionnaire with linkage to results of the physical examination for 2,067 individuals.

***Figure 1**: Timeline of studies; type of data obtained and age groups of cohorts*



A random sample of 5,124 individuals was selected to participate in the EHIS, out of which 3,680 participated given a response rate of 72%. Awareness for hypertension or diabetes was assessed according to self-reported data on the hypertensive and diabetic status of the participants in response to the question: 'Have you had the disease/ condition-(hypertension/diabetes) in the past 12 months?'[3]

In order to obtain more robust information about the health of the population, DG SANCO has embarked on a European Health Examination Survey (EHES) in 2014-2015; a pilot examination survey collecting information on both diabetes and hypertension was performed in 2010. Although, this pilot study had a small sample size of 221 individuals which may limit its validity, the sample was representative of the population. Information obtained from the EHIS and EHES (pilot study) has been amalgamated to give a more robust picture of the perception and actual presence of diabetes and hypertension in the population.

Results

Results (Table 1) show that the awareness index for hypertension 41-60 age-group has increased over the thirty-year period; today's 41-60-year olds are more aware of their condition than they were 30 years ago. Awareness for hypertension increases with age in that the original cohort of 41-60 year olds became more aware of hypertension as they grew older. However, no difference has been found in awareness in today's 41-60 year olds when compared to those who are 60+ years of age.

Results showed that whilst the prevalence of high blood glucose has remained the same, there was a dramatic decrease in awareness index from 0.73 to 0.57 in 41-60-year olds over a period of 30 years. However, as the 1981 41-60-year cohort reach 60+, awareness for raised blood glucose approached maximum level from 0.73 to 0.96, which is a positive finding.

Results show that the awareness index for both conditions has increased over a thirty- year period as the 41-60-year old reached 60+. In fact, 55% of those having a raised blood pressure were aware of the condition and 96% of those found to have elevated blood glucose were cognisant of the condition. This finding contrasts to what was found in the two 41-60 year-age cohorts i.e. the 1984 and 2008/2010 cohorts, when although awareness for hypertension increased that for diabetes decreased.

***Table 1**: Awareness Index for Blood Pressure and Blood Glucose*

Age Group	Study & date	Cohort No.	Blood Pressure (BP)			Blood Glucose (BG)		
			Perceived	Measured	**Awareness Index**	Perceived (%)	Measured (%)	**Awareness Index**
41-60 yrs	Diabetes[1] 1981	BG n=949	27(%)	67(%)	**0.40**	9(%)	12(%)	**0.73**
	MONICA[2] 1984	BPn=917						
	EHIS[3] 2008	BGn=1278 BPn=1283	25(%)	46(%)	**0.55**	7(%)	12(%)	**0.57**
	EHES[3] 2010	BG n=125 BP n=115						
60+ yrs	EHIS[3] 2008	BG n=923 BP n=921	47(%)	86(%)	**0.55**	21(%)	22(%)	**0.96**
	EHES[3] 2010	BG n=76 BP n=83						

[1] Diabetes Survey: Perception and measurement of of blood glucose
[2] MONICA SURVEY: Perception and measurement of blood pressure
[3]EHIS: Perception of blood glucose and blood pressure
[4]EHES: Measurement of blood glucose and blood pressure using a weighted sample; weights were applied against EHIS because of small study. Inforamtion obtained from EHIS and EHES has been amalgamanated to give a more robust pictureof the perception and actual presence of diabetes and hypertension2

Discussion

When interpreting the results one must be cognisant of the fact that the cohorts studied, in particular the 41-60-year old cohort, are heterogeneous with the consequence that the age of onset or age of diagnosis of hypertension or diabetes differs. This heterogeneity is likely to impact on both prognosis and awareness. Awareness for a condition may lead an individual to undergo a medical check-up which could in turn lead to early diagnosis of the condition. On the other hand being diagnosed with a condition does not necessarily result in good control of the condition. Improvement in awareness for hypertension from 40% to 55% was noted among Maltese persons aged 41-60-years in 1981/84 upon reaching age 60+ years in 2008/2010. This is supported by findings from the Eurobarometer 2007,[6] NHANES[7] and from the Canadian Health Measures survey.[8] However, current awareness levels at 55% are less than satisfactory given the wider availability of health promotion and educational material and the relative ease of access to care. One has to question whether the message is reaching our population and having the desired effect. The European Health Literacy Survey revealed that nearly half of the Europeans have inadequate or problematic ability to understand, assimilate and act on health messages received. This is associated with riskier behaviour, poorer health, less self-management and higher hospitalization and health costs.[9]

Comparing the two 41-60 year-age group cohorts i.e. the 1981/4 and 2008/2010, shows that over a 30-year period, there was improved awareness for hypertension but decreased awareness for diabetes. Less awareness for diabetes is very surprising since diabetes is usually symptomatic and tends to be diagnosed early. This finding may be attributed to the small numbers studied. Although the study showed that there seems to be no increase in prevalence in diabetes in the two 41-60-age cohorts (1981/4 and 2008/10), there is a possibility that the number of diabetics was inflated in the Diabetes survey due to the fact that the survey did not identify non-diabetics who said that they had been diagnosed with diabetes. Deep lack of awareness in the 41-60-age group cannot but be the harbinger of more diabetic complications once this cohort reaches old age and is cause for concern as diabetes tends to contribute heavily towards morbidity, hospital stays and

mortality in Malta and calls for deeper exploration.

As the population gets older, awareness improves considerably with awareness for elevated blood glucose in the 60+ years age group being noticeably higher (96%) than for high blood pressure (55%). This may be due to the fact that elevated blood glucose is more symptomatic and individuals tend to seek medical advice earlier on. Increased awareness may be attributed to several factors including; (i) more visits to the family doctor, (ii) increased registration of patients with a specific family doctor, (iii) increased access of family doctors through E Health portal to previous blood glucose results and thus closer monitoring of the patient, (iv) improved access to health promotion campaigns through the conventional channels but also through the social media, (v) increased availability of home monitoring devices among family and friends that encourage people to check for hypertension or diabetes and (vi) increased availability of these tests in community pharmacies. More awareness enhances the checking of blood pressure and blood glucose with possible earlier diagnosis of the condition.

Whilst the above trends in awareness and measuements have not been reported previously, this discussion would be incomplete if certain changes in underlying contributory factors, already reported elsewhere in the literature, are not considered. These include a significant increase in the percentage of persons with a normal BMI within the 41-60 age-group and an increase in percentage of persons having a desirable serum cholesterol level in both age groups in 2010 (Table 2).

***Table 2**: BMI and cholesterol measures in the populations under study*

Age Group	BMI%			Total Cholesterol %		
	Normal	Overweight	Obese	Desirable	Borderline	High
41-60 (1981) *n*=930	20.9	42	37.1	n.a.**	n.a.**	n.a.**
41-60 (1984) BMI *n*=838 CHOL *n*=566	23.4	39.4	37.2	14.1	25.1	60.8
41-60 (2010) BMI *n*=104* CHOL *n*=120*	35.6	28.8	35.6	26.7	46.7	26.7
60+ (2010) BMI *n*=87* CHOL *n*=77*	24.1	41.4	34.5	27.3	41.6	31.2

*weighted count, weights applied to the sample against EHIS because of very small study
**Cholesterol measurements were not taken in the diabetes study

When the persons aged 41-60 years in 1981/1984 reached the 60+ years in 2010, the improvement in their BMI is negligible but the percentage of individuals with a desirable serum cholesterol level has doubled. This may be due to multiple confounding variables; increased receptiveness to health promotion messages stressing the need to monitor serum cholesterol, the availability of better and free cholesterol lowering drugs on the Schedule V Government Formulary and the interest of the pharmaceutical industry.

However, the same cannot be said for messages advocating a change in lifestyle, as the BMI remained grossly unchanged. This implies selective uptake of health promotion messages. Furthermore, lifestyle modifications are more difficult to instil in later life. The Diabetes Prevention Programme (DPP) demonstrated that lifestyle interventions involving a healthy, low calorie, low-fat diet and moderate physical activity, in individuals at risk of developing diabetes are cost-saving in individuals younger than 45 years of age and cost-effective in all age groups when compared to Metformin and placebo interventions. The lifestyle intervention was highly cost effective, costing $1,100 per QALY when compared to the Metformin intervention costing approximately $31,300 per QALY.[10] Cost-saving interventions present no difficulty with respect to policy implications and should be introduced earlier on in life especially in individuals

at high risk of developing diabetes. Cost-saving should also be factored in when devising guidelines. Guidelines should be effective in reducing morbidity and mortality but would provide added value if they are cost-effective. Evaluation of the 2014 guidelines for US adults was made using the Cardiovascular Disease Policy Model to simulate; (i) drug-treatment and monitoring of costs, (ii) costs averted for the treatment of cardiovascular disease and (iii) quality-adjusted life years (QALYs) gained by treating previously untreated adults between the ages of 35 and 74 years from 2014 through 2024. The implementation of these guidelines could potentially prevent about 56,000 cardiovascular events and 13,000 deaths annually. Treatment of stage 1 hypertension was found to be cost-effective for all men and for women between the ages of 45 and 74 years (defined as <$50,000 per QALY) amongst other benefits.[11] Thus besides providing the optimal treatment for a condition, guidelines provide added value if they are cost-effective.

Strategies help us achieve our goals but they need to have realistic, measurable targets that are attainable within stipulated time frames. For instance, there is no available evidence that the key targets outlined in the Health Vision 2000 published in 1995 for blood pressure and blood glucose have been achieved. These stated that by 2005, the diastolic blood pressure distribution in the general population should be reduced by 10mmHg and that by 2000, the prevalence of non-insulin dependent diabetes mellitus among those aged 34 and older is to be reduced to 7.5% or less and Impaired Glucose Tolerance should be reduced to 9% or less. Although these targets may not have been achieved, a downward trend in the age-standardized mortality rate from diseases of the circulatory system is observed. Recent strategies have formulated three (3) targets for the reduction of risk factors for circulatory diseases include: (i) reducing the prevalence of self-reported hypertension in Maltese adults by 3%, (ii) limiting the prevalence of diabetes among persons aged 34 years and over to 10%,[12] (iii) curbing and reversing the trend of overweight and obesity in children and adults, thus diminishing the consequences of excess body weight on health, social and economic aspects.[13] Hopefully these strategies will have the desired outcomes.

This study has certain limitations as although the results are representative of the population it was not possible to divide the population by gender as the EHES numbers were too small. The low power may limit the conclusions drawn from the observed potential decline in awareness index for diabetes in the 41-60 year olds from 1981/4 to 2010. The following assumptions were made that (i) the sample taken of the 60 plus age group (2008/2010) was representative of the original samples of the 41-60 age groups of the 1981/84 groups and (ii) there were no significant changes in the health profiles of these two groups.

Conclusion

Life expectancy in Malta has increased and this presents the health service providers with new challenges. A sustainable healthcare system must be responsive to the changing needs of the population. The results illustrate that the formulation of strategies as standalone initiatives do not lead to the desired health outcomes. Notwithstanding their inherent validity, they need to be supported by new work practices and work processes. Also, one must keep in mind the importance of lifelong health promotion and education targeting all the population young and old, so that healthy habits are instilled early, thus delaying onset of disease.

In order for public health messages and initiatives to reach and be understood by the population, the cultural belief, patients' perspectives and health literacy levels need to be considered. Identifying gaps in awareness can help physicians and policymakers improve disease management and education programmes.

The introduction of cost-saving or cost effective interventions in individuals at high risk to develop diabetes or hypertension presents no difficulty with respect to policy implications and should be introduced earlier on in life.

The role of all health professionals and in particular family doctors cannot be overemphasized as the latter are usually the first point of contact of the patients. Family doctors are encouraged to perform opportunistic screening for hypertension and diabetes and to keep abreast with guidelines on weight management and developments in the treatment of hypertension and diabetes so that they can manage these conditions optimally.

Improved awareness for risk factors of circulatory disease, in particular for hypertension and diabetes, would empower persons to seek advice earlier from better informed health

professionals. In fact, the strategy entitled "A National Health Systems Strategy for Malta 2014-2020"[14] proposes leaps in health attainment by improving and increasing preventive, screening and health promotion services to 'healthy' citizens and by promoting and streamlining interactions between different services to ensure continuity of care. Improving access to healthcare and better synergy between primary and secondary care would translate in better health outcomes for the population at large.

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Original Article

Glycaemic control in children with type 1 diabetes mellitus in Malta (2013 - 2014)

Nancy Formosa, John Torpiano

Abstract

Background: Suboptimal glycaemic control, measured by glycosylated haemoglobin (HbA_{1c}), increases the risk for long-term complications in Type 1 diabetes mellitus (T1DM).

Aims and objectives:

- To calculate and compare glycaemic control in children with T1DM in Malta during the period 2013 to 2014.
- To identify any need for changing way services are structured and delivered.

Methods: An estimated 96% of all children with T1DM less than 16 years of age in Malta are cared for by the same paediatric diabetes team, based at the main state hospital. The average HbA_{1c} of all measurements taken every 3 months by HbA_{1c} analyser was calculated for each patient and these results were validated by annual laboratory measurement of HbA_{1c} from venous samples.

Results: Overall, 43.8% of participants in 2013 and 49.6% of participants in 2014 achieved an HbA_{1c} target of < 7.5%. The mean HbA_{1c} in 2013 was 7.69±0.16% and in 2014 7.67±0.17%. A higher proportion of patients in the younger age-group achieved an HbA_{1c} target of <7.5%. The patients most likely to have a higher HbA_{1c} were in the older age-groups.

Conclusion: Glycaemic control achieved in Malta in children aged < 16 years with T1DM was stable over the two years analysed. Our data is comparable, or slightly better, to that achieved in other European countries. However, there is always room for improvement, as Swedish data have shown. Multidisciplinary team meetings could be one way to address those patients not achieving adequate control.

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Keywords

Audit, Type 1, diabetes mellitus, paediatric, HbA_{1c}, Malta

Abbreviations

Type 1 Diabetes: T1DM

Introduction

Suboptimal glycaemic control in persons with Type 1 Diabetes Mellitus (T1DM) increases the risk for long-term complications.[1-3] The HbA_{1c} is the best indicator of long-term diabetes control. Every 1.0% point decrease in HbA_{1c} can reduce the risk of microvascular complications by 40%.[1] Intensive glycaemic control has been unequivocally proven to substantially lower the incidence of diabetes-related complications and extend life-expectancy.[4] International treatment guidelines recommend glycaemic targets to preserve health and reduce the risk of complications[5-6] however, many young people with T1DM fail to achieve these targets.[7-10] This audit, comparing glycaemic control in individuals less than 16 years of age with T1DM in 2013 and 2014, is the first report of its kind in Malta. It is the first step to compile annual data about T1DM in children in Malta, and provides a facility for monitoring and benchmarking of services and an opportunity to develop more effective treatment strategies.

Aim

- To examine current levels of glycaemic control in young people with Type 1 Diabetes in Malta

and compare our results with similar European data.

- To calculate the proportion of young people with Type 1 Diabetes in Malta who are attaining HbA_{1c} goals of < 7.5% (< 58mmol/mol) as recommended by the International Society for Paediatric and Adolescent Diabetes (ISPAD) and the American Diabetes Association.[5-6]
- To identify any need for changing the way services are structured and delivered with the ultimate aim of improving quality of care, glycaemic control and outcomes for children and adolescents with T1DM in Malta.

Methods

Study design and population

An estimated 96% of children with T1DM in Malta are seen by the paediatric diabetes team on a regular basis at the main state hospital. Demographic and clinical data of all patients newly diagnosed with T1DM are collected on a Microsoft Excel® spreadsheet and up-dated annually with new information such as average annual HbA_{1c} and Body Mass Index. In 2013, a point of care HbA_{1c} analyser (Siemens DCA Vantage®) was made available to the paediatric diabetes team, so that HbA_{1c} could be measured at each clinic visit, every 3 months. These results were validated by annual laboratory measurements of HbA_{1c} from venous samples.

The average HbA_{1c} ±95% CI of all the measurements taken in 2013 and 2014 was used in this study to assess overall glycaemic control. Multiple HbA_{1c} measurements have been used on each patient to give a more accurate assessment of diabetes control over the entire year of care, and to bring the analysis in line with other international reporting audits and registries, making benchmarking more representative. HbA_{1c} values using the Diabetes Control and Complications Trial (DCCT) aligned measures of percentage (%) were converted to the newer IFCC-standardised measures in mmol/mol using the formula: IFCC (mmol/mol) = (10.93 x DCCT (%)) - 23.50.

Results

Participants

In 2013, there were 137 children with diabetes mellitus <16 years of age registered with the paediatric diabetes team. Two children in the partial remission phase and thus having a low total daily insulin dose of <0.5 units/kg/day, three children with Wolfram Syndrome and four children with Type 2 diabetes were excluded from this study. The two children in the partial remission phase had an HbA_{1c} of 6.0% and 5.6% respectively and were excluded so that they would not bias the results. Thus, 128 children with T1DM were included in 2013 study.

In 2014, there were 135 children with diabetes mellitus <16 years of age registered with the paediatric diabetes team. Three children with Wolfram Syndrome and five children with Type 2 diabetes were excluded from analysis of the 2014 data. Thus, 127 children with T1DM were included in 2014 study.

Table 1 outlines the number of patients on our database in 2013 and 2014 respectively. The children were divided into 3 age-groups: 0-4.9 years, 5.0-11.9 years, 12-15.9 years. For the purpose of comparing results with other published studies the cohort of patients were also analysed in 3 other age groups 0-10.9 years and 11-15.9 years (Table 2), 0-12.9 years and 13-15.9 years (Table 3) and less than 6 years.

***Table 1**: Number of infants, children, and young people with T1DM by age band in 2013 and 2014*

	Age (years)							
	0-4.9		5-11.9		12-15.9		Total	
Year	**2013**	**2014**	**2013**	**2014**	**2013**	**2014**	**2013**	**2014**
Male	1	3	43	40	29	31	73	73
Female	2	2	30	28	23	23	55	53
Total	3	5	73	68	52	54	128	127

***Table 2**: The mean HbA_{1c} ± 95% CI achieved in the whole cohort, in boys and girls, and in the 2 age groups 0-10.9 and 11-15.9 years*

Year	2013	2014
Mean HbA_{1c}(%) ± 95%CI	7.69±0.16	7.67±0.17
Boys	7.76±0.19	7.72±0.14
Girls	7.59±0.26	7.60±0.26
0-10.9 years	7.53 ±0.16	7.53±0.17
11-15.9 years	7.85±0.26	7.80±0.29

***Table 3**: The proportion of children with T1DM in Malta who achieved target HbA_{1c} <7.5% compared to international data*

Age group (years)	<13		13-15.9	
Year	2013	2014	2013	2014
Total number of Maltese T1DM patients	85	87	43	40
Proportion achieving HbA1c <7.5% in Malta	45%	51.7%	39.5%	45%
USA data (Wood et al 2013[10])	27%		23%	
Swedish data (Samualsson et al 2013[11])	60%		36%	
TEENs Study[12]	32%		29%	
TEENs Study[13] (European Data)	39.4%		36.5%	

Insulin regimen

Over the 2-year period, 68% of participants were on a basal bolus regimen using insulin glargine and mealtime bolus doses of short-acting insulin. 32% were on a twice-daily insulin regimen using isophane and soluble insulins. Insulin pump technology is not yet available in Malta. All patients check blood glucose levels at least 4 times daily with their own portable glucometer.

Glycaemic control

In 2013, the mean HbA_{1c} achieved in our cohort of patients was 7.69±0.16% (61±1.75 mmol/mol). The boys had a mean HbA_{1c} of 7.76±0.19% (61±2.07 mmol/mol) and the girls had a mean HbA_{1c} of 7.59±0.26% (59.4±2.84 mmol/mol). The mean HbA_{1c} in the 0-10.9 year age group in this period was 7.53±0.16% (59±1.75 mmol/mol) with a comparable mean HbA_{1c} in boys of 7.51±0.23% (58.6± 2.5 mmol/mol) and in girls of 7.55±0.28% (59±3.06 mmol/mol). The mean HbA_{1c} in the 11-16 year age group in 2013 was 7.85±0.26% (62.3±2.84 mmol/mol). The boys had a mean HbA_{1c} of 8.04±0.3% (64.4±3.28 mmol/mol) and the girls had a better mean HbA_{1c} of 7.63±0.44% (60± 4.81 mmol/mol).

In 2014, the mean HbA_{1c} achieved in our cohort of patients was 7.67±0.17% (60±1.75 mmol/mol). The boys had a mean HbA_{1c} of 7.72±0.14% (61±2.07 mmol/mol) and the girls had a mean HbA_{1c} of 7.60±0.26% (60±2.84 mmol/mol). The mean HbA_{1c} in the 0-10.9 year age group in this period was 7.53±0.17% (59±1.75 mmol/mol) with a comparable mean HbA_{1c} in boys of 7.54±0.18 % (59±2.5 mmol/mol) and in girls of 7.51±0.32% (58.5±3.06 mmol/mol). The mean HbA_{1c} in the 11-15.9 year age group in 2014 was 7.8±0.29% (61.7±2.84 mmol/mol). The boys had a mean HbA_{1c} of 7.9±0.39% (62.8±3.28 mmol/mol) and the girls had a better mean HbA_{1c} of 7.68±0.4% (60.4± 4.81 mmol/mol). Table 2 summarises the mean HbA_{1c} ± 95% CI achieved in the whole cohort, in boys and girls, and in the 2 age groups 0-10.9 and 11-15.9 years.

In 2013, 43.8% (95% CI 35-52%) of our patients achieved an HbA_{1c} of < 7.5% (< 58mmol/mol). 41% (95% CI 30-52%) of males and 47% (95% CI 34-60%) of females achieved

target HbA_{1c}. Another 25% (95% CI 15-35%) of males and 29% (95% CI 17-41%) of females achieved an HbA_{1c} of 7.5 - 8% (58-64mmol/mol). The percentage of patients with an HbA1c of > 9.5% (> 80mmol/mol) was 4.6% (95% CI 1-8%).

In 2014, 49.6% (95% CI 41-58%) of our patients achieved an HbA_{1c} of <7.5% (<58mmol/mol). 44.6% (95% CI 33-56%) of males and 56.6% (95% CI 43-70%) of females achieved target HbA_{1c}. 18.9% (95%CI 12-26%) of our patients achieved an HbA_{1c} of 7.5 - 8% (58-64mmol/mol). The percentage of patients with an HbA_{1c} of > 9.5% (> 80mmol/mol) was 3.9% (95% CI 0.6-7.3%). These results are summarised in Figure 1. Figure 2 and 3 show the distribution of HbA_{1c} according to age group. Table 3 and 4 compare Maltese data with international data.

Figure 1: *Distribution of HbA_{1c} levels according to year*

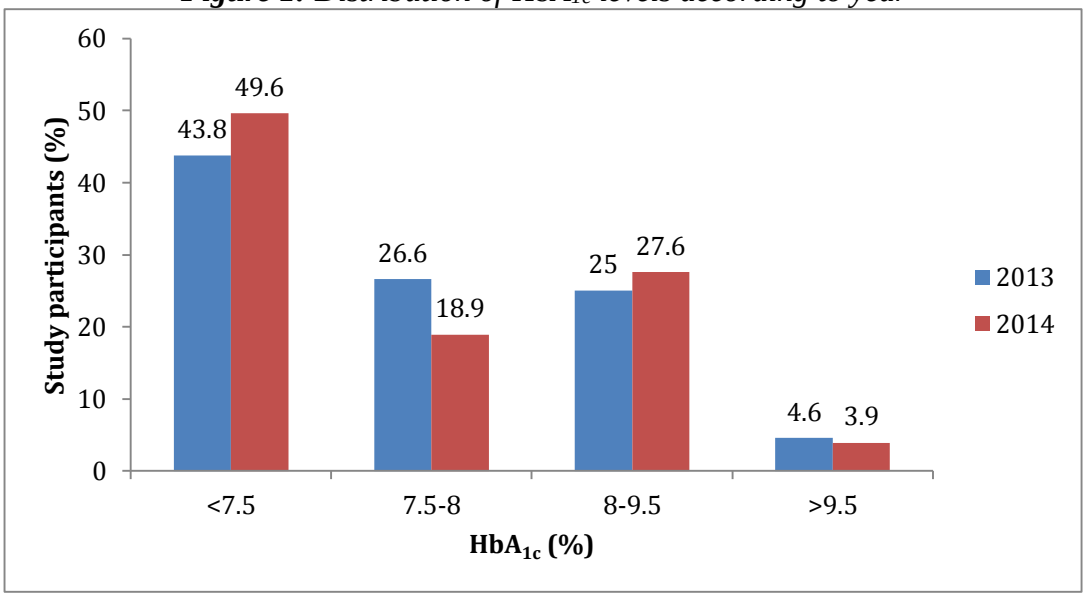


Figure 2: *Distribution of HbA_{1c} levels according to age group 2013*

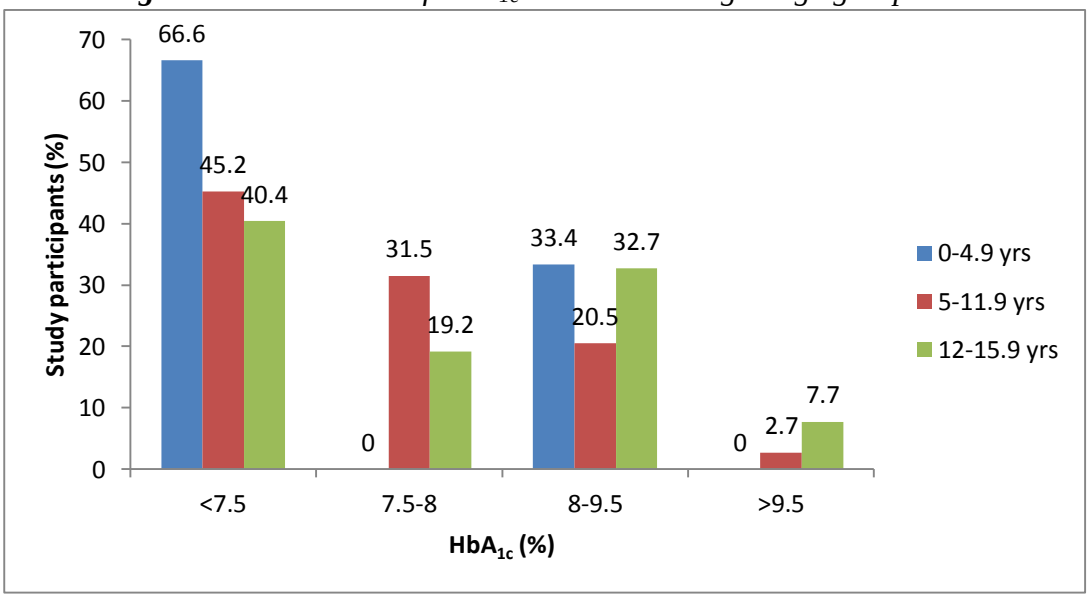
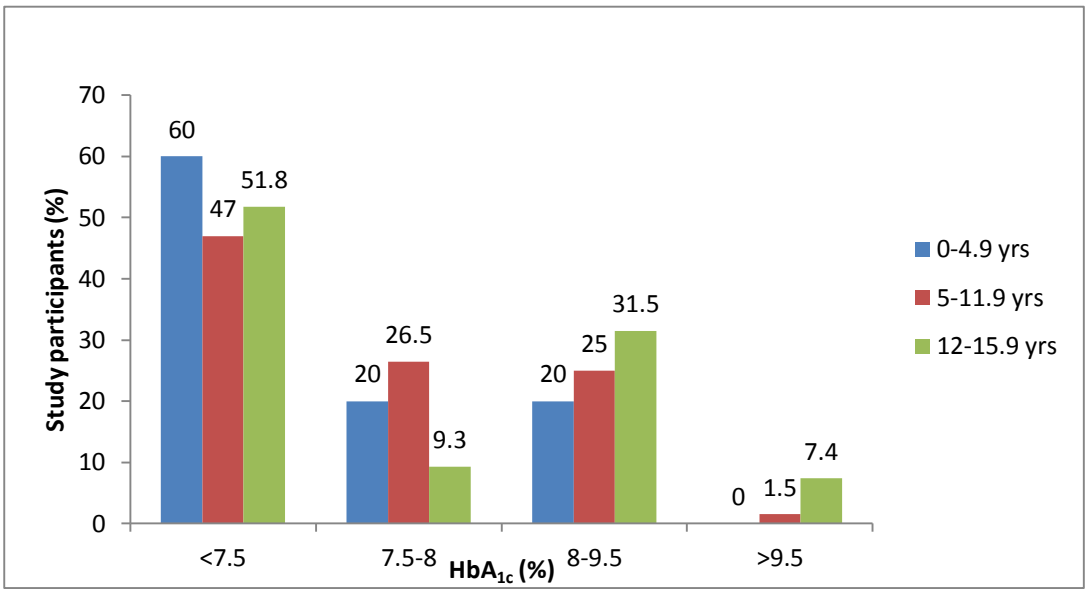


Figure 3: *Distribution of HbA_{1c} levels according to age group 2014*



Discussion

The National Paediatric Diabetes Audit Report carried out by the Royal College of Paediatrics and Child Health using data collected by diabetes units in England and Wales showed that the percentage of children and young people with T1DM achieving an HbA_{1c} of < 7.5% (< 58mmol/mol) was 15.8% in 2012-13 and 17.1% in 2013-14.[7-8] The percentage of children and young people with a very high HbA_{1c} (greater than 80 mmol/mol) putting them at high risk of developing diabetic complications has decreased from 25.8% in 2012/13 to 24.2% in 2013/14. There is significant variation in levels of HbA_{1c} across different units delivering care for infants and young people with diabetes in England and Wales with a mean HbA_{1c} ranging from 8.6 to 9% (70-75mmol/mol) in 2012-13 and from 8.5 to 8.9% (68.9-73.6mmol/mol) in 2013-14. The mean HbA1c for England and Wales was 8.8% (73mmol/mol) in 2012-13 and 8.7% (71.6mmol/mol) in 2013-14.[7-8] The mean HbA_{1c} achieved in our cohort of patients in 2013 was 7.69% (61mmol/mol) and in 2014 7.67% (60mmol/mol) (Table 4).

Table 4*: Maltese data compared to data from National Paediatric Diabetes audit report (England/Wales) 2012-2013[7] and 2013-2014[8]*

	Maltese data		**Data (England/Wales)**	
	2013	**2014**	**2012-2013**	**2013-2014**
Mean HbA_{1c} (%)	7.69	7.67	8.8	8.7
Proportion achieving HbA_{1c} <7.5%	43.8%	49.6%	15.8%	17.1%
Proportion achieving HbA_{1c} 7.5-9.5%	51.6%	46.5%	58.4%	58.7%
Proportion achieving HbA_{1c} >9.5%	4.6%	3.9%	25.8%	24.2%

Data from the German/Austrian Prospective Diabetes Follow-up Registry (DPV) showed that an HbA_{1c} of < 7.5% (< 58mmol/mol) can frequently be achieved in children with Type 1 diabetes who are less than 6 years of age.[9] 56% of children less than 6 years of age met the recommended HbA_{1c} goals of <7.5%. In our cohort of patients there were 16 children less than 6 years of age in 2013. 10 out of these 16 i.e. 63% (95% CI 39-86%) achieved an HbA_{1c} < 7.5% (< 58mmol/mol), 2 out of 16 had an HbA1c of 7.5-8% (58-64mmol/mol) and 4 out of 16 had an HbA1c of > 8% (> 64mmol/mol). In 2014, there were 7 children less than 6 years of age. 5 had an HbA_{1c} < 7.5%. The other 2 had an HbA_{1c} of

7.6% and 8.8% respectively.

In the United States, only 27% of children younger than 13, and 23% of those between 13 and 19 years of age, meet the recommended HbA_{1c} goals of < 7.5% (< 58mmol/mol).[10] On the other hand, in Sweden, 60% of those younger than 13 and 36% of individuals between 13 and 18 years had an HbA_{1c} < 7.5% in 2013.[11] In Malta, 39 out of 85 (i.e. 45%) and 45 out of 87 (i.e. 51.7%) children with T1DM <13 years of age achieved an HbA_{1c} < 7.5% (< 58mmol/mol) in 2013 and 2014 respectively. 17 out of 43 (i.e. 39.5%) and 18 out of 40 (i.e. 45%) of young people with T1DM 13-16 years of age achieved the target HbA_{1c} in 2013 and 2014 respectively (Table 3).

The TEENs study, funded by Sanofi, is one of the largest ever to assess T1DM management and the factors that affect it, including psychosocial parameters. The data comes from 5960 individuals aged 8 to 25 years seen at 219 diabetes centers in 20 countries in the developed and the developing world, including Europe, the United States, Latin America, the Middle East, North and South Africa, and India. Results of the TEENs Registry Study were presented at the American Diabetes Association (ADA) 2014 Scientific Sessions by Professor Lori Laffel.[12] Average HbA_{1c} levels were 8.3% for the 1724 children aged 8 to 12 years and 8.6% for the 2854 adolescents aged 13 to 18 years. The proportions reaching the recommended targets were 32% of the younger children and 29% of the teens. Overall, 72% were not meeting the targets. 18%, nearly 1 in every 5 patients, had HbA_{1c} levels of 10% (86mmol/mol) or higher.[12] The 2943 European youths from 11 centers involved in the TEENs study had a mean HbA_{1c} of 8.1±1.6% (65.0±17.5 mmol/mol).[13] The mean HbA_{1c} varied by age: 7.9±1.4% (62.8±15.3 mmol/mol) in the 8-12-year age group, 8.2±1.7% (66.1±18.6 mmol/mol) in the 13-18 year age group. One-third of participants achieved HbA_{1c} targets (39.4% in the 8-12-year age group, 36.5% in the 13-18 year age group).

Conclusions and recommendations

This audit report shows that glycaemic control achieved in Malta in infants, children and young people with T1DM was stable over the 2 years analysed. Our results are comparable, or better, to that achieved in other European countries and the United States of America. However, there is always room for improvement as the Swedish data[11] have shown, and we should continue to strive to increase the proportion of our patients achieving the recommended target HbA_{1c} < 7.5% (< 58mmol/mol). Recently, the National Institute of Clinical Excellence (NICE) has set even lower HbA1c targets of 6.5% (48mmol/mol) for young people with T1DM.[14]

The TEENs study has identified many modifiable factors which significantly predict HbA_{1c} target achievement.[12] These have been summarized in Table 5. Up to the middle of 2015, protocols by the Maltese Department of Health mandated that only isophane and soluble insulins could be funded for patients at the outset of T1DM diagnosis. Insulin analogues would only be funded after a minimum period of 6 months from initial diagnosis, and only if a number of strict clinical criteria were met. Since 2015, we have been allowed to start patients on insulin analogues from diagnosis. Over the last few years in our clinical practice, there has been a move towards intensification of insulin therapy including the use of multiple daily insulin regimens and the introduction of insulin dose adjustment for carbohydrate intake which, however, is still in its infancy in Malta as more input by dietitians is required.

All patients are advised to check capillary blood glucose at least 4 times every day, and the overwhelming majority of our patients comply with this advice. Since September 2014, the number of blood glucose strips provided free-of-charge, for individuals under 18 years of age with T1DM in Malta, was increased to 4 per day. This reduced the financial burden of this essential practice and also served as an incentive for regular monitoring of capillary blood glucose levels. All of our patients are taught how to adjust insulin doses according to capillary blood glucose results so that persistent dysglycaemia is avoided at most times. Patients are also advised to contact our diabetes team if they do not feel confident in making any necessary adjustments themselves. Clinic visits are frequent, every 2-3 months depending on need. The significance of HbA_{1c} results is explained to patients and treatment goals are clearly defined as target-setting has been shown to improve metabolic outcome.[15] Patients with unacceptably high HbA_{1c} levels are admitted to hospital for a short period to stabilise their blood glucose. During their in-patient

stay they meet with the diabetes multidisciplinary team to re-inforce diabetes education. A clinical guideline on how to treat patients with a high HbA_{1c} will be formulated and put into practice.

***Table 5**: Factors significantly predicting HbA_{1c} target achieved from TEENs study*[12]

Demographic factors	***p*<0.001**
Absence of financial burden related to T1DM management	
Shorter T1DM duration	
Age <12 years	
Treatment factors	***p*≤0.005**
Pump therapy	
Blood glucose monitoring >3 times daily	
CHO counting	
Exercise >30 minutes/week	
No history of DKA in the past 3 months	
Family factors	***p*<0.019**
Parental involvement in T1DM care	
Absence of diabetes specific family conflict	
Living with 2 parents in the home	

In the coming year, we would wish to start organising multidisciplinary team (MDT) meetings to discuss patients who are not achieving the recommended treatment goals on an individual basis. The aim of these meetings is to come up with an individual care plan to help such patients improve glycaemic control: changing the insulin regimen, reinforcing structured diabetes education, offering support to the family/patient to help them in self-management tasks, telephone contact in between clinic visits, psychological help, identifying psychosocial dysfunction within families and enrolling the help of psychologist/social worker to work through the issues. We do not have these MDT meetings regularly as yet because of a significant lack in human resources, especially with regard to diabetes nursing staff. This shortage in human resources needs to be addressed by the Department of Health and our hospital's administration.

We need to set up a formal annual review so that all of the seven key processes of diabetes care: HbA_{1c}, BMI, blood pressure, urinary albumin, lipid screening, eye screening, and foot examination are done regularly and systematically as stipulated by international guidelines.[5,14] The audit data, including also acute complications such as diabetic ketoacidosis and severe hypoglycaemia, will be collected and analysed annually to assess whether the changes implemented have resulted in an improvement in outcome for children and adolescents with T1DM in Malta.

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Original Article

Treatment of psoriasis with biologic agents in Malta

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Abstract

Introduction: Biologic therapy has revolutionalised the treatment of moderate to severe psoriasis leading to improved clinical outcomes and quality of life scores. This study aims to determine current biologic use in psoriatic patients at our Dermatology department at Sir Paul Boffa hospital, Malta.

Method: All patients who were administered biologic therapy for psoriasis in Malta until the end of 2014 were included. Data included demographic details, disease duration and severity, biologic use and duration, previously attempted treatments, side effects, early and late response to biologic using Psoriasis Area Severity Index (PASI) scores and Dermatology Life Quality index (DLQI) scores.

Results: A total of 36 patients were started on a biologic between 2009 and 2014 for psoriasis (M:25, F:11) with a mean age of 46.9 years. These included etanercept (*n*=22), infliximab (*n*=8), adalimumab (*n*=4) and ustekinumab (*n*=2). Secondary failure was the main reason why biologics were stopped and switched. Most patients had an improvement in their PASI scores after 2 to 4 weeks of starting the biologic and had a PASI 90 score improvement. All patients had more than a 5 point improvement in DLQI score.

Discussion: Biologic use in our department is on the increase. Our patients had considerable improvements in their PASI and DLQI scores. Secondary failures have occurred usually after 2 to 4 years and switching has yielded positive results. Biologics are expensive drugs and recently we have switched to cheaper biosimilars. Doctors should be aware of the treatment options available for psoriasis patients, their possible side effects and when to refer to our department. In most cases a satisfactory response can be achieved.

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Keywords:
psoriasis, biologics, Malta

Introduction

Treatment of psoriasis has improved dramatically over the past few years with new options becoming readily available. First line treatment includes topical therapy followed by ultraviolet (UV) therapy, with acitretin and the oral immunomodulators methotrexate and ciclosporin, as second line interventions.[1] Biologics have revolutionised the management of severe psoriasis offering improved clinical outcomes and quality of life scores. They target specific immune pathways in the pathophysiology of psoriasis. These are expensive drugs, with typical drug cost ranging from 10,000€ to 18,000€ per patient per year.[2]

Current local guidelines (based on European and UK guidelines) recommend four biological

agents in psoriasis. These are indicated in patients with moderate to severe psoriasis who have failed or are intolerant of other treatment options. These include infliximab, etanercept, adalimumab and ustekinumab.[1,3] Secukinumab and the cheaper biosimilars of infliximab have also been recently approved for use in psoriasis.[4] New biologic agents are constantly being developed targeting different immune pathways (Table 1). A cheaper biosimilar of adalimumab is expected to be available in 2018 when the European patent of the originator drug (Humira©) expires.

***Table 1**: Biologics approved in psoriasis, year of FDA approval, mode of action and other approved indications (until date of submission)*

Biologics for Psoriasis (Year of FDA approval)	Mode of Action, Dose and Administration	Other Approved Indications
1. Etanercept (Enbrel®) *(2004); adults and children >6yrs*	TNF alpha blocker; 50mg (0.8mg/kg) s.c. once a week	Rheumatoid arthritis, Psoriatic arthritis, Juvenile Idiopathic Arthritis, Ankylosing spondylitis
2. Infliximab (Remicade®) *(2006)* *Remsima™(EMA approved 2013)* *Inflectra™ (EMA approved 2013)*	TNF alpha blocker; 5mg/kg i.v. infusion at weeks 0, 2, 6 and then every 8 weeks	Rheumatoid Arthritis , Ankylosing spondylitis, Psoriatic arthritis, Inflammatory Bowel Disease
3. Adalimumab (Humira®) *(2008)*	TNF alpha blocker; 80mg s.c., followed by 40mg every 2 weeks	Rheumatoid arthritis, Juvenile Idiopathic Arthritis, Psoriatic arthritis, Ankylosing spondylitis, Inflammatory Bowel Disease
4. Ustekinumab (Stelara®) *(2009)*	Interleukin 12 & 23 blocker; 45mg (90mg if >100kg) s.c., repeated after 4 weeks, and then every 12 weeks	Psoriatic arthritis
5. Secukinumab (Cosentyx®) *(2015)*	Interleukin 17A blocker; 300mg s.c. at weeks 0, 1, 2, and 3 and then every 4 weeks	Nil

Since biologics are expensive drugs, cost effectiveness is an important factor to consider in the commencement and availability of these drugs. Clear evidence-based eligibility criteria are important to target the appropriate psoriatic population.

The Psoriasis Area Severity Index (PASI) score is used to assess disease severity and response to treatment in psoriasis. A PASI score of $\geq$10 (range 0–72) has been shown to correlate with a number of indicators commonly associated with severe disease such as need for hospital admission or use of systemic therapy.[1] Satisfactory response is usually considered to be a 75%, or even better, a 90% improvement as compared to baseline score. This is reported as PASI 75 and PASI 90 respectively. The Dermatology Life Quality index (DLQI) score is a validated tool to assess the impact of skin diseases ranging from 0 to 30, with scores more than 10 indicating a significant impact on quality of life.

Biologic use in Malta started in 2009 and this study gives an overview of the patient characteristics and clinical outcomes to date.

Aim

A cross sectional study to determine current biologic use in psoriasis: a local perspective.

Method

All patients who were administered biologic therapy for psoriasis in Malta until the end of 2014 were included in the study. Patients who were started on a biologic for psoriatic arthritis by the rheumatologists were excluded. Data collected included gender, age, nationality, biologic used, date of commencement, concomitant medications, disease duration prior to biologic, associated co-morbidities, previously attempted treatments, reason for stopping previous treatments, investigations before starting a biologic, early and late response to biologic using PASI and DLQI scores and side effects reported.

Results

There were a total of 36 psoriasis patients who were started on a biologic between 2009 and 2014 (N=36); 25 of the patients were male, 11 were female. They were all patents with stable chronic plaque psoriasis and none had the erythrodermic or pustular forms. Twenty-two of these patients were on etanercept, 8 patients were on infliximab, 4 patients were on adalimumab and 2 patients were on ustekinumab. The biologic was indefinitely discontinued in 12 out of these 36 patients. Reasons for discontinuation included patients going abroad indefinitely, death from other causes, non-compliance, patient refusal and worsening of heart failure post myocardial infarction. In 2014, there were 24 patients who were on biologics for psoriasis: 14 were on etanercept, 6 were on infliximab and 4 on adalimumab.

The ages of the 36 patients ranged from 19 to 70 years, with a mean age of 46.9 years and a median of 46 years. Twenty-nine of the patients were Maltese, two were Canadian, three patients were from the UK and two patients were Italian. The patients were on a variety of concomitant medications with methotrexate being the commonest (*n*=14). Disease duration prior to biologic therapy ranged from 2 to 55 years, with a mean of 16.7 years and a median of 14 years. Six of the patients had psoriatic arthritis as a later co-morbidity, but were started on a biologic by a dermatologist.

Psoriatic treatments attempted before the current biologic included: phototherapy [narrow band UVB (28) or psoralen UVA (4)], methotrexate (29), acitretin (16), ciclosporin (15), etanercept (4), infliximab (2) and ustekinumab (2). The reason for stopping these medications included: inadequate control (24) and side-effects from methotrexate (6), ciclosporin (5) and acitretin (4). Secondary failure was the main reason why biologics were stopped and switched.

All patients had routine bloods, hepatitis screen, tuberculosis screen (Mantoux or Quantiferon and Chest X-ray) taken, according to protocol. HIV testing is done in high risk patients and ANA testing is carried out if indicated. Patients on infliximab are seen every two months in the dermatology ward whilst the patients on other biologics are usually seen according to response and and according to whether they are on concomitant methotrexate. Quantiferon test is not done annually and none of the patients had latent TB.

Most patients had an improvement in their PASI scores after 2 to 4 weeks of starting the biologic. Currently, of the 14 patients on etanercept, 57% (*n*=8) achieved a PASI 90, 29% (*n*=4) have a PASI 75 and 14% (*n*=2) had secondary failure after 2 years. Of the 8 patients on Infliximab, 63% (*n*=5) had a PASI 90, 25% (*n*=2) had a PASI 75 and 13% (*n*=1) had secondary failure after 1 year. There were 4 patients started on adalimumab in 2014; 3 of them achieved a PASI 90 and 1 patient achieved a PASI 75. All our patients had more than a 5 point improvement in DLQI score. Facial and periorbital swelling, lethargy and a chest infection were reported as possible side effects with etanercept. No side effects were reported for infliximab, adalimumab and ustekinumab. Injection site or infusion reactions, reactivation of tuberculosis, severe infections and sepsis were never reported as side effects for any biologic used.

Discussion

Biologic use in our department is on the increase but is heavily determined by the treatment options listed on the national health formulary and available resources.

Biologic use for psoriasis in Malta started in 2009, with etanercept being the first biologic available, followed by infliximab in 2011 and later adalimumab in 2014. Etanercept stopped being available for new psoriasis applications in 2013, but patients doing well on etanercept continued to receive it. Ustekinumab was never available on the national health system - the two patients on ustekinumab in this study had the drug provided for them through private arrangements which were subsequently withdrawn. In our study, patients on biologics were predominantly male (69% male, 31% female), suggesting that men are at a higher risk for severe psoriasis. This is also the situation in other countries.[5-6]

This study shows that our department is following the latest guidelines. Our patients are first treated with topical therapy, then phototherapy or second line agents including methotrexate, acitretin and ciclosporin. If these fail, are contraindicated or cause intolerable side effects, a biologic is started. It is interesting to note that most patients had an adequate (≥75% decrease in PASI score) and sometimes impressive response initially to the biologic, with most patients achieving complete or

almost complete clearance of their psoriasis. There were a few patients whose psoriasis started to relapse (described as secondary failure) after 2 to 4 years of successful treatment with the biologic, that necessitated switching to another biologic to maintain control of the psoriasis. Switching between biologics that act on the TNF alpha pathway, such as etanercept to infliximab or adalimumab, and infliximab to adalimumab or etanercept, has yielded positive results in these few cases in our department.

There is evidence that concomitant treatment with methotrexate might increase biologic efficacy by reducing the antigenicity towards biologics and their clearance.[7-8] Sixty-one percent of our patients on biologics are on concomitant methotrexate therapy, usually at low dose (often 7.5 mg per week). In our experience there were never any serious side effects reported and this combination has been working well.

In 2015, patients who were started on a biologic in the previous years will be kept on the same treatment whilst new patients will be started on the cheaper biosimilar of infliximab (Remsima™) as determined by our national health system. This should result in a 30 percent decrease in the total cost of biologic therapy per patient per year. Future considerations to increase cost-effectiveness of psoriasis treatments include the provision of psychological support in this often stress-related condition and nursing support with topical medications, especially in the elderly. It is also important to follow up patients regularly so that treatment failures can be identified early and treatment changed accordingly. Testing of drug and antibody levels will probably play an important role in optimizing treatment in the near future. [9-10] For example, it has been estimated that one-third of patients on standard doses of adalimumab have drug levels higher than the therapeutic range.[11]

In the case of severe side-effects with Remsima™, or if primary or secondary failure develops to it, an application to the Exceptional Medicinal Treatment Committee (Directorate for Pharmaceutical Affairs) would need to be made to allow switching to another biologic. This could be to another TNF alpha blocker (Adalimumab or Etanercept) or to a biologic acting on a different immune pathway (Ustekinumab or Secukinumab). A limitation to the availability of all of these biologics on the National Formulary is, of course, their high cost.

Conclusion

Psoriasis is a chronic condition that can have a significantly negative impact on quality of life. Our patients had considerable improvements in their PASI and DLQI scores with biologic treatment. It is important that primary care doctors are aware of the treatment options available for patients with psoriasis, their possible side effects and when to refer patients to our department. In most cases a satisfactory response can be achieved.

*Figure 1: Patient with psoriasis **before** biologic treatment*

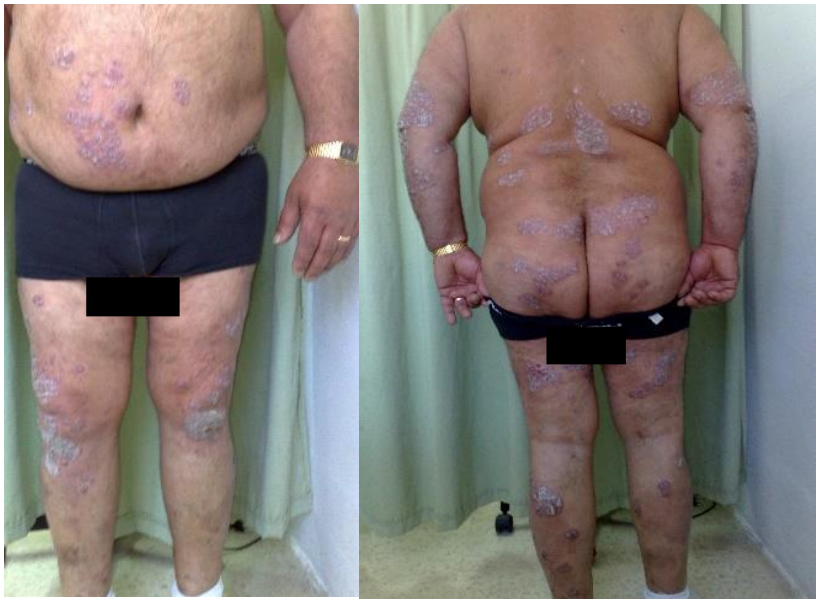
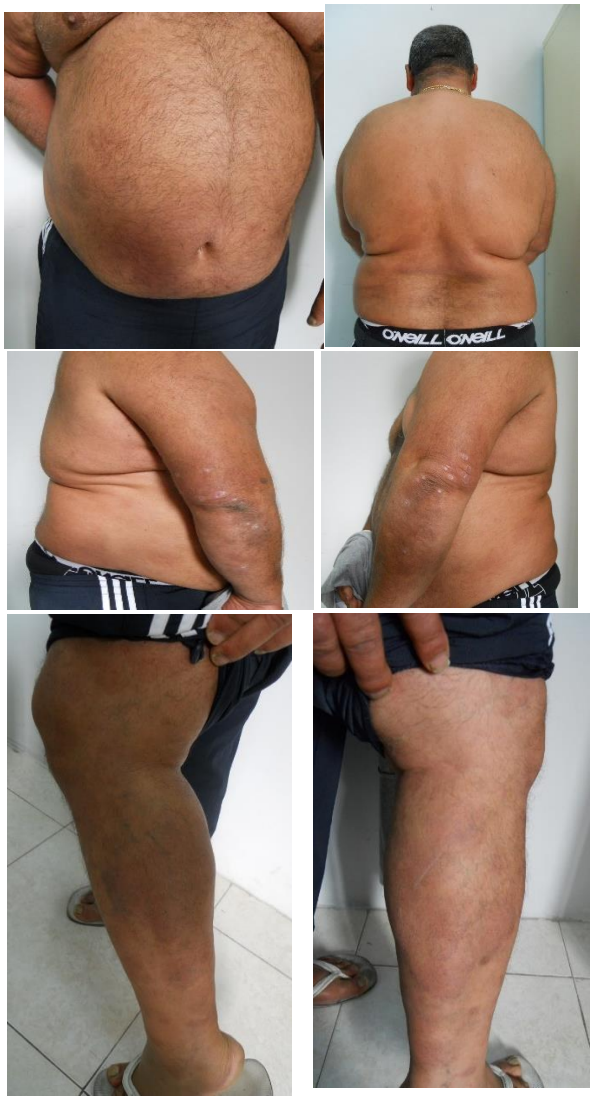


*Figure 2: Patient clear from psoriasis 6 months **after** commencing biologic treatment with Ustekinumab*



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Original Article

A review of attendances at Paediatric Accident and Emergency Department at Mater Dei Hospital for neurological complaints Patient

Bettina Duca, Amaris Spiteri, Adriana Cappello, Stephen Attard

Abstract

Aims: Attendances at paediatric accident and emergency department (A&E) during a six month period were reviewed to determine the proportion of children with neurological complaints, type of symptoms and the outcomes in terms of admissions, discharges and out-patient referrals.

Methods: Neurological complaints were classified as (a) febrile convulsions, (b) unprovoked seizures, (c) status epilepticus, (d) headaches, (e) altered consciousness, (f) acute ataxia, (g) flaccid weakness, (h) visual loss, or (i) others. Outcomes of these attendances were also recorded as either admission, referrals to out-patient clinics or discharges from A&E.

Results: A total of 7670 children attended paediatric A&E during the study time of which 352 (4.5%) presented with neurological complaints. 173 children (49%) presented with headache, 54 (15.3%) presented with unprovoked seizures, 51 (14.4%) presented with febrile convulsions, 34 (9.6%) presented with altered consciousness and the remaining 40 children (11.7%) presented with various other complaints. 24.8% of children who presented with headache were admitted, 34.1% were referred to out-patient clinics and 41% were discharged. In contrast, 75.5% of children you presented with unprovoked seizures were admitted, 22.2% were referred to out-patient clinics and 3.7% were discharged. There were no deaths.

Conclusion: 1 in 20 children who attended paediatric A&E presented with neurological complaints. One half of these children presented with headache, around one third presented with seizures (febrile and unprovoked), around 10% presented with altered consciousness. Around a half of these children were admitted, a quarter were discharged home and the other quarter were referred to out-patient clinics.

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Key Words

Emergency Service, Hospital; Neurologic Manifestations; Paediatrics

Introduction

The development of specialized health services translates into a better holistic service for patients. T he introduction of paediatric sub-specialities at Mat er Dei Hospital (MDH) is an important developmen t in paediatric health care in Malta. Periodic review is necessary in order to encourage further service de velopments or improvements in quality of such pae diatric specialist services.

There is a paucity of literature about attendance s at paediatric Accident and Emergency (A&E) for neurological complaints, both on a local as well as

on an international level. We looked at attendances at paediatric A&E at MDH for neurological complai nts, with the aim of determining the following:

a. The number of children with neurological com plaints, and their ages
b. The proportion of children who presented with neurological complaints when compared to the total attendees at paediatric A&E
c. The main type of complaints
d. The proportion of admissions, discharges and o ut-patient referrals.

Methods

This was a prospective case-note review of all paediatric A&E attendances for neurological compl aints over a six month period from January to June 2013. Details of patient age, gender, main symptom s and main outcome of all such A&E episodes were compiled. The main presenting symptoms were cla ssified as follows:

- Febrile convulsions
- Unprovoked seizures
- Status epilepticus
- Headaches
- Altered consciousness
- Acute ataxia
- Flaccid weakness
- Visual loss
- Others

This data was compiled using standard audit for ms and all data was analysed using Microsoft excel.

Results

A total of 7670 children attended paediatric A&E during the six month period between Jan 2013 and June 2013. Of these, 352 children (4.5 %) had one or more neurological complaints. Patients' ages ranged from 2 months to 16 years with a mean age of 6 years and a standard deviation of 4.7 years. 45% were female and 55% were male. (Table 1)

173 children (49%) presented with headache, 54 (15.3%) presented with unprovoked seizures, 51 (14.4%) presented with febrile convulsions and 34 (9.6%) presented with altered consciousness. These four types of complaints accounted for 88.3% of all paediatric attendances for neurological complaints during the study period. The remaining 40 children (11.7% of attendees) presented with various other complaints: Acute ataxia (4 cases), visual loss (3 cases), head lump; neck pain; ptosis; Marcus Gunn phenomenon; sudden inability to bear weight; torticollis and occipital swelling (6 cases).

Looking at these attendances as a whole, 43.4% were admitted, 27.6% were discharged home and 29.4% were referred to out-patient clinics. Only one child required ITU admission, and there were no deaths. Of the admissions, 75% of attendees were admitted under the care of the general paediatric consultants, and 25% of attendees were admitted under the care of the paediatric neurologist.

Further analysis of the most common neurological complaints

A. Headache complaints

173 children (49%) attended paediatric A&E with headache symptoms of which 90% were over 4 years of age. 24.9% were admitted, 41.2% were discharged and 34.3% were referred to out-patient clinics. Of the admissions, 79.1% were admitted under a general consultant and 20.9% were admitted under the neurology consultant. (Table 1)

B. Unprovoked seizures

53 children (15.3%) attended paediatric A&E with unprovoked seizures. The majority of patients (68%) were under 8 years of age, and the remaining 32% of patients were 8 to 16 years of age. There was only one case of status epilepticus. 75.5% were admitted, 22.6% were referred to out-patient clinics and 3.7% were discharged. Of the children with unprovoked seizures who were admitted, 47% were admitted under the care of the general paediatric consultants, and 53% were admitted under the paediatric neurologist.

C. Other complaints

The remaining 11.7% of attendees presented with the following complaints: acute ataxia (4 cases, 1.1%), visual disturbance (3 cases, 0.8%), status epilepticus (1 case, 0.28%) and other miscellaneous complaints: head lump, neck pain, ptosis, Marcus-Gunn phenomenon, sudden inability to bear weight, torticollis, occipital swelling and non-specific headache associated with other complaints (32 cases, 9%).

***Table1**: This table shows main findings of this review of Paediatric A&E attendances for neurological complaints*

	Neurological complaints	%	% of total no of children attending paediatric A&E From Jan to June 2013
Total no of children attending Paed A&E	7670	-	-
Children presenting with neurological complaints	352	-	4.5
Gender			
Male	191	45	-
Female	161	55	-
Headache	173	49	2.3
Discharged	71	41	-
Referred to Out-patient clinics	59	34.1	-
Admitted (total)	43	24.8	-
Admitted under General Paediatricians	34	79	-
Admitted under Neurology Consultant	9	21	
Seizures	105	29.8	1.3
Unprovoked seizures	54	15.3	0.7
Discharged	2	3.7	-
Referred to Out-patient clinics	12	22.6	-
Admitted (total)	40	75.5	-
Admitted under General Paediatricians	19	47	-
Admitted under Neurology Consultant	21	53	-
Febrile seizures	51	14.4	0.7
Altered consciousness	34	9.6	0.4
Other presenting complaints	40	11.6	0.52

Discussion

The study has shown that 4.5% of children who attended Paediatric A&E at Mater Dei Hospital during the period January 2013 and June 2013 presented with neurological complaints.

Headache accounted was the most common presenting complaint (49%) and 25 % of this group required hospital admission and further investigation. In contrast to unprovoked seizures, attendance to A&E was uncommon under 3 years of age. Headache accounted for 2.25% of all paediatric medical A&E attendances and in comparison to other studies, headache seems to be commoner in our cohort. For instance, the proportions of children presenting with headache reported by Burton et al [1], Kan L et al [2] and Conicella et al [3] were 1.3%, 0.7% and 0.8% respectively. This comparison needs to be interpreted with caution as our study period was only 6 months and our setting may be very different from other centres. It is plausible that given that A&E is relatively very accessible in Malta when compared to other countries, children with functional headache and also anxiety related headache may be over-represented in our cohort. 45% of patients who presented with headache were referred to outpatient clinics, raising the question of how of many these patients could potentially be managed on a non-urgent basis by GPs or their paediatricians on an out-patient basis.

Unprovoked seizures and febrile convulsions were the second most common cause of attendance to paediatric A&E for a neurological complaint. 105 children attended with seizures and roughly half of these were febrile seizures and half were

unprovoked seizures (first unprovoked, epileptic seizures or other non-epileptic events). (Table 1) This accounts for 1.36% of all paediatric A&E attendances during the six month study period. In contrast to headache patients, children with seizures tended to be young, i.e. 1 to 7 years of age. This observation may be explained by the fact that half of the group of children with seizures had febrile convulsions which tend to present between the 2nd and 5th years of life. It is also known that certain forms of epileptic seizures also tend to present in certain age groups, and that overall epilepsy tends to present in the first few years, declines towards the latter part of the first decade and rises again in adolescence. These factors may also have shifted the age of presentation of seizures to the lower age groups in this cohort.

Martindale JL et al [4] found that 2% of all paediatric A&E attendances were for seizures, while Smith LJ et al [5] found that A&E attendances in children over one year of age accounted for 1.2% of all district general hospital A&E attendances. This suggests that our cohort compares well with the literature.

10% of our cohort presented with altered consciousness and this accounts for 0.4% of all paediatric attendances to A&E. (Table 1) Although the numbers are small, the data shows a tendency for this problem to be commoner in the older age groups in this cohort. Altered consciousness calls for prompt recognition, admission, careful monitoring and appropriate investigation, especially in young and non-verbal children. There is a clear lacuna in the literature about paediatric attendance at A&E for altered consciousness. In adults, Kanich W et al 2002 [6] reported that altered consciousness accounts for 5% of all adult medical A&E attendances. In contrast, Kekec et al 2008 in another adult study reported that 0.57% of all A&E attendances had altered consciousness and that 6% of these patients i.e. 0.003% of all attendances were under 14 years of age[7].

Regarding the outcomes of attendances to paediatric A&E with neurological complaints, there were no deaths during the six month period of this study. The majority of children who attended with headache were discharged, referred to out-patient clinics, or in a smaller proportion of cases admitted under the care of the general paediatric consultants. In contrast, children you presented with unprovoked seizures were either admitted under the care of the paediatric neurologist and the general paediatricians in roughly equal proportions, or referred to out-patient clinics, but only rarely discharged.

The strengths of this study are that given that paediatric A&E at MDH caters for the whole of the Maltese population (including urgent referrals from the private sector), this data is representative of the whole paediatric population in Malta. Moreover, data collection was performed prospectively using clear and consistent criteria, and the results have answered the research questions clearly. This information is clinically relevant and may influence future administrative decisions about paediatric services at MDH.

Although 352 attendances is not a small number, 6 months as the duration of this study is a relatively short period of time.

This review invites further research particularly about the frequency and quality of management of neurological emergencies in A&E, particularly status epilepticus. This could be approached through an audit of the management of status epilepticus, taking NICE guidelines and other guidelines as the standards. Further review of children attending paediatric A&E with headache may be called for, looking at their final diagnoses as classified by the International Classification of Headache, the level of functional disability, referral patterns to out-patient clinics and interim management. This could be approached with a prospective study that looks into level disability at the time of presentation, childrens' and families' perception of the symptoms during the interval until they are reviewed in clinic and their final diagnoses.

Regarding patients presenting with seizures, further review of final diagnoses and referral pattern to out-patient clinics will be useful, particularly with a view to see whether the introduction of a first seizure clinic would improve patient management and waiting time.

Conclusion

This review of a group of 352 children who attended paediatric A&E at MDH for neurological complaints during a six month period shows some important points. During this period, around 1 in 20 children seen at paediatric A&E presented with neurological complaints. One half of these children presented with headache, around one third presented with seizures (febrile and unprovoked), and the rest presented with altered consciousness

and other complaints. Around a half of these children were admitted (including one child who required admission to intensive care unit), a quarter were discharged home and the other quarter were referred to out-patient clinics. There were no deaths.

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Original Article

Orthogeriatrics in Malta: a 3 year experience

Paul Zammit, Peter Ferry, John Cordina, Mark Vassallo, Stephanie Dalli, Antoine Vella, Vincent Bugeja, Jeffrey Muscat, Kristian Zammit

Abstract

The orthogeriatric service in Malta started in 2012 and expanded in 2014. From admission, the patient is offered a ward based hip fracture programme that includes orthogeriatric assessment, management and co-ordinated multidisciplinary review.

457 patients were seen by the orthogeriatric service when this study was done. Mean age was 83 and 69% of patients were female. The Nottingham Hip Fracture Score (NHFS) is a scoring system that reliably predicts 30-day and 1-year mortality for patients after hip fracture. It is made up of seven independent predictors of postoperative mortality that have been incorporated into a risk score. The score ranges from 0-10 and the mean score for this cohort was 5.1. There was a statistically significant correlation between age and high NHFS scores. 30 day mortality was 5.9% and 1 year mortality was 24.4%. Compared with the Nottingham data both 30 day and 1 year mortality were less for the orthogeriatric department in Malta.

The orthogeriatric service in Malta achieved better results when comparing mortality with the UK. In the future expansion of data collected should be considered to better evaluate standards of care in the department.

Keywords

Orthogeriatrics; Hip fractures; Mortality; Older people.

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Introduction

Hip fractures are associated with significant morbidity and mortality. Approximately 10% of patients who have a neck of femur fracture die within a month from the traumatic event, and 30% within a year. About half of these patients do not return to their pre-fracture level of mobility and only half eventually return home. 80% of older women say they would rather die than experience the loss of independence and quality of life associated with a hip fracture. It is common as well as expensive with 80,000 hip fractures and direct costs of 2 billion pounds each year in the United Kingdom.[1]

Orthogeriatrics is the subspeciality area in geriatrics involved in the care of older people with fragility fractures.[2] It was introduced when it was found that that there was a need to improve the efficiency and quality of hip fracture injury treatments and care of patients involved with such injuries. To this end, the geriatricians and orthopaedic surgeons organized an effort toward forming so called "orthogeriatrics" collaboration in various countries.

Orthogeriatrics offers to fragility fracture patients' pre-operative assessment/optimisation, management of peri-operative complications, rehabilitation, as well as falls and bone health assessments.[3] It has been shown that a good service reduces mortality, complications, length of stay and improves functional outcomes such as mobility and return to independence.[1]

Orthogeriatrics in Malta

The orthogeriatric service in Malta was started in January 2012 with the introduction of a 6 bedded unit within an acute orthopaedic ward. Elderly over the age of 60 with a proximal fracture femur were eligible for this unit. The service was run by the geriatric department in collaboration with orthopaedic department. Daily proactive ward rounds by the geriatricians were done and the patient was seen till discharge to their home or to a rehabilitation unit.

The service was expanded in February 2014. All older people with a proximal hip fracture over the age of 70 present in any orthopaedic ward were eligible to be under the care of an orthogeriatrician. The aim of the study was to assess NHFS scores and mortality statistics in the orthogeriatric service in Malta and compare these with the United Kingdom.

Data

Data was collected for all patients seen by the orthogeriatric service from its introduction till January 2015. Descriptive data including age and sex was collected from the. Mortality data and Nottingham hip fracture scores (NHFS) were also collected retrospectively. The NHFS is a weighted score of 7 independent admission variables that reliably predicts 30-day, 1-year postoperative mortality and functional outcome. The variables are sex, age, admission haemoglobin, abbreviated mental test score, living in institution, number of co-morbidities and malignancy. This data was taken from the patient's history and the total score calculated. Informed consent from patients was done and the data protection team approved this study. The range for the score is 0-10.[4] The score calculation can be seen in Table 1. Data was analysed by using SPSS 13.0.0.

***Table 1**: Nottingham Hip Fracture Score*

Variable	Value	Score
Age	<66	0
	66–85 yr	3
	≥86 yr	4
Sex	Male	1
Admission Hb	≤10 g dl^{-1}	1
MMTS	≤6 out of 10	1
Living in an institution	Yes	1
Number of co-morbidities	≥2	1
Malignancy	Yes	1

Results

There were a total of 457 patients seen. 318 (69.5%) were female whilst 139 (30.5%) were male. Mean and median age of the patients was 83 years with a 6.6 standard deviation (SD). Age range varied between 61 and 98 years. Till January 2014 monthly admissions seen by the orthogeriatric service ranged from 6 to 15. From the expansion of the orthogeriatric service this went up with monthly admissions seen ranging from a minimum of 17 to a maximum of 44.

Mean levels for NHFS were 5.1 with a median of 5.0, 1.3 SD and range was 0 to 8. Univariate analysis found a significant link between mortality

and increasing NHFS (p=value <0.01). One way ANOVAs found a significant link between increasing age and higher NHFS (p-value <0.01).

There were a total of 27 deaths out of the 457 (5.9%) patients seen by orthogeriatrics in the first 30 days from admission. 50 patients out of 209 (data of patients from admission till March 2014) died within 1 year of admission to orthogeriatrics which was 23.9% of total. The mean death rate was 135.2 days whilst the median date rate was 68.0 days.

Discussion

The current results show that compared to studies done in the United Kingdom and Denmark admissions in Malta tend to be older (83 vs 82 years) and there is a higher percentage of males with fractures (30.5% in Malta vs 21.7% in the United Kingdom).[2,4-5] The NHFS scores in Malta tend to be higher than in the United Kingdom (5.1 vs 3.9).[2,4] This suggests that patients been seen by the orthogeriatric service in Malta tend to be older and frailer than in other European countries.

As regards mortality various studies and metanalyses have shown that the overall 1 month mortality in hip fracture patients is 13.3%.[6] The overall 1 year mortality is 24.5% but ranges between 18.8-33%.[6-7] The result from our data show that our 1 month mortality is very low when compared with these studies. As for the 1 year mortality this is marginally lower with data found in these studies. Patients in the orthogeriatric service in Malta who die tend to do this within the first 3 months.[8-9] This is similar to data in other studies.

Conclusion

In conclusion data collected during the first 3 years of the orthogeriatric service in Malta shows that it is doing well as regards mortality compared with other countries despite having frailer patients. Despite this, more data needs to be collected to view performance in reducing length of stay in hospital, discharge destination and independence level on discharge post rehabilitation.

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Original Article

The effect of community-based drug rehabilitation programs on recidivism in Malta

Claire Axiak

Abstract

Background: The argument for financing therapeutic community-based drug rehabilitation programs for inmates is compelling. Numerous studies have established the positive effect of such treatment on reducing recidivism, especially treatment based on the therapeutic community model. Methods: This quasi-experimental retrospective cohort study examined the impact of therapeutic community-based drug rehabilitation programs on recidivism amongst drug inmates released from the national prison of Malta between 2005 and 2008 (i.e. "the reference period"). An experimental group consisting in all drug inmates who participated in at least one program during the time spent in prison for a conviction that ended during the reference period was compared to two comparison groups of inmates who did not attend such a program or who had attended in the past. Chi-square tests and ANOVA were employed in the analysis.

Results: There was no statistically significant difference (p<0.05) between the three groups with regard to sex, age on admission and occupation but there was a highly significant difference with regard to the number of previous convictions, prison-basedopioid substitution treatment (given to all inmatesconvicted for heroin-related offences) and prison-based psychiatric treatment. On fitting a generalized linear model with a logit link function to control for opioid substitution treatment and the number of previous convictions it emerged that the difference between groups was not significant and thus the null hypothesis was not rejected.

Conclusion: Participation of inmates in therapeutic community-based drug rehabilitation programs did not in itself emerge as a significant predictor of recidivism. In this regard, possible limitations that may have contributed to the lack of significant results were discussed. Inmates who were not administered any opioid substitution treatment (i.e. corresponding to all those who were incarcerated for drug offences other than heroin) were 74% less likely to reoffend compared to those who were given methadone or tramadol. Moreover, the likelihood of recidivism was 1.7 times greater for each additional prior incarceration (p<0.001).

Keywords

therapeutic community-based rehabilitation, inmates, recidivism, incarcerations, opioid substitution treatment.

Abbreviations

p: Probability value, CI: confidence interval, sig: significance, CCF: Corradino Correctional Facility

Background

Malta has often been described as "the Jewel of the Mediterranean" and a heaven for locals and tourists alike. However, beneath its impressive exterior and in sharp contrast with its idyllic lifestyle lies a serious social phenomenon: drug abuse. Prevalence of drug use amongst adults reaches 14% amongst those aged 18-24 years.[1] Besides the well-known harmful effects on one's health and welfare, substance misuse has serious repercussions on society such as the strain on public finances spent on medical interventions, loss of production, social benefits, court proceedings, etc.

Even during these challenging times of financial crisis, the argument for financing therapeutic community-based drug rehabilitation programs for inmates is compelling because research has shown that these have a positive effect on reducing recidivism.[2-5] The main goals of treatment in a therapeutic community-based program center around a radical change in the person's lifestyle including moderation, self-

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restraint, abstinence, removal of anti-social behaviour and fostering of pro-social values and conduct.[6]

Corradino Correctional Facility (CCF)is the only correctional institution in Malta and houses all people who have been remanded in custody or convicted by the local courts. Inmates (on drug-related offences) who satisfy a number of criteria and pass an assessment by the Prison Substance Abuse Assessment Board are given permission to attend a drug rehabilitation program for the rest of their custodial sentence which must not exceed two years. There are three such programs currently in operation in Malta: the "New Hope" program operated by the Caritas Malta Foundation (part funded by the Government), the prison-based Substance Abuse Therapeutic Unit and the "Santa Marija" program operated by Agenzija Sedqa. These programs differ in regime and intervention approach but are all based on the therapeutic community model. The residential phase corresponds to the period of the remaining prison sentence. Participation is voluntary but subject to strict rules. Notwithstanding the potentially crucial benefits to inmates and society at large and the significant expenditure incurred, the use and impact of these programmes is not monitored in an extensive or systematic manner and no study has ever been undertaken which examines their efficacy in preventing recidivism.

The main purpose of this study was to determine the efficacy, or otherwise, of the three local drug rehabilitation programs in reducing recidivism amongst drug inmates at CCF. It also sought to identify predictors and risk factors for reoffending with implications for future risk management.

Recidivism in this study was defined as any offence (i.e. not necessarily drug-related offences) committed after release from CCF during the reference period for which the offender had been given a conviction by the Maltese Courts necessitating a custodial sentence and re-entry into prison. Convictions resulting in a conditional discharge, probation or suspended sentences were not taken into consideration.

Literature Review

The literature (consisting of studies conducted almost exclusively in the US which is unsurprising given that therapeutic communities originated there) contains concrete evidence pointing towards the effectiveness of therapeutic community-based drug rehabilitation programs on reducing recidivism amongst inmates with a history of drug abuse and drug-related convictions.[2-5] However a common point of criticism is that studies that demonstrate such effectiveness are methodologically weak. Moreover, the benefits of such treatment in reducing drug relapse are still unclear at best.

In a meta-analytic study conducted in 2007, the authors examined the effectiveness of five types of prison-based drug treatment programs including those based on the therapeutic-community model in reducing recidivism and drug use.[2] It was found that in six out of seven evaluations, inmates who attended therapeutic-community based programs recidivated less than those who did not. The overall mean-weighted effect size was 0.133 (p=0.025). This finding was consistent despite changes in any methodological variations or changes in sample sizes or the specific features of the programmes. The authors also analysed ten studies that explored the relationship between residential therapeutic-community based programmes and recidivism and found that these generated a mean odds ratio of 1.30 (95% CI 1.10–1.76) for recidivism outcomes thus proving the effectiveness of such programs in that regard. Interestingly, the association between participation in the programmes and lower rates of recidivism remained strong irrespective of factors such as age, gender, type of offence and coercion-based participation. There were however mixed results with regard to the effect of therapeutic-community based programmes on drug relapse. Two out of four studies analysed in the study found that inmates who participated in prison therapeutic-community based programmes had lower rates of drug relapse when compared to those that did not, while the other two evaluations found the exact opposite. The overall mean odds ratio of these four studies was 1.02 (95% CI 0.48 – 2.15) thus indicating no difference. The authors emphasise the fact that most of the evaluations analysed in their study were methodologically weak. In fact, 20% of such evaluations were classified as weak quasi-experiments, 43% as standard quasi-experiments, 30% as rigorous quasi-experiments and 7% as experimental designs. According to the authors, there is therefore a possibility that being methodologically weak, the available research overestimates the effects of therapeutic community-

based prison programmes on recidivism and there may be alternative explanations for reductions in recidivism other than those due to the positive effects of the programmes.

In another study, the author analysed the outcomes after release from prison over a period spanning five years post-release for 2,809 inmates who had participated in therapeutic community-based substance misuse treatment programs or control groups in a number of correctional facilities in Pennsylvania, US between January and November 2000.[3] It was found that participation in a therapeutic community-based program had a strongly significant effect on reducing recidivism over a five year post-release period ($p<0.05$) and that this was independent of community aftercare. The impact on re-arrest rates was slightly significant ($p<0.09$) while that on drug relapse was negligible ($p>.10$). The author also found that with regard to two of the three analysed outcomes (i.e. recidivism and drug relapse), the severity of previous offences had no impact on recidivism and that employment after release from prison was the strongest predictor variable amongst all the outcomes.

The literature review makes a strong case for the existence of other predictor variables that have a significant effect on reducing recidivism. The likelihood of recidivism was found to be almost one and a half times more for each additional prior incarceration ($p=0.002$).[7] Post-release employment[3], stable housing[8], and the number of prior arrests[9,3,5], were reported to be significant to strong predictor variables of the outcome of recidivism. Inmates with co-existing disorders[8], and those whose drug problem was more severe or whose drug of choice was heroin,[10] are also more likely to recidivate. It is also reported that it is significantly less likely for female inmates who undertake prison-based treatment to recidivate than male inmates and the latter were reconvicted significantly sooner than their female counterparts.[8-9] It has also been reported that retention is a significant predictor of long-term success and that the effects of participation in therapeutic community-based programs on recidivism are most consistent for treatment completers rather than for dropouts.[11]

Methodology

This was a quasi-experimental retrospective cohort study that compared recidivism outcomes for three groups of drug inmates. Recidivism was defined as any offence committed between release from CCF (limited to release during the reference period) until December 2012, for which the offender had been convicted by the Maltese Courts and given an effective custodial sentence. Existing data consisting of electronic files maintained and kept at CCF was gathered from three groups of inmates having a history of substance abuse all of whom were released from CCF during the reference period.

The total sample size consisted of 361 inmates who were serving custodial sentences for drug-related offences. Group 1 consisted of all inmates who did not participate in any therapeutic community-based drug rehabilitation program during the time spent in prison for a conviction that ended during the reference period but who had participated in any such program in the past ($n=27$). Group 2 consisted of all inmates who never participated in any such program ($n=229$). Group 3 consisted of all inmates who participated in at least one of such programs during the time spent in prison for a conviction that ended during the reference period ($n=105$).

The covariate predictors of sex, age on admission, age at first conviction, occupation, prison-based psychiatric treatment, prison-based opioid substitution treatment and the number of prior incarcerations were included in the analysis since these could possibly be predictive of the outcome under study as evidenced in the literature review. Other factors found to predict recidivism in the literature review such as social support, educational level, participation in aftercare and duration of post-release period from prison were not available for inclusion in the analysis.

Prison-based opioid substitution treatment is the replacement of heroin under medical supervision with a longer acting but less euphoric opioid such as methadone or tramadol. For the purpose of this study, all inmates who were incarcerated for heroin-related offences were administered opioid substitution treatment, while the rest (i.e. incarcerated for other drug-related offences) were not administered such treatment.

Statistical analysis

PASW Statistics version 18.0.0 was used for data analysis. Pearson chi-square tests, Fisher's Exact Test and a Generalised Linear Model with a

logit link function were used to compare categorical variables (including sex, occupation, prison-based opioid substitution treatment, prison-based psychiatric treatment and the number of previous convictions) between groups, ascertain any possible relationship between recidivism and such variables and ultimately test the null hypothesis that offenders with substance-use disorder who participate in a therapeutic community-based drug rehabilitation program are not less likely to reoffend than offenders who do not participate in such programs. An alpha level of 0.05 for all statistical tests was used.

Table 1 presents a summary of the descriptive data for the study participants on a number of variables such as, gender, age on admission, age at first conviction, occupation, previous convictions, prison-based opioid substitution treatment and prison-based psychiatric treatment. Group 2 had the largest number of no previous convictions. In fact, 5.1% of group 1, 72.2% of group 2 and 22.8% of group 3 had no previous convictions. In Group 1, 74% were on methadone, 7% on tramadol only and only 18% were not administered any opioid-substitution treatment. In Group 2, 52% were on methadone, 11% were on tramadol only and 37% were on no opioid-substitution treatment. No opioid substitution treatment was most common in Group 2. In Group 3, 74% were on methadone, 10% were on tramadol only and 16% were on no opioid-substitution treatment. Inmates in Group 2 were the least likely to be on psychiatric treatment. In Groups 1 and 3, 89% were on psychiatric treatment, whilst in Group 2 this was 69%.

***Table 1**: Summary of descriptive data in relation to sex, age on admission, age at first conviction, occupation, number of previous convictions, prison-basedopioid substitution treatment and prison-based psychiatric treatment.*

Variable		**Group 1** (*n* = 27)	**Group 2** (*n* = 229)	**Group 3** (*n* = 105)	**Total** (*N* = 361)
Sex	# Males (%)	27 (100)	213 (93)	98 (93)	338 (94)
	# Females (%)	0 (0)	16 (7)	7 (7)	23 (6)
Age on admission	Mean (SD)	29.85 (5.88)	29.5 (9.15)	28.21 (7.4)	29.15 (8.47)
Age at 1st conviction	Mean (SD)	25.11 (5.15)	27.31 (7.96)	24.46 (5.85)	26.31 (7.33)
Occupation	# Unemployed (%)	26 (96)	177 (77)	82 (78)	285 (79)
	# Employed (%)	1 (4)	52 (33)	23 (22)	76 (21)
Previous convictions [a]	# 0 (%)	12 (44)	171 (75)	54 (51)	237 (66)
	# 1 (%)	3 (11)	18 (8)	22 (21)	43 (12)
	# 2 (%)	7 (26)	16 (7)	9 (9)	32 (9)
	# 3 (%)	5 (19)	24 (10)	20 (19)	49 (13)
Drug treatment[b]	# No opioid substitution treatment (%)	5 (19)	84 (37)	17 (16)	106 (29)
	# On tramadol only (%)	2 (7)	25 (11)	10 (10)	37 (10)
	# On methadone with or without tramadol (%)	20 (74)	120 (52)	78 (74)	218 (61)
Psych treatment[c]	# No psychiatric treatment (%)	3 (11)	70 (31)	11 (10)	84 (23)
	# On psychiatric treatment (%)	24 (89)	159 (69)	94 (90)	277 (77)

a. Thiscategorical variable was coded as follows: 0 = no previous convictions, 1 = one previous conviction, 2 = two previous convictions and 3 = three or more previous convictions.
b. In-prison opioid substitution treatment
c. In-prison psychiatric treatment

Notes: Group 1 - inmates who attended a program in the past, Group 2 - inmates who never participated in a program, Group 3 - inmates who participated in a programduring reference period

Results

There was no statistically significant difference between groups with regard to gender, p=0.537 (2-tailed), age on admission, F (2, N=358)=9.38, p=0.392 and occupation, χ^2 (2, N=361)=5.31, p=0.070. There was a highly significant difference between groups on a number of previous convictions χ^2 (6, N=361)=32.51, p<0.001, prison-based opioid substitution treatment χ^2 (4, N=361)=18.44, p=0.001, and prison-based psychiatric treatment χ^2 (2, N=361)=18.69, p<0.001. Collinearity was observed between opioid substitution treatment and psychiatric treatment. In fact, 89% of inmates who were administered opioid substitution treatment were also on psychiatric treatment, whilst only 46% of those who were not having opioid substitution treatment were on psychiatric treatment. It was thus decided that psychiatric treatment should be eliminated from further statistical analysis.

A generalized linear model with a logit link function was thus used to compare the reoffence rate between groups when controlling for opioid substitution treatment and the number of previous convictions (Table 2). It emerged that the difference between groups was not significant when controlling for opioid substitution treatment and number of previous convictions and thus the null hypothesis was not rejected. It was found that those inmates who were not administered any opioid substitution treatment were 74% less likely to reoffend compared to those who were given methadone or tramadol. Interestingly, the number of previous convictions emerged as a significant predictor of recidivism. Results indicated that the likelihood of recidivism was 1.7 times greater for each additional prior incarceration (p<0.001).

***Table 2**: Parameter Estimates - Comparison of reoffence rate between groups when controlling for opioid substitution treatment and number of previous convictions.*

Parameter	B	Std. Error	95% Wald CI		Hypothesis Test			Exp(B)	95% Wald CI for Exp(B)	
			Lower	Upper	Wald x^2	df	Sig.		Lower	Upper
Group 1	.665	.4985	-.312	1.642	1.781	1	.182	1.945	.732	5.167
Group 2	-.088	.2638	-.605	.429	.112	1	.738	.915	.546	1.535
Group 3		.	.	.	.	.	.	1	.	.
PREV[c]	.571	.1177	.341	.802	23.561	1	.000	1.770	1.406	2.230
[REPL=0][d]	-1.329	.2829	-1.883	-.774	22.061	1	.000	.265	.152	.461
[REPL=1][e]	.159	.3773	-.581	.898	.177	1	.674	1.172	.559	2.455
[REPL=2][f]	1[b]	.	.	.	.	.	.	1	.	.

a. Set to zero because this parameter is redundant.
b. Fixed at the displayed value.
c. Number of previous convictions
d. No prison-basedopioid substitution treatment
e. In-prison opioid substitution treatment - on tramadol only
f. In-prison opioid substitution treatment - on methadone treatment with or without tramadol

Notes: *Group 1 - inmates who attended a program in the past, Group 2 - inmates who never participated in a program, Group 3 - inmates who participated in a program during reference period*

Discussion

The null hypothesis in this study was not rejected when controlling for opioid substitution treatment and the number of previous convictions. Quite surprisingly recidivism was higher in the group that attended a program (55.2%) than in the group who never participated in a program (44.8%). Thus participation in a drug rehabilitation program was not a significant predictor of recidivism for inmates at the CCF in this study. This result was not consistent with studies outlined in the literature review and it may well be the case

that the limitations of this study (particularly the study design and the small sample size) contributed significantly to influence statistical results leading to a failure in rejecting a null hypothesis that was false.

In keeping with findings from other studies that reported that inmates whose primary drug of choice was heroin were more likely to recidivate, it was found that those inmates who were not administered any opioid substitution treatment (i.e. consisting only of those inmates who were incarcerated for drug-related offences other than heroin) were 74% less likely to reoffend compared to those who were given methadone or tramadol.[10] Also, the finding that the likelihood of recidivism was almost two times greater for each additional prior incarceration replicated the findings of earlier studies.[12-14] However age on admission (p=0.392) was found not to be a significant predictor of recidivism despite the consistent finding reported in other studies that younger offenders were most likely to recidivate.[3,8-10]

Limitations

The major limitations of this study are the study design, the small sample size and the use of recidivism as an outcome measure.

Being a quasi-experimental design, this work studied pre-established groups of participants rather than participants that have been randomly assigned to experimental conditions. In other words, participants are not randomly assigned to levels of the independent variable (i.e. recidivism). This type of design was appropriate and indeed made necessary because the author used existing archived data kept at CCF and thus it was neither possible nor feasible to randomly assign individuals to groups. The main problem with a quasi-experimental retrospective design (as against a true experimental design) is that there is a real risk that results could be due to one or more confounding variables. Quasi-experiments tend to have lower internal validity in comparison to true experiments and it may be difficult to interpret results as group equivalence is not assumed. In this study, the analysis included two comparison groups to help control for some of the variance. This notwithstanding, selection bias remains a real threat to the internal validity of this study. A number of covariate predictor variables that were available to include in the analysis some of whom were identified in the literature review (including age on admission, number of prior incarcerations, prison-based psychiatric treatment, prison-based opioid substitution treatment and occupational status) were entered so as to adjust for possible differences between the groups on available variables. However other factors found to predict recidivism in the literature review such as social support, educational level, participation in aftercare and duration of post-release period from prison were not available for inclusion in the analysis. Also the retrospective design of the study meant that the author did not have control on the choice, accuracy or completeness of the data presented to her.

Another limitation of this study is the sample size as well as the disproportionate sizes between Group 1 and the other two groups. While the sample size in the present study (361 inmates) was deemed modest but adequate for the proposed study design, the possibility that larger samples might have led to significant differences in recidivism rates cannot be discounted. Indeed, studies identified in the literature review that reported significant treatment effects utilised larger samples ranging from 690,[9] to 715,[15] and 1,343 inmates.[16]

Furthermore, using recidivism as an outcome measure and as defined in this study has a number of possible limitations. For instance, inmates released during the reference period who reoffended and were convicted by Court but awarded non-custodial sentences were not considered recidivists. On the other hand, an inmate who was released during the reference period, did not reoffend but was convicted by Court and awarded a custodial sentence for a crime that was committed in the past was considered a recidivist. This means that recidivism rates at least within the scope of this study may be inaccurate and/or misleading since a decrease or increase in such rates might not necessarily reflect a genuine decrease or increase in reoffending but might reflect unrelated factors such as commission of less detectable offences, or more likely, delays in the processing and conviction of offenders for pending charges (unfortunately a common occurrence in the local justice system). Also, using recidivism in general as a performance indicator does not take into consideration the seriousness of the crime for which an inmate is re-incarcerated. Unfortunately, data concerning the types and nature of crimes for which inmates were re-incarcerated was not available for the purpose of this study.

Conclusion

The present study failed to replicate the findings of a large number of other studies that participation in drug rehabilitation programs based on the therapeutic community model is a significant predictor of recidivism. While the limitations of the study, especially the study design and modest sample size, are important considerations when evaluating its outcomes, a possibility that cannot be excluded is that the prison inmate programs offered to inmates at the Corradino Correctional Facility are not accomplishing their intended objectives and goals at least in terms of ensuring that clients do not return to prison. On the other hand, lack of supervision, support and community after care post-release from the programs might be defining factors that influence and possibly eliminate the possible benefits ensuing to inmates from participation.

Future research should ideally be conducted using a large sample (as well as proportionate groups) and a different design, perhaps incorporating a longitudinal perspective that includes face to face interviews with inmates and analyses of the influence on treatment outcomes of factors such as variations between the programs, the duration of such programs, inmates' characteristics, post-release psycho-social stressors and confounding variables such as social support, employment status and participation in aftercare.

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Original Article

Referral tickets to secondary healthcare: is communication effective?

Matthew Cassar, Janine Mifsud, Daniel Vella Fondacaro, Joseph Debono

Abstract

Communication between primary and secondary health care relies primarily on referral tickets. They determine how patients' details are conveyed and hence the quality of care. The aim of this study was to assess the quality of referral tickets at the Surgical Outpatients at Mater Dei Hospital in Malta and to develop recommendations for improvement. Consecutive referral tickets between the 7th February and 4th March 2015 were prospectively included in the study and analysed for completeness. The data was entered into a *proforma* which was revised after the first ten entries. A total of 351 referral tickets were included in the study. Names and surnames were present in all reports and identification number in 99.42% of cases. 44.16% of referrals were inappropriate according to clinical details. The majority of the forms had a history of presenting complaint (98.29%) while the past history, drug history / allergies and examination findings were available in 69.23%, 67.81% and 76.64% respectively. The source of referral was not clear in 56.13%. Only 69.23% of all referral tickets were completely legible while 30.77% were partly legible. This study shows the need for an overhaul in the referral system. Recommendations include the use of electronic referrals and the introduction of feedback letters by hospital specialists.

Keywords

Malta, communication, referral and consultation, secondary care

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Introduction

Effective communication between primary and secondary care is an integral aspect of the national healthcare system ensuring cost-effective, timely, smooth transition and specialised care for the patient.[1] Elective referral of patients in Malta requires completion of referral tickets by general practitioners / family doctors and the Accident & Emergency Department, and inter-speciality referral.

This referral form is a generic two page form applicable to all specialties available at Mater Dei Hospital, Malta which has been revised a few years ago. In 2009, Chetcuti *et al*[2] described the poor quality of referral to the Vascular Surgery team with use of the older version of the form.[2] Despite revision of the this form the quality of referral is still being questioned, an issue which has been present internationally over time and across medical specialties.[1,3–7]

The aim of this study is to assess the quality of referral tickets at the Surgical Outpatients, Mater Dei Hospital, Malta and to develop recommendations to the current setup.

Methodology

Consecutive referral tickets received by the Surgical Outpatients, Mater Dei Hospital, Malta between 7th February 2015 and 4th March 2015 were prospectively included in the study. All referral tickets marked for review by a general surgeon and submitted on the standard form were included. Patients referred to any subspecialty within general surgery were excluded from analysis. The referral tickets were analysed for completeness of the report and the data available was input into a *proforma*. Since no standards for the said *proforma* are available in the medical literature and this study evaluates the local scenario, this form was reviewed by the investigators following the first ten entries and revised accordingly.

The data collected included date, patient demographics (name, surname, national identification number, address, contact number, age, gender, next of kin name / surname / contact details), appropriateness of referral according to clinical details provided in the report, clinical details (history of presenting complaint, past medical history, drug history and allergies, examination findings, investigations if applicable), source of the referral (general practitioner, Accident & Emergency, other specialties), details of referring doctor (name / surname, signature / stamp, medical registration number) and legibility. The latter was defined as completely legible (all words read by 2 assessors), partly legible (at least 1 word not read by 2 assessors) and completely illegible (no words read by 2 assessors).

The data was analysed using Microsoft Excel.

Results

A total of 351 referral tickets received by the Surgical Outpatients, Mater Dei Hospital, Malta between the 7th February and 4th March 2015 were included in the study.

The date was available in 97.15% (341/351) while the names and surnames were present in all the reports. The identification number was present in 99.42% (349/351) of cases while the address, contact details, age and gender were available in 94.87%, 86.32%, 82.62% and 89.45% respectively (Table 1).

***Table 1**: Patient demographics number and percentage of completed fields from a total of 351 forms*

	Number of fields completed	%
Name	351	100%
Surname	351	100%
Identification number	349	99.42%
Address	333	94.87%
Contact number	303	86.32%
Age	290	82.62%
Gender	314	89.45%
DoB	81	23.08%

The patients' next of kin name and/or surname was complete in 17.66% of the referral tickets and the contact details in 13.67%. The referral was inappropriate in 44.16% (155/351), with the majority 38.75% (136/351) which would be more appropriately referred to the surgical subspecialties. 5.41% (19/351) of all referrals were wrongly referred to the surgical clinic.

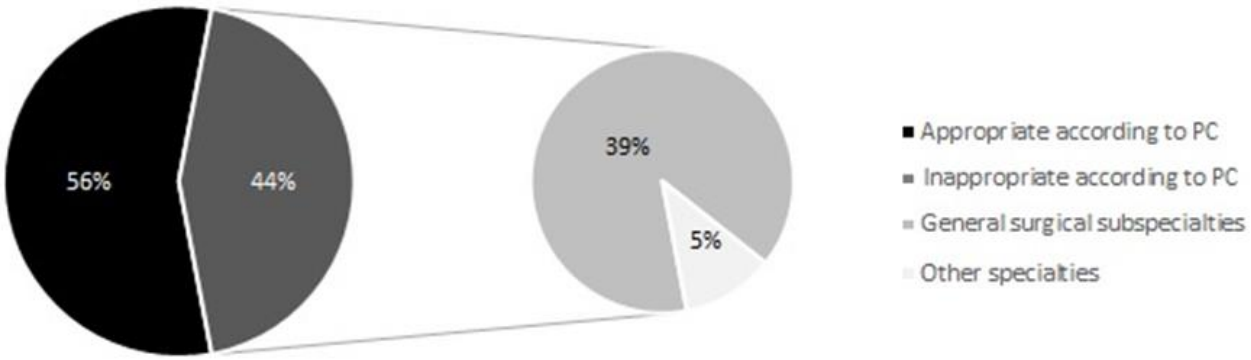
A significant proportion of the referral tickets had a history of presenting complaint (98.29%) while the past history, drug history / allergies and examination findings were available in 69.23%, 67.81% and 76.64% respectively. Only 74.93% of patients were investigated prior to referral. If investigation was not needed according to the referee's diagnosis the referral ticket was analysed with the "*investigated*" category.

Most of the patients were referred to the Surgical Outpatients by the general practitioner (33.05%), followed by A&E (8.83%) and other specialties (1.99%), however the source of referral was not clear in 56.13% of referral tickets.

The details of the referring doctor were available in most of the completed forms with the name / surname, signature / stamp and registration number available in 94.59%, 97.15% and 96.30%.

Only 69.23% of all referral tickets were completely legible while 30.77% were partly legible and none of the forms were completely illegible. Nearly all tickets were hand written with only 1.42% (5/351) of referrals in the printed form.

***Figure 1**: Appropriateness of referral*



Discussion

Referral letters are an essential tool to the management of patients by hospital specialists. The above data reveals the inadequacy of the information provided to secondary healthcare which potentially impacts on the patients' quality of care and safety.

Basic patient details were missing in a significant proportion of patients with some referrals lacking the important unique identification number and also contact details. Despite the appointment details being sent by post, the address was not available in 5% of the completed forms. Clinical details were also poor with a third of referrals not having a past medical or drug history, and examination findings not written for one fourth of patients. Furthermore, the forms were completely legible in only two thirds of cases limiting further the amount of information reaching the hospital specialists.

This study did not attempt to verify the information available to the hospital physicians so it is safe to assume that there is an underestimation of the inaccuracy in the scrutinised referral tickets.

Despite revision of the referral form template the quality is regrettably substandard and, although unable to compare directly with a similar study by Chetcuti *et al*,[2] does not show significant improvement from data obtained in the current study.

The results presented highlight the need for a major overhaul in the referral system, thus enhancing communication between primary and secondary care. With increased familiarity and access to technology a possible solution lies in the use of electronic referrals, which ensures completion through use of compulsory fields, legibility, instant receipt and acknowledgement apart from being environmentally friendly. Implementation of this form of referral requires the appropriate infrastructure, especially with respect to data protection and patient confidentiality. More importantly a culture change is needed to adopt this method of referring patients, unless this is the sole method of referral following phasing out of the conventional forms.[8]

Communication is bidirectional therefore introduction of feedback letters by the hospital specialists to the primary care physicians should be introduced and taken up as standard practice. This will undoubtedly boost the quality of care, ensure appropriate patient follow up in the community and indirectly improve the quality of referrals to hospital specialists.[2,9]

In conclusion, referral tickets are an important means of communication between primary and secondary care. The current study shows substandard referral forms and highlights the need for changes in the current system. Possible improvements are the introduction of electronic referrals and provision of feedback letters by the specialists within secondary care.

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Original Article

Terrorist attacks and the male to female ratio at birth: The bombings of Madrid (3/2004) and London (7/2005)

Victor Grech, Julian Mamo

Abstract

Introduction: Males are usually in excess of females at birth and the ratio is often expressed as M/F (male divided by total births). Several factors have been shown to be associated with changes in M/F, including major terrorist attacks. These are associated with a transient lowering of M/F for a one month period, three to five months after such events. This study was carried out in order to ascertain whether the Madrid March 2004 bombings and the London July 2005 bombings were similarly associated with changes in M/F in their respective populations.

Methods: Monthly live births by gender for Madrid and Spain for 2004 and for England and Wales for 2005 were obtained from the two countries' National Statistics Offices.

Results: There were no significant dips in M/F for any of the months following the March 2004 bombings in Madrid or in Spain. There were no significant dips in M/F for any of the months following the July 2005 London bombings.

Discussion: Research to date has shown M/F dips following catastrophic or tragic events, including major terrorist actions with extensive media coverage. Equivalent dips were not noted in this study for the terrorist acts in these instances. The reasons for this may be one or a combination of the following. The population size was not sufficiently large in order to detect an M/F dip. Alternatively, the events were not felt to be sufficiently momentous by the populace such that an M/F dip was not produced. Yet another possibility is that these particular populations are somehow hardier and more resistant to such influences. Not all terrorist events universally cause a significant reduction in M/F.

Key Words

Sex Ratio, Infant, Newborn, Birth Rate/*trends, Terrorism, Madrid, London

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Introduction

Males are born slightly in excess of females,[1] and the ratio of male-to-female live births is often (albeit technically incorrectly) expressed as M/F (male births divided by total births). Many factors have been shown to be linked to this ratio and this appears to be in accordance with the Trivers-Willard hypothesis which states that evolution should have favoured parents who can influence M/F according to conditions around conception and during pregnancy. This is because in polygynous species, a strong son who is conceived under favourable environmental conditions has greater reproductive opportunities than an equivalent daughter who is biologically constrained by pregnancy and lactation. Conversely, under unfavourable conditions, a male foetus (which is weaker than a female foetus) will be less likely to be carried to term and to survive to reproductive age. Furthermore, such surviving adult males would compete poorly with more robust males. However,

a frail female is likelier to survive and reproduce. Hence, under unfavourable conditions, the parental passage of genes is favoured if less males are produced through the culling of weaker male.[2]

Many forms of population level stress have been shown to be linked to a reduction in M/F, including not only frank warfare,[3] but also civil unrest.[4] Terrorist attacks have also been shown to be linked to a sudden lowering of M/F. This was noted after the September 11 attacks, after which transiently less males were born not only in New York,[5] but in the entire United States.[6]

The mechanism for these M/F dips has been demonstrated to be that of excess of male foetal loss.[5] For example, after September 11, it was shown that an excess of male foetal losses were responsible, with a decline in male births three months after September 11, implying an effect on women who were already pregnant.[6] A similar result was also noted following the Los Angeles Rodney King riots (1994) and the Breivik (Norway, 2011) and Sandy Hook (Connecticut, 2012) shootings.[7] Furthermore, the same effect was noted after the assassination of President John Kennedy.[8]

The Madrid bombings (also known in Spain as 11-M) on 11 March 2004 occurred just three days before Spain's general elections and exactly 911 days after the 11 September 2001.[9] The bombings consisted of ten coordinated and almost simultaneous explosions on Madrid's Cercanías commuter train system on four trains during rush hour on a Monday morning between 07:37 and 07:40.[9] Deaths totalled 191 and there were an additional 1500 injured individuals. The official investigation concluded that the attacks were directed by an al-Qaeda-inspired terrorist cell.[10]

The 7 July 2005 London bombings (often referred to as 7/7) consisted of a series of coordinated terrorist suicide bomb attacks in central London.[11] These attacks targeted civilians using the public transport system during the morning rush hour and were conducted by four Islamist extremists.[11] They detonated three bombs in quick succession aboard the London Underground trains across the city and, later, a fourth on a double-decker bus in Tavistock Square.[11] This resulted in 52 deaths and over 700 injuries, constituting the United Kingdom's worst terrorist incident since the 1988 Lockerbie bombing. This was also the country's first ever Islamist suicide attack.[11]

This study was carried out in order to ascertain whether the Madrid March 2004 bombings were linked to changes in M/F in Spain or in Madrid, and whether the London July 2005 bombings influenced M/F in England and Wales.

Methods

An ecological study was conducted linking routinely available monthly birth data by gender with the timing of major terrorist events.

For Spain, monthly birth data by gender for 2004 for the entire country and for Madrid alone was available from the website of the The National Institute of Statistics (Instituto Nacional de Estadística: INE).

For England and Wales, monthly birth data by gender for 2005 was obtained from the English Office for National Statistics (Ms. Debbie Hague, Life Events & Population Sources – personal communication). No other related data at greater level of detail (e.g. for England or for London alone) was available.

Excel was used for data entry, overall analysis and charting. The quadratic equations of Fleiss were used for the calculation of 95% confidence intervals for ratios.[12] Chi tests and chi tests for trends for annual male and female births were used throughout using the Bio-Med-Stat Excel add-in for contingency tables.[13] A p value ≤ 0.05 was taken to represent a statistically significant result.

Results

There were no significant dips in M/F for any of the months following the March 2004 bombings in Madrid or in Spain. A small dip but nonsignificant M/F dip was present in August 2004 (five months after the event) for all of Spain and also for Madrid.

There were no significant dips in M/F for any of the months following the July 2005 London bombings (table 1, figure 1).

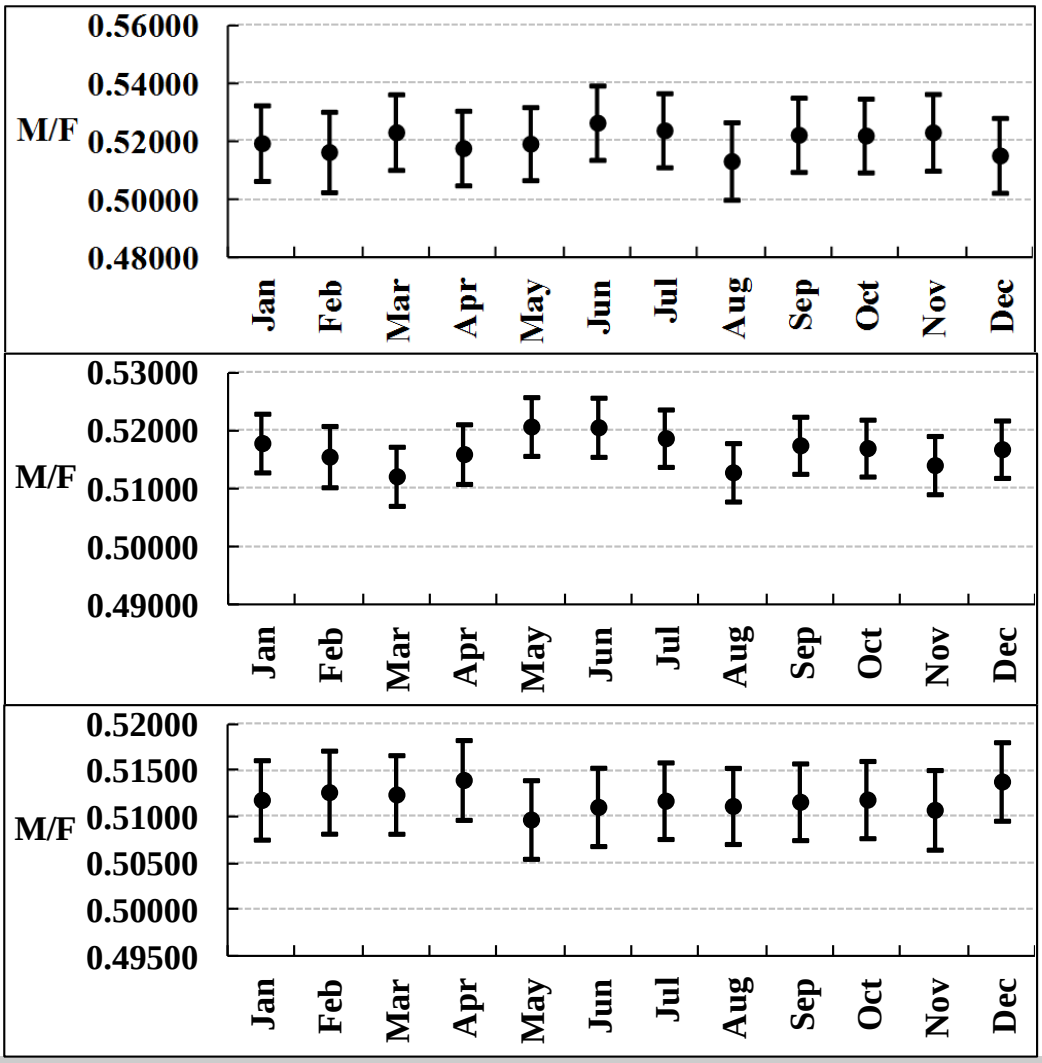
Discussion

Extant research has documented M/F dips following catastrophic or tragic events if these were felt to be momentous enough or to cause sufficient population stress. For example, an M/F dip was noted in the United Kingdom after the accidental death of Lady Diana, Princess of Wales in 1997, a loved public figure.[14]. A dip in M/F was also noted in Quebec a few months after a closely-run referendum proposing secession from Canada.[15]

Table 1: *M/F ratios with 95% confidence intervals by month for: top, Madrid 2004; middle, Spain 2004; bottom, England and Wales 2005*

		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Spain	Male	19474	17794	18996	18776	19521	19263	20373	19475	20566	20707	19642	20288
2004	Female	18129	16721	18095	17613	17966	17738	18902	18500	19175	19344	18566	18967
	Total	37603	34515	37091	36389	37487	37001	39275	37975	39741	40051	38208	39255
	UCL	0.5229	0.5208	0.5172	0.5211	0.5258	0.5257	0.5237	0.5179	0.5224	0.5219	0.5191	0.5218
	M/F	0.5179	0.5155	0.5121	0.5160	0.5207	0.5206	0.5187	0.5128	0.5175	0.5170	0.5141	0.5168
	LCL	0.5128	0.5103	0.5070	0.5108	0.5157	0.5155	0.5138	0.5078	0.5126	0.5121	0.5091	0.5119
Madrid	Male	2966	2616	2986	3039	3181	3092	3116	2787	3101	3134	2892	3003
2004	Female	2744	2450	2721	2831	2945	2781	2832	2643	2836	2869	2636	2826
	Total	5710	5066	5707	5870	6126	5873	5948	5430	5937	6003	5528	5829
	UCL	0.5325	0.5302	0.5362	0.5306	0.5318	0.5393	0.5366	0.5266	0.5351	0.5348	0.5364	0.5281
	M/F	0.5194	0.5164	0.5232	0.5177	0.5193	0.5265	0.5239	0.5133	0.5223	0.5221	0.5232	0.5152
	LCL	0.5064	0.5025	0.5102	0.5048	0.5067	0.5136	0.5111	0.4999	0.5095	0.5093	0.5099	0.5023
England	Male	26886	24650	27503	26761	27327	27639	28928	29256	28855	28468	26703	27624
and	Female	25641	23430	26168	25303	26283	26439	27598	27974	27541	27146	25576	26136
Wales	Total	52527	48080	53671	52064	53610	54078	56526	57230	56396	55614	52279	53760
2005	UCL	0.5161	0.5172	0.5167	0.5183	0.5140	0.5153	0.5159	0.5153	0.5158	0.5160	0.5151	0.5181
	M/F	0.5119	0.5127	0.5124	0.5140	0.5097	0.5111	0.5118	0.5112	0.5116	0.5119	0.5108	0.5138
	LCL	0.5076	0.5082	0.5082	0.5097	0.5055	0.5069	0.5076	0.5071	0.5075	0.5077	0.5065	0.5096

Figure 1: *M/F ratios with 95% confidence intervals by month for: top, Madrid 2004; middle Spain 2004; England and Wales 2005*



It has been reported that the Madrid bombings engendered significant stress and other negative emotions throughout the country.[16] Similarly, the London bombings also caused strong emotions in the United Kingdom.[17]

Following the Los Angeles Riots (1994), the Breivik (2011) and the Sandy Hook (2012) shootings, a transient dip in male births was noted for a single affected month. This dip was calculated at 4.3, 23.2 and 24.6/1000 births respectively.[7] An equivalent M/F dip was not noted in this study. The reasons for this may be one or a combination of the following. The population size was not sufficiently in order to detect an M/F dip.

Alternatively, the events were not felt to be sufficiently momentous by the populace such that an M/F dip was not produced. Yet another possibility is that these particular populations are somehow hardier and more resistant to such influences. The latter is unlikely, at least for the UK population, in that the death of Lady Diana transiently but significantly reduced M/F.

As with all ecological studies, data is not individually linked and is subject to *ecological fallacy*. It is difficult to detect exposure-outcome relationships with such studies. This, in addition to the fact that data is all retrospective implies there is no claim to any causative links here.

This study has therefore shown that not all terrorist events universally may be linked with a significant reduction in M/F.

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Case Report

Laparoscopic omentoplasty and split skin graft for deep sternal wound infection and dehiscence patient

David Sladden, Francis. X. Darmanin, Benedict Axisa, Kevin Schembri, Joseph Galea

Abstract

Treatment of sternotomy dehiscence secondary to infection is complex. We describe a case where following debridement and negative pressure therapy the greater omentum was harvested laparoscopically, pedicled on the right gastroepiploic artery and transposed through a subxiphoid window and laid into the chest wound. The omentum was covered with a split skin graft. The omental transposition provided a healthy vascular bed for the skin graft to be laid on top of. This technique allows for larger defects to be closed when due to the amount of bone loss the sternum cannot be brought together.

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Such procedures are normally performed when all other measures have failed and myocutaneous flaps cover the omentoplasty. Our case is novel in that the laparoscopic harvest and the use of direct skin grafting make this an option to be considered earlier as a single definitive procedure.

Keywords

chest wall reconstruction, deep sternal wound infection, omentoplasty, laparoscopic omentoplasty, sternum dehiscence, wound healing,

Introduction

Median sternotomies have been used for nearly a century and yet the management of its complications remains difficult. Deep sternal wound infection is a major cause of sternal dehiscence that is not secondary to technical reasons or wire failure. The incidence of deep sternal wound infection (DSWI) in cardiac patients ranges between 1 to 3 %[1-3] and carries a 30-day mortality of 7.3% compared to 1.6% in patients without infection.[4]

The risk factors for sternal wound infection are diabetes, obesity, bilateral internal mammary harvest, prolonged operation time and blood transfusions perioperatively. Prevention of this serious complication is the first priority and this can be achieved by pre-operative chest hair shaving, perioperative antibiotics, meticulous midline sternotomy and its wire closure and sparing use of bone wax and diathermy. [5]

The most common pathogens responsible for DSWI are gram-positive bacteria, namely *Staphylococcus aureus* and *Staphylococcus epidermidis.* Gram-negative organisms and fungi are rarely cultured.

Sternal separation can either be the cause of DSWI by letting superficial infections penetrate deeper or it can be the result of already present

infection causing sternal incompetence. Once this happens the dead space between mediastinal structures and skin is filled with a fibrinous matrix, which harbours the pathogens and makes antibiotic treatment much less effective. Collections form behind the dehisced sternal edges and osteomyelitis of the sternum becomes more significant after a few weeks. This explains why these infections are notoriously difficult to treat.

Traditionally these wounds are treated with debridement, antibiotics and wound packing. Eventual closure will require some sort of flap, usually pectoral myocutaneous flaps. However, it has been shown that obliteration of the dead space offers improved outcomes following wound debridement and prior to flap closure. The greater omentum is an ideal candidate for this role as it is resistant to infection due to plenty of immunologically active cells, is very vascular and absorbs wound secretions.[6]

The Case

A 52-year-old male, diabetic and ex-smoker with a body mass index (BMI) of 42.3 underwent coronary artery bypass grafting in January 2013. He presented to casualty with a non-ST elevation myocardial infarction (NSTEMI) and was found to have left main stem stenosis with mid left anterior descending (LAD) artery and mid circumflex artery disease. The right coronary artery was blocked with some retrograde filling. The ventriculogram gave an ejection fraction of 36%. The left internal thoracic artery (LITA) was used as a pedicled graft onto the LAD and a saphenous vein graft was grafted onto the first obtuse marginal branch. The antiplatelet drugs clopidogrel and aspirin had been stopped one week before surgery.

Post-operatively the patient suffered from atelectasis and copious chest secretions resulting in episodes of relative hypoxia. It was noted that the patient was not compliant in adopting chest protective manoeuvres while coughing. Glycaemic control was poor.

On the tenth post-operative day he developed a serosanguinous discharge from the wound that was negative on swab culturing. Antibiotics were started empirically but over the next few days this discharge became purulent and the sternotomy wound dehisced completely. The patient became febrile and methicillin resistant *Staphylococcus aureus* was cultured from both the wound and blood cultures. He was started on teicoplanin and gentamycin according to the sensitivity results.

***Figure 1**: The sternal wound one-month post-CABG before debridement*

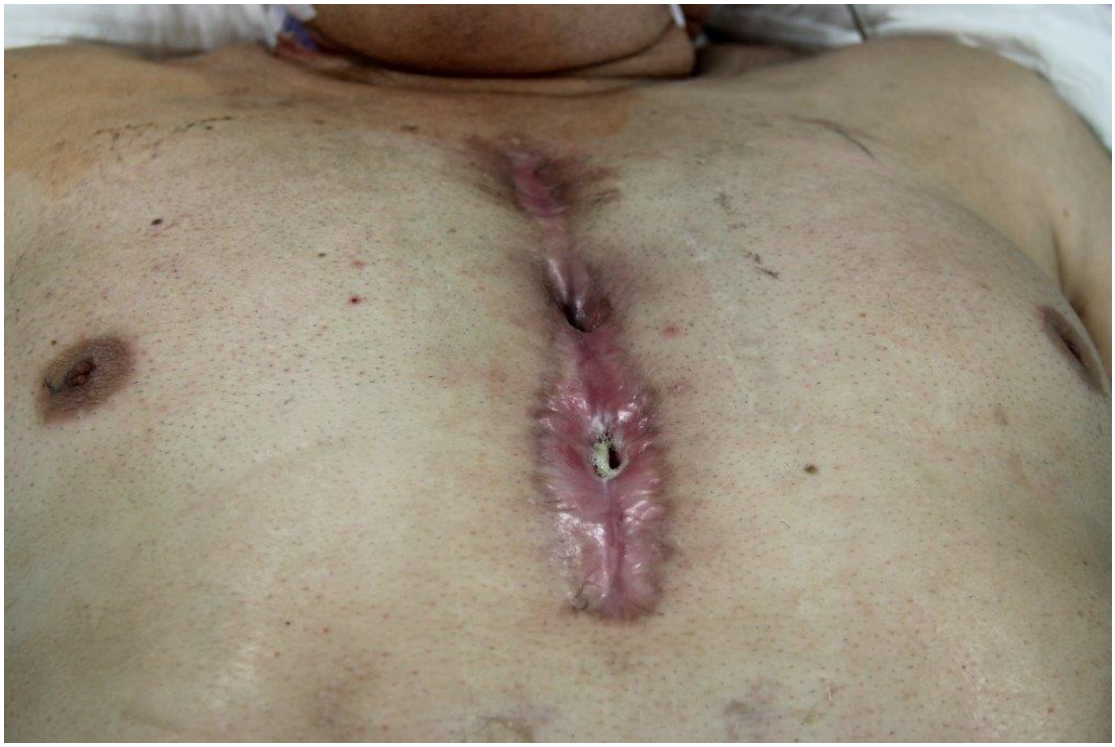
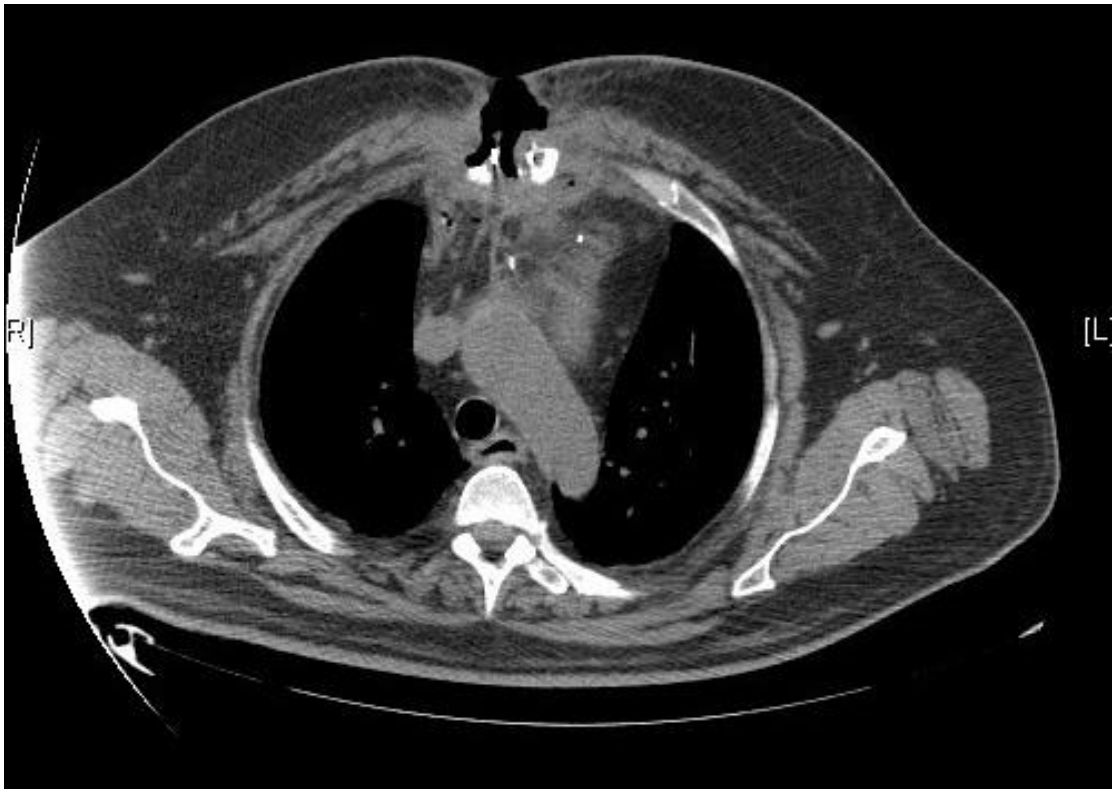


***Figure 2**: CT thorax showing the infective sinus and sternal dehiscence with mediastinal collection*



The wound was surgically debrided and all wires were removed two weeks after the first wound discharge was noticed. The patient spent the following six weeks on negative pressure wound therapy (NPWT) therapy, regular wound irrigation and change of dressings. Antibiotics were continued intravenously for four weeks and then orally for another two weeks. By the end of this course of antibiotics the wound was clean and clinically free from infection and therefore omentoplasty and skin grafting were organized.

***Figure 3**: The sternal wound after thorough debridement*

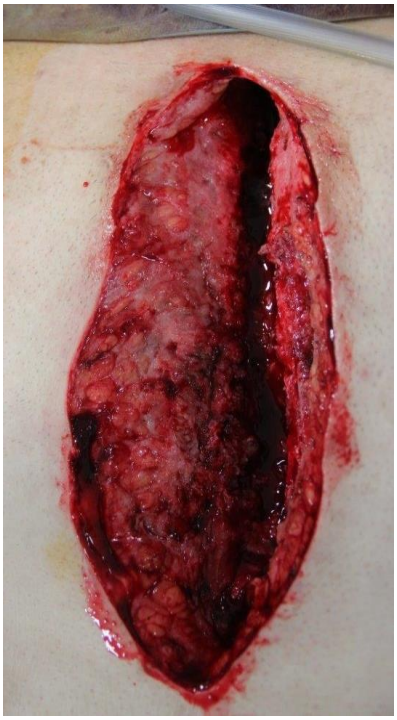
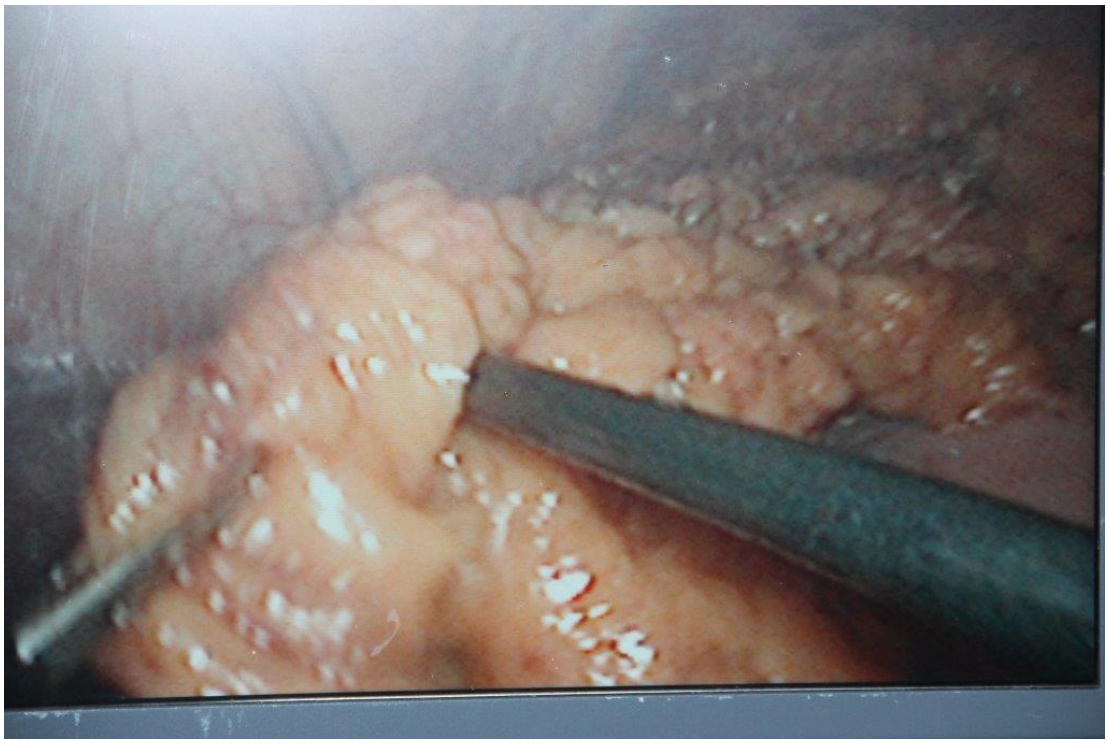


***Figure 4**: The laparoscopic harvest of the greater omentum*



Ten weeks after CABG the patient underwent wound debridement and laparoscopic omentoplasty under general anaesthesia. The ulcer edges and bed were thoroughly excised and debrided. A deep sinus located at the cranial end of the wound was identified and its depth defined using methylene blue dye. The residual clean wound was packed and covered with a sterile dressing. Four laparoscopy ports were inserted and the greater omentum was mobilized off the stomach and transverse colon, ligating the small gastric arteries and the left gastroepeploic artery. The omental flap was pedicled on the right gastroepiploic artery.

The omentum was delivered through a small subxiphoid midline incision and laid in the chest wound. The omentum was well vascularised after this transfer. The omentum was fixed with sutures to the subcutaneous tissue.

The omental flap was covered with a meshed split skin graft, which was harvested from the right thigh, and was stapled in place.

Graft take at the cranial end of the repair was incomplete and another split skin graft procedure was performed under local anaesthetic to cover the residual defect. Two weeks after this grafting the patient was discharged home with a follow-up plan.

The wound healed well, and is covered by healthy looking skin. The patient improved steadily, his functional outcome was good and he went back to work as a taxi driver. There was eventual fibrous union that gave the patient rib cage relative stability.

Discussion

The first laparoscopic omental harvest was reported in 1993 by Salz *et al*. [(7)] Later, it was reported as a flap for sternal wound closure with many variations. Some report it without prior NPWT and others use pectoral muscle flaps over the omentum.[6,8-11]

In our case the combination of NPWT, omental flap and skin graft was used. A case series by Van Wingerden JJ *et al* reported 6 patients treated with NPWT and omentoplasty, however 5 out of these 6 received local myocutaneous flap closure and only 1 had a skin graft to cover the omentoplasty. A few points to note from this study were the use of large amounts of foam in the wound when on NPWT therapy, as done in our case and also the use of fibrin glue to attach the omentum and skin graft rather than sutures as in our case. They concluded this three-pronged approach to be effective in severe postoperative mediastinitis.[12]

The severity of mediastinitis is described using the Oakley-Wright classification in table 1 below.[5]

***Figure 5**: Retrieval of greater omentum flap through an opening in the diaphragm and out of the sternal wound*

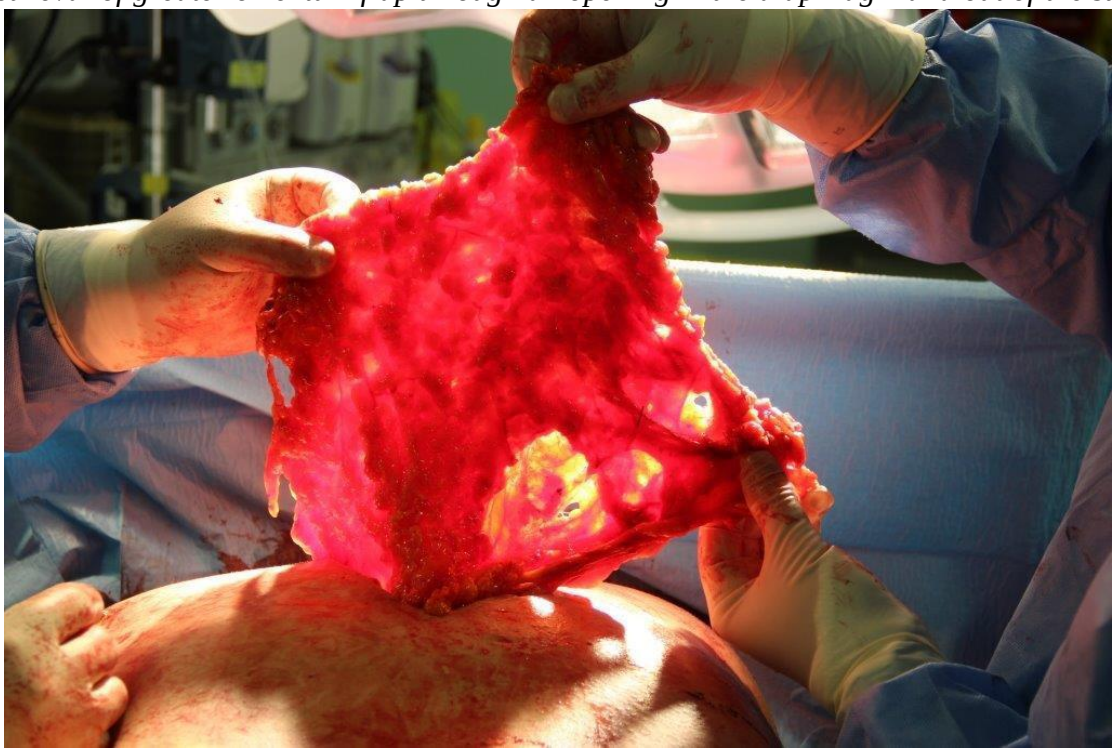


***Figure 6**: Omentum in the sternal defect*

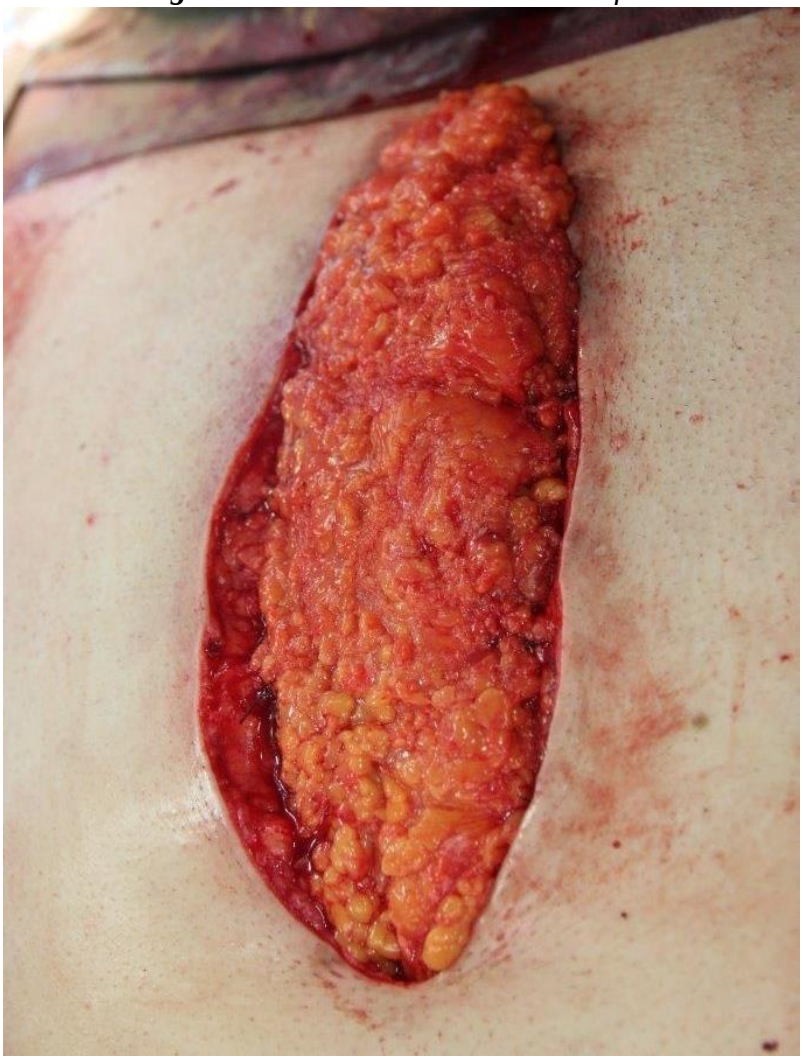


***Figure 7**: Split skin graft overlying omentum and stapled in place*

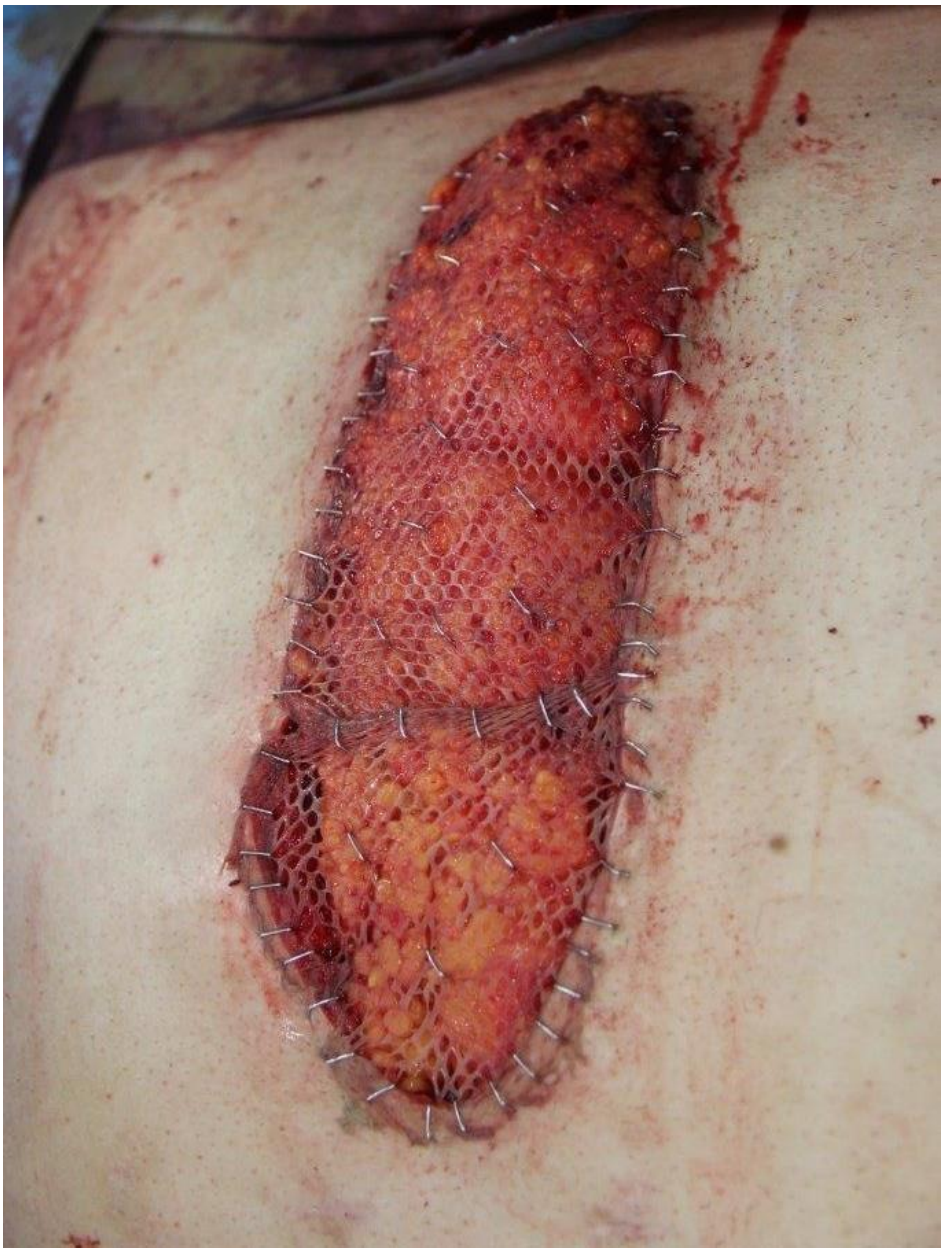


***Table 1**: Oakley-Wright classification of post sternotomy mediastinitis. A therapeutic trial involves a surgical intervention such as prior grafting*

Class	Description
Type I	Mediastinitis presenting within 2 weeks of operation in the absence of risk factors
Type II	Mediastinitis presenting in 2-6 weeks of operation in the absence of risk factors
Type IIIa	Type I plus one or more risk factors
Type IIIb	Type II plus one or more risk factors
Type Iva	Type I, II or III after one failed therapeutic trial.
Type IVb	Type I, II or III after more than one failed therapeutic trial.
Type V	Mediastinitis presenting more than 6 weeks after operation.

The risk factors for post-operative infection are mentioned in the introduction. Our patient has more than one risk factor due to being diabetic and obese. He also suffered from heavy bouts of coughing post-op. Therefore, our patient classifies as a Type IIIB mediastinitis.

De Brandere K. *et al.* used the same protocol as Van Wingerden JJ, with negative pressure, omentoplasty and myocutaneous flap advancement. They also performed thorough wound debridement and kept the patients on IV antibiotics and NPWT therapy for several weeks prior to grafting. They note the debate over which gastroepiploic artery is the best pedicle for the omentum. They used the right artery due to its larger size as seen in our case too, however both have been shown to be equally effective [6,12]

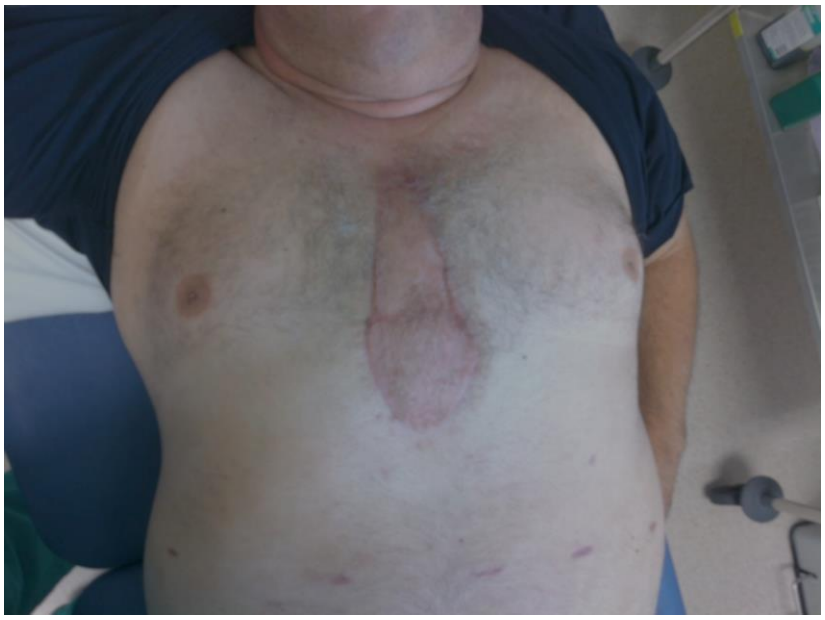
Domene CE. *et al*[13]. report a case of a 62 year old who underwent pectoralis muscle flap reconstruction, which necrosed. The patient then required re-debridement and omental flap harvested laparoscopically and covered by a split skin graft. The results were satisfactory.

There are other more modern techniques reported in the literature such as plate fixation with myocutaneous flaps following aggressive resection for infection.[14] However, there is significant risk involved when introducing such a large amount of foreign material such as this longitudinal plate and numerous sternal wires. Another option is the use of allogenic bone grafting or sternal transplantation. In both cases the allograft was held in place by titanium plates and results were excellent.[15-16] The problems of introducing foreign material and allograft into a previously infected wound are still present and the difficulties associated with obtaining the allograft and performing the procedure make this less applicable in most centres. Today the availability of a made to measure 3D printed sternum can offer structural stability and fill the space that the omentum was filling. The advantages as such are a better long-term result however the need for plate fixation and the quantity of foreign material makes it risky in the context of infection.

There are potential complications associated with the kind of procedure described here too. De Brabendere *et al* reported an incisional hernia in one patient and a partial dehiscence in another, which settled conservatively [6] Rutger M. *et al* had a 27.3% wound dehiscence rate and an 18.2% incisional hernia rate from the 11 cases treated with omental flap reconstruction.[4] Ghazi *et al* had an overall recipient site morbidity of 23% and a donor site complication rate of 27% from 52 patients undergoing omental flap transposition.[17] It is worth mentioning that the majority of these patients had a laparotomy for omental harvest and hence the complication rate may need to be reviewed for laparoscopic omental harvest. Lopez-Monjardin *et al* conclude that using omental flaps for the treatment of mediastinitis following open heart surgery is more effective than simply using myocutaneous flaps.[18]

Most studies seem to agree that the most important factors are aggressive early local wound debridement (to remove osteomyelitic bone), NPWT therapy and multiple antibiotics for several weeks. Then once infection free one proceeds to laparoscopic omental harvest, transposition into chest pedicled on either gastroepiploic artery and covered by either pectoral myocutaneous flap or by split skin graft. The case we report here followed the above treatment bundle and the patient recovered successfully. The literature concludes that this treatment bundle is highly effective in treating cases that have failed other attempts at treatment, therefore class IVa or IVb. However, here we describe it as a treatment option for a type IIIb patient and in the light of data favouring omental flap versus pectoral flap alone, this seems justified in such patients who have multiple risk factors for wound infection and dehiscence. The stability of the sternum is good and our patient is able to live a normal life with a cosmetic result that is acceptable to him, although further surgery is on offer by the plastic surgical team to refashion the scar into a less visible one.

***Figure 8**: Visible result 3 months after the omental flap and graft*



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Case Report

A Case of Neuroborreliosis in a Maltese Patient

Julian Cassar, Malcolm Vella, Josanne Aquilina

Abstract

Introduction: Lyme disease is the most common tick borne disease in the Northern Hemisphere. Is endemicity in Malta is however not known, as no specific studies have yet been carried out.Malta. We report here the case of a Maltese lady with a significant travel history and features of a cranial neuropathy and polyradiculoneuropathy confirmed to have what to our knowledge is the first case of Neuroborrelioisis on the Maltese Islands.

Case: A 38 year old female presented with right facial weakness, sensory symptoms of her upper limbs and pain in the lower back radiating down both lower limbs. Neurological examination confirmed features of a lower motor neuron facial palsy on the right and predominantly lumbo-sacral polyradiculoneuropathy. Initial blood and imaging investigations were unremarkable. CSF analysis revealed a lymphocytic pleocytosis. Symptoms deteriorated and a repeat lumbar puncture indicated a worsening lymphocytic pleocytosis. On questioning she admitted to having lived in Bavaria, Germany for a number of months in the year prior to presentation. Serum antibodies for *Borrelia* proved positive. CSF infection with *Borrelia* was also confirmed on specific testing. She was subsequently treated with a four week course of ceftriaxone which resulted in significant improvement of her symptoms, and resolution of the lymphocytic pleocytosis on repeat CSF analysis.

Discussion: Neurological symptoms of *Borrelia* typically occur months to years after initial inoculation of infection. Characteristic features include cranial nerve palsies more commonly of the facial nerve and meningoradiculitis with lymphocytic pleocytosis on CSF analaysis. This case highlights the importance of careful evaluation of even remote travel history in patients with such presentation.

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Key words

Borrelia; Malta; Ceftriaxone; *Facial* Paralysis; Polyradiculoneuropathy;

Introduction

Lyme disease is the most common human tick-borne disease in the Northern Hemisphere.[1] Responsible pathogens are species of spirochete bacteria belonging to the genus *Borrelia*, which are inoculated into the skin via a tick bite, from ticks of the genus *Ixodes.* Typically patients present initially with non-specific symptoms such as headaches, malaise, muscle soreness and fever, and with a characteristic rash – erythema chronicum migrans.[2] These symptoms however do not occur in every single case of Lyme disease, and presentation can be insidious. We present what to our knowledge is the first case of neuroborreliosis diagnosed on the Maltese Islands.

Case

A 38 year old lady presented to Mater Dei Hospital with an eight day history of pain and tingling sensation at her right upper limb and low back pain radiating down both lower limbs. Five days prior to presentation she had developed a right sided facial weakness that was treated unsuccessfully as "Bell's palsy" with prednisolone. Her past medical history was unremarkable and the patient denied any recent travel history of note.

Examination on admission revealed a lower motor neuron facial weakness on the right side. On examination of the extremities the tone and power were normal. Reflexes were normal in the upper limbs but were absent in the lower limbs. Sensory

examination revealed patchy loss of sensation to light touch and reduced sensation to pin prick in the right upper limb and both lower limbs. Gait was normal.

Routine bloods on admission were found to be within normal limits. Erythrocyte Sedimentation Rate (ESR) was 6mm in the 1st hr and C-Reactive Protein (CRP) was <6mg/L.

Chest X-ray was found to be normal. Magnetic resonance imaging (MRI) of the brain and whole spine was also normal.

A lumbar puncture revealed a lymphocytic pleocytosis with a lymphocyte count of 200 x 10^6 cells/L. The cerebrospinal fluid (CSF) protein was raised at 2756mg/L and CSF glucose was 2.8 mmol/L. CSF was negative for cryptococcal antigen, india ink and acid fast bacilli. Blood glucose level was 6.3mmol/L. CSF testing for oligloclonal bands was negative.

Nerve conduction studies showed a mild patchy demyelinating motor polyneuropathy.

Her symptoms got progressively worse and the pain could not be controlled with analgesics including codeine and amytryptiline. At this point ESR was found to be elevated at 64mm in the 1st hr but CRP remained normal.

A repeat lumbar puncture revealed a lymphocytic meningitis with a markedly higher lymphocyte count at 1290 x 10^6 cells/L and a higher protein count (3000mg/L) when compared to the first lumbar puncture. Flow cytometry of the CSF lymphocytes was indicative of a reactive process.

On specific questioning about travel history the patient admitted that she had lived in the countryside in Germany for a number of months during the previous year. Serum infectious screen revealed a positive *Borrelia* Immunoglobulin G. Western Blot for *Borrelia* on a serum sample further confirmed this. Treatment with ceftriaxone was therefore started.

Repeat MRI of the whole spine with contrast showed abnormal leptomeningeal enhancement along the cauda equina roots. Specific testing on CSF revealed the presence of *Borrelia* antibodies.

Echocardiogram revealed no abnormalities and electrocardiogram showed normal sinus rhythm with no evidence of heart block.

While an inpatient receiving antibiotic treatment the patient experienced increasing facial pain and radicular low back pain, which was eventually controlled with pregabalin.

However after a four week course of ceftriaxone she showed a marked improvement with significant reduction in the CSF protein level and lymphocyte count.

Six weeks following discharge the patient was asymptomatic except for the lower motor neuron facial weakness which was also showing signs of improvement.

Discussion

When infection with *Borrelia* occurs, the disease progresses through three stages. Following the tick bite, dissemination of *Borrelia* occurs over a number of days through skin, spreading to various organs over months to years.[3-4] Prevention of inoculation of infection can be attained by paying careful attention to wash scalp, armpits and groin properly when travelling to high risk areas, as ticks must be attached to their hosts for prolonged periods of time in order to inoculate the host.[5]

Classification has changed slightly. Refer to British association guidelines which divide them into early localized, early disseminated and late rather than in stages. Neurological symptoms can occur in both the early disseminated (facial and meningoradiculitis) as well as in the late stage where it resembles more MS.

Lyme disease is divided into three stages, early localized, early disseminated, and late disease.[4] The first stage refers to the early localized infection occurring in the first month after the bite. The presentation is of a non-specific febrile illness and a characteristic "bulls-eye" rash of isolated erythema chronicum migrans may be seen. This is seen in 80% of individuals who contract Lyme Disease.[6] The appearance of the rash should warrant prompt treatment with doxycycline to prevent further spread.

Early disseminated disease occurs weeks to months after the bite and is secondary to haematogeneous spread. Joint and cardiac involvement may be present with joint pains, heart block and fibrinous pericarditis.[4] Neurological modes of presentation can also be seen, with these frequently being cranial and peripheral radiculoneuropathies.[7] Presentation with these symptoms indicate dissemination into CSF. Seventh nerve palsy is the commonest cranial neuropathy, occurring in up to 60% of patients with neuroborreliosis. The inflammatory radiculopathy seen in Lyme Disease is referred to as Bannwarth's

Syndrome[8] and is characterized by lymphocytic pleocytosis in the CSF and sharp pain with nocturnal exacerbations that may be unremitting for weeks or months.[9] This presentation can mimic a mechanical radiculopathy, however, in patients with Lyme disease, there is no history of antecedent injury and findings on non-contrast imaging studies are usually unimpressive. Specific magnetic resonance imaging findings are of cervical, thoracic, and lumbar nerve root contrast enhancement[10] – hence the importance of carrying out a contrast study on this patient.

Late disease refers to chronic infection, where symptoms persist for several months after initial inoculation. Late neuroborreliosis may consist of previously described mononeuropathies and polyradiculopathies which persist for more than 6 months. Late polyneuropathy is often observed in association with acrodermatitis chronic atrophicans (ACA) – a typical dermatological manifestation that may result in widespread skin atrophy. CNS manifestations of late neuroborreliosis can present with cognitive decline, gait disorders and autonomic symptoms such as impaired bladder control.[7]

Borrelia infection is diagnosed with indirect methods to detect serum antibodies to *B. Burgdorferi*. This is based on a 2-step method by using an initial enzyme immunoassay (EIA), or an enzyme-linked immunosorbent assay (ELISA) or immunofluorescence assay (IFA), followed by confirmation of a positive or equivocal initial test by immunoblot or Western blot.[11-13]

Treatment consists of high dose antibiotics. In this case a four week course of intravenous ceftriaxone was used.[14] A positive response to treatment was confirmed by the improvement in the patient's symptoms soon after starting treatment and improvement in the CSF picture at the end of treatment.

Studies have shown that the earlier antibiotics are initiated the more effective the treatment response will be. A double-blind, randomised trial to investigate the efficacy of oral doxycycline versus intravenous ceftriaxone in the treatment of European Lyme Neuroborreliosis showed that both drugs offer equally effective results.[15-16]

Recommended dosage forms in Lyme Neuroborreliosis are a two to three week course of twice daily oral doxycycline 200mg or a two to four week course of daily intravenous ceftriaxone 2g.[14]

Doxycycline is however contraindicated in pregnancy and breastfeeding, with ceftriaxone preferred in these cases. These treatment modalities have been shown to be largely effective, however complete cure can never be guaranteed, and persisting symptoms despite treatment are not uncommon.[17]

Conclusion

Lyme disease can present very insidiously and may lead to severely disabling symptoms if it remains untreated. Although not typically associated with Malta, Borreliosis should always be considered in the differential diagnosis of patients presenting with lower motor neuron facial weakness and features of polyradiculitis and meningitis with a significant travel history, as prompt treatment results in a much better prognosis.

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