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Feminization of the medical profession in Malta

Joseph Cacciottolo

Gender is becoming an increasingly significant issue with respect to health-care delivery, as it affects men and women differently, both as service providers and as recipients. The health-care system itself in most European countries has traditionally been segregated: men were overrepresented in the medical profession, and women in ancillary health-related professions. From the Middle Ages onwards, women mainly practiced obstetrics, folk healing and alchemy, with some notable exceptions.[1] Women were barred from enrolment into medical schools and the admission of Elizabeth Blackwell, the first women to receive a medical degree, in 1849 in New York State, was quite by accident.[2] Elizabeth Garrett Anderson was the first woman to qualify as physician and surgeon in Britain, in 1865, and later went on to co-found the London School of Medicine for Women. There was complete exclusion of women from admission to the Royal College of Physicians until 1909, when a by-law was passed allowing them to take examinations.[3]

Participation of women within the medical profession in Malta is relatively recent, and even though Blanche Huber became the first woman to graduate in medicine, in 1925, throughout her professional life she practiced as a pharmacist.[4] Between the years 1925 and 1982, only 33 women qualified in medicine from the University of Malta, whereas between 1983 and 2014, a total of 636 women qualified.

Significant and stable changes in the level of participation of women within the Maltese medical profession started in the mid-1980's, and since 2004, more females than males are graduating in medicine, averaging around 52% per year, with a high of 62% in one particular class. In 2014, the largest annual cohort qualified in medicine from the University of Malta: of the 112 graduates, 56 were women. The stability of this 10-year trend will be maintained, at least over the next five years, given the demographic profile of the current medical student body in Malta.[5]

The shift in gender balance stems from several influences and there is a possibility that men are becoming less attracted to the medical profession. This may partly have its genesis in boys' relative educational underachievement at secondary school level, a geographically-widespread multifactorial phenomenon, and one that can be perceived at several domains in the context of Malta's educational system.[6-7] It is possible that men are being increasingly attracted to careers in finance and IT, as less arduous and shorter career paths, as well as means of offering more lucrative prospects earlier on in life. Indeed, a BMA cohort study looking into people's motivation to study medicine found that men place greater emphasis on status and income than do women, and this must have a relative impact on career attractiveness.[8]

The changing demographic profile vis-à-vis genders within the medical profession in Malta mirrors the situation in several other European countries, and reflects changing community-specific social milieux, and decline in prejudice and discrimination. Jane Dacre, current President of the Royal College of Physicians suggested that feminization is a fact and that 'there is a tsunami of women coming through'. More women are becoming consultants, and more female medical leaders are emerging, however this is a phase of reaching equality by bridging the gender divide, and not one of over-feminization.[9]

The differences in levels of feminization of medical professions across countries may be partly explained by differences in cultural and economic settings, as well as the extent of social organization safeguarding women's rights. Countries with restrictive cultural and social norms also tend to have marked gender inequality and poor representation of women in the medical profession. On the other hand, Nordic economic and social models promote gender equality and extensive egalitarian benefits, in tandem with policies to maximize labour-force participation. These social policies have encouraged and sustained the large participation rates of women within Scandinavian medical workforces, as well as their broad representation in all specialties.

Division of labour on the lines of gender within the medical profession in most countries is unequal and there is vertical segregation, with overrepresentation of men at the higher levels of the profession, as well as horizontal segregation, with concentration of women in certain areas of practice. It is clear that women have tended to gravitate towards certain specialties: the reasons for this selection are manifold and would include level of investment of time and effort, predetermined concepts, and a variety of real or conjectured hurdles. It may be that some women make conscious decisions to avoid certain areas of specialization for several reasons; some personal, others professional.

As more women enter the medical labour market in Malta, gender representation within particular segments of the medical profession is rapidly changing, and on comparing different areas of specialization, ratios are considerably uneven. Women make up 56% of the workforce in public health medicine, 50% in obstetrics/gynaecology and 42% in paediatrics. Around

25% of specialists in internal medicine and psychiatry are female, while they are significantly underrepresented in all branches of surgery.[10] The gender-divide of medical specialties in Malta concords broadly with the patterns in many other developed countries, and in general, more women than men seek professional pursuits that provide people-oriented and comprehensive care, when choosing a career in medicine.[11-13]

Women may be attracted to specialties that afford closer interpersonal relationships, as it is possible that women are generally more understanding in their approach to medical problems with strong social or emotional accents. This conventional stereotype may not however be an accurate one, and the reasons for attraction to particular specialties may be more pragmatic and mundane, such as flexible yet predictable work-patterns often sought by working mothers, avoidance of anti-social hours, and compromise between personal lifestyle and medical career.

Increasing feminization of the medical profession raises a variety of issues at different levels. The principal issue pertains to relative quality of care, as this matter is not only crucial at policy level, but also one that would concern individual patients most. There is no evidence to suggest that women differ from men in their evaluation of medical problems; however they do tend to be more interactive with patients, facilitating discussion of psychosocial issues and emotions.[14] The gender of the medical practitioner usually determines approach and style of communication, rather than content of the consultation and resulting decisions.

Significant changes in the gender-composition of the medical profession affect the organization and delivery of healthcare. Feminization of the profession is having immediate and practical effects not only *per se*, but also within contexts of rapid changes in the practice of medicine, as well as society's rising expectations, and at times suspicion, of the medical profession itself.

The increasing female participation in delivery of medical services requires different approaches to human resources planning. Women are more likely to work on a part-time basis and to take breaks at some stage in their career in relation to motherhood and childcare. Appropriate strategies to accommodate the increasing number of women doctors would include provision of more flexible working arrangements and adequate crèche and child-minding facilities. Statutory policies that encourage and facilitate shared parental leave can also be way of creating a fair professional playing-field between genders. A counterpoint to the debate of female participation in medicine has recently been put forward by J Meirion Thomas, Professor of Surgical Oncology at Imperial College London, who suggests that part-time work on a large scale, especially in general practice, although politically correct, may not be in the public interest, mainly on economic grounds.[15]

The situation vis-à-vis the gender demographic profile in Maltese medical workforces is fluid, yet given current data and trend, it is also highly predictable: 34% of practitioners on the Principal List of the Malta Medical Register are female, rising to 53% on the Provisional List. The size and gender ratio of the medical workforce in Malta is now such that allows adequately powered studies and it is crucial that factual data informs future state health manpower policies.

There is a pressing and practical need for accurate information about the current participation, role and level of utilization of women as a workforce in the delivery of medical care in Malta. There is a need to identify and qualify possible reasons for any hurdles that women may come across both at undergraduate and at postgraduate medical education levels. At a conceptual level, one would wish to study to what extent the changes in balance of gender representation in medicine are due to nature, and to nurture.

The increasing feminization of the medical profession is only one of several facets of gender issues relating to healthcare delivery in Malta. There is scant information about interactions of medical practitioners with patients of their own gender, or otherwise, and questions may arise as to whether male and female patients are treated differently. The social construction of illness has many dimensions and varies with gender; in conjunction with viewpoints of the medical profession, it is necessary to study Maltese patients' perspectives regarding gender issues in their interactions with male and female doctors.

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Cover Picture:
'San Martin'
Watercolours
By Mario R Borg

Mario R Borg graduated in Pharmacy at the University of Malta in 1986. After a number of years working in quality control and retail pharmacy practice, he pursued both a BA and an MA in History of Art. Following a brief apprenticeship at the Neue Pinakothek in Munich, he joined St Martin's College in the capacity of art teacher where he has been teaching for the past seventeen years.
Apart from a passion for art and art history he also shows a keen interest in film.

Original Article

The male to female ratio at birth in different regions in Malta

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Abstract

Introduction: Males are usually born in excess of females and the ratio of male births to female births is conventionally referred to as M/F. Many factors, including stress, privation and natural disasters are associated with a lowering of M/F.

Malta has a North-South divide, with a more affluent North as opposed to a more industrialised and less prosperous South. This study was carried out in order to ascertain whether regional economic differences influenced M/F in Malta.

Methods: Births by gender, year of birth and locality from 1999 to 2013 were subdivided into ten regions in a geographic distribution devised by the Department of Health Information and Research. Regions were also amalgamated into two groups of five which represented North-West and South-East Malta. The island of Gozo was considered separately.

Results: There were no statistically significant differences in M/F between the ten regions nor between North-West, South-East and Gozo regions. There were no significant secular trends in M/F in these regions.

Discussion: M/F declines under adverse environmental factors (including economic stress) but despite the overall poorer economic circumstances in the South of the Island, this study failed to show a significant difference in M/F by region. This may be due at least in part to the relatively small numbers involved. Alternatively, the purported socio-economic differences may not have been sufficiently large so as to skew M/F to statistically significant levels.

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Keywords

Sex Ratio, Birth Rate/*trends, Infant, Newborn Malta

Introduction

Males are usually born in excess of females and the ratio of male births to total births is conventionally referred to as M/F. Many factors have been shown to influence this ratio.[1-2] These include stress,[3] privation,[4] and natural calamities,[5] all of which tend to lower M/F.
Studies regarding the Maltese population have shown that the M/F appears to favour the male conceptus during the antenatal period, markedly so by the beginning of the third trimester, a situation that persists throughout most of childhood and into the reproductive phase of life.[6] It appears that the female foetus with congenital malformations is more likely to succumb and die during the second and third trimesters of pregnancy. Other biological and nutritional factors may also play a role in favouring the male conceptus during antenatal existence.[6]

Indications of seasonal variation in M/F in Malta has also been documented,[7-8] as well as evidence that parliamentary elections tend to lower M/F.[9]
Malta has traditionally had a North-South divide, with a more affluent North as opposed to a more industrialised and less prosperous South and this has been confirmed by several studies including a national social status survey and the latest (2011) census.[10-11] These showed overall higher literacy and educational achievement in the North with larger dwellings and a greater proportion of home ownership as opposed to renting arrangements for personal housing.

Furthermore, there were higher levels of unemployment in the South along with lower individual and family incomes, older and poorer quality personal

housing conditions. Differences between North-South included even differences in important amenities such as having a kitchen or bath/shower in the house. There were also differences in less important household amenities such as ownership of a gararge, a dishwasher and internet access.[10-11]

Stress related to contracting economies and unemployment has also been shown to decrease M/F.[12] This study was carried out in order to ascertain whether regional economic differences influenced M/F in Malta.[10-11]

Methods

Anonymised births by gender, year of birth and locality were directly obtained from the Directorate for Health Information and Research for 1999-2013 (Dr. Miriam Gatt – personal communication).

Data was subdivided into ten regions in a geographic distribution devised by the Department of Health Information and Research (table 1). The regions were also amalgamated (in an attempt to gain greater statistical power) into two groups of five which represented North-West and South-East Malta. Gozo was also considered separately.

Microsoft Excel was used for data entry, overall analysis and charting. The quadratic equations of Fleiss were used for exact calculation of 95% confidence intervals for ratios.[13] 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.[14] A p value ≤ 0.05 was taken to represent a statistically significant result

***Table 1**: Malta by region*

North-West group of regions				
West	**North**	**Central**	**Central North**	**Central West**
Zebbug	Mellieha	Hamrun	Sliema	Attard
Siggiewi	Mgarr	Sta Venera	St. Julian's	Balzan
Mdina	St Paul	Msida/G'Mangia/Pieta	San Gwann	Birkirkara
Dingli	Gharghur	Gzira/Ta' Xbiex		Lija/Iklin
Rabat	Mosta			
	Naxxar			
South-East group of regions				
Central East	**Harbour**	**Central South**	**South**	**East**
Fgura	Valletta	Qormi	Gudja	Zejtun
Paola	Floriana	Marsa	Kirkop	Birzebbugia
Sta Lucia	Vittoriosa		Luqa	Ghaxaq
Tarxien	Senglea		Mqabba	Marsaxlokk
	Cospicua		Qrendi	Zabbar/Xghajra
	Kalkara		Safi	Marsascala
			Zurrieq	

Results

Live births by region are shown in table 2. There were no statistically significant differences in M/F between regions. There were also no statistically significant differences when North-West was compared with South-East or when any of the two regions (or their sum) were compared with Gozo.

There were no significant time trends in M/F in the three main regions studied over the period of study (North-West, South-East and Gozo; figures 1-3 respectively).

The years 2000 and 2010 showed significantly low/reversed M/F in the South-East region. There were no such dips for the NW region. Gozo also had a similar M/F dip in the year 2000. These dips were statistically significant (table 3).

***Table 2**: Live births by gender and M/F for Malta by region, 1999-2013*

	North-West (NW)					
	West	**North**	**Central**	**Central North**	**Central West**	**Total**
M	2920	5106	2103	3621	3224	16974
F	2776	4886	1883	3416	3060	16021
T	5696	9992	3986	7037	6284	32995
UCI	0.5257	0.5209	0.5432	0.5263	0.5255	0.5198
M/F	0.5126	0.5110	0.5276	0.5146	0.5130	0.5144
LCI	0.4996	0.5012	0.5120	0.5028	0.5006	0.5090
	South-East (SE)					
	Central East	**Harbour**	**Central South**	**South**	**East**	**Total**
M	2232	1593	1579	2207	4800	12411
F	2113	1468	1408	2056	4377	11422
T	4345	3061	2987	4263	9177	23833
UCI	0.5287	0.5382	0.5466	0.5328	0.5333	0.5271
M/F	0.5137	0.5204	0.5286	0.5177	0.5230	0.5207
LCI	0.4987	0.5025	0.5105	0.5026	0.5128	0.5144
	NW	**SE**	**Gozo**			
M	16974	12411	2221			
F	16021	11422	2034			
T	32995	23833	4345			
UCI	0.5198	0.5271	0.5261			
M/F	0.5144	0.5207	0.5112			
LCI	0.5090	0.5144	0.4962			

***Figure 1**: M/F by year for the North-West Region, 1999-2013*

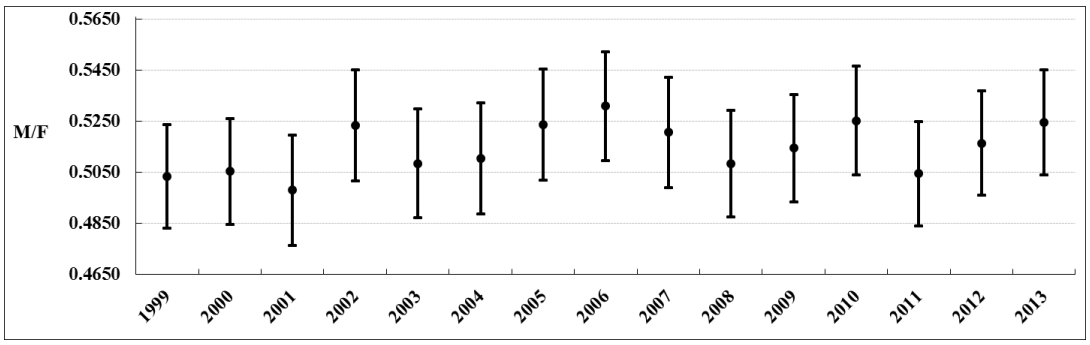

***Figure 2**: M/F by year for the South-East Region, 1999-2013*

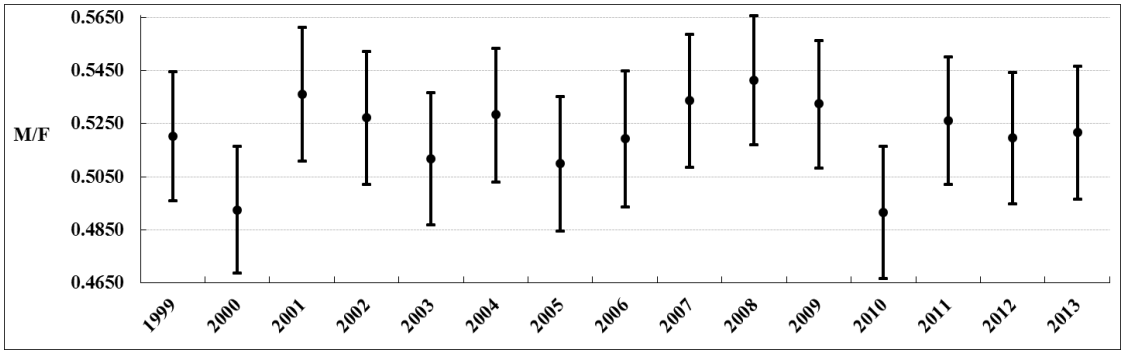

***Figure 3**: M/F by year for Gozo, 1999-2013*

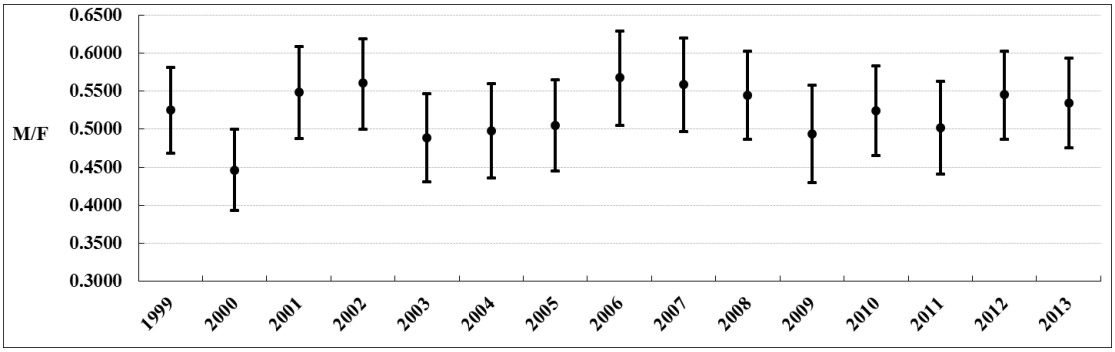

***Table 3**: Chi tests for years wherein M/F dipped*

	SE 2000	SE minus 2000	SE 2010	SE minus 2010	Gozo 2000	Gozo minus 2000
M	844	11567	773	11638	153	2068
F	870	10552	800	10622	190	1844
T	1714	22119	1573	22260	343	3912
UCI	0.5164	0.5295	0.5164	0.5294	0.5004	0.5444
M/F	0.4924	0.5229	0.4914	0.5228	0.4461	0.5286
LCI	0.4685	0.5163	0.4664	0.5162	0.3929	0.5128
chi		5.9		5.8		8.6
p		0.015		0.016		0.003

Discussion

M/F generally declines under conditions of adverse environmental factors (including economic stress).[12] this is in accordance with the Trivers-Willard hypothesis which suggests that natural selection has selected parents who bias investment in favour of the sex with the best reproductive prospects in accordance with extant periconceptual and gestational conditions.[15]

More specifically, poor ambient conditions may preclude the carriage of a male foetus to term since a male requires a greater maternal investment in terms of physical resources for gestation.[16] Should such pregnancies reach term, the outcome may be a frail male who may not survive infancy and childhood. Furthermore, a frail adult male would not be able to compete for mating privileges with stronger males. However, even under adverse circumstances, a female foetus is likelier to be successfully carried to term and survive, and eventually have offspring of her own.

On the other hand, under favourable conditions, a robust male has far more reproductive opportunities than an equivalent female who is hampered by a long gestational period and subsequent nursing. Thus, since resource abundance or scarcity affects reproductive success, the Trivers–Willard hypothesis predicts that natural selection has favoured parents who tend to produce females under poor conditions and males in good circumstances. [15]

Research has shown that one possible mechanism is that of excess prenatal foetal losses under stressful/adverse conditions which are skewed such that male foetuses are lost at a higher rate than female foetuses, reducing M/F.[17]

Despite the overall poorer economic circumstances in the south of the island, this study failed to show a significant difference in M/F over the period studied. Indeed, the analysis showed an overall higher M/F in the Southern part of the region, albeit not at a statistically significant level. This may be due to the relatively small numbers involved, which may lead to a type 2 error. Alternatively, the purported socio-economic differences may not have been sufficiently large such as to skew M/F to statistically significant levels. The authors are unable to explain the significant dips noted in specific regions in this study.

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Original Article

Auditing thrombolysis service for stroke at Mater Dei Hospital

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Abstract

Objectives: Thrombolysis for acute ischaemic stroke was introduced locally in October 2010. In 2012, the practice was audited to analyse the prevalence of inclusion and exclusion criteria for thrombolysis. Data about the local incidence of stroke, demographics and outcome was also obtained.

Methods: All patients admitted to Mater Dei Hospital with a diagnosis of stroke over an 8 month period were recruited. Standard data collection sheets were used to obtain data.

Results*:* 251 patients were admitted with a confirmed stroke over the 8-month period. The time of onset was recorded in only 37.4% of cases. All patients had CT scanning of the brain within 24 hours of presentation, of which 70% were performed within 3 hours. The commonest 5 reasons for which thrombolysis was withheld were: presentation beyond 3 hours of symptom onset (73.7%), age over 80 years (29.9%), hypertension (13.9%), haemorrhagic stroke (13.1%) and minor deficit or rapid improvement (8.4%). Overall, only 4 patients (1.59%) were eligible for thrombolysis in our cohort, all of whom received the treatment.

Conclusion: The study identified late presentation to A&E as the commonest exclusion criterion for thrombolysis. This prompted the launch of a stroke awareness 'Act FAST' campaign and increasing efforts to educate general practitioners to refer patients with acute stroke immediately. In addition, stroke pathway booklets were reviewed and simplified to increase their use. Since July 2013, the time window has been widened to 4.5 hours in accordance with international guidelines. Ongoing audit of thrombolysis is being carried out.

Keywords

Thrombolysis, cerebrovascular accident, stroke

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Introduction

Background

Most strokes occur secondary to arterial occlusion in the circulation to the brain. Thrombolysis in such circumstances was first studied in the late 1960s and the 1970s but these studies had to be abandoned in view of a high risk of intracranial haemorrhage. Since then, new thrombolytic agents such as recombinant tissue plasminogen activator (rtPA) have been developed. Studies carried out in late 1980s and early 1990s reported positive outcomes with respect to recanalisation and safety of the new drugs.[1] The positive results prompted further studies, including a larger randomised, placebo-controlled trial by the National Institute of Neurological Diseases and Stroke, the results of which were published in 1995. This study ensured that patients were treated within 3 hours of symptom onset and found that there was significant benefit in patients who received thrombolysis, compared to those treated with placebo. This benefit was evident at three months from stroke onset, with no increase in mortality.[2] The first National Clinical Guidelines for Stroke were published by the Royal College of Physicians (RCP) in the year 2000. At the time, the use of rtPA was limited to specialist centres under strict criteria. The drug was not yet licensed in the UK.[3] In contrast, latest RCP guidelines published in 2012 recommend that thrombolysis is considered within 3 hours of symptom onset "regardless of age or stroke severity" provided there are no contraindications. Patients under the age of 80 should be considered for treatment between 3 and 4.5 hours of symptom onset.[4]

Aims of the audit

In 2008, after the publication of the third edition of the National Clinical Guidelines for Stroke by the Royal College of Physicians of London, a local audit was carried out to compare the practice with the standards set by the guideline.[5]

Based on the results of the audit, stroke guidelines were formulated at Mater Dei Hospital. These have been readily available as booklets at the Accident and Emergency department. The pathways were introduced in October 2010 together with a thrombolysis service, aiming to ensure that patients eligible for thrombolysis are identified at triage and are fast-tracked through the necessary investigations. The documents also cover the management of patients who do not receive thrombolysis based on international recommendations.

In 2012 a second study was carried out. The main aim was to audit the practice of thrombolysis in acute ischaemic stroke with an analysis of the prevalence of the inclusion and exclusion criteria. Secondary aims included obtaining data about the incidence of stroke, demographics and outcome.

The results were then analysed to identify any outstanding inclusion or exclusion criteria that could be addressed in order to increase the number of patients who could benefit from this treatment.

Methodology

Patient Population

The audit covered the 8-month period between the 1st March and the 31st October 2012. Patients who were discharged with an alternative diagnosis including that of a transient ischaemic attack, were excluded. In-patient strokes were not included due to the absence of an effective mechanism to identify these patients.

Data collection Sheet Design

Standard data collection sheets were designed. Data collected in the audit was based on the content of local stroke guideline booklets. The audit focused on the inclusion/exclusion criteria for thrombolysis.

Data Collection

Ethical approval was obtained from the University of Malta Research Ethics Committee. Data was collected prospectively, recording documentation of assessment, results and management. Sources of data collection included access to patient files, nursing notes, PACS (Picture Archiving and Communications System), iSOFT (Healthcare Software) and ECS (Electronic Case Summary).

Results

Recruitment

Over the 8-month period of the audit, a total of 321 patients were admitted to hospital with a clinical diagnosis of stroke, of which 70 were excluded due to a different discharge diagnosis.

Demographics

The total number of patients included was 251; of whom 137 were male and 114 female. The mean age was 73 years (range 21 – 95), with a median age of 75 years.

Time of onset, presentation and discharge outcome

The time of onset of symptoms was known in 37.4% of patients (*n*=94). Of those with unknown onset, 7.9% (*n*=20) were wake up strokes. 72.6% (*n*=182) presented to the emergency department between 8.00 a.m. and 8.00 p.m (Figure 1). Figure 2 displays the type of stroke classified by the arterial territory involved, if it was possible to determine it clinically or by imaging. 26.2% (*n*=66) presented within 3 hours of initial symptoms (Figure 3).

***Figure 1**: Percentage of strokes classified by time of symptom onset*

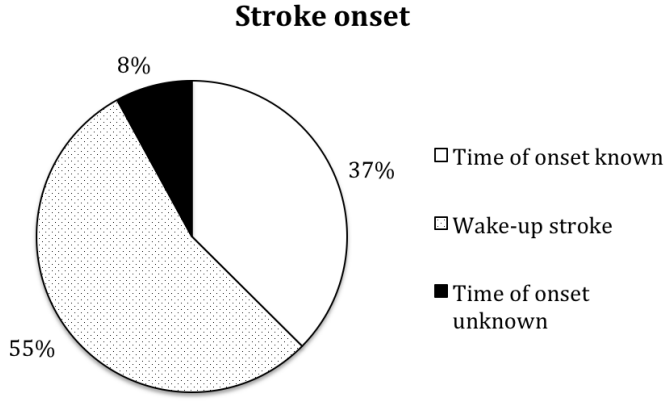


***Figure 2**: Type of stroke as determined by symptomatology and/or imaging*

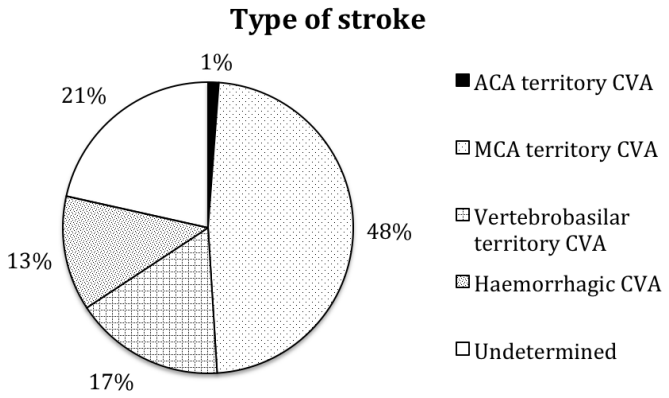
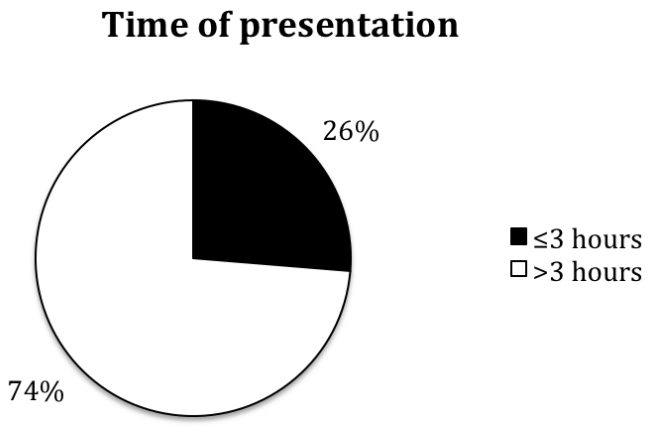


***Figure 3**: Time frame between symptom onset and presentation to the Accident and Emergency Department*



Brain imaging

All patients presenting with a presumed stroke underwent CT scanning of the brain within 24 hours of presentation. 70% of scans were performed within 3 hours of presentation. Data regarding the timeframe between symptom onset and CT scanning is limited because the time of onset was only documented in a minority of cases. The time delay from symptom onset and from presentation to CT imaging is illustrated in figure 5.

***Figure 4:** Pie chart showing the discharge destination of patients admitted with stroke*

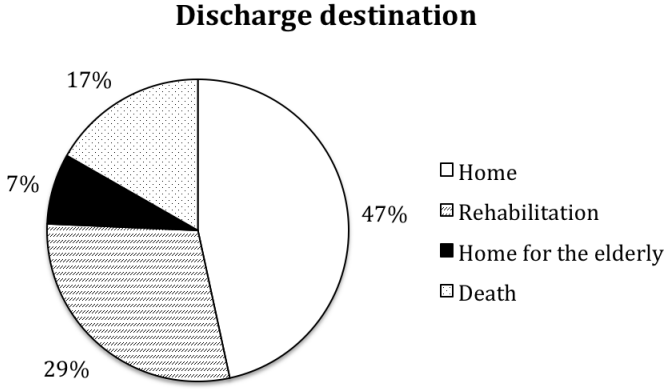
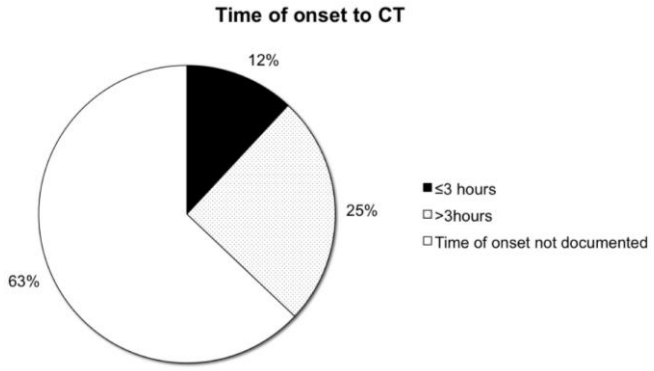
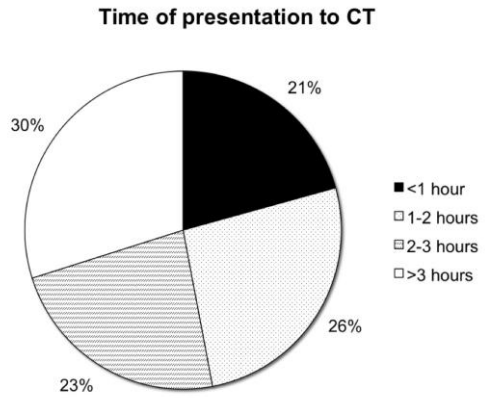


***Figure 5**: Pie charts showing the time frame between (a) symptom onset and (b) time of presentation to cross-sectional brain imaging*





The scans showed features of early ischaemic change in 51 patients (20.3%), extensive ischaemic change (more than a third of MCA territory) in 10 patients (4.0%), and haemorrhage in 33 patients (13.1%). No significant abnormality was reported in the remaining cases. Results of CT scans are presented in figure 6.

***Figure 6**: Findings on cross-sectional brain imaging of patients admitted with a diagnosis of stroke*

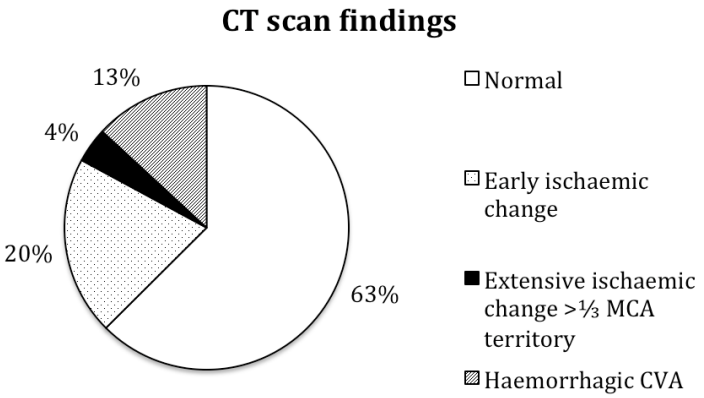
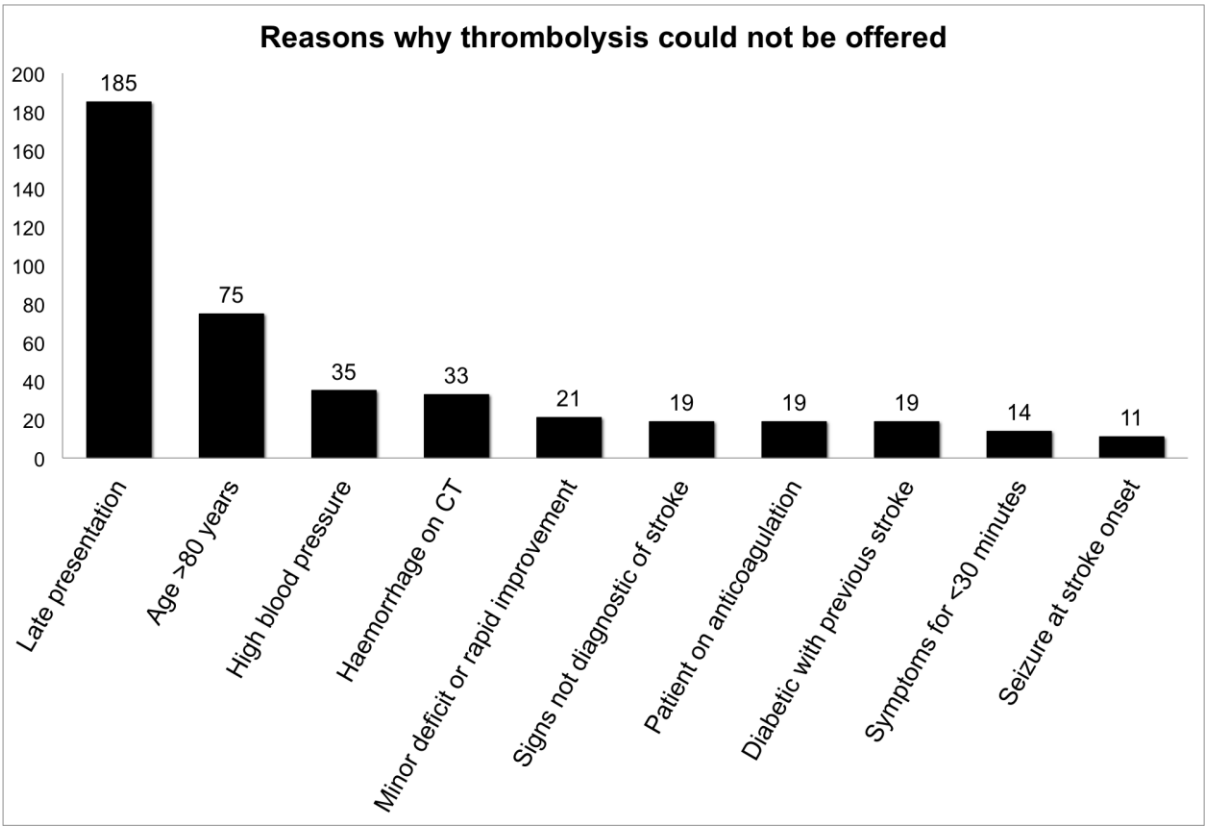


***Figure 7**: Reasons why thrombolysis could not be offered*



Thrombolysis

4 patients (1.59%) were eligible for thrombolysis after evaluation of all the inclusion and exclusion criteria, all of whom accepted to receive this treatment modality. The commonest ten reasons why thrombolysis could not be offered to the patients are listed below and shown in figure 7:

1. presentation after 3 hours of onset of symptoms: 185 patients (73.7%)
2. age >80 years: 75 patients (29.9%)
3. blood pressure above 185/110 mmHg: 35 patients (13.9 %)
4. haemorrhagic stroke: 33 patients (13.1%)
5. minor deficit or improving symptoms: 21 patients (8.4%)
6. signs and symptoms not diagnostic of stroke: 19 patients (7.6%)
7. prior anticoagulation: 19 patients (7.6%)
8. diabetes with previous stroke: 19 patients (7.6%)
9. symptoms lasting less than 30 minutes: 14 patients (5.6%)
10. seizures: 11 patients (4.4%)

The characteristics of the thrombolysed patients are presented in the table below:

***Table 1**: Characteristics of the thrombolysed patients*

Patient	**Age**	**Sex**	**NIHSS**	**CT** min	**Complications of rTPA**	**24h NIHSS**	**Outcome**
1	57	M	9	11	No	4	Rehabilitation
2	57	F	11	9	No	13	Rehabilitation
3	59	M	14	28	No	15	Died after 4 days
4	65	M	11	41	No	15	Home

Documentation

Documentation was found to be poor in the audit, even after introduction of the stroke pathway booklets. The ROSIER scale used at triage of patients at the Accident and Emergency Department was completely and appropriately filled in most cases. However the stroke booklet was filled only in a minority of cases, and the data was scattered. National Institute of Health Stroke Scale (NIHSS) was documented for only 55 patients (22%). Documentation of the presence of inclusion or exclusion criteria was often absent or unclear. For example, for 9 patients for whom thrombolysis was withheld, the reason was only evident after going through the patients' case notes thoroughly.

Discussion

Thrombolytic therapy is of proven and substantial

benefit for select patients with acute cerebral ischaemia. The evidence for thrombolysis in stroke to date includes 21 completed randomized controlled clinical trials enrolling 7152 patients, using various agents, doses, time windows, and intravenous or intra-arterial modes of administration.[6]

Despite being the most effective therapy if instituted within the first 4.5 hours, thrombolysis is still underused worldwide.[7] A study published from the Intercollegiate Working Party for Stroke showed that thrombolysis rates are currently low in the UK. 28% of patients presented within 3 hours of admission. Of these only 14% met all four National Institute of Neurological Disorders and Stroke study inclusion criteria. By increasing the time window to 4.5 hours only another 2% became eligible. Overall only 1.4% of patients were thrombolysed[8], which is in fact comparable to our 1.59%. Locally, the time window has been widened from 3 to 4.5 hours of symptom onset since July 2013, in accordance with international guidelines based on ECASS-3 trial results.[9]

The local guidelines introduced in October 2010 were geared at recognising patients who will be eligible for thrombolysis from triage. Despite short distances and relatively easy access to medical services in Malta, we note that delayed presentation to A&E was the commonest reason for non-suitability for thrombolysis. Prompt presentation relies on the patients' or witnesses' ability to identify physical changes and recognize the need for urgent medical assistance. Hence the call for nationwide promotion of stroke awareness, by simple achievable means, such as advertising on public media the 'Act FAST' campaign – i.e. "Facial weakness, Arm weakness or Speech problems? Time to call emergency services". Stroke awareness leaflets have been developed in collaboration with the Health Promotion Department and launched in October 2013. Likewise, since 2008, there have been efforts to educate general practitioners to refer immediately and appropriately for medical treatment. The results of a public education campaign will probably take time to become evident but efforts at continuing to raise the awareness should intensify.

Poor compliance with the use of local guideline booklets raised the necessity to review the stroke pathway booklets and simplify them to make them more user-friendly. Review of these booklets was accompanied by refresher courses for the medical doctors in the department of A&E and department of Medicine. The local guidelines are continuously being updated, based on the recent changes in international guidelines[4].

These efforts seek to increase the number of patients who benefit from thormbolysis. To date, 37 patients have received this treatment for ischaemic stroke. Ongoing audit of thrombolysis is being carried out. We hope to publish results after five years of service.

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Benchmarking local practice in view of introduction of thrombolysis for stroke in Malta

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Abstract

Objectives: The aim of the study was to benchmark the quality of local stroke care in view of introduction of thrombolysis.

Methods: Stroke patients admitted to Mater Dei Hospital over 6 weeks in 2008 were recruited. A questionnaire based on the 2006 Royal College of Physicians (RCP) National Sentinel Stroke Audit phase II (Clinical Audit) was used. Results were compared to the 2008 RCP National Sentinel Stroke Audit phase II (Clinical Audit) report.

Results*:* 42 confirmed strokes were admitted. All patients underwent CT scanning within 24 hours. 97% received aspirin within 48 hours. 26.2% spent >50% of their stay in the neurology ward. 81% were discharged alive. At 24 hours from admission, 54.7% were not screened for swallowing. 47.6% were not assessed by an occupational therapist. 81% were assessed by physiotherapy at 72 hours of admission. None of the patients had documented goals set by a multi-disciplinary team. If thrombolysis were available, 16.7% would have been eligible. The commonest contraindications were late presentation (52.4%) and age >80 years (35.7%).

Conclusion: Local results compared well to the RCP 2008 results in initiation of aspirin, imaging, and nutrition. However, we noted need for improvement in the assessment of swallowing, mood and cognitive function as well as involvement of a multidisciplinary team. Since then, adherence to international guidelines has improved by the introduction of thrombolysis, a dedicated multidisciplinary service and the use of local guidelines for stroke.

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Introduction

Background

Stroke is a leading cause of death and disability worldwide and constitutes a considerable burden for patients, their carers and the community. With newer technology to assess cerebrovascular events, improved techniques to treat events acutely and intense rehabilitation by a dedicated team, stroke also has the potential of becoming a more successfully managed medical emergency.

Aims of the audit

The Royal College of Physicians of London (RCP London) first published stroke guidelines in 2000[1], with

the aim of improving the quality of care delivered for everyone who suffers a stroke. Since then, more recent guidelines have been published in 2012[2] (4th edition). We have thus used the Royal College of Physicians' guidelines to benchmark the quality of local practice.

Methodology

Patient Population

All patients admitted to Mater Dei Hospital with a primary diagnosis of stroke, over a six-week period between 1st of June 2008 and 15th of July 2008, were recruited prospectively. Patients with a diagnosis of Transient Ischemic Attack (TIA) as well as patients who were discharged with a diagnosis other than stroke were excluded from the audit. In-patient strokes were excluded due to the absence of an effective mechanism to identify these patients.

Questionnaire Design

A standard questionnaire sheet was designed for data collection. This questionnaire was based on the National Sentinel Stoke Audit 2006[3]and the RCP London National Clinical Guidelines of Stroke 2004.[4] Similar to what was carried out in 2004 RCP questionnaire, those patients that were deemed for palliative care or did not have a deficit requiring rehabilitation were considered as not requiring assessment. The Neuromedical ward at Mater Dei Hospital was considered the closest equivalent to a Stroke Unit.

Data Collection

Ethical approval was obtained from the University of Malta Research Ethics Committee. Data was collected in a prospective manner recording documentation of inpatient assessment, results and management. Sources of data collection included access to patient files, access to nursing notes, PACS (Picture Archiving and Communications System), iSOFT (Healthcare Software) and PAS (Patient Administration System). Data was collected only if recorded in any of the available documentation and recording methods.

Data analysis

Data was compared to the outcomes of the Royal College of Physicians National Sentinel Audit of 2008[2]. Data analysis focused mainly on the nine key indicators identified by the Royal College of Physicians. (Table1)

Results

Recruitment

Over six-weeks a total of 63 patients were admitted to Mater Dei Hospital with a diagnosis of stroke. 20 patients were excluded as the final diagnosis was not that of stroke, while 1 patient was excluded because medical notes were not available. Figure 1 demonstrates the recruitment stage of the audit.

Demographics

Of the eligible 42 patients, 21 were male (50%). Ages ranged between 37 and 93, with a median age of 76 years and an average age of 75.7 years (Figure 2).

Time of presentation, inpatient stay and discharge outcome

47.6 % (*n*=20) presented within 3 hours of initial symptoms, 38.1% (*n*=16) presented between 3-24 hours, whilst 6 patients (14.3%) presented over 24 hours after initial symptomatology. 26.2% (*n*=11) spent more than 50% of their stay in the Neuromedical Ward at Mater Dei Hospital. 9.5% (*n*=4) required ITU admission.

81% (*n*=34) were discharged alive from Mater Dei Hospital, while the remaining 8 patients (19%) died during in hospital stay. Of the surviving patients, 44.1% were discharged home, 26.5% (*n*=9) were discharged to a rehabilitation unit, while 7 patients (20.6%) were transferred to a long-term care/care of the elderly facility (Figures 1 and 3)

The average length of stay (LOS) from admission until live discharge was 9 days (range 1-30 days), while the average LOS from admission until inpatient death was 5 days (range 1-9 days). The average LOS for patients discharged home was 5.5 days (range 1-20 days), for patients discharged to a rehabilitation unit 11 days (range 5-30 days), while for patients discharged to a long-term care facility was 17.8 days (range 7 – 30 days).

Brain imaging

All patients presenting with a presumed stroke underwent CT scanning of the brain, and all scans were done within 24 hours of presentation, with 62% of scans being performed within 3 hours of presentation. 10 patients had features of an acute ischaemic infarct (23.8%), 10 patients had features of old ischaemic changes, while only 2 patients (4.8%) had sustained a haemorrhagic event. Brain scan for the remaining 20 patients (47.6%) was reported to contain no significant abnormalities. Of these 20 patients, 5 underwent a second scan, which in all instances confirmed an acute infarct.

Comorbidities and Secondary Prevention

The large majority of patients (85.7%) had at least one previously diagnosed co-morbidity, the commonest being hypertension (73.2% of patients), previous CVA/TIA (43.9%), diabetes mellitus (39%) or evidence of vascular disease (MI/angina in 39%) (Figure 4). Concomitant past cerebrovascular events and diabetes was present in 38.1% of the cohort, this being an exclusion criterion for thrombolysis at the time. 33.3% underwent Carotid Doppler scanning with 3 patients

having evidence of significant carotid stenosis. 9.76% were found to be in atrial fibrillation. Serum lipids were checked in 36.6%, while an echocardiogram was requested for 23.8%, with the majority of patients (53.7%) having no documented reason for not undergoing secondary prevention assessments. Of note, 29.4% of patients were discharged with prescription for lipid-lowering agent. 76.5% of patients were prescribed anti-hypertensive agent/s at discharge.

Medical Management and Assessments

94% of patients with no contraindication received aspirin within 48 hours of presentation. Nutrition was started within 72 hours for 90.5% (n=38), with 61.9% receiving oral feeding, 21.4% receiving nasogastric/PEG feeding, and only 7.1% remaining dependent on intravenous supplements at 72 hours. 6 patients (14.3%) required urethral catheterisation, with the main indication being assessment of fluid balance, and less commonly for retention or to prevent skin trauma. No documentation of weight was found in any of the 42 patients. Of the eligible 34 patients (81%), excluding patients too unwell, cognitive assessment was documented for only 1 patient, while none of the patients underwent mood assessment. 11.9% of patients required social worker involvement.

Rehabilitation

At 24 hours from admission, 69% (*n*=28) had not been screened for impaired swallowing, while at 72 hours 61% (*n*=26) of patients had not been screened. Speech and language assessment was carried out in 33% (*n*=14) within 7 days, but in 38.1% (*n*=16) this was deemed not to be required. 22% (*n*=7) of patients had visual field assessment within 24 hours and of the remaining patients in 26% (*n*=11) this was deemed not to be required. 23.8% (*n*=10) were assessed by an occupational therapist within the first week of admission, of the remaining 76.2% in 28.5% (*n*=12) it was deemed not to be required. 76.9% (*n*=27) had been assessed by a physiotherapist within 72 hours of admission and of the remaining patients in 15.38% (*n*=7) it was deemed not to be required. None of the patients had a documented plan for rehabilitation goals agreed by a multi-disciplinary team. None of the patients had documentation of advice being given regarding lifestyle modifications including smoking cessation, diet and exercise.

Thrombolysis

If thrombolysis were available, 7 patients (16.7%) would have been eligible for thrombolysis at time of admission. This percentage is similar to that obtained in the Royal College of Physicians' Sentinel Audit of 2008 (15%).[5] The commonest contraindications to thrombolysis were: presentation after 3 hours of onset of symptoms (52.4% of all admissions), age >80 years (35.7%), blood pressure above 185/110 (26.2%) and significant stroke severity (19%).

Benchmark

Table 1 displays the outcomes of the 9 key indicators in management of stroke patients (as highlighted by the RCP), compared to the UK National Sentinel Stroke Audit phase II 2008.

***Table 1**: The nine key indicators of stroke care identified by the Royal College of Physicians, with outcomes at Mater Dei Hospital compared to RCP 2008.*

The nine key indicators of stroke care	Mater Dei (%)	UK (%)
1. Patients treated for 90% of stay in stroke unit	26	58
2. Screen for swallowing disorders within first 24 hours of admission	31	72
3. Brain scan within 24 hours of stroke	100	59
4. Commenced aspirin by 48hours after stroke	97	85
5. Physiotherapy assessment within 72hours of admission	77	84
6. Assessment by an Occupational Therapist within 4 working days of admission	23	66
7. Weighed at least once during admission	0	72
8. Mood assessed by discharge	0	65
9. Rehabilitation goals agreed by the multi-disciplinary team	0	86

Discussion

The Audit highlighted lacunae in stroke management. There are 9 key indicators of good stroke care according to the RCP.[2] In order to qualify stroke care at Mater Dei Hospital, we benchmarked our results against the results of the RCP UK National Sentinel Stroke Audit phase II 2008.[2]

The first key indicator of good stroke care is spending 90% of hospital stay in a stroke unit. Randomized trials have shown that stroke unit care prevents 1 death and 1 institutionalisation for every 33 and 20 patients treated, respectively.[6] According to the Stroke Unit Trialists' Collaboration, the basic characteristics of a stroke unit should be: (1) a dedicated unit, (2) staff with a special interest in stroke or in rehabilitation including physician(s), nurse(s), assistant nurse(s), physiotherapists(s), occupational therapist(s), social worker(s), speech therapist, dietician and a

psychologist, (3) multidisciplinary team care with regular meetings at least weekly, (4) procedures for diagnostic evaluation, acute monitoring, and acute treatment, (5) early mobilisation, and a very strong focus on rehabilitation, (6) early setting of rehabilitation plans involving carers (7) early assessment and planning of discharge needs. At the time, the Neuromedical ward catered for characteristics 1, 2, 5. The dedicated neurology ward catered for 26% of patients.

The second key indicator of stroke care is screening for swallowing disorders within 24 hours. 36.1% our patients compared with 72% in the UK fulfilled this criterion. Reasons for this discrepancy include lack of documentation, time constraints and possibly lack of adequate staffing levels. To address this, the 50ml swallowing assessment was incorporated into the admission protocol, providing clear criteria for referral to the speech language pathologists for formal assessment.

Imaging of the brain is a vital part of the initial assessment of stroke patients. All our patients underwent a CT scan within the first 24 hours. With the advent of thrombolysis the role of urgent scanning has become increasingly important. The advantage of having a centralised acute general hospital is evident when one considers that in the UK 59% of patients have a CT within 24 hours. MDH has a 24 hour CT service which enables patients to be worked up within the time-frame for thrombolysis. Whilst MRI is now being used in certain centres in acute stroke management, it has its own limitations, including cost, limited availability and patient contraindication such as inability to stay still in such a claustrophobic environment. In the latest AHA guidelines of 2013, "non-contrast enhanced CT definitely excludes parenchymal haemorrhage and can assess other exclusion criteria".[7]

There is a 13% relative risk reduction with aspirin vs placebo for a recurrent stroke after an ischaemic event.[8] 97.1% of patients in our cohort vs 85% in the RCP stroke audit, were started on aspirin within 48 hours.

The fifth key indicator is physiotherapy assessment within the first 72 hours. Locally, 77.2% of patients underwent this assessment. 23% of patients at Mater Dei Hospital vs 66% in the UK were referred for occupational therapy assessment (sixth key indicator) within 4 working days. Possible reasons for these low rates include patients being deemed too fit or too ill, without adequate documentation; or failure to document referral to physiotherapist services.

Referral to physiotherapy, occupational therapy, social worker and speech language pathologist services were given prominence in the new local guidelines. Besides assessments being carried out by the aforementioned professionals, formal multidisciplinary meetings have been proven to improve outcomes (ninth indicator). None of the patients in our cohort had multidisciplinary team rehabilitation goals documented in the medical notes. UK patients had goals set by a multidisciplinary team in 86% of cases.

Where stroke unit admission is not possible (e.g. lack of bed space availability), a 'Stroke/TIA Nurse Specialist' can provide an essential outreach service and liaise with the key members of the multidisciplinary team. In addition, a specialist nurse would provide the much essential and often lacking educational aspect, both for patient and relatives.

Regular weighing of patients provides an indirect measure of nutrition.[9] None of the patients in our cohort were weighed contrasting significantly with the UK. This has been addressed in the guidelines.

Mood assessment plays a vital role in outcomes. Whilst in the UK 68% of patients had a formal mood assessment, none of the patients in our cohort did. The GHQ-12/ PHQ-9 mood scoring systems were included in the guidelines to standardise mood assessment. This provides clear cut-off points for referral to a psychiatrist.

Secondary prevention of stroke is an important part of acute stroke care. In the majority of cases essential investigations including echocardiography, carotid dopplers and serum lipids, were not carried out or booked during the in-patient stay. A flaw of our study is that we only looked at investigations documented during the in-patient period. Failure of documentation may have been an issue or the investigations might have been booked during follow up visits.

Lifestyle modification including smoking cessation, diet and exercise are keystones of secondary prevention. In none of the patients' notes did we find documentation of these important parts of the consultation. Failure to document discussions regarding these lifestyle changes again might be an important contributing factor. The guidelines address all these issues.

The main limitations of our audit were poor documentation of investigations and referrals causing underestimation. Our audit contained 42 patients. The small number of patients audited means that certain categories only contained a few patients, with the possibility of skewing the results. The short duration did not allow us to get data on seasonal variability; however the aim was to benchmark the quality of care independent of this variable.

Based on the results of the audit, stroke guidelines have been formulated and are currently being used at Mater Dei Hospital. Reaudit and closure of the audit loop were planned after the guidelines were implemented. These were carried out in 2012, and results are due to be published soon.[10]

***Figure 1**: Recruitment and outcome of enrolled patients.*

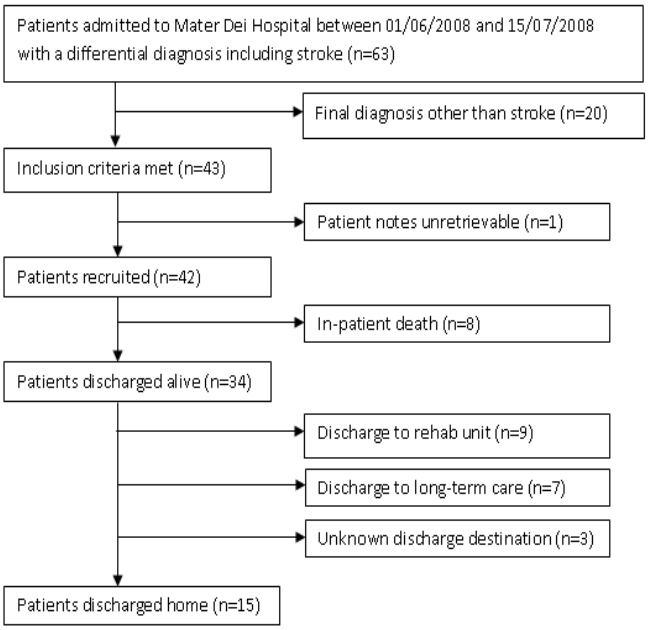


***Figure 2**: Demographics: Age and Gender distribution.*

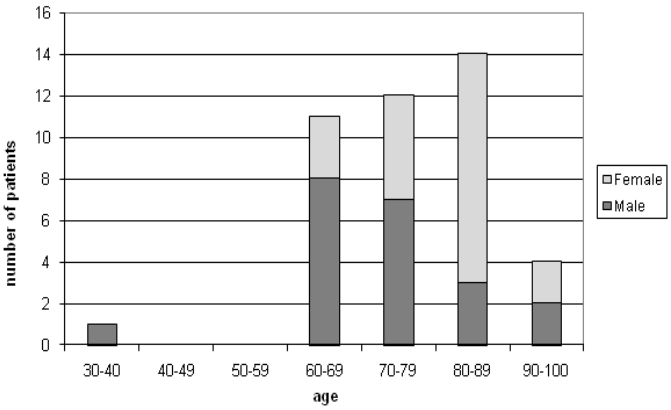


***Figure 3**: Discharge Destination*

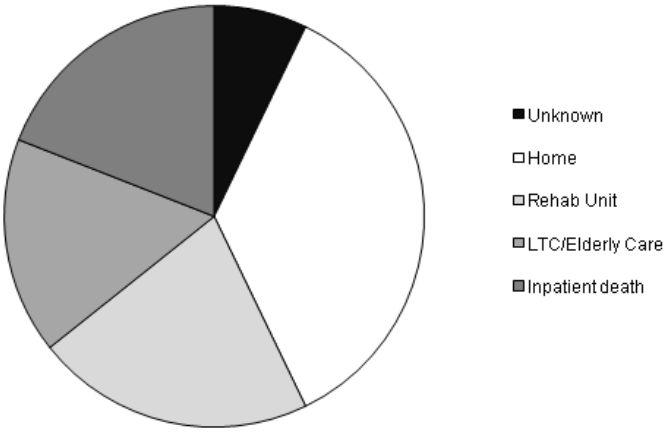


***Figure 4**: Comorbidities at Presentation.*

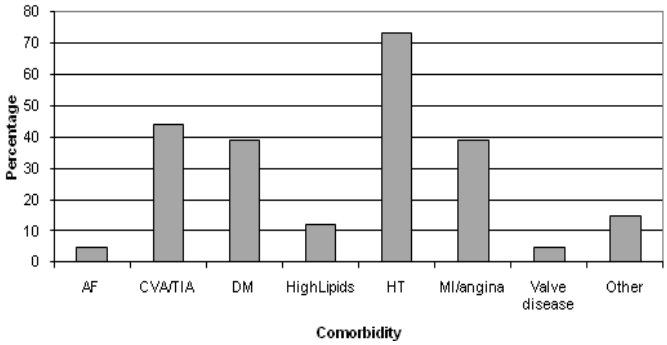
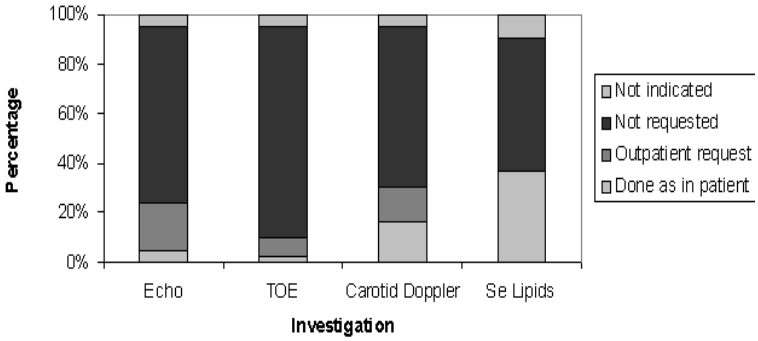


***Figure 5**: Secondary Prevention.*



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Original Article

Excision Margins in Breast Conserving Surgery

Noel Cassar, Paul Torpiano, Joseph Debono

Abstract

Objective: The ideal excision margin in breast conserving surgery is still a matter of debate. We aim to see if there is any correlation between increasing excision margin distance and local recurrence rate.

Materials and Methods: Patients who had breast conserving surgery at Mater Dei Hospital in 2009 had their notes reviewed retrospectively. Patient demograpichs, including the excision margins were recorded. Local recurrences within a 3 year follow up period were noted. Chi square was used to compare categorical data and a p value of less than 0.05 was considered statistically significant.

Result: 91 patients were recruited into the study. 74 patients (81.5%) had negative margins (>1mm), 10 patients (11%) had close margins (<1mm) while 7 patients (7.5%) had positive margins. 5 patients (5.5%) had local recurrence. The highest recurrence rate (14%) was in patients with positive margins, and no statistical signficant difference in recurrence rates was noted with wider excision margins.

Conclusion: As long as the margins are negative, increasing excision margins will not result in a better local recurrence rate.

Keywords

Breast Cancer, Breast-consvering surgery, Local Recurrence, Surgical Margin

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Introduction

Breast conserving surgery, thus avoiding mastectomy, has become the standard of treatment in early breast cancer (Stage I and II tumours).[1-2] Breast conserving treatment aims at achieving an acceptable cosmetic result whilst at the same time achieving good local control of disease, thus avoiding local recurrence.

Debate still exists however as to what constitutes the ideal excision margin, i.e. the minimum distance between the frontline of the tumour and the edge of the resected specimen, with proposed distances varying from less than a millimetre to over a centimetre. Studies have shown that patients with involved margins (i.e. tumour at the edge of the resection) have a higher incidence of local recurrence, with a relative risk of 1.4 to 9 fold. [3-9] However how much normal tissue around a tumour needs to be removed (i.e. the excision margin) is a still a matter of contention between surgeons. In a 2007 UK questionnaire survey, 65% of surgeons wanted a margin of 2mm or more, 24% wanted a margin of at least 1mm, whilst 7% were ready to accept margins of less than 1mm as long as there were no tumour cells touching the margin.[10]

The aim of this study was therefore to see if there is any correlation between increasing excision margin distance and the rate of local recurrence.

Materials and Methods

Patients who underwent breast conserving surgery at Mater Dei Hospital in 2009 under the care of a consultant general and breast surgeon (JD) were recruited into the study. A retrospective study of their notes was done. Surgery was carried out within a dedicated breast unit where decisions are taken within the framework of a specialised multidisciplinary setup consisting of surgeons, pathologists, oncologists, physiotherapists and breast care nurses.

Patients who had locally advanced tumours (Stage III and IV), recurrent disease, or had missing information in their notes were excluded from the study. Surgery was carried out by the consultant or under his direct supervision. Patient demographics were collected and any local recurrence during the 3 year follow up period was noted. Chi-square was used for comparison of categorical data and a p value of <0.05 was considered significant.

Results

91 patients were recruited into the study, with a

mean age of 60.2 yrs (range 32 – 87). Mean size of tumour was 20.5mm (range 3 – 63). Most tumours were grade 2 invasive adenocarcinomas (55%). Their characteristics are shown in Table 1. All patients were female. Most patients (81.5%) had negative margins, i.e. tumour not touching the edge of the resected specimen (table 2). Amonst these patients with negative margins (i.e. complete excision of tumour), there were varying distances of negative margins, as can be shown from table 3. Ten patients (11%) had close margins, i.e. the tumour cells were within less than 1mm from the edge, whilst seven patients (7.5%) had positive margins, i.e. tumour cells were touching the edge of the resected specimen.

***Table 1**: Patient Demographics*

	No.of patients
Age (yrs)	
30-50	22(24%)
51-70	44(48%)
71-90	25(28%)
*Size of tumour (mm)**	
0-20	48(60%)
21-50	27(34%)
51-70	5(6%)
Tumour grade	
Grade 1	20(22%)
Grade 2	50(55%)
Grade 3	11(12%)
DCIS	7(8%)
LCIS	3(3%)
Lymph node	
*Involvement***	45(57%)
Negative	24(31%)
1-3	5(6%)
4-6	5(6%)
7 or more	

**the size of some tumours was not available*
***Not all patients had lymph node removal*

***Table 2**: Excision Margins*

	No. of Patients
Negative	74 (81.5%)
Close	10 (11%)
Positive	7 (7.5%)

***Table 3**: Negative Margins*

mm	***No. of Patients***
1-2	12 (16%)
3-5	11 (15%)
6-10	14 (19%)
>10	37 (50%)

***Table 4**: Recurrence Rates*

Margin Distance (mm)	**Number of recurrences***	**Recurrence Rate (%)**
Positive	1/7	14
Close	0/10	0
1-2	0/12	0
3-5	1/11	9
6-10	0/14	0
>10	3/37	8

***denominator implies patients in that category**
p=0.34

Five patients (5.5%) had local recurrence. As expected, the patients with positive margins had a higher recurrence rate (14%). Wider excision margins did not translate in a lower local recurrence rate. In fact there was no statistically significant difference between the various categories (p=0.34).

Discussion

This study is in keeping with published literature on the topic. A systematic review on the effect of margin distance on local recurrence by Singletary[3] found that centres who used 1 or 2mm margins, as opposed to wider excision margins, actually had some of the lowest recurrence rates. A large meta-analysis on the topic by Houssami et al. [4] confirmed that wider margins do not correlate with reduced local recurrence rate, but rather had a negative impact on cosmesis as more tissue is removed. Interestingly this meta-analysis also confirmed an increased rate of recurrence for close (i.e. less than 1mm) margin. Compared with a close margin, a 1mm margin was significantly associated with a lower recurrence rate. Unpublished data from Edinburgh is also in keeping with this view. [11] Although the issue is far from closed, international opinion and current evidence therefore favours a 1mm excision margin as the minimum acceptable margin for patient safety.

There are a number of drawbacks in this study. This

was a retrospective study with all the limitations such a study entails. Also we had a relatively small number of patients (91) when compared to other studies. For instance we did not find any significant difference between close margins and negative margins. Even the 14% recurrence rate for positive margins was not statistically significant. However we acutally had only five recurrences in all, with only one in the positive margin group. With these small numbers, it is difficult to produce statistically robust results. In addition two of the patients who had recurrence had DCIS (in the more >10mm group), and one might argue that these shouldn't have been added to the study as DCIS is a separate entity from invasive cancer. The follow up period was also relatively short at three years.

This study is however in accordance with international published data that as long as the excision margins are negative, by increasing excision margin distance, the recurrence rate is not affected. With respect to patients with positive margins, further studies are necessary to identify patients who will not require further excision.

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Original Article

A review of the metered dose inhaler technique in asthmatic and COPD patients

Lara Angelle Micallef

Abstract

Aim: To assess the pressurised metered dose inhaler (pMDI) technique using a large volume spacer (LVS) in asthma and Chronic Obstructive Pulmonary Disease (COPD) patients who were admitted in medical wards or attending the outpatient clinic.

Method: Asthma or COPD patients were randomly recruited over an eight-month period from the wards and outpatients clinics at Mater Dei Hospital. Only patients using the pMDI were included. Data was collected using a questionnaire filled in by an interviewer who also assessed the inhaler technique using a checklist of 8 steps necessary for appropriate pMDI use.

Results: A total of 174 patients, 118 (67.4%) of which are asthmatics while 56 (32%) are COPD patients, were involved. A total score of 8 was achieved by 21 of the asthma patients and 3 of the COPD patients. 154 (88%) of all the patients owned a LVS but only 100 (57.5%) of all the patients used the LVS with pMDI regularly.

Conclusion: This study shows that despite the fact that it is a well-known fact that appropriate drug delivery is key to controlling Asthma and COPD, patients still tend to have poor pMDI technique hence the need for patient education with repeated assessment of the technique in follow-up clinics and prior to discharge.

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Key words

inhaler technique, Metered dose inhaler, patient education

Introduction

Asthma and Chronic Obstructive Pulmonary Disease (COPD) are among the most common chronic diseases that lead to recurrent hospital admissions and presentations to the local health centres (LHC). Asthma is a chronic inflammatory disorder associated with airway hyper-responsiveness leading to airflow obstruction that is reversible.[1] COPD, on the other hand, is a chronic obstructive disorder that is treatable and preventable in which airflow remains persistently decreased. In COPD, lung function deteriorates progressively. COPD is the 4th leading cause of death worldwide, according to the World Health Organisation,[2] even though it is a preventable and treatable disease.[3] Both disorders are treated mainly with inhaled medications in several forms, including the pressurized Metered Dose Inhaler (pMDI). Unfortunately, appropriate delivery of the chosen drug depends heavily on the patient's inhaler technique. Both the Global initiative for Asthma (GINA) and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) suggest that the correct use of inhalers is an important feature in preventing exacerbations of both asthma and COPD. Several studies have shown that poor use of the inhaler device is a main feature in poorly controlled disease.[4-9] The pMDI is one of the most commonly used device in management of asthma and COPD. This can unfortunately be difficult for patients to use and even with repeated demonstration and assessment some patients will still find co-ordination of the whole technique challenging, failing to master it despite repetition.[10]

A study performed locally states that 244 asthmatic patients (from a population of >400,000) presented to the emergency department with an acute exacerbation of asthma over a 10 month period, from January to October, of which 51.6% needed medical admission and 8.6% discharged themselves against medical advice.[11] Sub-optimal disease control has a negative impact on patient's quality of life, health care costs and a burden on society when this leads to, for example, increased absence from work. This study was aimed at finding out whether there is any statistically significant difference

between patients who were admitted to hospital as opposed to those who attended regular outpatient clinic and were never admitted to hospital. The pMDI used in combination with the large volume spacer was the technique assessed in this study.

Method

This study was conducted from April to November 2013 in Mater Dei Hospital (MDH). Patients were recruited from the asthma clinic, the lung function lab and from the medical wards of MDH. Only the patients suffering from asthma and COPD using the pMDI were involved in the study. There is no patient duplication as patients were randomly assessed on different days. Patients from the wards were recruited by checking the hospital treatment charts and their past medical history. No other inhaler type technique was assessed.

***Box 1**: Checklist of 8 steps used to assess the inhaler technique*

Checklist for MDI with LVS technique

1. Shaking the inhaler
2. Locking the lips appropriately around the mouth piece
3. Exhale fully prior to pressing the canister
4. Holding the MDI between the index and thumb and pressing the canister
5. Inhaling via the spacer as soon as the canister is pressed
6. Taking a deep breath slowly and deeply in
7. Holding the inhaled air for 5 – 10 seconds after
8. Re-shaking the inhaler for the second puff

The assessment was done through a formulated questionnaire, which was filled in by an interviewee at the bedside or at the outpatient clinic. The questionnaire (see Appendix) included an assessment of the inhaler technique through a checklist of 8 key steps (Box 1) ticked while the patients demonstrated how they used their inhaler. A score out of 8 was recorded for each patient. Patients were informed of the purpose of this questionnaire and consented prior to asking them the questions. A small number of patients on the wards had to be excluded from the study either due to the fact that a nurse or carer did the inhaler for them or because they were too ill to be interviewed. Most patients did not have their large volume spacer (LVS) with them at the time of interview especially the ones attending the outpatient clinic. These patients were still asked to demonstrate and explain how they would use it.

Results

A total of 174 questionnaires were collected and analysed. The age range was from 16 – 97 years. 118 (67.4%) of the patients had asthma while 56 (32.0%) had COPD. Of the inpatients, 40% were asthmatics and 60% were COPD patients. 86.5% of the outpatient clinic patients were asthmatics and 13.5% were COPD patients.

Tables below show the age groups of the patients suffering from asthma and COPD respectively and the number of these patients who were admitted at the time of the study. It is clear that most of the inpatients suffering form either disease are over 60 years of age.

***Table 1**: Number of patients in the different age groups who were involved in the study and the number of patients who were admitted at the time of survey.*

Asthma patients		
Age groups	No. of patients	No. of inpatients
10 - 20	11	0
21 - 30	9	2
31 - 40	9	1
41 - 50	9	1
51 - 60	24	4
61 - 70	28	6
71 - 80	20	8
81 - 90	8	6
Totals:	118	28 (24%)

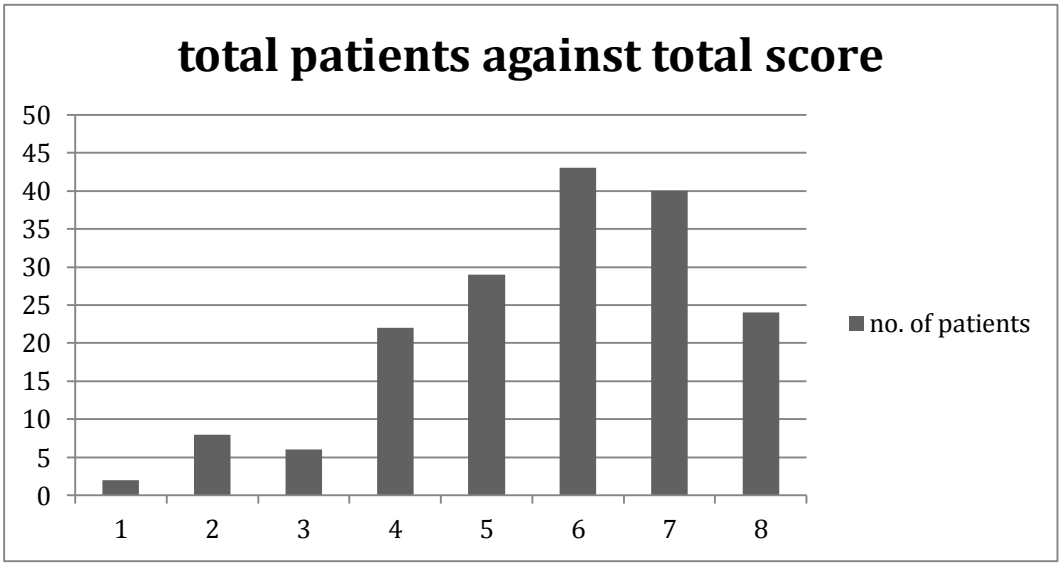
COPD patients		
Age groups	No. of patients	No. of inpatients
41 - 50	1	1
51 - 60	6	2
61 - 70	17	11
71 - 80	18	16
81 - 100	14	12
Totals:	56	42 (75%)

The patients were also asked whether or not they have a large volume spacer and whether they use it regularly with their pMDI. Results are shown in the table below. As, shown in Graph 1, only 24 (13.7%) of the patients involved managed to score a total of 8. 40 (22.8%) scored a 7 out of 8 showing that they could nearly do the inhaler rather well but the rest, 111 (63.5%) patients scored 6 or less. The most common score in COPD patients was 4 (21.4% of the COPD patients) while in asthmatics the most common score was 6 (27.1% of the asthmatic patients) as shown in Graph 2.

***Table 2**: Summary of the number of patients who own a LVS and the percentage of them who actually use the LVS regularly*

Asthma			COPD		
Age groups	Owns a spacer	% of patients who own a spacer and always use it	Age groups	Owns a spacer	% of patients who own a spacer and always use it
10 - 20	10 (91%)	60%	41 - 50	1 (100%)	100%
21 - 30	7(78%)	43%	51 - 60	5(83%)	60%
31 - 40	9(100%)	78%	61 - 70	15(88%)	67%
41 - 50	8 (89%)	63%	71 - 80	18(100%)	44%
51 - 60	23(96%)	70%	81 - 100	10(71%)	50%
61 - 70	23(82%)	78%			
71 - 80	19(95%)	63%			
81 - 90	6(75%)	100%			

***Graph 1**: Graph showing the total number of patients (both COPD & Asthma) against the total score achieved*



***Graph 2**. Graph showing asthmatic and COPD patient percentage across all age groups against total score acquired on assessment*

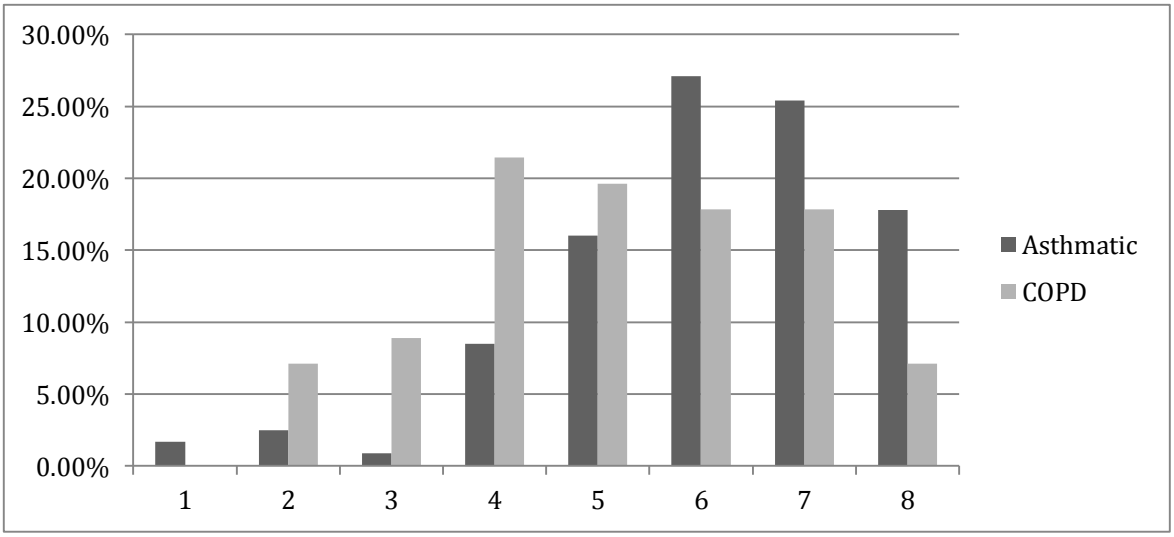


***Table 3**: The highest score obtained by the asthma patients in each age group with the percentage of patients who managed to obtain that score and the commonest score for each age group with the percentage of patients who obtained that score*

Asthma				
Age groups	Highest score obtained	% of patients who obtained the highest score	Most common score obtained (out of 8)	% of patients with the commonest score
10 - 20	8	9%	7	36%
21 - 30	8	22%	4	33%
31 - 40	8	22%	7	33%
41 - 50	8	11%	6	44%
51 - 60	8	38%	8	38%
61 - 70	8	7%	6	36%
71 - 80	8	20%	6	35%
81 - 90	7	13%	6	14%

***Table 4**: The highest score obtained by the COPD patients in each age group with the percentage of patients who managed to obtain that score and the commonest score for each age group with the percentage of patients who obtained that score*

COPD				
Age groups	Highest score obtained	% of patients who obtained the highest score	Most common score obtained (out of 8)	% of patients with the commonest score
41 - 50	5	100%	N/A	N/A
51 - 60	8	17%	6	33%
61 - 70	8	12%	7	24%
71 - 80	7	28%	7	28%
81 - 100	7	8%	4	36%

Table 3 and Table 4 summarise the scores obtained according to the age group for asthma and COPD patients separately. 9(38%) asthmatic patients aged between 51 and 60 obtained a full score of 8. The COPD patients had overall very poor scores and only 3 obtained the full score.

Out of the 8 steps that were checked, most patients did not exhale prior to pressing the canister in preparation for a deep inhalation. 109 (62.6%) of all the patients missed this step. Re-shaking the inhaler before the second puff and taking a deep breath slowly were other two very commonly missed steps, with 40.5% and 39.4% respectively.

Another aspect that was considered in this study is the patients' perception of how well they can use their inhaler and LVS. 163 (93.6%) patients rated their inhaler technique at 7 or more out of 10 (10 being the highest mark).

Discussion

An inappropriate inhaler technique tends to be a significant feature in patients suffering from asthma or COPD needing hospital admission or frequent nebulised bronchodilators from the LHC. The main aim was to get

a picture of the local situation, as so far there is not much local data on this matter. A similar study published in 2005 regarding the paediatric population showed that only 17% of the patients had a poor technique.[12] In this small study, 38.5% of the patients scored less than 6 indicating that a significant amount of patients do not use their inhaler appropriately. This is a known cause of repeated admissions.

The need to collect more data on the local situation is all too evident, as is the importance of better patient education, which can prevent morbidity and mortality in these patients, embitter their quality of life and, just as importantly, aid cost-reduction and effectively reduce the burden on the local health-care system.

Patients should have their inhaler technique assessed repeatedly. Patient education is the main tool to target this problem. Programmes and different methods can be used to explain to patients and ensure improvement in technique, ultimately enabling patients to master the proper method. Moreover, even if a patient does on one occasion demonstrate that the proper technique has been grasped, regular re-assessment is important and recommended as patients have been shown to lose the adequate technique over time.[10] Inhaler technique, as well as the aerosolised particle size, are main factors in particle deposition within the lungs.[13]

Two teaching strategies – the brief intervention and the teach-to-goal methods were investigated by Press *et al*. (2012), with the teach-to-goal method having been found to be the most effective method overall. This approach involves repeated demonstration and allowing the patient to demonstrate it back thus enhancing the memory on allowing the patient to "teach it back" to the healthcare professional.[14] A study by Cordina et al. (2001) indicated that pharmacist intervention in monitoring asthma management in general was well received by the patients involved and had good influence on the patients' inhaler technique.[15]

While performing the questionnaires for this study it was noted that most of the patients, especially the inpatients, had a low level of literacy. No statistical evidence was recorded, but on asking whether a leaflet with written instructions on how to use the pMDI would help, 47.1% of them said that it would be of no use to them as they would not be able to read this. In fact, patients with a low level of education tend to have poorer inhaler technique – illiteracy being a proven impediment in the management of asthma and COPD.[16–19] This further shows the importance of verbal explanation.

The patient has to co-ordinate a number of steps which may be difficult, especially in the elderly who may have better delivery with the use of a LVS.[20] The pMDI is the most commonly used inhaler device in the elderly population.[18] Several studies that correlate age to the appropriateness of the inhaler technique show the elderly tend to have poorer skill.[21-25] In this study, when age is correlated to the total score, there is a rather weak negative correlation between the two (r= -0.234).

The type of inhaler used in a patient should be tailored to his/her ability, age and need. The patient's capacity to use the particular inhaler should be taken into consideration by the prescribing physician.[8] Exhaling, pressing the canister and inhaling are the main three steps that need to be co-ordinated in chronological order for optimal delivery. In this particular study it was shown that most patients tend to not exhale in preparation for a deep inhalation. There seems to be a misconception among patients on how the necessary drug gets to its target organ.

Another point highlighted in this study is the patients' perception on how well they can use their MDI. Most patients over estimate how good their inhaler technique is. In fact when considering the actual scores and the self-rating values there is a substantial difference. 93.6% of the patients gave themselves high marks, that is 7-10 out of 10, for their inhaler technique when in actual fact only 36.8% got a good score, that is 7-8 out of 8, for their technique on assessment. This is also shown in other studies which indicate that the correlation between patient's perception and actual performance is poor.[10, 21] This highlights the fact that even patients who have been using their inhaler for a long time need continuous reviewing of their technique.

While the present study is indicative and does provide a valuable insight into the local situation (especially on consideration of the fact that up till now no other similar studies have been conducted locally), it also suffers from a number of limitations. One of the main limitations is the sample size. This study was not performed on a large scale. Neither was it performed over a long period of time. Another limitation is the fact that not enough demographic data was documented. Gender, occupation and level of education were not recorded. These could have shown which sector of the population is most at risk of repeated admissions and which patients need to be focused on the most. Also the questionnaire used is not a validated standard questionnaire.

Conclusion

Despite the well-known fact that a good pMDI technique is of utmost importance, patients still tend to have a relatively poor technique. Overall this study highlights the need for continuous patient education when it comes to appropriate drug delivery in Asthma and COPD and serves as a reminder to clinicians in general of the importance to monitor inhaler technique often. It might be a good idea to device programmes catering for different patients with different needs and possibly training specialised nurses, pharmacists and

GPs to monitor this technique. Well-targeted programmes can go a long way towards improving the inhaler technique, thereby decreasing the morbidity and mortality in these two treatable, preventable and controllable diseases.[15] This study also emphasises the need for more local statistics to give us healthcare professionals a clearer picture of the severity of these two very common illnesses, this with the ultimate aim of improving the asthmatic or COPD patient's quality of life.

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Appendix:

Questionnaire:

1) Age:
2) Inpatient/Outpatient
3) Diagnosis: Asthma/COPD
4) Attends regular asthma/lung clinic: yes/no
5) Do you have a spacer? Yes/no
6) Do you use the spacer with your MDI? Always/often/sometimes/never
7) Do you think you know the technique well enough? Rate from 1 – 10

1 2 3 4 5 6 7 8 9 10

8) Inhaler technique: (tick 1 for every correct move)

- ☐ Shaking the inhaler
- ☐ Locking the lips appropriately around the mouth piece
- ☐ Exhale fully prior to pressing the canister
- ☐ Holding the MDI between the index and thumb and pressing the canister
- ☐ Inhaling via the spacer as soon as the canister is pressed
- ☐ Taking a deep breath slowly and deeply in
- ☐ Holding the inhaled air for 5 – 10 seconds after
- ☐ Re-shaking the inhaler for the second puff

Total score:

Original Article

Maltese with genetic susceptibility to poliomyelitis: sibs with paralysis at different times

H.V. Wyatt

Abstract

I found the records of 1,072 Maltese cases of poliomyelitis in the islands of Malta from 1909 to 1964. These cases and baptism matched controls were traced to their great grand-parents and all marriages were checked for consanguinity. There were no twins among the polios or controls, but there were 70 pairs of sibs. Of these, 13 pairs suffered poliomyelitis in different epidemics even though the younger sib was born after the elder was paralysed. The 27 pairs of polio sibs were directly related to more than twice as many other polios (through grand-parents and great grand-parents) as the 22 pairs of control sibs. The families of polio sibs contained more consanguineous marriages than either the 21 sibs of which one was a polio and the other a control or the control sibs. The polio sibs provide further evidence of genetic susceptibility to poliomyelitis and possible problems arising from the eradication of the disease.

Keywords

consanguinity, epidemics, genetic susceptibility, Malta, poliomyelitis, sibs

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Introduction

In many epidemics of poliomyelitis, researchers have noted a few cases where two sibs have been paralysed, but have ignored the possibility of genetic susceptibility. After 1935 when the 'vaccines' failed, researchers thought that a child with polio excreted more virulent and more virus, thus increasing the risk to the sib. This was not a testable theory. An alternative explanation is that the sibs were genetically susceptible[1-2] and this is most likely when the sibs were paralysed at different dates and epidemics.

There was an epidemic of poliomyelitis in the Maltese islands in 1918, but no records remain, although the disease was made notifiable. A few cases were reported until the large epidemic of 1942-1943: the last case occurred in 1964. Almost all the cases were in Maltese children under four years, but some were unrecognised at the time and not reported. All adults were immune and babies were protected by maternal antibodies until about six months old. I have found the records of 39 Maltese cases which occurred from 1909 to 1938. Some British children were included in the *Annual Reports*, but others were treated by army doctors and so were unreported.

Method

From 1982 to 1987, with the approval and support of the Chief Government Medical Officer, I examined the notes of the Infectious Diseases Hospital stored in the old Lazarreto on Manoel Island: I found the original notes of 1,072 Maltese cases of poliomyelitis from 1909 to 1964. I looked at, and noted only the information of name and date of birth of the child. The records have since been trashed by unknown intruders. I also checked the names against the original physiotherapy notes at St. Lukes Hospital as well as some notes of cases prior to 1926 when seen for orthopaedic care. With the approval and support of the Public Registrar (a lawyer), the Archbishop of Malta, the Bishop of Gozo and the kappillans (parish priests), I traced their parents, grand-parents and great grand-parents, together with baptism matched controls, from the public parish birth and marriage records, as well as the Public Registry where necessary. Polios and controls were allotted to the parishes of their great grand-parents. I have traced more

than 4,500 births and 16,000 marriages. The Vatican dispensations for consanguinities of marriages were noted. Details of cases or controls were entered on cards and all names were entered alphabetically for each parish or village and these were also amalgamated as far as possible.

This is the first study to find all the cases of poliomyelitis in a large population over many years, rather than unconnected studies of individual epidemics or individuals.

Results

After the polio epidemic of about 430 Maltese cases in 1942-1943 in Malta and Gozo, Professor Seddon of Oxford University was flown to the island and examined all the cases. He noted six pairs of sibs with paralysis [3] to which I have added three more pairs in which the paralysis of the younger sib was only recognised later (my records). I have found a further 18 pairs of polio sibs: among four pairs, both were paralysed at the same time, but 14 pairs were affected in different epidemics. In 13 cases the younger was born after the elder was paralysed and in one village the elder was not infected in the 1942 epidemic, but was paralysed later. The younger sibs were born from five months to 11 years after the older was paralysed. In one case, the family had moved house before the younger sib was born 11 yr after the elder was paralysed (Table 1)

***Table 1**: Pairs of sibs with polio who were paralysed at different times in Malta and Gozo*

	Related to	**Consanguinity**
Case 862 was born years after the elder sib, 415 was paralysed	via paternal ggp to 889, via maternal ggp to 424 and via g-ggp to 5 other polios	
Case 875 was born years after the elder sib 700 was paralysed	via ggp to 918, 1034, 1063	parents II + III, paternal gp IV
Case 610 was born more than 1 yr after the elder sib 244 was paralysed	via paternal ggp to 243	maternal gp IV
Case 1024 was born years after elder sib 297 was paralysed	father related to 3 polios in Mellieha	
Case 650 was born years after the elder sib 250 was paralysed		parents III
Case 696 was born years after the elder sib 143 was paralysed		[mother from Europe]
Case 6 was born years after the elder sib 5 was paralysed		[family had moved to a new house]
Case 1100 was born years after the elder sib 1100B was paralysed		maternal gp II
Case 809 was born years after the elder sib 179 was paralysed	via mother's nephew to 157, and mother's niece to daughter 767	paternal gp II
Case 669 was born after the elder sib 382 was paralysed	via paternal gp to 736 and ggp to 149, via maternal ggp to 788	
Case 803 was born years after the elder sib 357 was paralysed	via maternal gp to 910, and ggp to 175 and via paternal gp to 12 and 111	
Case 880 who was born in1929 was paralysed at 22 yr, 8 yr after a younger sib 144 was paralysed	via maternal ggp to 630, via mother's niece to 701	maternal gp IV
Case 683 was born after the elder sib 346 was paralysed		
Case 745 was born after the elder sib 699 was paralysed		

gp: grand-parent ggp: great grand-parent

The 27 pairs of polio cases were related through grand-parents and great grand-parents to another 33 polios, more than twice as many as those related to the 22 pairs of control sibs (Table 2). The families of polio sibs contained more consanguineous marriages of parents and grand-parents than either the 21 pairs with a polio and a control or the 22 control pairs (Table 3). With the small numbers involved, these differences might be due to chance (Fisher's Test) although all point to a difference. In the 21 pairs of sibs with polio and control children, the control might be genetically a 'polio' who did not develop paralysis either because the poliovirus was less virulent than in other epidemics or because the child was not yet sufficiently primed.[4]

***Table 2**: Pairs of sibs in Malta and Gozo*

	Nos.	Connected to				Consanguinities	
		others	polios	controls	none	parents	grand-parents
Both sibs polios	27	16	33	15	11	4	7
one polio + one control	21	10	8	6	11	1	5
both controls	22	12	16	14	10	-	3

***Table 3**: Histories of consanguinity among pairs of sibs in Malta and Gozo*

	Nos.	Consanguinities						
		parents		grand-parents				
		II	III	II	II/III	III	III/IV	IV
Both sibs polios	27	2	2	3			1	3
one polio + one control	21		1		1	2		2
both controls	22					2	1	

Of the nine pairs of sibs who were paralysed in the 1942-1943 epidemic, four pairs were from Malta, but five pairs occurred on the small sister island of Gozo: #465 and #467, #180 and #493, #158 and #159 with #207 and #564, and #468 and #469 in Victoria. Gozo had a population one tenth that of Malta.

In one small isolated village there were eight cases of polio and another case where the mother came from a different village (Wyatt, in preparation). In this village there were two pairs of sibs with paralysis at different times. On the island of Malta, there were 956 polio cases of which 54% were related as sibs and first and second cousins (Wyatt, in preparation). On the smaller island of Gozo, which had a greater proportion of consanguinous marriages than Malta (paper submitted), of the 116 cases, 67% were related as sibs and first and second cousins.[10]

Discussion

In his Report of the 1942 Malta epidemic Seddon commented: '...result of exposure to small doses of virus sufficient to confer immunity without producing more than an occasional case of definite paralysis. But many children under 5 and some under 10, had failed, either through lack of exposure or because of some intrinsic defect, to become immunised'.[3] There was no explanation of what an 'intrinsic defect' could be or how this minimal exposure over the previous twenty years had suddenly changed, but only for the young children. That the Maltese cases were only small children shows that over the years almost everyone in the islands had been infected by successive waves of virus: there were, however, 58 cases among the adult British servicemen [3]. In later epidemics, all save one of the Maltese cases had been among the thousands of children born since the previous one.

There were no entries for sibs in the extensive 93 page subject index of the bibliography of poliomyelitis[5], nor in Paul's wonderful history of polio.[6] In his chapter on Aycock, Paul did not mention Aycock's fascination with a genetic background to polio or his many papers with examples of families with multiple cases. In discussing this chapter with Paul, I asked why he had omitted the papers on genetic susceptibility. Paul had no memory of them, but later wrote to me that he had found his letter to the Rockefeller Foundation in which, as a referee, he had advised against a grant to Aycock to study genetic susceptibility. Paul would have considered the search for a vaccine to be the priority. Wickman gave many examples of sibs who had suffered attacks in epidemics, but did not distinguish between those with permanent paralysis and those who recovered ie, non-paralytic.[7] Other papers of genetic susceptibility to polio are discussed in ref. 4.

Burnet in a lecture in America said that 'there is good reason to believe that paralytic polio and overt tuberculosis depend more on the presence of individual genetic susceptibility to an initial infection than to the virulence or dose of the infecting strain.[8] No references were given in this paper, but the only source of this belief is likely to be mine in *Medical Hypotheses* where Burnet was prominently displayed as one of the five Advisory Board.[4,9]

Conclusion

Although genetic susceptibility has been ignored for 100 years and WHO says that only 1 in 200 is paralysed, one in 50 was paralysed in dozens of epidemics.[9] In 1948 a virgin soil epidemic affected two out of 53 Inuit children and 26 % of the adults: Sabin interpreted this to be 'an isolated highly inbred population of special genetic susceptibility', but failed to recognise that the Hardy-Weinberg ratio was

2% p^+p^+ 24 % p^+p^- and 74% p^-p^- [see ref. 4]. How could genetic susceptibility be confined only to an Inuit group? How can strains of different virulence only cause paralysis to the same proportion of cases (up to 2 % in very young children and up to 24% among adolescents and adults) unless there is an underlying genetic susceptibility? In epidemics due to importation of poliovirus from Egypt by eg British servicemen in 1942 and Maltese soldiers and dockyard workers in 1945 and 1947, when everyone was infected, the same families suffered children with paralysis. My study shows that many cases of genetic susceptibility occurred in the large population of more than 300,000 Maltese.[10]

Genetic susceptibility for poliomyelitis in populations has been ignored.[11] but familial cases and pairs of sibs with polio, provide ample evidence for it and the need for realistic planning for the post-eradication age. When ten years elapse without a case of poliomyelitis, immunisation will cease. After that time, two per cent of children will then be at risk without immunity should a virus reappear. But ten years later, there will be cohorts of young people of whom up to 24 % will be at risk of paralysis. When polio cases no longer occur and immunisation ceases, there will still be a danger that a polio or polio-like virus may emerge. Polio or similar viruses may escape from unsuspected sources in laboratories, may be deliberately manufactured, may mutate from other enteroviruses or may have lain dormant in the environment. Plans must be made for the possibility that many with genetic susceptibility and no immunity might be infected. It will be prudent to have stocks of vaccine available for an emergency, but the knowledge that so many people might be susceptible to paralysis demands that far larger stocks of vaccine than presently envisaged may be required.

I have arranged that all the notes, cards, printouts etc will be deposited with the Melitensis Collection of the University of Malta where they will be available to those with permission from the Medical Ethics Committee. I am grateful to the Royal Society for a travel grant in 1985 and to all those kappillans and doctors who helped me.

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Current GOLD recommendations and its implementation within hospitalised COPD patients in Malta

Jonathan Gauci, Kentaro Yamagata, David Bilocca, Maria Mifsud, Stephen Montefort

Abstract:

Introduction: In 2012, GOLD revised their classification of Chronic Obstructive Pulmonary Disease patients, incorporating spirometry, symptoms and recent exacerbations.[1]

Aims and Objectives: To assess if patients admitted with an exacerbation of COPD were properly staged prior to the admission, and whether their treatment on presentation was in accordance with GOLD recommendations.

Materials and Methods: All patients admitted to Mater Dei Hospital, Malta with a COPD exacerbation during February, May and August 2013 were studied. Spirometry was considered relevant if performed within the previous two years. The mMRC score of each patient, the number of exacerbations over the previous 12 months, and patient co-morbidities were also recorded.

Results: A total of 124 patients were admitted with an exacerbation during the study period. Of the patients who were known to have COPD, only 48.5% had spirometry performed in the previous two years. Most patients admitted were in GOLD Stage 3 (34.0%), and most were classified as GOLD Group D (73.2%). A long acting bronchodilator was not prescribed in 48.8% of cases where it was indicated. An inhaled corticosteroid was not prescribed in 25.6% of cases where it was indicated, while 10.3% of patients were prescribed an inhaled corticosteroid when this was not indicated.

Conclusion: It is noted that there is a need to improve diagnosis and treatment of COPD on a local basis.

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Introduction

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) maintains that Chronic Obstructive Pulmonary Disease (COPD) is a clinical diagnosis that should be based on history-taking, the presence of symptoms and assessment of airway obstruction. GOLD recommends spirometry as the gold standard for accurate and repeatable measurement of airway obstruction, measured as the post-bronchodilator Forced Expiratory Volume in one second (FEV_1). GOLD regards a FEV_1/FVC ratio (Forced Expiratory Volume in one second / Forced Vital Capacity) of less than 0.70 as compatible with COPD.

It was previously believed that most COPD patients followed a path of disease progression in which the severity of the disease process paralleled the severity of the airflow limitation. However, more recent studies have shown that on an individual patient basis, the level of airflow limitation (FEV_1) on its own is an unreliable marker of the severity of breathlessness, exercise limitation, and health status impairment. This has led GOLD to revise its guidelines in 2011, presenting a new way of assessing COPD patients, taking into account level of patient's symptoms, severity of airflow limitation, and recent exacerbations, as well as the presence of comorbidities. The most recent GOLD update from January 2015 has retained this combined level of assessment.[1]

The first aim of our audit was to check if patients admitted to Mater Dei Hospital with an exacerbation of COPD, were staged by spirometry at any point during the previous two years. Secondly, the audit aimed to compare the treatment on admission of each patient, with that recommended by GOLD guidelines for the particular GOLD patient group in question.

Materials and Methods

Inclusion and Exclusion Criteria

All patients admitted to Mater Dei Hospital with an exacerbation of COPD during February, May and August 2013 were included in the study. Those patients who were newly diagnosed with COPD and those who were not previously residing in Malta prior to the admission, were excluded from the rest of study, because understandably no previous spirometry would be available in the Mater Dei Hospital records.

Current Level of Patient's Symptoms

The modified Medical Research Council Dyspnoea Score (mMRC) was used to assess patient symptoms. The patients were contacted and asked how they would rank themselves on the mMRC score in the month preceding the hospital admission, rather than the last few days prior to admission. This is because the GOLD guidelines being highlighted by this audit, are focused on the management of stable COPD, not the actual exacerbation.

Severity of the Airflow Limitation

The post-bronchodilator Forced Expiratory Volume in one second (FEV_1) was used as the measurement of airway limitation. The FEV_1 readings were considered to be valid if they were recorded at any point during the previous two years. Spirometry performed prior to this arbitrary two-year period, was considered to be old and not an accurate reflection of the patient's airflow limitation during the period immediately prior to the COPD exacerbation. Using the FEV_1 from spirometry carried out during the hospital admission (if any) was not considered appropriate since the GOLD guidelines being highlighted by this audit, are centred on the management of stable COPD, not the actual exacerbation. The FEV_1/FVC ratio of each patient was also checked, since a ratio of more than 0.70 is not compatible with COPD. Table 1 shows the GOLD classification system used.

Recent Exacerbations

The number of COPD exacerbations leading to hospitalisation in the preceding 12 months for each patient was obtained from the Mater Dei Hospital Electronic Case Summary database. Each patient was then called in order to collect data on the number of exacerbations which did not lead to hospitalisation.

***Table 1**: GOLD Stages*

GOLD Stage 1 – post-bronchodilator $FEV_1 \geq 80\%$ predicted
GOLD Stage 2 – post-bronchodilator FEV_1 50 to 80% predicted
GOLD Stage 3 – post-bronchodilator FEV_1 30 to 50% predicted
GOLD Stage 4 – post-bronchodilator $FEV_1 < 30\%$ predicted

GOLD = Global initiative for chronic Obstructive Lung Disease,
FEV1 = Forced Expiratory Volume in one second

Presence of Co-morbidities

Patient co-morbidities were obtained from the discharge summary available on the Mater Dei Hospital Electronic Case Summary database.

Combined Assessment of COPD

Each patient was classified into a GOLD patient group by combining airflow limitation (spirometry), symptoms and recent exacerbations, as shown in Table 2.

***Table 2**: Combined Assessment of COPD*

GOLD Group	Symptoms	Airflow Limitation	Exacerbations over past 12 months
A	mMRC 0-1	Low Risk Stage 1 or 2	Low Risk 0 or 1 not leading to hospitalisation
B	mMRC ≥2	Low Risk Stage 1 or 2	Low Risk 0 or 1 not leading to hospitalisation
C	mMRC 0-1	High Risk Stage 3 or 4	High Risk ≥2 or ≥1 leading to hospitalisation
D	mMRC ≥2	High Risk Stage 3 or 4	High Risk ≥2 or ≥1 leading to hospitalisation

GOLD = Global initiative for chronic Obstructive Lung Disease,
mMRC = modified Medical Research Council dyspnoea score

When assessing risk, the highest risk according to airflow limitation or exacerbation history should be used. For example, a patient with a mMRC score of 1 with a post-bronchodilator FEV_1 of 70% (therefore Gold Stage 2) and 2 exacerbations over the past year, was classified as Group C.

Pharmacologic Therapy for Stable COPD

The patients were asked what treatment they were taking prior to the admission, and this was compared to that recommended by GOLD. The Recommended First Choice and the Alternative Choice were considered optimal for the particular GOLD group in question (Table 3). The treatment options listed in the Other Possible Treatments section of the GOLD guidelines, were not considered optimal.

***Table 3**: Optimal Pharmacological Therapy*

GOLD Group	Recommended First Choice	Alternative Choice
A	SAMA prn or SABA prn	LAMA or LABA or SAMA + SABA
B	LAMA or LABA	LAMA + LABA
C	ICS + LABA or LAMA	LAMA + LABA or LAMA + PDE-4 inhibitor or LABA + PDE-4 inhibitor
D	ICS + LABA and/or LAMA	ICS + LABA + LAMA or ICS + LABA + PDE-4 inhibitor or LAMA + LABA or LAMA + PDE-4 inhibitor

SAMA = short-acting anti-muscarinic agent,
SABA = short-acting beta-agonist,
LAMA = long-acting anti-muscarinic agent,
LABA = long-acting beta-agonist,
ICS = inhaled corticosteroid,
PDE-4 = phosphodiesterase type 4

Results

Patient Demographics

A total of 124 patients were admitted with a COPD exacerbation during the study period. 57 patients were admitted in February, 40 in May, and 27 in August 2013. The patient age ranged from 40 to 98 years, with a mean of 70 years and a median of 71 years. The length of admission ranged from 1 to 25 days, with a mean of 5.9 days and a median of 5 days.

Current Level of Patient's Symptoms

Fig. 1 shows the distribution of patient according to mMRC score.

Severity of the Airflow Limitation

Table 4 shows that 48 patients (38.7%) had valid spirometry, i.e. performed in the last two years. After eliminating the newly-diagnosed COPD patients and those not previously residing in Malta, only 48 patients (48.5%) were found to have valid spirometry. Of these patients, 34.0% were classified as Stage 3. Both Stage 2 and 4 comprised 27.7% of patients, while 10.6% were classified as Stage 1.

Recent Exacerbations

The mean number of exacerbations per patient over the past 12 months, was 1.2. The range was 0 to 14. 67 patients (54.0%) were classified as Low Risk, meaning they had 0 or 1 exacerbations over the past 12 months, which did not lead to hospitalisation. 57 patients (46.0%) were High Risk, having at least 2 exacerbations over the past 12 months, or at least one exacerbation which led to hospitalisation.

Presence of Co-morbidities

COPD was found to be highly co-morbid with a number of disorders, as shown in Fig. 2.

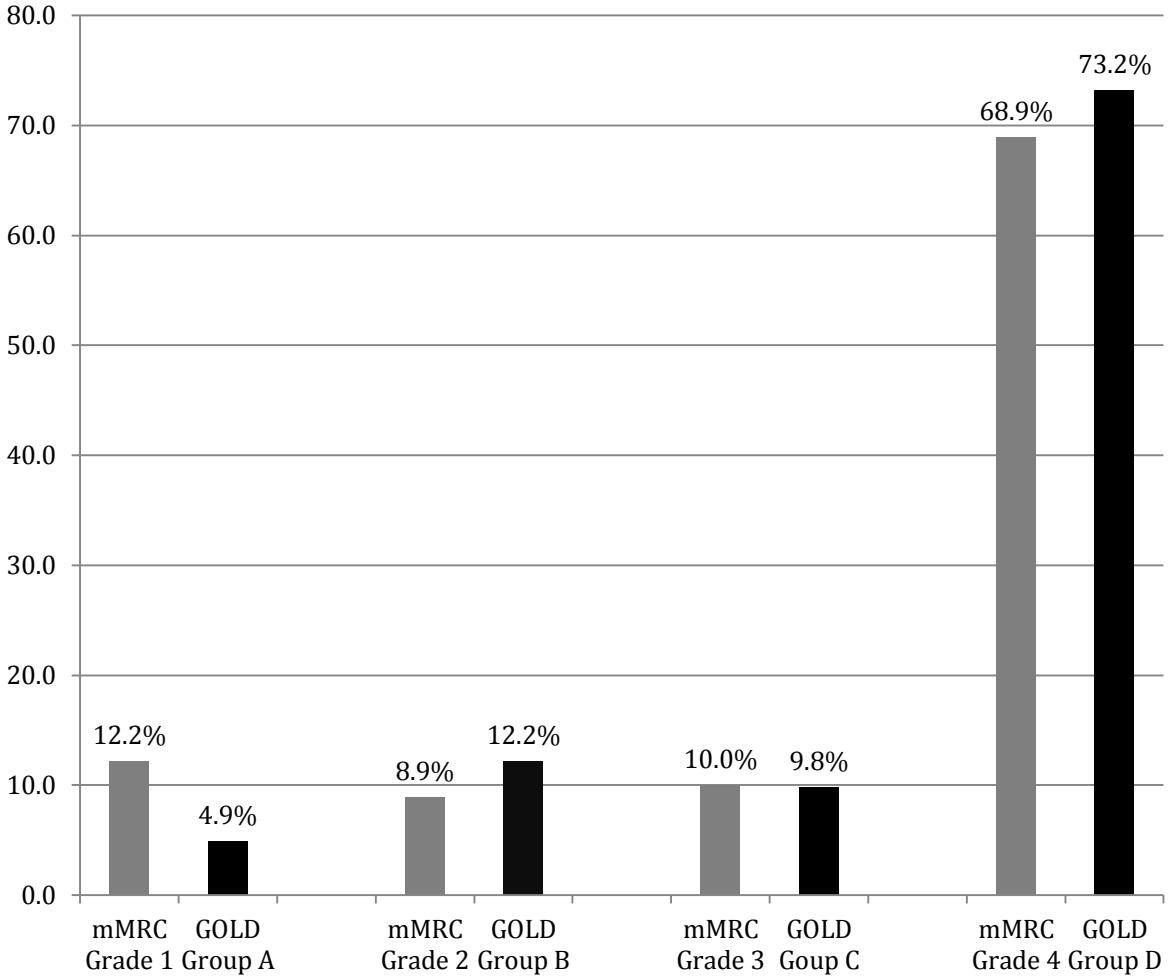
Combined Assessment of COPD

Fig. 1 shows the distribution of patients according to GOLD group, with 73.2% of patients being classified as Group D.

Pharmacologic Therapy for Stable COPD

The treatment of only 14 patients (36.0%) was in accordance with the first recommended choice or the alternative choice recommended by GOLD. The remaining 64.0% of patients were not on optimal therapy. Inhaled long-acting beta-agonist (LABA) treatment is recommended for all patients in Group B to D, of which 48.8% were not receiving LABA therapy. Inhaled corticosteroid therapy (ICS) is recommended for all patients in Group C and D, of which 25.6% were not on ICS treatment. On the other hand, 10.3% of patients in Groups A and B were on ICS therapy, when this is not recommended by GOLD (Fig. 3).

***Figure 1**: Patient Symptoms and GOLD Group*



mMRC = modified Medical Research Council dyspnoea score,
GOLD = Global initiative for chronic Obstructive Lung Disease

***Table 4**: Validity of Spirometry*

Spirometry	Percentage
Spirometry in last 2 years	38.7%
Spirometry more than 2 years ago	11.3%
No Spirometry done since migration to MDH	29.8%
New diagnosis of COPD	16.1%
Non-Residents	4.0%

***Figure 2**: Presence of Co-morbidities*

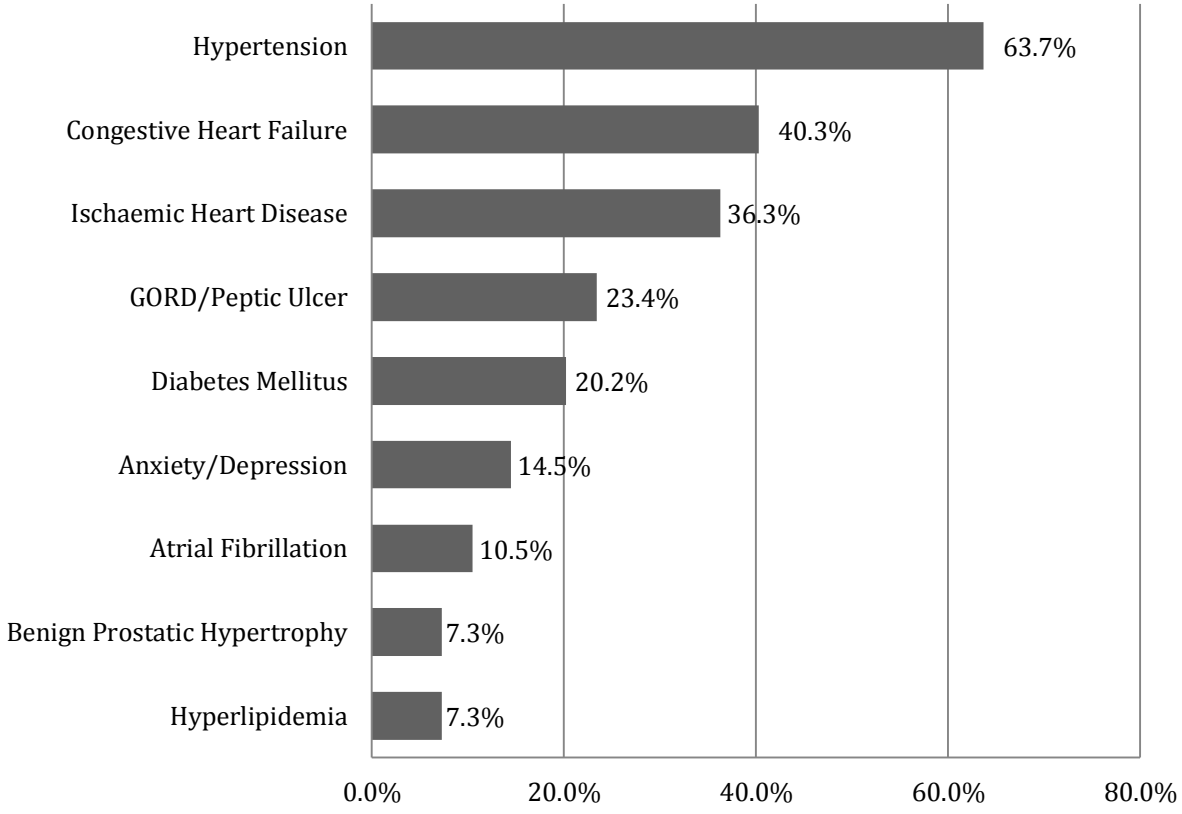
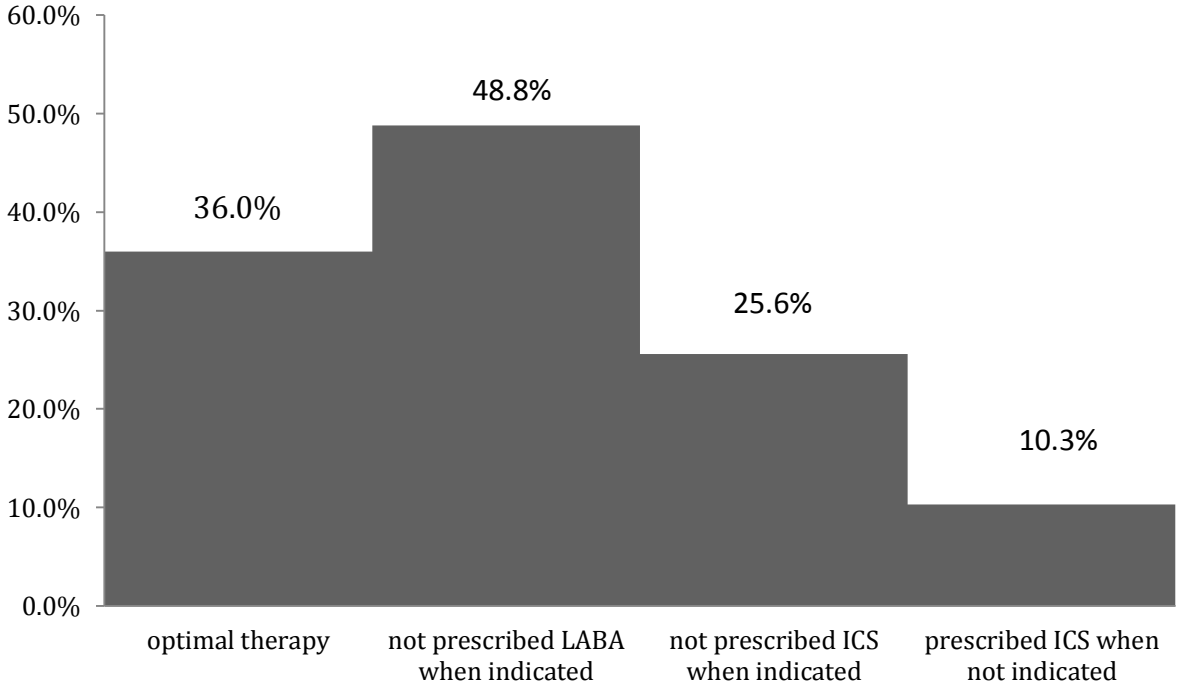


***Figure 3**: Pharmacological Therapy*



LABA = long-acting beta agonist,
ICS = inhaled corticosteroid

Discussion

The results obtained from this local audit are comparable to the figures from the 2010 European COPD Audit, which was an observational multicentre study, collecting data from 15821 patients in 422 hospitals around Europe, including Mater Dei Hospital, with the aim of assessing hospital care for COPD patients.[2] The number of patients in the local study was 124, with a median age of 68, while the number of Maltese patients included in the European study was 112, with a median age of 72 years. The median length of hospital stay for an exacerbation of COPD in Malta was found to be 5 days in both studies, when compared to 8 days for Europe as a whole. The mean number of exacerbations per patient over the previous year was 1.2 in the local study, similar to the median number for Europe, which was 1.

Our present audit found that 48.5% of patients admitted with a COPD exacerbation had spirometry in the last 2 years. This was almost identical to the figure reported in the European audit for Malta - 48.2% - though this figure included any previous spirometry, not only that performed in the previous 2 years. The mean European figure was 59.6%, meaning that Malta was more than 10% below the mean. While our own figures for stratification of severity are very similar to the 2010 total European figures, they were however quite different from the 2010 Maltese figures (Table 5).

***Table 5**: Comparison of COPD Severity Stratification Data*

GOLD Stage	Gauci et al. (2013) Malta	European COPD Audit (2010) Europe	European COPD Audit (2010) Malta
Stage 1	10.6%	15.3%	46.3%
Stage 2	27.7%	23.3%	5.6%
Stage 3	34.0%	39.3%	24.1%
Stage 4	27.7%	22.1%	24.1%

Inadequate staging of COPD patients in Malta is primarily due to a lack of spirometry requests. There are several possible reasons for this. A 2013 qualitative study in Chicago concluded that the most common explanation behind primary care physicians not requesting spirometry, was that spirometry was deemed not necessary to make a clinical diagnosis of COPD.[3] GOLD maintains that spirometry is required for the diagnosis of COPD, and states that primary care physicians are in an ideal position to be able to detect COPD in its early stages and perform spirometry to confirm the diagnosis.[1]

Research has shown that the primary benefit of spirometry is to identify those symptomatic patients who might benefit from pharmacological therapy in order to decrease frequency of exacerbations. However, monitoring with spirometry to guide additional therapy or to initiate interventions in patients without bothersome respiratory symptoms does not appear to be beneficial.[4]

The local audit found that underprescription of inhaled LABA was common in Malta. The European study showed a very wide variation in the percentage of COPD patients who were receiving a LABA prior to admission, ranging from 0.6% to 45.9%.[2] The mean value for Europe was 9.3%, and the value quoted for Malta was 12.5%, meaning that LABAs are also underprescribed in several other European countries. Our audit also described inappropriate prescription of ICS in mild COPD and underprescription in severe COPD. The European study looked at the percentage of COPD patients who were receiving ICS, and gave a mean value of 12.4% for Europe, and a value of 54.5% for Malta. Malta was in fact the country where ICS were most prescribed, by almost 20%.

One possible reason for suboptimal pharmacological treatment is the lack of clear evidence that optimization of therapy improves outcomes in COPD. The 2015 systematic literature review carried out by Wilt *et al*. concluded that pharmacological interventions reduced the relative risk of exacerbations by 20 to 25%, and reduced hospitalisations by 4 to 7%, while mortality was not significantly different.[4] The review concluded that the primary benefit of pharmacological intervention is to reduce exacerbations in patients with troublesome respiratory symptoms and severe to very severe airflow obstruction (FEV_1 < 50% predicted).

Another possible explanation behind underprescription is the fear of side-effects. LABA therapy could have been purposely avoided in patients with cardiac co-morbidities, because beta-agonists are associated with an increased risk in these patients. Au *et al*. described a dose-response relationship of increased hospitalisation and death due to heart failure in patients with congestive heart failure who received increasing

amounts of beta-agonist.[5] On the other hand, there appeared to be no association between the use of inhaled beta-agonists and the risk of developing congestive heart failure. Studies specifically investigating the cardiovascular safety of LABAs have shown that both formoterol and salmeterol have a good cardiovascular safety profile[6]. GOLD also maintains that there is no evidence that COPD should be treated differently in the presence of IHD or CHF, but recommends avoidance of high doses of beta-agonists in unstable angina, as well as closer monitoring for patients with CHF.[1]

Inhaled corticosteroids are being inadvertently prescribed in patients with mild COPD, possibly because of them being wrongly diagnosed as asthmatics. Although the role of Asthma & COPD Overlap Syndrome (ACOS) is becoming more evident, we must consider tailing off ICS gradually in mild to moderate COPD patients (Groups A and B). On the other hand, GOLD recommends adding ICS to our more severe COPD pts (Groups C and D) as this has been shown to decrease hospitalisation and exacerbations in these patients.[1] Because of increasing concern about the long-term safety of ICS use in COPD patients, the WISDOM study has evaluated the need for ICS use in severe COPD, via stepwise withdrawal of ICS in COPD patients in Stage 3 and 4 on dual bronchodilation (ICS+LABA).[7]

Limitations of the Study

Those patients who were not contactable for the purpose of enquiring about patient symptoms, were excluded from the rest of the analysis. This included those patients who were deceased, who were probably more likely to be patients from Group D, meaning that the sickest patients may have been excluded from the study.

Spirometry was considered valid if performed during the previous two years. Patients who were classified as Stage 4 on spirometry more than two years previously, may purposely not have had repeat spirometry booked since there is little or no gain from restaging a patient who is already known to be end-stage in a progressive disorder such as COPD, meaning that once again, the sickest patients may have been excluded from the study.

Recommendations for Malta

The audit concludes that the staging of COPD patients in Malta should be improved. There is a need for increased awareness about the role of spirometry in the diagnosis and staging of COPD. This is especially important in those patients with bothersome respiratory symptoms since the primary benefit of spirometry is to identify those symptomatic patients who might benefit from pharmacological therapy in order to decrease frequency of exacerbations.

Increased access to spirometry in Malta would facilitate the staging of COPD. The introduction of spirometers at Health Centres would be beneficial since primary care physicians are in an ideal position to be able to detect COPD in its early stages and perform spirometry to confirm the diagnosis.

The audit emphasizes the importance of classifying COPD patients into GOLD Group A to D, based on spirometry, symptoms and recent exacerbations. There is a need for increased awareness among doctors working in Malta about the updated GOLD guidelines. This would then allow Maltese patients to be offered the optimal pharmacological therapy in accordance with the GOLD recommendations for each GOLD patient group. This is particularly beneficial in reducing exacerbations in patients with troublesome respiratory symptoms and severe to very severe airflow obstruction ($FEV_1 < 50\%$ predicted), thereby reducing the burden of medical admissions to Mater Dei Hospital.

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Review Article

When Intra-partum Electronic Fetal Monitoring becomes Court Business

George Gregory Buttigieg

Introduction to the subject of intra-partum electronic monitoring

Sadly but inevitably, the clinical fruit of all scientific research, like the profile of the Roman god Janus, presents us with two faces - one is patient benefit while the other is medico-legal vulnerability. As part of defensive medicine, there are situations where malpractice risk is minimised by actual elimination of certain high-risk procedures e.g. in the case of some neurosurgical[1] operations. Intra-partum electronic fetal monitoring (IPEFM) is the commonest obstetric procedure in the developed world,[2] producing valuable information of fetal well being as co-related to maternal uterine activity with a scope of guarding fetal well-being in labour. It is a prime example of the therapeutic/ legal liability duality which haunts modern Medicine.

The rationale of the use of IPEFM is based on the fact that labour is the shortest but most dangerous trip ever undertaken by man. Every uterine contraction – indispensable for the mechanical process of exteriorisation of the fetus – is associated with a diminution of blood flow to the feto-placental cardiovascular unit. The resulting challenge may not be handled well by the unborn infant resulting in the complex known as fetal distress (the use of this term is being increasingly challenged by the American College of Obstetricians and Gynaecologists – on grounds considered very debatable in this author's opinion. The term is still used by the Royal College of Obstetricians and Gynaecologists of London. It can still be used –and without any apologies). This is especially likely but certainly not limited to[3] the scenario where the patient enters the obstetric arena with an 'ab initio' poorly functioning placenta.

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Short history

It is instructive to take a short look at the present form of IPEFM. Clinically available in the 1960s, IIPEFM in the form of Cardiotocography (CTG) quickly substituted[4] the old fashioned Intermittent Auscultation (IA) method of direct fetal stethoscope listening to the fetal heart [Normally done at regular intervals by the midwife using a Pinard stethoscope (one of many types)]. Clinical widespread cardiotocography commenced by 1966 when Hammacher developed a suitable recording system, which was freely available for routine use in 1968.[5] Caldeyro-Barcia [Roberto Caldeyro-Barcia (26 September 1921 – 2 November 1996), nominated for a Nobel Prize for his work on Feto-Maternal Medicine] was not only a great contributor to the discipline through his work on uterine physiology and patho-physiology but also coined the original nomenclature which he himself found unsatisfactory on further evaluation and stopped using by the 1970s. By that time, CTG monitoring was used in 84% of all U.S. births, regardless of whether the primary caregiver was a physician or a midwife.[6] Intrapartum CTG use is now universally entrenched in spite of any varying albeit methodology of interpretation (one unit may use computerised analysis, another may combine with ST analysis of the fetal ECG STAN etc.). Hospitals and physicians have billed and been collectively paid many millions of dollars for the use of CTGs since its universal acceptance in the 1960s.[7] IPFM in the form of a permanent CTG tracing strip has also proved to be manna from Heaven in the hands of lawyers instituting action in cases with undesired end result where a child suffers hypoxic intrapartum damage.

Clinical and legal equivocity

In spite of evidence demonstrating limited neonatal benefit, the medico - legal climate often pressurises obstetricians to integrate continuous IPEFM in the form of CTG as surveillance into their care of the pregnant labouring patient,[8] even if the various Colleges such the American College and the U.K's Royal College of Obstetricians and Gynaecologists have published specific guidelines as to when to implement such monitoring. The medico-legal aspect of IPEFM itself is rendered extremely complex firstly because of the applicability of legal principles to a phenomenon which by medico-legal standards has somewhat of the properties of "shifting sands". This

fascinating aspect cannot be dwelt on in any depth here but suffice it to quote here the high observer subjectivity of interpretation of CTG tracings. Another reason adding to the complexity of IPEFM in the Courtroom is a corollary of the "shifting sands" aspect and that is that to the plague of subjectivity one must add the scientific controversy[9] which surrounds the subject. Among these we find the already referred to poor inter and intra-observer reliability,[10] high false positive rate of up to 60%,[11] the unquestioned contribution to an increased Caesarean Section rate[12] as well as its failure to deliver the much expected pregnancy outcome improved as compared to |IA.[12]

Diminishing the medico-legal risk

The scope of this article is to attract clinical attention to a few of the innumerable, salient points which come into their own once IPEFM enetering the legal arena.

The use of correct nomenclature

Shakespeare's oft quoted dictum in Romeo and Juliet ("*a rose by any other name would smell as sweet*") would not hold much water in the subject at hand. It is annoying at best, misleading at worst and open to challenge in Court at any stage to refer to a CTG strip using the old Caldeyro Barcia classification (such as using 'Type I dips' or 'Type II dips.) Sometimes, ironically the ante-deluvian term 'dips' is actually mish-mashed with the correct term 'decelerations' *in the same sentence*. These are not airy-fairy changes of nomenclature but reflect genuine physiological principles which are scientifically challengable in Court. Other terms such as 'beat to beat' variation rather than 'variability' reflect knowledge pertaining to the older CTG machines and though not quite as misleading as 'dips', still render medico-legally vulnerable through lack of updated knowledge. While good obstetric practice demands the use of the most recent, standardized, quantitative nomenclature to interpret intra-partum CTG, to minimise miscommunication, propagate consistent, evidence-based responses to CTG patterns, and systematize research terminology[13] the standards of Court litigation demand no less precision.

With this mind it is disconcerting to hear the Court itself delivering a scientifically challengeable statement (as late as 2009) in *Whiston v London Strategic Health Authority*:

It is said that if the CTG had still been available the court would be able to tell when it was discontinued and whether there were Type II dips and, if so, for how long (i e whether they were continuous).[14]

One wonders at the possible sequelae at a Court of Appeal if the very momenclature employed was outdated, for appeals have been won or lost on much weaker technical points. The Court has a firm "commitment to mainstream science, so that we could avoid inconsistent verdicts in mass tort litigation".[15]

By contrast, it is a veritable pleasure to read the clear and scientifically correct exposé in *Smith v West Yorkshire Health Authority (t/a Leeds Health Authority).* The Judge speaks of 'baseline variability', 'decelerations and correctly refers to the reassurance generally elicited by accelerations with uterine contractions or movements. In reverse to the fit adult, accelerations of the fetal heart rate during the challenge of a maternal uterine contraction or a fetal movement, are a reassuring indicator of fetal well-being.

Baseline variability describes the changes in the baseline of the FHR. Such changes occur slowly unless there is an acute accident. Accelerations are the increases in the FHR and they are a positive and reassuring sign if they occur as a response to uterine contractions or movements in which case they are seen occasionally. They may not occur regularly but they should be seen occasionally. Decelerations are reductions in the FHR of more than 15 beats per minute from the baseline rate, while accelerations are increases in the FHR of more than 15 beats per minute.[16]

No serious case can be put forward either by plaintiff or defendant unless correct information on current nomenclature and guidelines is provided by correct expert advice. A good example comes across in *Brodie McCoy v East Midlands Strategic Health Authority*, (reference being made in this case to an antenatal and not intrapartum CTG tracing) where defence was not only well versed with the 1987 FIGO Guidelines for CTG interpretation but intelligently and justifiably attacked one of its Achilles tendons :

...reference was made to the 1987 FIGO Guidelines for interpreting CTG traces. Mr Porter pointed out that there was an apparent internal inconsistency in the FIGO classification of decelerations in antepartum CTGs, as these state that the "absence of decelerations except for sporadic, mild decelerations of very short duration" is consistent with a normal fetal heart pattern; but "sporadic decelerations of any type unless severe" are part of the definition of "suspicious" fetal heart patterns. Thus in cases such as this, where decelerations are difficult to identify, it is not obvious whether a CTG should be classified as normal or "suspicious".[17]

The case was dismissed 0n the grounds that neither did the plaintiff prove breach of duty through care below what is expected – although neither did the defendant prove that such care was delivered.

Correct CTG interpretation

It is a sad fact that there *are* obstetricians in training, or otherwise, who cannot interpret a CTG

tracing correctly. A ghastly indictment of one such obstetrician can be found in *Azzam v General Medical Council.*

The expert evidence, which was accepted by the appellant, was that if he had not made an error in the assessment of a cardiograph (CTG) reading, it was likely that the child would have been delivered successfully. In October 2007, a Fitness to Practise Panel (the panel) of the respondent General Medical Council (GMC) found that the appellant had not interpreted or recognised signs of fetal distress as shown by the CTG trace…. The panel's conclusion was that the appellant's assessment of the CTG scan had been inappropriate, inadequate and irresponsible, not in the best interests of the mother and below the standards which could reasonably have been expected of a competent obstetrician.[18]

Again, the defendant in *Simms v Birmingham Health Authority,* may have opted for euphemistic language but he had botched up his management with disastrous results:

"With hindsight I consider it showed some reduced variability and was thus abnormal. This reduced variability warrants continued observation but it does not warrant Caesarean section, unless other significant abnormalities develop."[19]

We speak of a serious and significant problem. In a series of 3600 deliveries at the Middlesex Northwick Park Hospital (UK) between 1996 and 2000, 22% of the management care problems were directly attributed to CTG misinterpretation.[20] More than 1 in 5 of serious mismanagements resulting from CTG misinterpretation in this serious were preventable. This preventability is stressed by Hove et al.,[21] who showed that all hypoxic brain injuries are potentially avoidable using established obstetric practice to avoid CTG misinterpretation - this in turn demands adequate CTG education and training. Such CTG misinterpretation with resultant fetal hypoxemia and/or academia ("birth asphyxia") in the unborn (the term 'fetal distress' has been lately reviewed with dislike by the American College of Obstetricians and Gynaecologists is still used and accepted by others, such as the Royal College of Obstetricians and Gynaecologists of London,) comes at a massive cost. In 2011 "birth asphyxia" comprised 50% of the UK NHS litigation costs,[22] and in the 2000-2010 decade, the same NHS forked out £3.1 billion for maternity medico-legal claims (the highest of any speciality) mostly involving cerebral palsy and CTG misinterpretation.[23]

The UK's National Health Service Litigation Authority's (NHSLA) emphasises that there is still need for improvement in general CTG education and has made formal attendance at CTG courses as a mandatory requirement to receive Clinical Negligence Scheme for Trusts (CNST) discounts.[24]

The interpretation of a baby's heart rate tracings requires special knowledge and experience. Quite often subtle changes in the CTG as early warning signs of asphyxia can only be interpreted by experienced doctors and junior doctors need to be supported and educated to acquire this skill. It is therefore crucial to have experienced obstetricians (consultants) working in labour ward during the out-of-hours period.[25]

Numerous reports have repeatedly recommend regular in-service education programmes, as part of the cure of the problem. Though all experts on whichever side should state the truth according to their conscience, IPEFM may allow a wider swing of opinion due to its inter-observer variance – one of the difficulties of the subject.

The Truth and nothing but…and on anticipating the unexpected.

All scientific Court statements ought to be assumed to come under the scrutiny of 'opposing' experts. Though all experts on whichever side should state the truth according to their conscience, IPEFM may allow a wider swing of opinion due to its inter-observer variance – one of the difficulties of the subject. This applies to obstetric defendant as well as Court appointed obstetric expert. One must avoid the fatal 'faut pas' of imagining that one is talking down to laymen just because there is no visible expert on site. In *Smith v West Yorkshire Health Authority,* Judge Silber J speaks with impressive authority when he demolishes an expert opinion on the fetal baseline heart-rate of an intrapartum CTG :

The fallacy of Mr Hare's contention is that he apparently regards the peaks as being the baseline. A much more realistic approach is that adopted by Mr Mackenzie of submitting that the baseline is 130 bpm, which is close to a little below the rate to which the fetal heart rate returned on a substantial number of occasions during the period in question and that rate also takes into account the peaks and the troughs of the FHR during that period. My reading of the trace is that the baseline would have been a little higher than Mr Mackenzie's figure and would in the 130-140 bpm region, but it certainly was not 160 bpm. As I will explain later when I turn to the causation issue in paras 227-230, I consider that Mr Mackenzie's estimates of the baseline are much more accurate than those of Mr Hare.

Any opinion, even if expressed *before* a case reaches Court, may come back to haunt. In *Gossland v East of England Strategic Health Authority* :

Mr Johnson agreed in cross-examination that he had been "putting it too high" when stating in his written report that before his delivery Omar showed all the features of a seriously sick baby; and he agreed that by some standards, including Beard and Finnegan's Foetal Heart Patterns and their Interpretation, 1974 at

28, Omar did not present a complicated tachycardia. He agreed that when describing the foetal heart beat as "severely abnormal" at 21.40 he was using "hyperbole".[26]

Hyperbole on one side and a doctor's career on the other! Furthermore, the same "expert" obstetrician provides us with yet another rich lesson:

... he had not anticipated that the Defendant would contest the case.[26]

In other words this expert is saying that he feels free with his opinion but once in Court he would execute better circumspection.

Furthermore the truth of the facts must be recorded legibly in the case file not omitting date, and time. A Court statement such as the following is a terrible indictment of carelessness:

On being recalled on 30 October, she accepted that it (the CTG tracing strip) should definitely have been dated and timed.[27]

Ensuring interpretability of CTG strip tracing.

It is crucial that CTG documentation should be of adequate quality for visual interpretation.[28]

Producing "miles" of por quality CTG strip tracing reflects either a *persistent* lack of interest in the patient or, equally condemning, long periods of absence from the bedside.

An example of this is clearly found in *Popple v Birmingham Women's NHS Foundation Trust (2011)*

When the judge came to deal with this, which he did in sub-paragraph (d) of paragraph 63 of his judgment (page 54), he said that he was quite satisfied that CTG does not reliably exclude a foetal bradycardia. He went on to repeat the view of the claimant's experts in their supplementary joint memorandum that all the obstetric experts have emphasised extreme difficulty in reliably interpreting the CTG traces due to poor quality and the obstetric experts in their meeting record that the CTG is uninterpretable from 14.21 onwards.[29]

To Sample or NOT to sample

Fetal blood sampling has been relegated to second division for so long and in so many units that the question seems to have now jumped from "is this CTG amanifestation of true fetal distress?" to "Should I section on this tracing or not?" This is both understandable as well as puzzling to those of us, mature enough to remember crouching on our knees in labour ward, struggling to obtain a fetal blood sample through amnioscopes – only to repeat the procedure within the hour. This by-passing of FBS seems NOT to have penetrated Court mentality:

In particular, it was submitted to the Lord Ordinary on behalf of the pursuer that at any of four points in the course of the labour on 1 October 1999, namely at 0810 hrs, 1230 hrs, 1345 hrs and 1600 hrs approximately, the CTG trace showed features which no competent obstetrician exercising reasonable care would have interpreted otherwise than as requiring the taking of a foetal blood sample, which failing, the carrying out of a caesarean section.[30]

This Court statement come in 2013 and it still equates fetal blod sampling with a "competent obstetrician". The purpose of sampling (a fetal blood sample is obtained from the scalp using a small bladed long handled knife passed through an amnioscope manoeuvred through the maternal cervix) is to measure the fetal pH, in stuations where IPEFM is abnormal and *may* be indicative of hypoxia. Besides the preponderance of habit veering to *non* performance of sampling in deference to a Caesarean Section, one needs to add the fact that existing evidence disproves intrapartum FBS as a gold standard of proving or excluding fetal hypoxia (Mahendru et al. 2011).[31] Incidentally the same authors further discount scalp lactate, pulse oximetry, fetal ECG waveform analysis, and central haemodynamics in labouring rhesus monkeys as providing such a gold standard.[31] Neither is omission of FBS likely to be challenged medico-legally in cases where with a fine neonatal outcome after a caesarean section. However this excludes the exceptionally litiginous patient challenging the omission as part of the grounds for a claim of an unnecessary caesarean or a caesarean section were severe complications supervene. Such a potential medico-legal scenario is similar to performing intra-partum EFM in a case where such monitoring is not formally indicated by most guidelines. As far back as 2008, Wiberg-Itzel et al.,[32] found no significant differences in rate of acidaemia at birth after the use of lactate analysis or pH analysis of fetal scalp blood samples (pH≥ 7.25 being considered normal, 7.21–7.24 as borderline and ≤ 7.20 as abnormal.) However, when all is said and done, in the section on determining hypoxia during labour, the NICE guidelines[33] *still* advise FBS (evidence level 1b) in the presence of a pathological FHR trace unless there is clear evidence of fetal compromise, such as a prolonged deceleration exceeding three minutes. In fact, the same guidelines recommend repeating the sampling after 1 hour if the result is normal but the FHR tracing remains pathological. Although little has been published as yet on the actual use of guidelines in litigation,[34] as matters stand, present Court opinion tends to be based on *witness* testimony in court regarding *what is done* rather than what *ought to be done*.[35] Non adherence to clinical guidelines does not automatically imply an adverse outcome for the defendant,[36] although the legal importance of guidelines is bound to increase.[36] In *Ludwig (by her mother & litigation friend Della Louise*

Ludwig) v Oxford Radcliffe Hospitals NHS Trust and another we find direct reference to the NICE guidelines:

The guidelines continue as follows:

"In cases where the CTG falls into the suspicious category, conservative measures should be used. In cases where the CTG falls into the pathological category, conservative measures should be used and fetal blood sampling be undertaken where appropriate/feasible. In situations where fetal blood sampling is not possible or appropriate then delivery should be expedited".[37]

Hence the answer to this section's title is likely to be "not", but in reality, medico-legally, one is traversing no man's land. This is likely to hold until a clear fool proof formula comes to the fore by which fetal distress is diagnosed, for example by a computerised programme evaluating CTG, ST analysis of the fetal ECG…

Spoliation of Evidence

In any Court case centring on damage from intra-partum asphyxia, the physical availability of the *original* CTG strip is of inestimable importance. If this goes missing (not a rare occurrence)– this is a form of what is termed spoliation of evidence. This is serious business indeed, because however scientifically challengeable, the Court tends to hold that:

the fetal monitoring strips would give fairly conclusive evidence as to the presence or absence of fetal distress, and their loss deprives the plaintiff of the means of proving her medical malpractice claim against the Hospital.[38]

No Court is likely to take the situation lightly. Comments at Court such as

"the fetal heart tracing has been missing since delivery,"[39]

do *not* wash down well with Judge or Jury. In *Martelly v. New York City Health & Hosp. Corp.*,[40] where the CTG tracing was missing, the Court gave the jury instruction to draw the strongest adverse inference against the defendant hospital which had a legal obligation both to safeguard the CTG strip as well as give a reasonable explanation for its disappearance.

Some hospitals legally bind the relevant personnel to preserve such tracings as an intrinsic part of the medical record. One such example comes from New York Hospital[41] where CTG strips must be safely preserved for whichever period is the longest, namely:

6 years from the date of patient discharge from hospital.

3 years after the child reached the age of maturity (18 years).

6 years after the child's death.

The Maltese Health system will eventually have to evaluate this point, either pro-actively or a result of bitter experience. When paper based systems are used, the original paper strip must still be preserved even if a photocopy or microfilm of it exists[42] and furthermore any photocopying must be in toto (special photocopiers must be used and if not available are available at newspaper printers) and *not* in separate segments. Where computerized clinical information systems (CIS) is in operation, various regulations apply in conjunction with advice from respective organisations or Colleges.[43]

Conclusion

Most Court cases centred around IPEFM are often both complex and contentious by nature of the subject . The subjective nature of CTG interpretation as well as the end scope of such subjectivity in a Courtroom are further challenging factors. As is standard in medico-legal litigation the plaintiff must establish that (a) There was a breach of duty by the defendant who delivered care below a reasonably expected standard and (b) It was this substandard care that led to the unsatisfactory final clinical result for which legal redress is being sought. It is not sufficient to prove substandard care but one must go the next step and show that this contributed to the damage in question.[44] With Courtroom CTG cases it is often (but not invariably) the second proviso which may elicit the greatest difficulty, the mechanics of which are beyond the scope of this paper.

There are many relevant aspects not addressed in this short article. However the final emphasis should be and is on the competency of interpretation of the CTGtracing. The UK's National Health Service Litigation Authority's (NHSLA) emphasises that there is still need for improvement in general CTG education and has made formal attendance at CTG courses as a mandatory requirement to receive Clinical Negligence Scheme for Trusts (CNST) discounts.[34]

The interpretation of a baby's heart rate tracings requires special knowledge and experience. Quite often subtle changes in the CTG as early warning signs of asphyxia can only be interpreted by experienced doctors and junior doctors need to be supported and educated to acquire this skill. It is therefore crucial to have experienced obstetricians (consultants) working in labour ward during the out-of-hours period.[45]

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Multiple Cerebral Infarctions In The Context Of Malignancy

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Abstract

Coagulation disorders are common in patients with malignancy, sometimes leading to arterial and venous thrombosis. Such patients are therefore at increased risk for ischaemic stroke. Though usually occurring in advanced stages of cancers, sometimes stroke can be the first manifestation of a hidden, yet undiagnosed, malignancy. In this report, I present a case of recurrent strokes secondary to malignancy-related thromboembolism in a 63-year old gentleman.

Key Words

Malignancy, Hypercoagulability, Stroke

Case Presentation

A 63-year old man presented to A&E department with altered mental status. He was found by his wife attempting to turn on the switch but being unable to locate it with his right hand. He also had dysarthria and was somewhat confused. He had a history of type II diabetes mellitus, hypertension and dyslipidaemia. Moreover, he had suffered an ischaemic stroke 3 months previous to this admission affecting the right middle cerebral artery territory. His medications included the antiplatelet agents aspirin and dipyridamole, the hypoglycaemic agent metformin and the HMG-CoA reductase inhibitor simvastatin. He had stopped smoking 15 years previously.

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This patient thus suffered two ischaemic strokes in different vascular territories in 3 months and a coagulopathy was considered to be the cause. A chest x-ray revealed a lesion in the right lung base, which was confirmed on CT; the latter also detecting right hilar and supracarinal lymphadenopathy. CT-guided biopsy of the lung lesion was then carried out which showed adenocarcinoma of the lung. Right lower lobectomy was performed but merely two weeks after surgery, the patient presented again with another left-sided stroke; the third one in four months. While an in-patient, he also had a deep vein thrombosis, despite being anticoagulated with enoxaparin. His general condition was very poor and he was treated palliatively until he passed away.

Discussion

The relationship between malignancy and hypercoagulability is well known and actually thromboembolic events occur in around 11% of patients with cancer and account for the second leading cause of mortality in cancer.[1] Almost all cancers are associated with coagulopathy but especially myeloproliferative disorders as well as cancers of the pancreas, prostate, colon, gallbladder, stomach and lung adenocarcinoma.[2]

This association between cancer and hypercoagulability was first described by Armand Trousseau in 1865, and since then malignancy-associated thromboembolic disorders have been termed Trousseau syndrome.[3] Its clinical manifestations include arterial thrombosis, recurrent venous thrombosis, non-bacterial thrombotic endocarditis and disseminated intravascular coagulation (DIC) as well as accelerated ischaemic heart disease and peripheral vascular disease.[4-5]

There are various pathogenic mechanisms, which explain the hypercoagulable state of malignancy. Tumour cells produce pro-coagulant factors like interleukin-1, interleukin-6, tumour necrosis factor-1, factor X and factor XII.[6] Moreover, adenocarcinomas produce a lot of mucin; high molecular weight, heavily glycosylated proteins that result in platelet-rich microthrombi.[7-8]

Malignancy can result in hypercoagulability in a variety of other ways. Some chemotherapeutic agents like mitomycin and some hormonal agents like tamoxifen are prothrombotic.[9-10] Trauma, as a result of surgery, can also play an important role by exposing subendothelial tissue factor, activating the extrinsic

coagulation pathway. Decreased mobility is also another risk factor.

Cancer patients with thromboembolic disease often have biochemical evidence of an activated coagulation cascade. Many have thrombocytosis, as well as high PT and APTT, and elevated levels of fibrinogen and D-dimers. However, since cancer can cause deranged clotting activity and many patients with thrombosis have normal levels of these markers, studies have shown that they are clinically neither specific nor sensitive to malignancy-associated thromboembolism.[11-12]

Although cerebrovascular events are quite frequent in cancer patients, stroke as the first manifestation of cancer, as happened in this case, is uncommonly reported.[13] When presented with multiple bihemispheric infarctions on diffusion-weighted imaging, early relapse or anaemia, one must consider the possibility of an occult cancer. In their study, Hiraga and colleagues claimed that the commonest cancer in stroke patients in the West is lung cancer, followed by gastrointestinal cancer. They recommend that a proper cancer work-up should be done in cases where the aetiology of stroke is unknown or where there are recurrent strokes and systemic thromboses, including thoracic imaging and measurement of tumour markers like CEA and CA19.9.[14]

The prognosis of patients with malignancy-associated thromboembolism is poor and management is very difficult. Recurrent arterial and venous thromboses mean that these patients should be on long-term anticoagulation. However warfarin is not a very good choice in these patients because of its narrow therapeutic window, need for frequent monitoring and tendency to interact with numerous other drugs. In a randomized controlled trial, Lee and colleagues compared warfarin against heparin in patients with active cancer and a confirmed DVT/PE. They found that fewer patients on heparin had recurrent venous thrombosis and the mortality rate was also less. On the other hand, there was no statistically significant difference in the rate of bleeding.[15] Recent studies have also shown a trend towards decreased mortality with low-molecular-weight heparin as compared to unfractionated heparin.[16-17]

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Case Report

Coronary Artery Fistulae: 4 cases repaired surgically

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Abstract

Coronary artery fistulae involve a communication between a coronary artery and a heart chamber or part of the pulmonary circulation. Most are asymptomatic and discovered incidentally, whilst larger ones may cause coronary steal syndrome. Fistulae may produce continuous murmurs and are diagnosed at echocardiography or angiography. Treatment is by percutaneous coil embolisation or open surgery. We review four cases treated with surgical closure. All patients were asymptomatic and diagnosed incidentally at angiography. One case involved a failed attempt at percutaneous coil embolization requiring immediate open surgery. The other three cases required other operative procedures and the fistulae were oversutured during the same procedure.

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Introduction

Coronary artery fistulae, although rare, are amongst the commonest congenital cardiac anomalies. They involve a communication between a coronary artery and a heart chamber or part of the pulmonary circulation. Most are asymptomatic and discovered incidentally. Larger ones may cause coronary steal syndrome, as blood is shunted from the coronary artery to the ventricle or pulmonary circulation, bypassing the myocardium, and causing symptoms of angina, arrhythmias or high-output heart failure.[1]

First described in 1908 by Maude Abbott, fistulae can be classified as a congenital abnormality of termination [2]. Embryologically coronary artery fistulae are thought to arise as a persistence of sinusoidal connections between the lumens of the primitive tubular heart that supply myocardial blood flow in the early embryologic period. Most coronary artery fistulae arise from the right coronary artery (40-60%) and those arising from the left coronary artery are predominantly from the left anterior descending artery. The right atrium or ventricle and pulmonary artery are the site of termination in 90% of cases.

Small fistulae may remain clinically silent and are recognized at routine angiography, echocardiography or autopsy. In small fistulae, the myocardial blood supply is not sufficiently compromised to cause symptoms. Although spontaneous closure usually occurs, some can dilate over time. The increased flow in the feeding artery may result in dilatation resulting in the commonly associated finding of coronary aneurysms. Fistulae may give rise to various complications, the commonest being myocardial ischaemia, including ischaemic cardiomyopathy, papillary muscle rupture from chronic ischaemia and congestive cardiac failure from volume overload. Older patients may present with signs of congestive heart failure, arrhythmias, syncope or chest pain. Bacterial endocarditis and sudden cardiac death have also been described [3]. Rare cases are described of multiple microfistulae causing angina. The management of such fistulae is with antianginal medication and risk factor control. However these reports are rare and no evidence based management is offered in the literature [4].

Case reports

The four cases described were discovered incidentally on angiography and were treated surgically.

One followed a failed attempt at coil embolisation and open surgery was performed urgently to retrieve the coil. The other three were repaired electively as the patients required coronary bypass grafting or valve replacement. All cases were performed on cardiopulmonary bypass. Two of the cases presented with multiple fistulae.

Case 1

A 49 year-old male was investigated for syncope. Exercise stress testing was positive and the patient underwent coronary angiography. He was found to have two fistulae, one arising from the ostium of the right coronary artery (RCA), draining into the right pulmonary artery (PA) (fig 1) and the other arising from the left anterior descending artery (LAD), bifurcating into two vessels both draining into the pulmonary trunk. Successful coil embolisation of the right fistula was performed angiographically (fig 2). The fistula arising from the LAD was entered and during deployment the coil migrated distally into the LAD (fig 3). Immediate surgery was performed, the coil was retrieved and the fistulae were oversutured with 5-0 non-absorbable suture throughout their length.

***Figure 1**: Fistula from RCA to right PA*

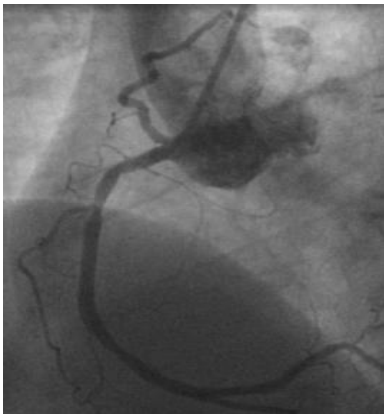


***Figure 2**: Fistula from LAD to pulmonary trunk (coil visible in RCA to PA fistula, guide wire visible in LAD)*

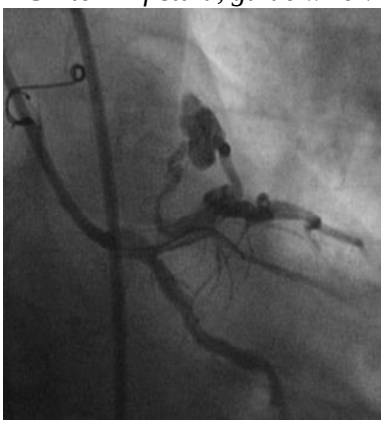
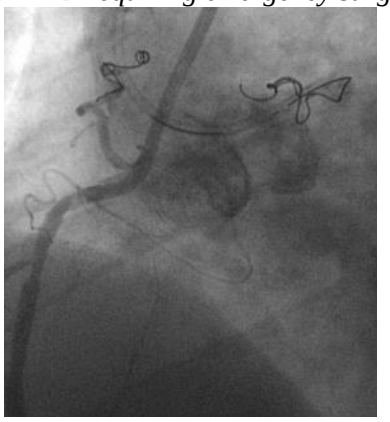


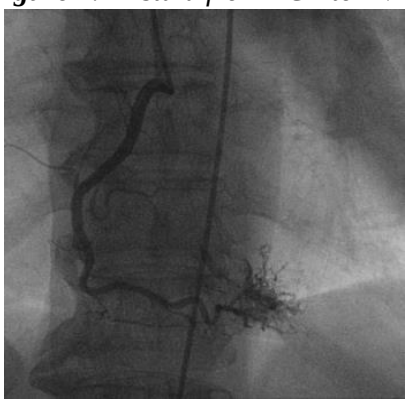
***Figure 3**: Coil in left fistula, which later migrated into distal LAD requiring emergency surgery*



Case 2

A 60 year-old female was referred for mitral valve replacement for rheumatic mitral stenosis. On preoperative coronary angiography a fistula was detected originating from the distal right coronary artery, draining into the right ventricle (RV) (fig 4). During the patient's mitral valve replacement the fistula was oversutured using 5-0 nonabsorbable suture along its entire length.

***Figure 4**: Fistula from RCA to RV*



Case 3

A 70 year-old male with chest pain and a positive exercise stress test underwent coronary angiography. Three fistulae were seen, one from the proximal LAD artery draining into the pulmonary trunk (PT) (fig 5) and the other two originated from the right coronary artery, one drained into the PT and the other into the right atrium (RA) (fig 6). The patient required coronary artery bypass grafting (CABG) and the fistulae were oversutured using 5-0 non-absorbable suture during the same procedure.

***Figure 5**: Fistula from LAD to PT*

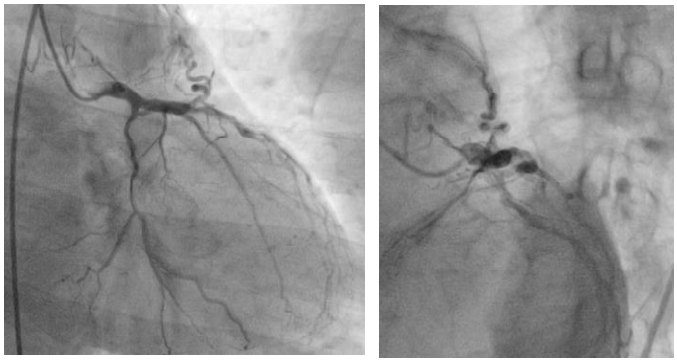
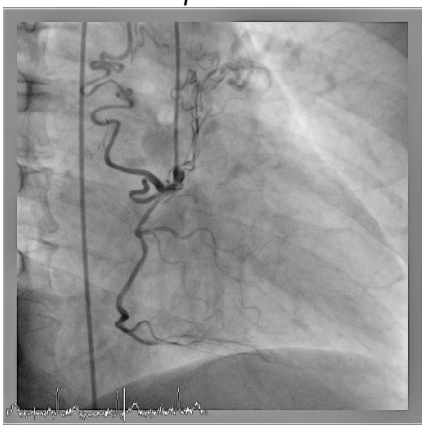


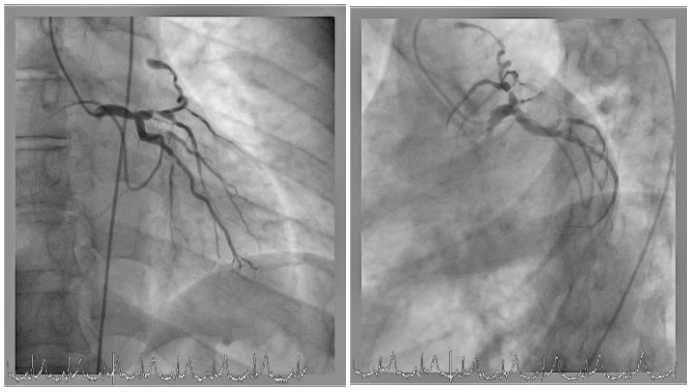
***Figure 6**: Fistulae from RCA to PT and RA*



Case 4

A 54-year-old male presented with a non-ST elevation myocardial infarction and coronary angiography showed multivessel disease requiring CABG. A fistula was seen arising from the proximal LAD, draining into the pulmonary trunk (fig 7). The fistula was oversutured during the CABG along its entire length using 5-0 non-absorbable suture.

***Figure 7**: Fistula from proximal LAD to PT*



Discussion

All the cases discussed above had favourable outcomes. The possibility of successful open surgical treatment of these fistulae is clearly identified. Patients being considered for open surgery for other reasons in whom such fistulae are discovered are best treated surgically as definitive cure may be anticipated without increasing the operative risk. The debate on how to treat these fistulae in patients not being planned for other open heart surgery persists.

Although no randomised control trial exists comparing surgical to percutaneous closure, surgery has been shown to yield lower recurrence rates.[5-9] Surgical techniques include oversuturing the fistula throughout its length, closing the fistula at its distal end, or closing the fistula via its receiving chamber.[11] The last technique requires cardiopulmonary bypass. There is no difference in outcome according to type of surgical repair.[9]

Said (2010) reviewed all coronary artery fistulae cases published between the year 2000 and 2009. 122 patients underwent percutaneous embolisation and 111 underwent surgical treatment. Surgical ligation was performed with cardiopulmonary bypass in 67% of cases and without cardiopulmonary bypass in 33%. Surgical correction yielded a 100% closure rate and 100% survival rate.[5] Percutaneous intervention had less positive results with 87% closure rate.[6] Included in this review was a paper reporting a recurrence rate of 9% with percutaneous intervention. Another study reported residual flow in one of the 25 patients after surgical repair at 9.6 years follow-up.[8]

Although the four cases discussed here were all asymptomatic, the same management can apply to symptomatic cases. Bogers et. al. (1987) presented 23 cases treated surgically. One patient died intraoperatively from other complex congenital cardiac disease. The other 22 achieved full resolution of symptoms and signs and many showed improved cardiac function on echocardiography. The surgical techniques used included oversuturing the fistula from the outside (8 cases), opening the distal fistula and closing the anatomical distal end (6 cases) and opening the receiving cardiac chamber or great vessel and closing the distal end (8 cases). There was no difference in outcome depending on the type of closure. The authors also reviewed the literature and concluded that surgical repair should be offered to all those who are symptomatic.[9]

The possibility of reducing myocardial ischaemia time by performing fistula ligation on the beating heart has been described. Yusuf reported eleven cases of coronary artery fistulae treated surgically. Seven cases were performed on cardiopulmonary bypass while four were performed on a beating heart. One patient underwent surgery for isolated fistula closure whereas all other patients underwent concomitant CABG.

Operative technique included identifying the fistula on the cardiac surface, dissecting it out proximally and clamping it to ensure disappearance of the thrill. The fistula was ligated proximally and distally. One patient required early re-operation as the fistula was still patent in intensive care immediately post-op. At echocardiogram follow-up 3 months later all cases achieved full resolution.[10]

Fistula repair without cardiopulmonary bypass is possible only when the fistulae are accessible without opening any chambers or disrupting the blood flow to the feeding coronary artery.[11] Stroeh et. al. (2012) described the case of a 22 year old patient with a fistula from the right coronary to the right ventricle. The right sinus of Valsalva and proximal right coronary artery were aneurysmal. The aneurysm was incised from the aorta and the fistula was closed with a pericardial patch on cardiopulmonary bypass.[12] Darwazah described the repair of an aneurysmal circumflex fistula draining into the coronary sinus.[13]

Successful percutaneous transarterial coil embolisation has been extensively described.[5-7] Isolated cases of percutaneous closure of large fistulae are also described. Lebreiro et. al. (2010) reported the use of an Amplatzer Vascular Plug (St. Jude Medical, USA) device for percutaneous closure in a 36 year-old patient with a large fistula from the right coronary artery to the superior vena cava.[14] They conclude that although most authors recommend surgical closure, they report a successful outcome despite the significant size of the fistula. Takaaki et. al. (2012) also reported a successful closure of a giant fistula arising from the right coronary artery in a 71-year-old with follow-up limited to 10 months.[15] Panduranga et. al. (2012) described a similar case followed up with coronary angiography 10 years later. The fistula closure remained sound, however there was aneurysmal dilatation of the proximal right coronary artery, around the origin of the fistula.[16]

Conclusion

The consensus is that all fistulae should be closed. The preferred method of closure, percutaneous or surgical, is open to discussion. Based on results reported in the literature, most authors favour surgical closure, especially in symptomatic patients. Although no randomised control trial exists, several case series show a higher recurrence rate after percutaneous closure. Although size is unlikely to be a contraindication to percutaneous closure, subsequent aneurysmal dilatation of the coronary artery feeding a large fistula at late follow-up would favour initial surgical closure. In cases where the fistulae have multiple connections, circuitous patterns or acute angulations, rendering catheter entry difficult, surgical repair would be the preferred option. In patients requiring sternotomy for other conditions such as valve replacement, congenital defect repair or bypass grafting then the risks of percutaneous embolisation are best avoided by repairing the fistulae during the same surgical procedure. Percutaneous trans-arterial embolisation has shown some promising results but as yet open surgical closure of coronary artery fistulae still gives the best patient outcomes.

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King George V Hospital in Malta – Sacra Infermeria for the Order of St. Lazarus of Jerusalem

Charles Savona-Ventura

Abstract

King George V Hospital, originally commissioned in 1922, saw its closure in 1967. It was eventually reopened under the management of the Department of Health as Boffa Hospital in 1970. In the interim years, the budding Maltese jurisdiction of the Military and Hospitaller Order of Saint Lazarus of Jerusalem made serious bids to assume the management of the hospital hoping to set up a service for public and private-paying patients.

Introduction

King George V Seamen's Memorial Hospital sited in Floriana just outside the fortifications of Valletta, Malta was originally formally inaugurated by H.E. the Governor of Malta Field Marshal Lord Plumer on the 30th November 1922.[1] This 32-bed hospital was build following an appeal by Governor Field Marshall Lord Methuen in August 1918 as a memorial to the men of the Merchant Navy who died in the First World War.[2] The Foundation Stone was laid by Lady Methuen C.B.E. on the 27th March 1919. The hospital was built and administered by the "Seaman's Christian Friends Society Hospital Trust" of London. The building site presented difficulties so that while works on the foundations started on the 4th August 1920, the building could only start on the 16th May 1921 since 48 000 cubic feet of stone needed to be laid in the foundations before work on the superstructure could commence. The responsible architect was Bridgeford Pirie; the contractor Michael Camilleri. The cost for the building amounted to £16 000.[3] The original hospital catered for both genders. The male services included one 12-bedded ward, two three-bedded wards, and three single-bedded rooms.

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For women, the hospital had one six-bedded ward and five single-bedded rooms, one catering for maternity cases. The second floor housed accommodation for the Medical Superintendent [Dr James Milne MB ChB Capt. RAMC], the Matron [Ms. M. Hamilton Watts RRC CMB] and four nurses [including Ms Stubbins CMB; Ms Esther Hamilton Watts; and Ms. Milne CMB]. A significant monetary contribution of £25 000 enabling an annual income of £1000 to cover running costs was made by Captain and Ms. Wisely.[1] The building was eventually extended to a capacity of 48 beds.

The King George V Seamen's Memorial Hospital was very severely damaged in April 1942 by enemy action during the Second World War. It was subsequently reconstructed by funds obtained among others from the Scottish Branch of the British Red Cross who contributed over £160 000, the Silver Thimble Fund contributed £27 000, and the Nurse of Britain Gift. The rebuilt larger hospital was inaugurated by Lady Louis Mountbatten on the 30th November 1948. The hospital catered for sick and injured seamen of all nationalities and also many dependants of the service personnel. Maltese patients were admitted when beds were available.

In the early 1960s, financial constraints were being felt though the managing trust – the Seaman's Christian Friend Society Hospital Trust – resisted the closure of the hospital in Malta since it was believed that it still had a functional role within the health care delivery system in Malta. A Maltese Council of Management was established under the presidency of H.E. the Governor Sir Maurice Dorman GCMG GCVO. The Managing Committee included: Chairman – Paul Sciberras; Secretary – Surgeon Major Richard L. Casolani; Members: Dr. Eddie A. Agius; Rev. J.R.L. Ash; Mrs C. Coleiro; J.J. Conroy; Prof. Alfred J. Craig; Prof. Joseph E. Debono; Josephine Debono; Capt. M. Everard; J.A. Harding; RN Surg. Crd. Dr. J. Kirkpatrick; J.A. Maitland; Rev. J.M. Milne; Rev. Fr. Peter Serracino Inglott; Hon. Dr. Vincent Tabone, Rev. Carmelo Xuereb; and H.E. Sir John Martin; and ex-officio: Matron KGV – J.T. Purcell and Treasurer KGV – R.D.

***Image 1**: King George V Seaman's Memorial Hospital*

Fiddaman. Early in 1966, a memorandum was drawn up explaining the needs for the future and set up a Medical Management committee in London under the chairmanship of Sir Clement Price Thomas, then President of the British Medical Association. In spite of efforts to find financial support to maintain the hospital, the Trust decided that the hospital would have to be closed down or to be transferred to the Malta Government. On the 17th November 1966, Sir Price Thomas sent a letter to the Maltese Minister of Health Dr. Alexander Cachia Zammit suggesting that the hospital would be taken over by the government indicating that the Trust were in concordance with this proposal. The trustees decided to close down the hospital on the 31st January 1967. The Maltese Council of Management prepared a Memorandum for the future of the King George V Hospital where all the options were laid out.[4]

The Order of St Lazarus interest

The Commandery of Malta of the Military and Hospitaller Order of Saint Lazarus of Jerusalem was set up with ten founder members on the 30th September 1966. The founder members included: Col. Joseph Vincent Abela [b.1903; d.1975; ad.1964] – Commander of Malta; Elias Zammit KLJ [ad.1967 – GC No. 2] – Hon. Treasurer; Anthony Zammit CLJ [d.2009; ad.1967 – GC No. 3]; Anthony Miceli Farrugia KLJ [b.1914; d.2002; ad.1967- GC No. 54] – Referendary; Robert Biasini dei Conti Stagno Navarra KLJ [b.1904; d.1995; ad.1967 – GC No.55] – Chancellor; Prof. Canon Carmelo Muscat KLJ [b.1926; ad.1967] – Chaplain; Prof. J.V. Zammit Maempel KLJ [b.1912; d.2001; ad.1967 – GC No. 59] – Hospitaller; Ms. Evelyn Abela OLJ [ad.1967 – GC No. 56]; Major Albert Edward Abela OLJ [b.1932; d.2007; ad.1967 – GC No. 57]; Joseph Amato Gauci KLJ [b.1909; d.1995; ad.1967 – GC No. 150] – Hon. Secretary. They were supported by Chev. Sir Hannibal P. Scicluna [b.1880; d.1981; ad.1962 – GC No. 127] who was a member of the Scottish Grand Bailiwick.[5] The closure of KGV Hospital was discussed during the third council meeting of the Commandery of Malta of the Military and Hospitaller Order of St. Lazarus of Jerusalem on the 18th May 1967. During this meeting, it was suggested that the Commandery should endeavour to interest a number of industrialists to finance the running of the hospital under the auspices of the Order. Should the financial outlay outstrip the resources of the Commandery, an alternative proposal was to run the establishment as a clinic. A decision was taken to set up an investigative commission which will seek to make representations to the Governor General. The Commission made up of Sir Hannibal Scicluna, Prof. J.V. Zammit Maempel and Anthony Miceli Farrugia met to discuss the matter on the 13th June 1967, wherein A. Miceli Farrugia reported on his representations made to J.A. Maitland representing the previous KGV Hospital Managing Committee and to the Hon. Minister of Health. Both had expressed themselves in favour of the project.[6] A delegation from the Commandery of Malta made up of Col. J.V. Abela, J. Amato-Gauci, A. Miceli Farrugia, Prof. J.V. Zammit Maempel and Sir Hannibal P. Scicluna met on the 19th June with the Governor General. The proposed plan for the management of KGV Hospital to be taken over by the Order of St Lazarus was warmly received. The outcome of the meeting was reported to Lt. Col. Robert Gayre Grand Bailiff General and Commissioner General of the Order wherein a request was made for the support of other

jurisdictions and individual members of the Order.[7] In response to this meeting, on the 19th July, the Governor General sent a number of enclosures relating to the history and management of KGV Hospital.[4]

A further meeting was held by the Hospitaller Commission of the Commandery of Malta with the Governor General with Lt. Col. Gayre and J.A. Maitland in attendance. On the 9th August 1967, Lt. Col. Gayre made several proposals as to future required actions, including the setting up by the Commandery of Malta of a Hospitaller Commission which would eventually serve as the Board of Directors for the Hospital and a Management Committee which would be eventually responsible to the day-to-day running of the hospital. A Board of Trustees would be responsible for the hospital funds. The latter was to be made up of: the Grand Master of the Order, the Commissioner-General, the Grand Bailiffs of England and Scotland, the Grand Administrator of the Order, and further members nominated by the Commandery of Malta, the Governor-General, the Malta Minister of Health, and the Scottish Red Cross. The scheduled timeline was to finalise discussion by September 1967, with a view of the Order assuming control of the hospital by the 1st January 1968 and opening fully functional hospital by March 1968. The proposed funding was to come through the adoption of beds by various jurisdictions of the Order, the business community of Malta, paying patients, private trusts such as the Nuffield Foundation, and the British Government.[8]

While the Malta Minister of Health was interested in the proposal and the offer to use the Order's contacts and influence with the original Seaman's Christian Friend Society Hospital Trust, he appeared reluctant to commit the Government as to what part the Order would play in the management of the reopened hospital. Lt. Col. Gayre requested a Letter of Intent from the Government of Malta to be in a legally viable position to open negotiations with the original Trust.[9] The apparent impasse was discussed by the Council of the Commandery of Malta on the 28th September. During that meeting, it was reported that the Archbishop had been informed and had given his approval for the Order's plans for KGV Hospital. During the subsequent Council Meeting of 9th November, Lt. Col. Gayre informed the Council that while the Order as a whole was ready to finance the running of the hospital, the Minister of Health had given a negative reply to the request for a Letter of Intent necessary for the Order to enter into negotiations.[10] KGV Hospital reverted to the Malta Government on the 27th November 1967.[11]

In spite of a number of representations made to the Governor-General and the Minister of Health by representatives of the Order, no progress was registered in obtaining a Letter of Intent from the Malta Government. At the Council Meeting of the Commandery of Malta on the 10th October 1968, a decision was made for a delegation to visit the Minister of Health. The meeting was held on the 21st October 1968. During this meeting, the Minister asked for a formal request from the Order to take over KGV Hospital stating clearly the purpose the hospital will be used for and who will be the intended beneficiaries. The Order was to provide proof of having sufficient funds to support the necessary restorations needed. It appeared that other organizations had shown an interest in acquiring the hospital as well. This formal application was sent to the Minister of Health on the 2nd November 1968.[12,13] No response was forthcoming from the Government to the formal application. During the Council Meeting of the Commandery of Malta on the 6th February 1969, the general impression obtained after informal talks with the Secretary to the Minister of Health was that the Order's application to take over the management of KGV Hospital had little chance of being considered. It was opinioned that the Sovereign Military Order of Malta may have also shown as interest in acquiring the property.[14] In fact during the first General Chapter of SMOM held on the 19-21st June 1967, the Grand Master of SMOM stated "Des accords sont été conclus, et sont en train de se realiser, pour la constitution de Dispensaires Anti-dibétiques, d'une banque de sang et pour assumer la gestion de l'Hôpital King George, sex deux derniéres initiatives relevent de l'Association Maltaise".[15] A request was made to the Medical Officer-in-charge, Royal Naval Hospital in Malta Surgeon Rear-Admiral Dudley P. Gurd who was a member of the Order of St. Lazarus (GC No. 129) to approach the Minister of Health to stress the continuing interest of the Order in acquiring KGV Hospital. Failing this, the Order would withdraw its formal application.[14] Rear Admiral Gurd met with the Minister of Health Dr. Cachia Zammit on the 21st February 1969. He was reassured that the Government was still positively disposed towards the application made by the Order of St. Lazarus though there were still some reservations that needed to be ironed out. The proposal had to be submitted to the Government Cabinet who had to decide whether the Malta Government was to assume full responsibility for KGV Hospital or devolve the responsibility to a managing organization. The report of that meeting was presented to the Council of the Commandery of Malta on the 5th March 1969 and forwarded to the Minister of Health on 7th March 1969.[16] During that Council Meeting, Col. J.V. Abela informed the members that Barclays Bank was prepared to authorize an advance of £10 000 – 25 000 provided suitable guarantors were available. It was stated that to date the Grand Master was ready to guarantee £500, Lt. Col. Gayre £1000, Chev. Zammit £50 and Col. Abela

£500.[17,18] Further guarantors were to be found to make available the necessary funds. In the subsequent days, other members of the Commandery of Malta accepted to serve as guarantors: Prof. Canon C. Muscat £100; and Ant. Miceli Farrugia £1000.[18] Dr Cachia Zammit eventually denied ever having received any offer by the Order of St. Lazarus to manage King George V Hospital.[19] On the 31st May 1969, the Malta Government announced that a decision had been made to take over the management of KGV Hospital.[20] On the 6th June 1969, the Commandery of Malta representing the Order informed the Minister of Health that the Order was withdrawing its offer to assume the management of King George V Hospital.[21]

Conclusion

The hospital renamed Sir Paul Boffa Hospital reopened in December 1970 under the management of the Department of Health.[22] The hospital has a symmetrical façade consisting of a central colonnaded portico with an identical terrace at first floor. The wings are plain having five windows at both ground and first floor on each side. Built in the shape of the letter "H" with an additional block erected later, the building is practically surrounded with a veranda at ground floor and a terrace at first floor, all columned and having wrought iron railings. On the left side are a series of utility buildings, some of which are not as old as the hospital. Within the hospital are a number of inscriptions and Second World War relics, including a piece of sculpture from Parliament House in London. Of note are the stained glass windows in the chapel. The Government Regulatory body MEPA has scheduled King George V Seaman's Memorial Hospital as a Grade 2 national monument as per Government Notice no. 628/08 in the Government Gazette dated July 21, 2008

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