

# Malta Medical Journal



# Editorial

Victor Grech

Academia is conventionally partitioned in an almost Straussian binary classification into “‘science’, arguably the last metanarrative with any significant cachet in the post-postmodern condition (which Lyotard himself defined ‘as incredulity toward metanarratives [...] a product of progress in the sciences’),<sup>1</sup> and, on the other hand, the humanities.”<sup>2</sup>

Very simply put, the Sciences investigate the natural sciences while the Humanities study human culture. Science fiction (SF) falls under the Humanities and constitutes a sub-genre of narrative fiction that speculates on changes that may be brought about by science and technology. However, SF straddles the gap in its attempts to gain credence by alluding to science for legitimacy and plausibility.

Star Trek (ST) is a popular SF narrative that commenced in 1966, and comprises well over 700 hours of viewing time. Malta will organise and host the first academic meeting worldwide dealing with ST, this summer ([www.startreksymposium.com](http://www.startreksymposium.com)). The meeting is being organised through HUMS, the Humanities, Medicine and Sciences Programme at the University of Malta. HUMS proposes to explore and encourage interfaces between the Humanities and medical science, and aims to facilitate and disseminate cross-disciplinary research.



Since disease remains uneliminated in the fictional ST future, doctors are often involved, not only as co-participants, but also on occasion as principal protagonists. Medicine, an applied science, is greatly aided in diagnostic and treatment modalities by ever improving technology. Indeed, advances in technology are often anticipated in SF and applied to narratives. A few examples in ST include whole body scanning (CT/MRI) and computer assisted diagnoses. These doctors’ accoutrements and gadgets are naturally correspondingly high tech, as befits the ST storyline that ventures into the 24<sup>th</sup> century.

The topics in this conference are varied and a preponderance of medical input is notable in the abstracts submitted to date ([http://www.startreksymposium.com/index\\_html\\_files/abstracts.pdf](http://www.startreksymposium.com/index_html_files/abstracts.pdf)). These include an exploration of the ethics of reproduction, the Hippocratic oath as a possible origin of the Prime Directive of non-interference in less developed cultures, cell culturing techniques and bioinformatics approaches, cardiopulmonary resuscitation, nursing, and the “tricorder” as a diagnostic tool.

The Star Trek Symposium should prove an interesting meeting not only for individuals with an interest in ST, but also for those with a general interest in the Humanities.

## References

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2. Lyotard JF. The Post-Modern Condition: A Report on Knowledge. University of Minnesota Press: Minneapolis; 1984.

## Cover Picture:

'Cul de sac'

Watercolours

By Astrid Muscat Baron

*Astrid Muscat Baron graduated MD from the University of Malta in 1988. Her paediatric specialisation initiated in Watford General Hospital, U.K. and at the Catholic University Hospital in Leuven, Belgium and then she continued working at St. Luke's Hospital in Malta. Dr. Muscat Baron attained the DCH (Lond.) followed by an MSc in Community Child Health at Warwick University, Coventry. Dr. Muscat Baron now works as a paediatrician in private practice and in local children's residential homes. Her interest in painting as well as in music started at an early age. Since 2008, Dr. Muscat Baron has been tutored in an open Art class by Mr. George Farrugia, mainly in watercolours; she also enjoys creating pencil and charcoal drawings. Several of her works have been displayed in collective art exhibitions Hospital between 1975 and 1978.*

# Subarachnoid Haemorrhage in Malta – Are outcomes adversely affected due to lack of a local neurovascular service?

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## Abstract

**Objective:** This study was performed to assess the incidence, treatment and outcome of non-traumatic Subarachnoid Haemorrhage (SAH) in an island which does not offer a neurovascular service and to determine whether such limitation is associated with a poor outcome.

**Method:** Data of adult patients with a diagnosis of non-traumatic SAH was analysed retrospectively over a two-year period from January 01, 2009 to December 31, 2010.

**Results:** The incidence of SAH in Malta is 3.16 cases per 100 000 population per year. An underlying aneurysm was found in 50% of all cases investigated with angiography. These patients were transported to the United Kingdom for definitive management and the outcome of all these patients at 6 months was excellent. (modified Rankin Scale of 0 or 1).

**Conclusions:** With the incidence of non-traumatic SAH being in the low range, setting up an interventional neuroradiology service in our country to treat aneurysmal SAH would not have the required numbers to maintain expertise and would probably translate into worse clinical outcomes. Despite having geographical and logistic limitations, our standards of care and survival rates are not below those of other international centres. Outcomes for patients with low initial Hunt and Hess scores have not been adversely affected by the lack of a local neurovascular service.

## Keywords

subarachnoid haemorrhage, aneurysm, incidence, Hunt and Hess Score

## Introduction

Subarachnoid haemorrhage (SAH) is a type of haemorrhagic stroke caused by bleeding into the subarachnoid space. The bleed can be secondary to trauma or non-traumatic. Aneurysmal SAH is reported to be the cause in about 80% of non traumatic bleeds. The rest are caused by perimesencephalic haemorrhage, vessel abnormalities such as arterio-venous malformations and other rarer causes.<sup>1</sup> Although SAH accounts for about 5% of all strokes, it is an important cause of stroke in young adults. The overall incidence is reported to be 6-10 per 100 000 per year. However, there is a significantly wide variation by region, as reported by a large World Health Organisation study where there was a 10-fold difference in incidence between countries from 2.0 per 100 000 in China to 22.5 per 100 000 in Finland.<sup>2</sup> At younger ages, the incidence is higher in men, but becomes more common in women after the age of 55.<sup>3</sup> SAH carries a significant mortality rate of up to 50% with 10-15% dying prior to reaching hospital. In

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surviving patients, there has been a decrease in overall mortality reported over the past 2 decades.<sup>4</sup>

Malta has a population of 417, 432.<sup>5</sup> No data is currently available on the incidence and outcomes of SAH in Malta. The purpose of our study is to assess the incidence, treatment and outcomes of SAH in the Maltese population. Also, in view of the lack of neurovascular services available in the country and the need for patients to be transported to a centre in the UK for definitive treatment, we aim to assess whether this has negatively affected outcomes.

### Study Methods

All patients admitted with a suspected SAH on the Maltese Islands are treated at the main public hospital, Mater Dei Hospital (MDH) by one of three consultant Neurologists. If patients present to a private clinic they are quickly transferred to this general hospital for further investigation and management. There are no other facilities on the island equipped to treat these patients.

Data of adult patients (>14 years of age) with a diagnosis of SAH from January 01, 2009 to December 31, 2010 was collected and analysed from four separate sources – (i) Patients who were admitted through the Accident and Emergency department of Mater Dei Hospital (MDH) with a diagnosis of suspected SAH from the casualty admission register; (ii) Patients who were discharged from Mater Dei Hospital with a diagnosis of SAH were identified from the hospital activity analysis, using ICD9 coding system; (iii) Patients who were referred abroad for treatment of aneurysms were obtained from the Treatment Abroad Committee; (iv) Patients whose cause of death on the death certificate was listed as “subarachnoid haemorrhage” from the Death Register. All patients with a traumatic SAH were excluded.

Only those patients who were not admitted to hospital because they died out-of-hospital or in the Accident and Emergency Department were solely identified from the death register. The rest of the patients were identified from more than one of the above mentioned sources, ensuring that data capture was thorough and complete. This data collection method guaranteed that no cases of SAH that were admitted to hospital were missed. All the case notes, radiology, blood and cerebrospinal fluid results of these patients were analysed.

### Results

The final number of patients with definite spontaneous non-traumatic SAH over the two-year study period was 26. Therefore the incidence of SAH in the Maltese population is calculated to be about 3.16 per 100 000 population per year.

### Patient Characteristics

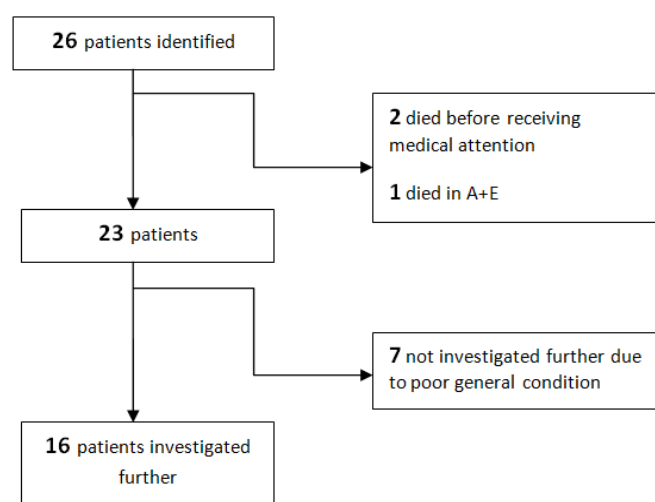
Of these 26 patients, 18 (69%) were female and 8 (31%) were male. The mean age was 55 (range 34-87) with a peak between 40-59 years of age.

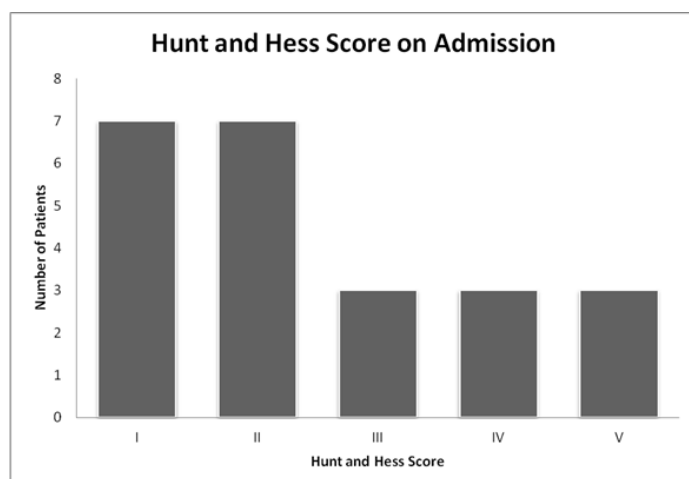
2 patients died before receiving medical attention and were certified dead from SAH according to their death certificate. One of these patients had a post-mortem examination which confirmed SAH secondary to a ruptured berry aneurysm. The other patient had a CT scan carried out 2 weeks earlier which revealed a giant anterior communicating artery aneurysm. No further action was taken in this case because of co-morbidities. SAH was listed as the cause of death on the death certificate. Another patient, a 60 year old, died soon after presentation at the emergency department. This patient also had a postmortem examination which confirmed SAH as the cause of death. The data of these 3 patients was not analysed further since the deaths were out of hospital or at the emergency department and no medical notes were available. (Figure 1)

### Presentation

Almost all patients presented in the first 24 hours. One patient had symptoms suggestive of a sentinel bleed one week prior to presentation. All patients presented with an acute headache except the three who presented in a comatose or confused state. Other common symptoms at presentation were nausea and vomiting, confusion, reduced level of consciousness, motor weakness and seizures. Figure 2 demonstrates the Hunt and Hess scores on admission.<sup>6</sup>

**Figure 1:** Flow chart of patients with non-traumatic SAH



**Figure 2: Hunt and Hess Score on Admission**

### Risk factors

Risk Factors for SAH in our cohort were hypertension in 9 patients and smoking in 8 patients. One patient had immune thrombocytopenia and a myelodysplastic syndrome.

### Investigations

Table 1 shows the investigations carried out on all patients with a diagnosis of spontaneous SAH. All patients had a non-contrast CT scan of the brain. SAH was confirmed in all cases except for one patient who had a normal CT. This patient had presented 5 days after the onset of headache.

A lumbar puncture was carried out only in two cases. In one case a suspicion was raised over the diagnosis of SAH from brain CT and in the other case the CT was normal. In both cases xanthochromia was present confirming the diagnosis of SAH.

Following a diagnosis of SAH from brain CT or lumbar puncture, 16 patients (70%), were investigated with further imaging modalities for the presence of aneurysms. Further investigations consisted of a CT cerebral angiogram (CTA) in 9 patients; Magnetic Resonance Angiography (MRA) in 4 patients and Digital Subtraction Angiography (DSA) in 8 patients. The choice of the imaging modality after diagnosis of SAH was at the discretion of the caring consultant neurologist. If an aneurysm was identified on CTA or MRA, the patient was referred for coiling/clipping directly, and had a cerebral angiogram during pre-operative planning. If no aneurysm was identified on CTA or MRA, the patient was further investigated with formal cerebral angiography.

7 patients (30%) (patients 9, 10, 15, 20, 21, 22, 23 in Table 1), did not have further investigations carried out because they were deemed unfit due to their low GCS on presentation or because of significant comorbidities. These patients were treated conservatively.

### Management

Most patients were admitted to the Neuromedical ward. Patients with a low GCS were admitted to Intensive Care. Treatment with nimodipine, lactulose and analgesia was initiated immediately in all cases upon diagnosis of SAH. Anticonvulsants were started only if the patient developed seizures.

Of the 16 patients (See Figure 1) that were investigated with further imaging modalities for the possibility of an underlying aneurysm, 8 patients (50% of those investigated) were found to have one or more aneurysms. These patients were referred to the United Kingdom (UK) for definitive treatment of the aneurysm within an average of 4.4 days (2-13 days) from the day of admission. Only one out of these 8 patients required ITU admission and was transferred to the UK after 13 days. The other 7 patients were transferred to the UK within an average of 3.1 days (2-4 days).

Table 2 shows the site and size of the aneurysms identified in 8 patients from CTA, MRA or cerebral angiography carried out in Malta and in the UK. Of note, 3 of these 8 patients had multiple aneurysms, although only the aneurysm suspected to have caused the SAH was treated with coiling or clipping. 6 patients with aneurysmal SAH were treated with coiling and aspirin  $\pm$  clopidogrel for about 28 days. Only one patient underwent clipping of the aneurysm. The decision to undergo coiling or clipping was decided by the caring Vascular Neurosurgeon in UK.

The time elapsed from diagnosis of SAH to definitive treatment of the aneurysm in the UK was 5.4 days (range 4-8 days).

### Length of stay

The average total length of stay of patients with aneurysmal SAH from presentation until discharge from hospital was 17 days (14 - 20 days) with most patients being well enough to be discharged directly home from the UK hospital.

The average length of stay of patients with angi-negative SAH who survived the initial presentation was 21 days (8 - 65 days).

### Outcome of SAH

Complications occurring in patients with aneurysmal SAH treated with coiling or clipping

There were no significant complications reported in the patients who underwent coiling or clipping except for a minor stroke in one patient, following which he made a full recovery. Another patient in this group developed Terson syndrome (vitreous haemorrhage associated with SAH). This patient also made a full recovery.

*Table 1: Investigations carried out on patients with SAH*

Patient	Non-contrast CT	Lumbar Puncture	CT Angiogram	MRA	Cerebral Angiogram
1	SAH confirmed		Abnormal		
2	SAH confirmed		Abnormal		
3	SAH confirmed				Abnormal
4	SAH confirmed		Abnormal		
5	SAH confirmed			Abnormal	
6	SAH confirmed			Normal	Normal
7	SAH confirmed		Normal		Normal
8	SAH confirmed		Normal		Normal
9	SAH confirmed				
10	SAH confirmed				
11	SAH confirmed	Xanthochromia		Non-diagnostic	Normal
12	SAH confirmed		Normal		
13	Normal	Xanthochromia	Non-diagnostic		Normal
14	SAH confirmed				Abnormal
15	SAH confirmed				
16	SAH confirmed			Abnormal	
17	SAH confirmed		Abnormal		
18	SAH confirmed				Normal
19	SAH confirmed		Normal		
20	SAH confirmed				
21	SAH confirmed				
22	SAH confirmed				
23	SAH confirmed				

**Table 2:** Characteristics of the aneurysms and the management undertaken in UK

Patient	Investigations in Malta			UK	Definitive Treatment
	CTA	MRA	Cerebral Angio	Cerebral Angio	
1	3mm Basilar Tip			3mm Basilar Tip 3mm Paraophthalmic	Coiling + Aspirin
2	6mm right Carotid Tip			P Comm	Coiling + Aspirin
3			6mm left P Comm	P Comm Left cavernous ICA Basilar fenestration	Coiling + Aspirin
4	6mm left MCA			N/A	Clipping
5		7mm left ACA		A Comm	Coiling + Aspirin
14			Basilar Tip	N/A	N/A
16		5mm A Comm		6mm A Comm	Coiling + Aspirin
17	4mm right vertebral  4mm left MCA			4mm right PICA  4mm left MCA	Coiling + Aspirin

MCA: middle cerebral artery

P Comm: posterior communicating artery

ACA: anterior cerebral artery

A Comm: anterior communicating artery

ICA: internal carotid artery

N/A: data not available

### Complications occurring in patients with SAH who did not undergo coiling or clipping

2 patients (9%) had a subarachnoid re-bleed, which occurred after one day post-admission in one patient and after 3 days in the other patient. 4 patients (17%) developed hydrocephalus and 3 of these patients underwent VP shunting. 3 patients (13%) developed seizures. 2 patients developed sepsis/ventilator associated pneumonia. 1 patient developed pulmonary embolism and another patient developed a massive middle cerebral artery infarction.

### Post-treatment follow-up

Patient 14 (Table 2) who was referred to the UK for definitive treatment of the aneurysm was of British nationality and did not return to Malta after transfer to the UK and was therefore lost to follow-up. The other 7 patients who underwent coiling or clipping were followed up at Neurology out-patients for at least 6 months. All 6 patients who underwent coiling had a

repeat cerebral angiogram at 3 to 6 months post-intervention. The angiogram revealed complete occlusion of the treated aneurysms in all cases. In one case the presence of another aneurysm was reported, but this was already reported in the CTA carried out on presentation with the SAH. Only the patient who underwent clipping of the aneurysm was not followed up with cerebral angiography.

### Mortality

Excluding the British patient that was lost to follow-up, 22 patients were followed for at least 6 months after the initial presentation with SAH or until the time of death. Out of these 22 patients, 7 patients (32%) died. All deaths occurred as in-patient with an average of 16 days (2 – 37 days). The cause of death was directly related to SAH in 4 patients (raised intracranial pressure/coning) and secondary to ventilator associated pneumonia, pulmonary embolism and stroke in 3 patients. All deaths occurred in the patients who were

deemed not fit to undergo further investigations soon after admission (patients 9, 10, 15, 20, 21, 22, 23 in Table 1).

Table 3 shows the Modified Rankin Scale 6 months after the initial presentation for the 22 patients that were followed up for at least 6 months.

**Table 3: Modified Rankin Scale**

Scale	Description	No. of patients (/23)*
0	No symptoms	13
1	No significant disability. Able to carry out all usual activities, despite some symptoms	2
2	Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities	0
3	Moderate disability. Requires some help, but able to walk unassisted	0
4	Moderately severe disability. Unable to attend to own bodily needs without assistance, and unable to walk unassisted	0
5	Severe disability. Requires constant nursing care and attention, bedridden, incontinent	0
6	Dead	7

adapted from Farrell et al, 1991 (6)

\* One patient lost to follow up

## Discussion

MDH is the main acute hospital in the country. All patients diagnosed with SAH on the Maltese Islands are ultimately referred to MDH because it is the only hospital that offers the service of a critical care unit. The way the data was compiled in our study is representative of almost all the cases of SAH that occurred in our country in the study period. The incidence of 3.16 per 100 000 population per year is on the low side of average incidence data. However, it further confirms the large variability across countries.<sup>2</sup> The Maltese population are mainly of Italian descent.<sup>8</sup>

Recent epidemiological studies from Italy have also shown similar data.<sup>9-10</sup> Reasons as to why the incidence is low could be due to the occurrence of less risk factors, or genetics. Further demographics are all in keeping with international data, with the highest presentation being in the 40-59 years age group, and mainly female.

MRA and CTA are being increasingly used as imaging modalities for the detection of intracranial aneurysms.<sup>11-12</sup> Studies have reported sensitivity of CTA to be in the region of 95%, with a recent multicentre study reporting a sensitivity of 99%, comparable to DSA.<sup>12</sup> However, if CTA is inconclusive, conventional DSA is still recommended.<sup>13</sup> In our cohort, 50% of the patients investigated with angiography were found to have an aneurysm. This number is definitely an underestimate because it does not include those patients who did not undergo angiography. Theoretically, if all the patients who did not undergo angiography did actually have an aneurysm, this percentage would increase to 62%. Therefore comparison of the percentage of aneurysmal bleeds in our cohort with that of international figures unfortunately cannot be made.

In Malta we do not have the facility of a neurovascular service mainly because of the limited number of SAH cases treated at our main hospital. We also lack the facility and expertise of an interventional neuroradiology service and since the number of cases is small, offering such a service would undoubtedly pose higher risks for the patients. This practice is in line with the latest American Heart Association/American Stroke Association guidelines which highlight the importance of specialised centres in the management of these patients. The recommendation is for low-volume hospitals with less than 10 cases of aneurysmal SAH per year to transfer patients to centres dealing with over 35 cases per year as this has been shown to significantly improve outcomes.<sup>13-14</sup> Malta has had very close medical ties with Britain for the past several years. There is an agreement between Malta and the UK stating that Maltese patients are treated in specialised centres in the UK should that service not be available locally, or local expertise is lacking. In view of the limited numbers of SAH on our island, these patients' treatment falls under this agreement. Patients are transported by air to specialised UK centres accompanied by a doctor and nurse escort. No complications were reported to have happened on the 3 hour flight to the UK. Emergency air medical transfer of patients with acute intra-cerebral bleed for definitive neurosurgical care appears to be both safe and effective, and facilitates early definitive diagnosis and operative intervention.<sup>15</sup>

The International Subarachnoid Aneurysm Trial (ISAT) has shown a clear superiority of coiling over clipping in those aneurysms deemed to be suitable for both treatments and has definitively changed the practice in most neurovascular centres.<sup>16</sup> In our study, all patients



except one had the aneurysm treated by endovascular coiling. All these patients had a good outcome at 6 months. The decision as to which mode of treatment was employed was decided by the caring vascular neurosurgeon in the UK.

Ideally, patients with SAH should be treated as early as feasible.<sup>13,17-18</sup> Effort is made on our end to organise the transport of patients as soon as possible; however some delay is inevitable. Limitations to earlier treatment result from the logistics of the transfer itself as well as the clinical condition of the patient as some patients need stabilisation prior to air transfer. In our patients, intervention was done at a mean of 5.4 days, having taken a mean of 4.4 days from the time of initial presentation to transfer to the UK. However, interventions done on our patients at slightly later times did not result in poor outcomes.

There is no doubt that intervention on low-grade (Hunt and Hess score I-II) SAH patients reduces morbidity and mortality.<sup>13,16</sup> Studies have shown a beneficial outcome in a proportion of aneurysmal SAH patients admitted with a poor grade.<sup>19-22</sup> However, in some of these studies the authors have stated that there is an element of selection bias when choosing patients for intervention, whereby unstable patients were excluded.<sup>19,21-22</sup> As yet, intervention for this patient group has not become established practice in all centres. If it can be proven conclusively that all patients with non-traumatic SAH should be treated acutely then it is essential to have a 24 hour endovascular service. Meanwhile, for the low grade patients it may be appropriate to refer them to centers that treat a larger number of cases per year. Indeed, this was proven in our study.

This study was not designed to evaluate if the outcome of patients with aneurysmal SAH transferred to the UK is better than those treated locally, as we do not offer this neurovascular service. The main aim was to evaluate the need or otherwise for such a service to be developed in Malta. If the outcome for our patients needing transfer overseas for treatment was shown to be poor, this would dictate the need for a local service. Unless the number of patients requiring endovascular treatment is significantly higher, it would not be justified to subject our patients to a poorer outcome due to limited expertise.

The main limitation of this study is the small number of patients with SAH seen in our country, making this study low-powered. The incidence of aneurysms is probably higher than reported as poor grade patients were deemed too unfit for further investigation. There is also underestimation if there were patients who died from SAH but this was not listed on the death certificate, especially if it was an out-of-hospital death and the cause of death is not attributed to SAH but to a cardiac or other event. Unfortunately, this

will remain a limitation in all similar studies.

## Conclusion

In this study we have shown that the incidence of non-traumatic SAH in Malta is in the range of low-incidence countries. Despite having small absolute numbers and logistic limitations for delivering definitive interventional treatment for aneurysmal bleeds, our standards of care and survival rates are not below those of other international centres for patients admitted with a low Hunt and Hess score. At present, the low number of non-traumatic SAH patients would not justify setting up an interventional neuroradiology service in our country to treat aneurysmal SAH. A local service would probably translate into worse clinical outcomes as the number of cases treated per year would be insufficient to maintain expertise.

Further studies on the outcome of patients treated at different centres are required to determine the minimum number of cases that need to be treated at a specific center to significantly reduce the morbidity and mortality associated with the treatment of aneurysmal SAH. This would potentially set a threshold to determine the number of specialised neurovascular centers required in different countries to achieve the best clinical outcome.

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# Relation between obesity and the oestrogen receptor status of breast cancer

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## Abstract

**Introduction:** Obesity is a growing problem in the Western world. Correlations have been found between increasing body mass index (BMI) and breast cancer. The objectives were to establish whether a relationship exists between BMI and breast cancer and to investigate any association between BMI and tumour oestrogen receptor expression.

**Method:** Clinical and socio-demographic details (age, menopausal status, height and weight) of a sample of women with breast cancer operated in 2010 were collected, dividing the group into oestrogen receptor positive (ER+) and negative (ER-) subgroups. The average BMI of each subgroup was compared to the mean BMI of a sample of the general Maltese female population obtained from the European Health Examination Survey 2010 Report (Pilot Study) by virtue of an ANOVA test. Subsequently, the relations between oestrogen receptor expression and each of menopausal status, age and BMI were statistically analysed using chi-squared analysis and two-sample t-tests.

**Results:** A total of 103 patients were studied. 72 patients (age range: 40 – 90 years) had ER+ malignancy and 31 patients (29 – 81 years) had ER- malignancy. The mean BMI's of the ER+ and ER- subgroups were 30.1 and 27.1 respectively, while that of the female general population (29 – 90 years) was 28.4. Analysis revealed a significant difference between the BMI's of the ER+ and ER- subgroups ( $p < 0.05$ ) but no difference between each receptor subgroup and the general population. Neither menopausal status nor age was found to correlate with positive oestrogen receptor expression.

**Conclusions:** Women with ER+ malignancy tended to be significantly more obese than those with ER- breast cancer. However, neither subgroup had a mean BMI significantly different from that of the general population.

## Keywords

Body Mass Index, Obesity, Age, Oestrogen Receptor, Breast Cancer

## Introduction

Obesity is a growing problem in Western developed countries. According to data from the European Health Interview Survey, published by Eurostat in November 2011, Malta ranked second, after the UK, in the prevalence of obesity in females, with 21.1% of women having a BMI over 30.<sup>1</sup> Research has long since demonstrated a relationship between obesity and various forms of malignancy, including colon cancer, endometrial cancer, renal cell carcinoma and oesophageal adenocarcinoma.<sup>2, 3</sup> In addition to this, several studies have also shown a strong correlation between body mass and postmenopausal breast cancer.<sup>4-6</sup> Moreover, it has been confirmed that overweight women with breast cancer have a poorer prognosis than thinner women,<sup>7</sup> with obese patients having a 46% increase in the risk of metastatic disease, roughly twice the risk of recurrence over a 5-year period and a 60% risk of death over a 10-year period.<sup>3</sup>

Our study aimed to establish whether the relationship between body mass and breast cancer also holds true in the Maltese populace, given the high prevalence of overweight and obese individuals. Moreover, we attempted to find an association between obesity and the oestrogen receptor status of the breast neoplasia.

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## Methodology

We performed a hospital-based retrospective study on a number of breast cancer patients seen by one of two surgical firms at Mater Dei Hospital Breast Clinic, Malta. Following acquisition of appropriate hospital approval, 103 histologically confirmed breast cancer cases were ascertained between the 1<sup>st</sup> of January 2010 and the 31<sup>st</sup> of December 2010. Eligible cases had to be females with a Maltese citizenship. For each case, various anthropomorphological details, including age, height, weight and menopausal status, were obtained from patient hospital records, and the BMI was then calculated by dividing the weight (in kilograms) by the height squared (in squared metres).

The sample was then divided into two groups; those patients with ER+ and those with ER– malignancies.

This data was subsequently compared with the average BMI of a sample of the Maltese female population, obtained from the European Health Examination Survey 2010 Report (Pilot Study),<sup>8</sup> taking only those females aged between 29 and 90 years (the same age range as the breast cancer patient sample), in order to investigate whether significant differences exist between the BMIs of the general Maltese female population, the ER+ sample and the ER– sample.

Using appropriate statistical tests, the relationship between tumour oestrogen receptor expression and each of menopausal status, age and BMI was subsequently analysed.

## Results

A summary of the BMI data in the histologically confirmed breast cancer cases and the general population is shown in *Table 1*. *Chart 1* compares the BMI distributions of the ER+ and ER– groups respectively.

By virtue of an Analysis of Variance (ANOVA) test, the mean BMIs of the ER+ sample, the ER– sample and the general population were compared in order to ascertain whether breast cancer patients in each subgroup were significantly more obese than the Maltese female general population. A significant difference was found between the three distributions ( $p=0.0246$ ). Post hoc Tukey testing demonstrated a significant difference (at the 95% significance level) between the BMIs of the ER+ and ER– groups only, but no significant difference between each breast cancer subgroup individually and the general population.

*Table 2* divides each oestrogen receptor subgroup according to menopausal status. The correlation between oestrogen receptor status and menopausal status was explored using a  $\chi^2$ -test. The resulting  $p$ -value for this analysis was 0.0820, suggesting that there is no correlation between oestrogen receptor status and menopausal status at the 95% significance level.

A correlation between oestrogen receptor status and age was sought using a two-sample t-test with equal

variance and this yielded a  $p$ -value of 0.0448, signifying that patients with ER– breast cancer tend to be younger than those with ER+ cancer. Using the same test, correlation between BMI and oestrogen receptor status yielded a  $p$ -value of 0.0116. This implies that both relations are significant at the 95% significance level, the latter correlation being considerably stronger.

Since age is a potential confounding variable in the relationship between the oestrogen receptor status of breast cancer and BMI, multivariate linear regression analysis was carried out in order to account for differences in age. The results are shown in *Table 3*. The results demonstrate a  $p$ -value of 0.011 for the oestrogen receptor status / BMI relationship and 0.700 for the age / BMI relationship, therefore reaching the conclusion that age does not significantly confound the relationship between tumour oestrogen receptor expression and BMI. Hence, positive oestrogen receptor status remains significantly associated with increasing BMI, even when adjusted for age.

## Discussion

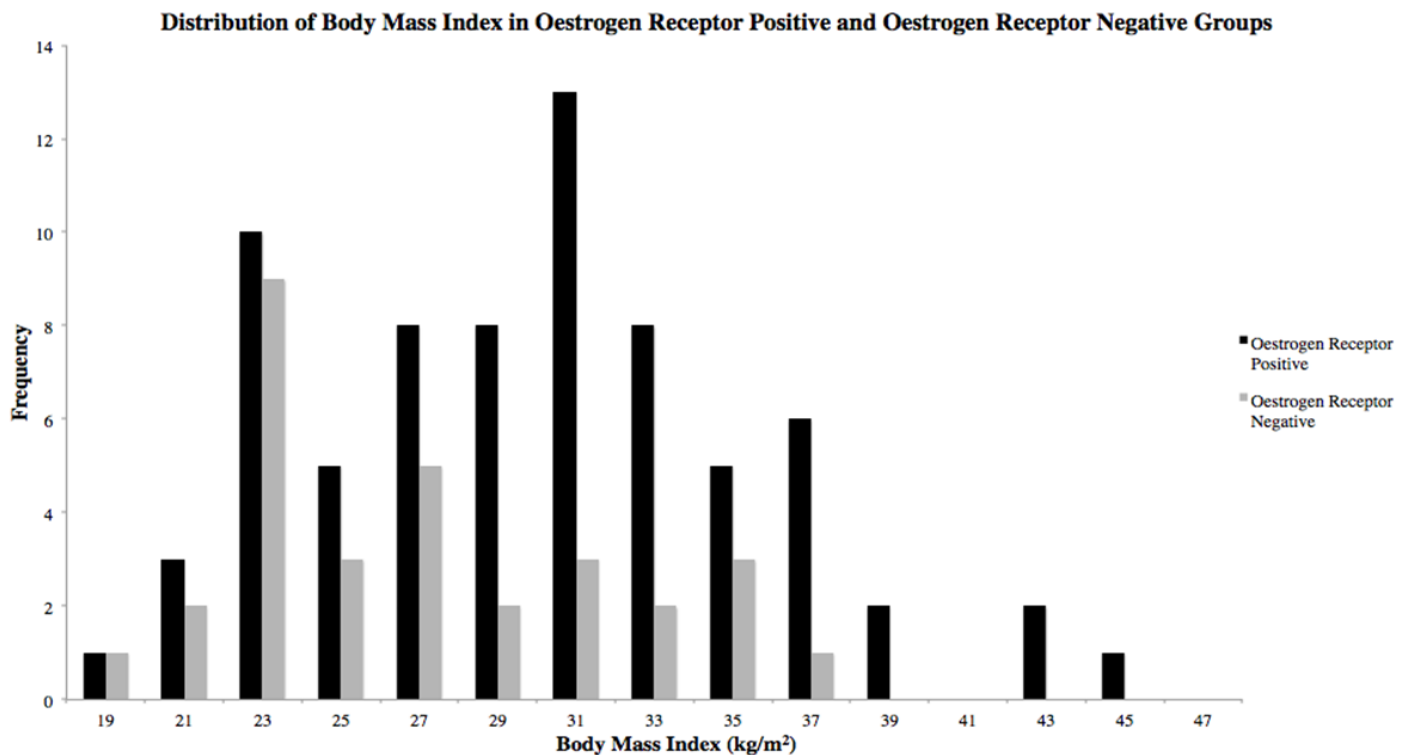
The study concluded a number of points in relation to breast cancer in the Maltese population. Firstly, Maltese women with breast cancer were found to be neither more nor less obese than the general female population. However, those women with ER+ malignancy are significantly more obese than those with ER– breast cancer.

Breast cancer is by far the commonest malignancy in females in Malta, with the incidence rate approaching 1 case per 1,000 people.<sup>9</sup> Obesity has been strongly linked with breast cancer in numerous studies,<sup>2-6, 10</sup> such that the observed rises in incidence in breast cancer might well be linked to the dramatic increases in the number of overweight and obese individuals.<sup>11</sup> Data from the European Health Interview Survey 2008 revealed that in Malta, 28.4% of females over the age of 15 years were overweight and 20.6% were obese,<sup>12</sup> while the European Health Examination Survey 2010 report revealed that in females over the age of 18 years, 25.6% were overweight but 32.0% were obese.<sup>8</sup> This demonstrates a very high and ever increasing prevalence of obesity in the Maltese Islands.

However, why this study demonstrated no statistically significant difference between the BMIs of the European Health Interview Survey 2010 sample, the ER+ sample and the ER– sample is not clear. One possibility is that the sample size is too small to detect the difference. Another possibility is that since the prevalence of obesity is so high in Malta, it is difficult to detect a difference between the overweight / obese and the normal weight population since the risk factor being studied (i.e. obesity) is not present in only a small minority of the population.

**Table 1:** Summary of BMI data in histologically confirmed breast cancer cases and general population

	Sample Size	Mean BMI (kg/m <sup>2</sup> )	Standard Deviation	95% Confidence Intervals
ER+	72	30.1	5.61	28.8 – 31.4
ER–	31	27.1	4.91	25.3 – 28.9
General Maltese Female Population	89	28.4	5.43	26.4 – 27.3

**Figure 1:** BMI distributions in ER+ and ER– breast cancer groups



**Table 2:** Menopausal status of breast cancer cases

	Premenopausal	Postmenopausal
ER+	14 (19.4%)	58 (80.6%)
ER–	11 (35.5%)	20 (64.5%)

**Table 3:** Multivariate analysis of oestrogen receptor status, BMI and age

BMI	Coefficient	Standard Error	t	p> t	95% Confidence Intervals
Oestrogen Receptor	3.081	1.192	2.590	0.011	0.717 – 5.446
Age	- 0.018	0.048	- 0.390	0.700	- 0.113 – 0.076
Constant (alpha)	28.168	2.875	9.800	0.000	22.463 – 33.872

In addition to this, the incidence of breast cancer in Malta is relatively low compared to that of other countries like Belgium and France, where the incidence rates are roughly 140 cases per 100,000 people,<sup>9</sup> and this may make finding a relationship between breast cancer and obesity all the more difficult.

The relationship between obesity and ER+ malignancy holds true in Malta. This relationship has been demonstrated repeatedly in other studies.<sup>11, 13-15</sup> The pathogenesis linking obesity and ER+ breast cancer is not completely clear. In post-menopausal women, oestrogen is largely produced by adipose tissue, which possesses the enzyme aromatase, which can synthesize oestrone.<sup>16</sup> Obese individuals have higher levels of circulating oestrogens and reduced levels of the steroid carrier sex hormone-binding globulin.<sup>7</sup> The high blood free oestrogen levels may be associated with increased, and possibly aberrant, division of breast epithelial cells. However, how, and even if, this high level of oestrogen results in anomalous oestrogen receptor expression on breast cancer cells remains unclear. It is likely that other adipocytokines apart from oestrogen are involved in the pathogenesis.<sup>7</sup>

This study demonstrated no association between positive oestrogen receptor status and menopausal status but showed an association between increasing age and positive oestrogen receptor expression. Clark, McGuire and Osborne found a similar result in almost 3,000 women with primary breast cancer, showing that when patient age and menopausal status were analysed together, the primary determinant of positive oestrogen receptor status was age.<sup>17</sup> Other studies, however, demonstrated that post-menopausal women had a greater tendency for developing ER+ disease.<sup>18, 19</sup> The positive correlation of oestrogen receptor status with age may stem, in part, from the correlation between age and an increasing BMI, with the European Health Interview

Survey (2008) and the European Health Examination Survey (2010) demonstrating increasing BMI with age in the Maltese population.<sup>8, 12</sup>

The fact that a small sample size was taken is a significant limitation of this study, as is the fact that the heights and weights of the sample of patients taken were obtained from the patient records rather than being measured directly. In addition, the impact of other potentially confounding variables (for example,

nulliparity, use of the oral contraceptive pill and smoking) were not investigated. Finally, the fact that BMI was taken as a measure of obesity may in itself be a limitation since BMI does not always correlate with body fat content.

### Conclusion

Maltese women with ER+ tumours have been found to be significantly more obese than those with ER– tumours but neither group was found to be significantly more or less obese than the general population. Positive oestrogen receptor expression correlated with obesity, with obese women being more at risk of developing ER+ malignancy.

### Conflict of Interest Statement

The authors declare no potential conflicts of interest.

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# A prospective audit examining non-attendance at a surgical outpatients clinic in Mater Dei Hospital, Malta, and methods to reduce this problem

Nathan Edwards, David Cini, Gordon Caruana Dingli

## Abstract

Non-attendance at hospital outpatient clinics is a longstanding issue that has potentially serious clinical implications, and contributes a significant financial burden to health care services. The aims of this study were to identify the rate of non-attendance at a surgical outpatients clinic in Mater Dei Hospital, Malta, ascertain the reasons for non-attendance, and to identify patients' opinions on the implementation of a text-messaging reminder system as a means of reducing the non-attendance rate. Four outpatient clinics were observed over one month and the total number of appointments documented. Non-attenders were contacted via telephone call and asked to explain their non-attendance and whether a text-messaging reminder system may have increased their likelihood of attendance. Of the 266 appointments (217 females, 49 males, mean age 56 + 16 years), 80 patients failed to turn up, representing a 30% non-attendance rate.

The main reasons for non-attendance were forgetfulness (53%), and unawareness of the appointment (26%). 90% of non-attenders stated that a text-messaging reminder might have prevented them missing their appointment, with 97% suggesting that such a system would be an acceptable method of trying to reduce this problem. Thus application of a text-messaging reminder system represents a potential solution for reducing the high rate of missed outpatient appointments, which is both cost effective and well accepted by patients.

## Key words

Non-attendance, Text-message, Outpatients

## Introduction

Non-attendance at hospital outpatient clinics is a longstanding issue that has potentially serious clinical implications for the non-attender, and deprives other patients of the opportunity to receive timely care.<sup>1-2</sup> Furthermore, the financial burden of non-attendance is significant, estimated at over £600 million per year in the UK.<sup>2</sup> This problem has been tackled by various strategies.<sup>3</sup> Overbooking clinics to compensate for the estimated number of non-attenders represents a poor use of resources. However, according to recent studies using automated reminders, in particular text-messaging reminder systems, offer the most promising solution to overcome this problem.<sup>3-4</sup> The major reasons for non-attendance reported in the literature are generally independent of specialty and include forgetfulness, illness, transport problems, patients seen in another clinic or unaware of the appointment, clinic running late, and work commitments.<sup>5</sup>

In addition to identifying the rate of non-attendance at a surgical outpatients clinic in Mater Dei Hospital, Malta, the aims of this study were to ascertain the reasons why patients missed their appointment, and to identify patients' opinions on the implementation of a text-messaging reminder system as a means of reducing the non-attendance rate.

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## Method

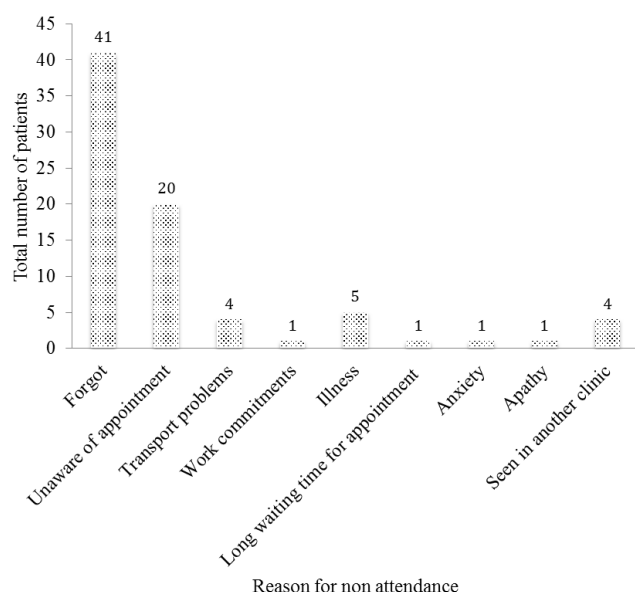
This study was conducted within Mater Dei Hospital, Malta, after being registered with the local audit committee and approved by the data protection management. Over a one-month period, four outpatient clinics of a general surgical firm with a specialist interest in breast surgery were observed. The total number of patients at each clinic was documented, along with the nature of their appointment (follow up or new case), patient age and sex. Patients who failed to attend were contacted via telephone call, and after being verbally consented for participation in a questionnaire, were asked to give an explanation for their non-attendance. Each patient was also asked if a text-messaging reminder system is an acceptable method of trying to reduce non-attendance and whether such a system might have prevented their non-attendance. The confidentiality of their responses was emphasised to all patients.

The results were tabulated and analysed using SPSS Version 20 (SPSS Inc., Chicago, USA). The test to determine differences between two population proportions was used where appropriate. Statistical significance was accepted at  $p < 0.05$ . Values are presented as mean + standard deviation.

## Results

Of the 266 patients (217 females, 49 males, mean age  $56 \pm 16$  years old) who were requested to attend one of the four outpatient clinics analysed during this study, 80 patients failed to turn up, representing a 30% non-attendance rate. Follow-up appointments had an increased rate of non-attendance compared to new case referrals (33% vs. 24%, respectively), although this difference was non-significant ( $p > 0.05$ ).

**Figure I:** Reasons for non attendance over four outpatients clinics



78 of the 80 patients who failed to turn up to their appointment were contacted via telephone call, all of which consented to the questionnaire. The reasons for non-attendance are shown in Figure I, with the main explanation being they simply forgot (41 patients; 53%), closely followed by patients not being aware of the appointment (20 patients; 26%). 70 out of the 78 patients contacted (90 %) stated that a simple text-messaging reminder might have prevented them missing their appointment. 76 out of 78 of the patients contacted (97%) suggested that such a system would be an acceptable method of trying to reduce non-attendance.

## Discussion

In 2009 the average non-attendance rate at Mater Dei Hospital, Malta was 29%, similar to the 30% rate of non-attendance noted in this present study and comparable to other studies.<sup>6-7</sup> To the authors knowledge this is the first study that attempts to establish the reasons why patients of the Maltese population fail to attend outpatient clinics within Mater Dei Hospital, Malta. The two main reasons for non-attendance, accounting for 79% of responses, were forgetfulness and unawareness of the appointment, and are similar to those reported in previous studies.<sup>1-5-7-8</sup>

Various solutions to non-attendance at outpatient clinics have been proposed, including the overbooking clinics to compensate for the expected number of non-attenders.<sup>9</sup> However, this represents an inefficient use of resources and may be counterproductive when the non-attendance rate is low, as in such circumstances appointment times would rarely be met.<sup>10</sup> While earlier studies report that telephone and postal reminders can reduce non-attendance rates, recently several studies report an increasing success and popularity of text-messaging reminders.<sup>2-3-4-7</sup> One such study reported a reduction of between 25% and 28% in missed outpatient clinic appointments at four community mental health clinics in London, translating to national cost savings of over £150 million per year in addition to the obvious clinical benefits afforded by patients turning up to their appointment.<sup>7</sup> Furthermore, a recent randomized control trial noted text-message reminders to be equivalent to telephone reminders in reducing the proportion of missed appointments in an academic primary care clinic and are more cost-effective.<sup>4</sup> This study also reported text-messaging reminder systems to be well accepted by all patients, a finding supported by our study.

This study has certain limitations. It was a single centre study involving predominantly female patients attending a general surgical outpatients clinic with a special interest in breast surgery. Thus in spite of our results being comparable to other studies, their application to other clinical settings may be limited. Moreover, although 90% of the patients who did not attend their appointment suggested that a text-messaging

reminder system might have prevented their non-attendance, it can only be surmised that the implementation of such a system may translate to fewer missed appointments. We suggest that more scientifically sound randomized controlled trials within the Maltese population are needed to confirm or refute this finding. To add further support for the need to reduce missed outpatient appointments, future studies should attempt to analyse the clinical significance of missed appointments.

This study focused predominantly on patient-related factors to explain the non-attendance rate. Future studies within Mater Dei Hospital, Malta, should also explore how aspects of the health care provider's service influence non-attendance at outpatient appointments. Indeed studies have shown how such aspects, including the amount of notice patients are given for their outpatients appointments, have a major influence in explaining the non-attendance rate at outpatient clinics.<sup>1-2</sup>

In conclusion, this study indicates that the non-attendance rate at a surgical outpatients clinic in Mater Dei Hospital, Malta, is high and comparable to other institutions. The main reasons why patients failed to attend their outpatient clinic were because they simply forgot or were unaware of the appointment. Application of a text-messaging reminder system represents a potential solution to this problem and is both cost effective and well accepted by patients.

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# Evaluating a prescription clinic at a primary health centre

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## Abstract

**Introduction:** One of the pillars of a good primary health system is the establishment of a good doctor-patients relation. Amongst other things, this will result in mutually accepted treatment plans, which are understood by all parties involved. This study aimed to describe and analyze one particular aspect of this care delivery, namely the repeat prescription clinic. In this clinic, which is run on an appointment basis, prescriptions are issued on a regular basis to patients and their relatives.

**Method:** A piloted questionnaire describing patients' demographics, diseases and treatment knowledge, was filled in during three randomly chosen clinics in November 2011.

**Results:** The clinic is attended by a relative majority of male clients, but both genders showed a peak attendance in the 60-69 age group. An average of 4 medications per person were prescribed and treatment in each patients was aimed at an average of 3 co-existent disease states. 56% of female attendees knew the complete list of their respective treatment as opposed to 45% of males attendees. Unfortunately, 73% of patients did not know the treatment they were on and did not have an up-to-date treatment list.

**Conclusion:** This study highlights the lack of knowledge of patients with respect to their treatment. However it can also be argued that this is a reflection of inadequate care being provided by doctors in the various fields. The clinic takes care of a significant number of patients whose treatment is not accounted for. This raises issues of safe prescribing. There is a need that all patients have an up-to-date treatment card, and a need for improvement in communication between all health care workers is noted, so as to improve the safety of all prescription practices in the island. This will lead to better disease control, less treatment interactions, and prescription errors.

## Background

Family medicine is a speciality where the patient-doctor relationship is crucial in the establishment of trust and therefore good clinical management. The crux in allowing the patient to attend with any complaint is the establishment of a mutual trust and agreement to liaise a negotiated treatment plan.

In the primary health care department, this is present to a lesser extent, since no patient registration is yet available, and doctors work on a shift system, even rotating health centres, and so the patient will not always find the same doctor when he / she attends the clinic. Health centres offer a vast number of services, including a GP (General Practitioner) walk in and treatment clinic, and appointment based clinics for repeat prescriptions, result explanation, ECG services, Diabetes clinic, Medical consultants' clinic, well baby clinic and gynae clinic. The primary care prescription clinic is a daily 3 hour clinic, held by appointment, where patients can renew their repeat prescriptions. Patients make an appointment for prescription clinic, where a specific time and date are given to the patient. They then attend the clinic and get their repeat prescription re-issued for a 1 or 2 month time span, depending on the drug prescribed. Nowadays, 3 sets of 2 monthly prescriptions are being handed to the patient, allowing 6 monthly appointments for repeat prescriptions. At prescription clinics, the GP is expected to see one patient every 4 minutes. Each person coming for his appointment can have a maximum of 3 sets of prescriptions to be renewed, further decreasing the time spent analysing each set of prescriptions. The yearly prescription clinic

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patient turnover at Floriana Health Centre (FHC) for 2011 was 6623. In November 2011, the month of our study, there was a turnover of 925 patients.

Prescription clinics are seen as a convenient way with which patients can get their repeat prescriptions every 2-6 months in an organised way, without wasting too much time thanks to an organised appointment system. However numerous studies in recent literature questioning various aspects of this method of prescribing led to the analysis of the local situation and the elucidation of the pros and cons of such a system.<sup>1-3</sup> Many times, it might be argued that a substantial number of patients are not fully aware of the medicines they are taking. At the health centres, some might bring out entitlement cards, even less patients might have a list of treatment. Albeit this, the impression is that patients go to their GP or health centres with no precise knowledge of what treatment they are taking.

In the work up for this study, a literature review was undertaken with respect to prescription clinics and patient knowledge of treatment.<sup>4-6</sup> Prescription clinics have been studied in numerous countries and many common problems were found. To date, there is no knowledge of a similar study in a local prescription study and literature review described no picture similar to the Maltese Islands.

## Aim

The study performed was aimed at getting a snapshot of the local situation with respect to the people attending prescription clinics, the diseases for which the prescription is being issued, the number of medications that the patient is on (thus analysis polypharmacy) and the patients' knowledge of treatment – be it through an up to date list or through memory retention of the list. The issue of communication between primary and secondary care physicians was also analysed through the checking of any available documentation of the treatment list and its place of issue.

## Method

A piloted questionnaire, created by the researchers, was filled in by the actual researchers during 3 randomly selected clinics in the month of November 2011. 99 patients were found to fit the criteria for filling in the questionnaire. To be able to fill in the questionnaire, one had to have the actual drug consumer in the clinic to be able to ask the relevant questions specifically to him / her. Thus, any attendees coming for friends' or relatives' prescriptions were excluded from the study. The patients were randomly selected according to the day of their appointment. The topics discussed in the questionnaire included the demographic information of the attendee ie: age, sex and locality, diseases being treated as listed on the front of the entitlement card, patient knowledge of all the names of the drugs and doses, identity of who

prepares medication for the attendee to take and the availability of an up to date treatment list and who set it up.

The questionnaire and study were approved by the University of Malta Research Ethics committee.

## Results

### *Demographic data*

Attendees were grouped in seven age groups, from 20-29 years, on to 80-89 year old attendees. More males attended the clinic, but the distribution of ages varied similarly for both genders, with a peak in the 60-69 year age group. There was a gradual increase in number of attendees up to the 60-69 year age group. From there onwards, there was a gradual decrease in number of attendees, with no attendees in the over 90 group.

### *Spectrum of Disease and number of drugs used*

Analysis of the epidemiological features of the attendees with regards to specific diseases, as seen in figure 1 (where epil refers to epilepsy, ra refers to rheumatoid arthritis, copd refers to chronic obstructive pulmonary disease, hf refers to heart failure, dm refers to diabetes mellitus, htn refers to hypertension, and psy refers to psychiatric conditions.), showed that male patients showed a higher prevalence of psychiatric disease and diabetes, than females, where a 2:1 male to female ratio was seen. A higher incidence of disease was noted in males, despite taking into consideration the male predominance of attendees. (see figure 1).

A range of 1 to 11 medications per person was noted, with an average of 4 drugs per person and 3 diseases being treated simultaneously. The largest number of patients were being treated for hypertension. The people with the largest number of medication, ie: the largest number of drugs per disease were noted to be the hypertensive group, followed closely by the diabetic patient group and then, by the patients with psychiatric conditions. The patients with the largest number of medication (11) was being treated for Diabetes Mellitus (DM), hypertension and asthma.

### *Patients' knowledge of treatment*

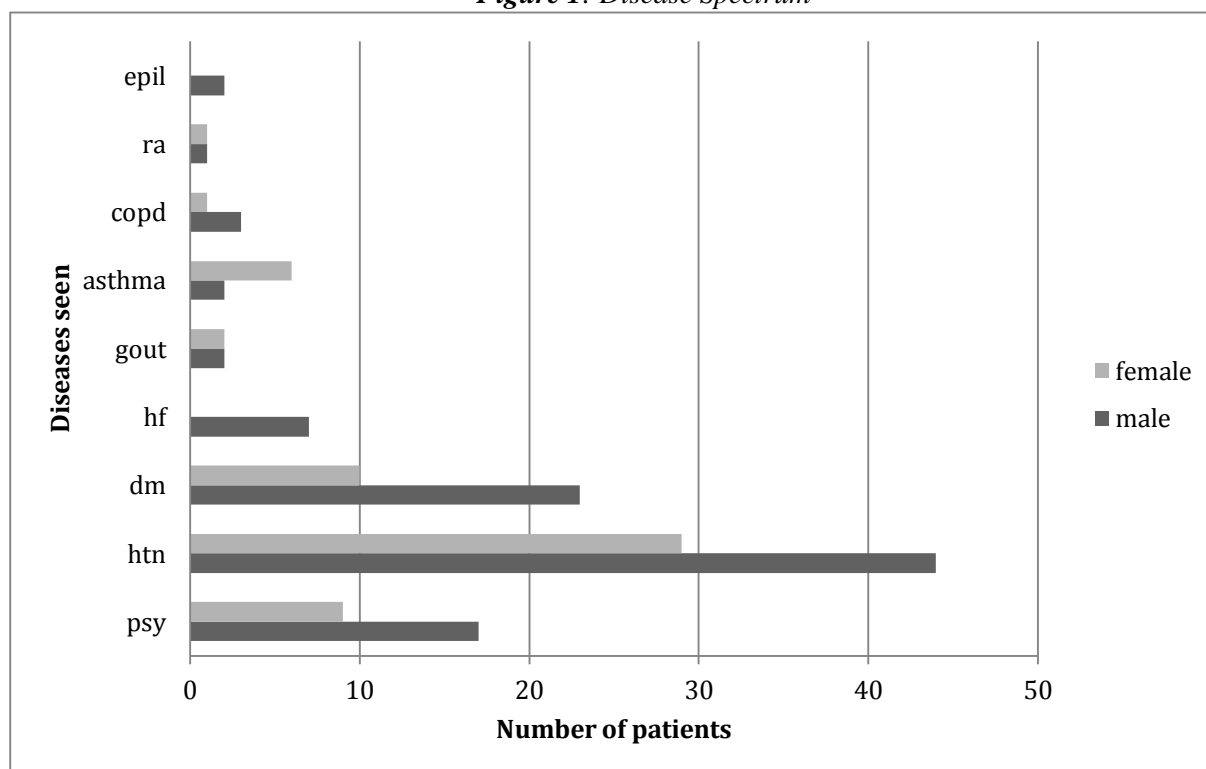
Looking at Fig 2, 56% of the female attendees knew their treatment list, whereas only 45% of their male counterparts did.

96% of the attendees prepared their own medication whereas three attendees had their children organising the medication into daily quantities.

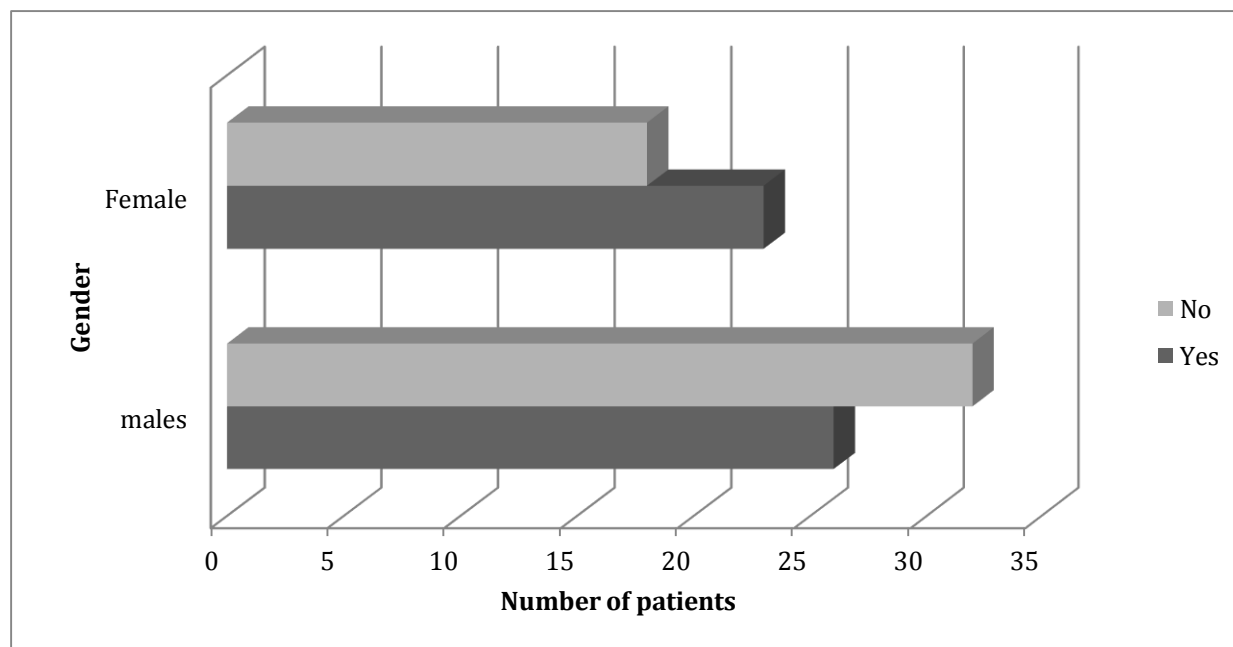
### *Availability of up to date treatment list*

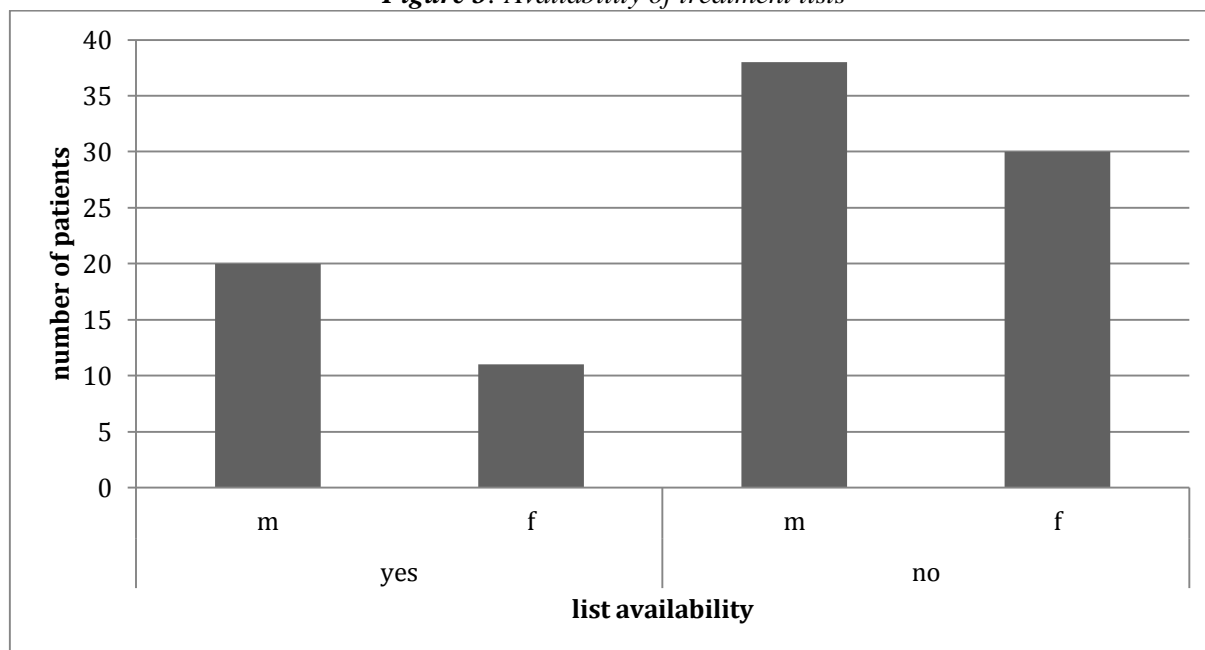
Figure 3 shows the availability of treatment lists in the separate sexes. Of the patients who knew the names to their medication, 4 had an up-to-date treatment card. Only 26% of the people who did not know their treatment list had an up to date card. The rest relied on the entitlement card itself as a treatment list.

*Figure 1: Disease Spectrum*



*Figure 2: Patient knowledge of treatment*



**Figure 3: Availability of treatment lists****Who prepared the treatment list**

46% of treatment cards were compiled by the patients' GP, compared to 26% of cards compiled by hospital staff. It was interesting to notice that 16% of attendees had compiled a treatment list themselves, highlighting the fact that they tried to establish some order in their daily treatment routine. The importance of the GP in the daily running of a patient's treatment routine was highlighted here.

**Discussion****Demographics**

The age and sex distribution demonstrated in our study is very similar to international literature.<sup>7-11</sup> In this study, on average, each person took 4 drugs. In addition, there was an average of 3 diseases being treated simultaneously, showing the largest number of people being treated for hypertension. Literature shows that overseas, an average of 3 drugs per patient are the average norm in repeat prescribing and the average number of diseases being treated is similar.<sup>1,3,12,13</sup>

**Safe Prescribing**

This discrepancy in the increased use of drugs in the local group studied could be due to the fact that locally, no drug combinations was provided on the schedule V system. The fact that the largest number of drugs was seen in the attendees on anti-hypertensive medication further supports this thought. Improvement with regards to the number of different drugs used, with the introduction of drug combinations<sup>12-15</sup> has been seen in literature. The issue of patient confusion with large drug numbers decreases compliance and drug effectiveness,<sup>16-18</sup> and increases drug wastage and risk of

interactions.<sup>19</sup> Increased functional health literacy is known to improve control of chronic disease like Diabetes Mellitus,<sup>20</sup> thus, investing in patient education during prescription clinic encounters might improve chronic disease management in the long term. Being able to interact regularly with the patient is known to increase patient trust in the caregiver and this, is known to improve compliance and thus, disease control.<sup>21</sup>

An increased occurrence of drug interactions with commonly used medications like Non steroidal anti inflammatories (NSAIDs) and over the counter (OTC) analgesia was documented in numerous studies.<sup>22-25</sup> Such interactions were documented with the use of very common drugs like low dose Aspirin and the patient's self administration of NSAIDs like Ibuprofen.<sup>23</sup> The figures of the average number of drugs noted in the attendees of the local prescription clinics highlights the risk of such interactions, especially if the patients are not asked about the purchase and usage of OTC medication, and they are also unaware of the risks of self administering drugs like NSAIDs in the case of the elderly.<sup>24,26</sup> This need further supports the importance of a drug review clinic more than a prescription clinic.

The average time spent with each patient at the clinic also highlights the issue of drug review and the facilitation of patient-doctor concordance with respect to the treatment.<sup>21,27,28</sup> Doctor- patient concordance implies an agreement reached by the doctor and the patient about the latter's need for treatment and agreement to compliance from the patient. The doctor however agrees to review the patient, answer queries and change treatment according to patient needs or side effects.

Lack of concordance decreases compliance, thereby increasing drug wastage and decreases drug and cost

effectiveness.<sup>21,29,30</sup> Having enough time to look at psychological, illness related or practical tangible problems which can lead to non adherence is essential.<sup>31-33</sup> Numerous studies highlight the importance of a low repeat: consultation ratio to increase overall efficacy and efficiency of these clinics.<sup>15</sup>

The issue of safe prescribing in such circumstances has many aspects including, patient knowledge of treatment, availability of up to date treatment lists and proper communication between health care professionals, (especially primary and secondary care physicians) by means of notes describing changes in treatment, or reasons for treatment withdrawal, All these were highlighted in studies as modes of increasing treatment compliance and concordance, thereby increasing treatment safety and clinic efficiency.<sup>12-15, 18, 19</sup>

With 50% of patients not knowing their treatment list, and less than half of these patients having an up to date treatment card, the need for a means of keeping up to date records of all the treatment prescribed and dispensed and the reasons for the initiation and withdrawal of treatment is imperative. This will be the first stepping stone towards the motivation and facilitation of regular treatment review with safe treatment modification by GPs. It is very frustrating and dangerous to be faced by a patient with a badly controlled chronic condition and not being able to improve control at the first consultation because the patient does not know what treatment he is on and has no up to date list. This decreases the efficiency of GP consultations since a second consultation is needed, thereby also decreasing opportunistic intervention and at times leads to complete lack of disease control since patients are not always willing to visit clinics again at such short intervals.

The main function of primary care clinics, that is, prevention, be it primary or secondary prevention, is being jeopardised through the lack of proper communication between health centre physicians, hospital based physicians and dispensing pharmacists. Having real time communication or record keeping would facilitate a multidisciplinary approach to treatment review, increasing the chance that dosage, medication errors and treatment interactions are identified and corrected.<sup>34</sup>

Such systems would also aid auditing of the pharmaceutical dispensing system, increasing the chance of identifying drug abuse or non compliance, thereby increasing drug efficacy and decreasing drug and financial wastage.<sup>35</sup> This might also serve as a means of stock keeping, decreasing the problem of out of stock medication.

Studies show increased safety with such measures and also increased patient satisfaction.<sup>34</sup> However, such systems carry their own disadvantages. These mainly

are the need for regular doctor-patient consultation, and increasing the time needed per patient appointment and at GP clinic, to allow time for updating of lists and medication review. Previous government dispensing pharmacies used to dispense 3 monthly supplies of drugs thereby necessitating 3 monthly appointments at the prescription clinic. At the time of study, the Pharmacy of your choice (POYC) system, where patients could choose a pharmacy close to home from where to collect their medications, necessitated 2 monthly appointments as 2 monthly supplies of drugs are dispensed. This had increased the burden on the prescription clinics. Today, 3 sets of two monthly prescriptions are being issued at each visit, thereby allowing for 6 monthly appointments. It can be argued, that in view of all of the above, the safety for such practice might be questioned. A major improvement with the computerisation of patient drug records, where all pharmacies involved in the POYC system have electronic records of the treatment list of their registered clients has already been seen. An improvement on this system would be, giving computer access to all registered doctors so that any change in treatment can be introduced into the system and a computerised prescription being routinely issued without the need of prescription clinic attendance. The drug would be issued under the signature of the last doctor prescribing it. Treatment duration, reason for initiation and any recommended interim measures (ex: renal function checks or review of prescription) would be highlighted on inputting the drug into the system. Prescription clinic would then be utilised as a review clinic with longer appointments every 6-8 months. Here one would review treatment lists and discuss follow up of the chronic conditions. Computerised systems were found to be efficient and safe ways of issuing repeat prescriptions without increasing the need for more doctors to be employed so as to cope with extra clinic times.<sup>35-38</sup>

### *The role of the GP*

Currently, the role of the GP in the repeat prescription clinic is that of issuing the prescriptions. Fortunately, seeing that 49% of the patients having up to date treatment lists had these issued by their GP, shows that GPs are willing to try and instil structure into an otherwise haphazard clinic. It is encouraging to see that some doctors take the extra time to fill up treatment cards to facilitate compliance. It is also encouraging to see that some patients themselves try and organise their drug lists to feel safer. This highlights the point that there is motivation to improve and that GPs play a major if not crucial role in safe prescribing and in the empowerment of patients towards compliance.<sup>3</sup>

### *Strengths and Limitations of the study*

The questionnaire was only filled in after



questioning the patient taking the medication himself / herself. In the study, no questionnaire was lost and all data was accounted for. The questionnaires were adequately filled in by the researchers.

Unfortunately the small number of patients involved detracts from the robustness of findings. Similarly, the fact that the study was carried out on few days in autumn might have affected the results. The fact that questionnaires were filled in only by the researchers, might have unknowingly introduced a form of bias, despite ensuring more reliable data input.

## Conclusion

This study aimed at reviewing an otherwise uncharted territory in the provision of primary health care ie repeat prescription clinics. The results show that a large percentage of the population studied does not know the medication they were on. In line with literature reviewed, there is an urgent need to improve upon the safety of the repeat prescription clinics and maximise the efficiency of such a system, exploiting the clinic to further empower and educate patients, with the global aim of improving drug compliance, treatment safety, condition control, and overall efficiency of the system.

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# An audit of compliance of inhaled steroid medication in Maltese asthmatic children. A comparison between 2008 and 2014

Cecil Vella, Gianluca Bezzina, Matthew Urpani

## Introduction

In the treatment of bronchial asthma, inhaled therapy with bronchodilators and corticosteroids represents the basis for acute and long-term management. Drug therapy in asthma is predominantly by pressurized metered dose inhalers. The impact of treatment on the disease morbidity and mortality depends to a large extent on appropriate delivery of drugs to the lungs by means of a spacer device and on the continuity of treatment. Poor compliance with medication is a well known problem in conditions which require long-term treatment. This is especially so in asthma where initial improvement may be followed by longer remission and a tendency to stop treatment. Compliance is "the extent to which a person's behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice." <sup>1</sup>. Compliance with preventive therapy such as inhaled corticosteroids (ICS), the effects of which are seen over a period of weeks, may be less than compliance with drugs that relieve asthma symptoms more rapidly such as bronchodilators. To our knowledge there are no previous studies which have assessed the prevalence of non-compliance with inhaled corticosteroids in Maltese children.

## Key words

Inhaled corticosteroids, asthmatic children, compliance.

## Aims

The aim of this audit was to assess and quantify the prevalence of poor compliance with prescribed inhaled corticosteroid medication in Maltese asthmatic children. Also the practice and prevalence of stopping therapy in the summer months will also be assessed. Finally the use of a spacer device will be documented and compared with the high usage as previously assessed in an earlier study <sup>2</sup>.

## Methods

One hundred and thirty one children between seven and fifteen years of age attending a children's outpatient clinic between December 2013 and March 2014 were assessed. The audit was questionnaire-based (figure 1). Questions asked form part of the routine assessment and management of asthmatic children attending for regular visits and for this reason, ethics committee approval was not required. Patients recruited attended outpatients for routine follow-up and were under the care of a single consultant. Results were compared to an identical audit that was carried out in one hundred and twenty four children attending the same clinic during 2008.

## Results

Questionnaires were completed for 131 children with a diagnosis of chronic bronchial asthma attending the paediatric outpatient department between December 2013 and March 2014. Results were compared to those from an identical audit carried out on 124 children in 2008. 162 were male (63%) and 93 were female (37%). 124 were between the ages of 7 and 10 years (49%) and 131 were between 11 and 15 years of age (51%).

### *Use of spacing device for delivery*

The use of a spacer device in the administration of inhaled corticosteroids was recorded as 98% in 2008 and 99% in 2014.

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*Figure 1: Sample of questionnaire*

<b>Age bracket</b>	
7-10	<input type="radio"/>
11-14	<input type="radio"/>
<b>Sex</b>	
Male	<input type="radio"/>
Female	<input type="radio"/>
<b>Do you make use of a spacer device whilst consuming your MDI?</b>	
Always	<input type="radio"/>
Most times	<input type="radio"/>
Sometimes	<input type="radio"/>
Never	<input type="radio"/>
Not applicable (for dry powder inhalers only)	<input type="radio"/>
<b>If not always making use of spacer device – Why?</b>	
Believe to have enough co-ordination to do without device	<input type="radio"/>
Too unsightly or bulky to use and carry around	<input type="radio"/>
Believe it makes no difference	<input type="radio"/>
Indifferent	<input type="radio"/>
<b>Are you regularly consuming your prophylactic inhalers as prescribed?</b>	
Always	<input type="radio"/>
Most times	<input type="radio"/>
Sometimes	<input type="radio"/>
Never	<input type="radio"/>

*Figure 1: Sample of questionnaire (cont.)*

<p><b>If not always complying with treatment regimen – Why?</b></p> <p>Do not feel it is necessary</p> <p>Fear of side effects</p> <p>Indifferent</p> <p><b>Parental impression: Do you think that your child takes his preventative treatment regularly?</b></p> <p>Always</p> <p>Most times</p> <p>Sometimes</p> <p>Never</p> <p><b>Do you stop you prophylactic inhalers during the summer months?</b></p> <p>Yes</p> <p>No</p> <p><b>If you do not stop your inhaler treatment, do you reduce the dose?</b></p> <p>Yes</p> <p>No</p> <p><b>If you do stop your inhaler treatment – Why?</b></p> <p>Advised by doctor</p>
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***Compliance with prophylaxis***

When asked about the regular use of prophylactic ICS, 90% claimed they always took their treatment. This was comparable to a compliance rate of 92% recorded in 2008.

Those patients who were non-compliant with regular use of ICS cited that they did not feel treatment was necessary in 36% in 2008 and 24% in 2014. The rest of the patients that were non-compliant were indifferent.

The parental impression of the regularity of treatment in their children compared well to the claims of the children themselves.

***Stopping prophylaxis in summer***

When asked if ICS were stopped during the summer months, 23% said that they stop their

prophylaxis in 2008. An improvement was noted in 2014 when the rate of patients who stopped treatment decreased to 18%. The commonest reason cited for stopping ICS in summer was that patients felt better and saw no benefit to continue. A significant percentage of children either stopped their treatment in summer following medical advice (28% in 2008, 21% in 2014) or reduced the dose of ICS (18% in 2008, 7% in 2014).

***Relation of compliance with age of patient***

Compliance in patients in the 11 -15 year old bracket was almost identical to compliance in younger children.

***Discussion***

Compliance, or adherence, as it relates to health care is the extent to which a person's behaviour coincides with medical or health advice. Medication compliance is



critical for all aspects of paediatrics, specifically in successful treatment, disease prevention, and health promotion.<sup>3,4,5</sup> Compliance depends on the patient's and physician's committing to the same objectives. It is unfortunate that numerous studies and physician accounts reveal difficulties in achieving compliance with paediatric medication therapy. Medication compliance in paediatric patients ranges from 11% to 93%.<sup>5</sup> Poor compliance places children at risk for problems such as continued disease, complicates the physician-patient relationship, and prevents accurate assessment of the quality of care provided.

This audit demonstrates that multiple factors may come between a prescription for an inhaled corticosteroid and the arrival of that medicine to its target organ, the lung. These factors have to be considered when assessing response to treatment. Frequently physicians fail to assess the impact that poor compliance has on disease control and will resort to the use of stronger and frequently more expensive medications with an aim of improving control. The patient or his carer, in the case of young children, should be directly questioned regarding compliance before major changes to therapy are made.

Patients fail to comply with asthma medication for a variety of reasons<sup>6,7</sup>. These range from physical inability to use an inhaler, through simple forgetfulness, to a conscious decision not to use medication as prescribed due to internal or cultural health beliefs or socioeconomic factors. In some patients, poor self-care because of deep-rooted psychological factors (i.e. factors of which patients have only limited awareness) can affect compliance<sup>8,9,10</sup>. Poor doctor-patient communication can be the cause in many other individuals. Patient indifference to administration of ICS was and still is a significant factor in non-compliance. The high percentage of use of spacer devices as well as the significant drop in the percentage of patients who decrease the dose of their treatment during the summer months is encouraging. The comparable high compliance rate in the older age group was surprising and reassuring. This may be a result of a non-patronising attitude with older asthmatic children and ongoing education of our asthmatics from an early age. We believe that the relatively good compliance rates observed locally are the result of close follow-up of asthmatic children on a regular basis and the repeated assessment of the technique of medication administration. Although the number of patients was relatively small, the similar results from both audits carried out several years apart represent a true picture of the local situation.

## Conclusion

There is no single solution that will improve compliance in all patients. Simplifying the regimen or

providing memory aids will be sufficient for some patients, while education will be more appropriate for others. Doctors can also use a range of communication skills to improve the way in which they present information, motivate patients and reinforce progress. These approaches, together with respect for patients' health beliefs and involving them in treatment decisions, can help foster an atmosphere of mutual responsibility and concordance over compliance with the treatment prescribed.

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# Continuity of Information and Care – a Pilot Study in a Health Centre

Michelle Bugeja, Jurgen Abela

## Abstract

**Introduction:** Family medicine is the first level of contact of individuals, the family and the community with the national health.<sup>1</sup> Quality of continuity is the degree of which a series of discrete encounters with health care professionals is coherent, connected, and consistent with the patient's medical needs and personal context.<sup>2</sup>

**Objective:** The aim of this study was to assess continuity of care in patients attending for General Practitioner consultations in Floriana Health Centre (FHC).

**Method:** The study focused on all the physician-patient encounters occurring in the GP consultation rooms between 8 a.m. and 5 p.m, which accounts for the overall majority of patient contacts in health centres over a 24 hour period. This was a pilot study and consequently the study was carried out in only one health centre. The field work was carried out on five working days, including a Sunday. The number of medical records which were given to patients was noted together with the total number of patients attending for a consultation. This data was then divided in morning (8a.m. – noon) and afternoon (noon – 5p.m) sessions. Medical records given to GPs were assessed to see whether an entry was actually made and the quality of the entry.

**Results:** A total of 529 patient encounters were included in the study. There were 411 patients attending the FHC for a GP consultation between 8a.m. and 5p.m. in four weekdays and 118 patients attending a consultation on Sunday. 23% of patients attending for a GP consultation during weekdays were given a file while 77% were not. A higher percentage of medical records were not given in the afternoons. 75% of GPs wrote a note in the patient's file when it was provided to them.

**Conclusion:** Continuity of care is an important and essential element in delivering good quality healthcare service to the patient. Continuity of care is not occurring to the desired degree in FHC and is possibly leading to sub-optimal care being provided to our patients. The intention is that in the future, this pilot study will be implemented on a larger scale in other health centres for a greater representation of the work being done at primary care level.

## Keywords

Records, Family Medicine, Health centres, Continuity of care

## Objective

The aim of this study was to assess continuity of care in patients attending for General Practitioner (GP) consultations in Floriana Health Centre (FHC).

## Introduction

### *1. Family medicine and Continuity of Care*

Family medicine is the first level of contact for individuals, their family and the community with the national healthcare system and constitutes the first element of a continuing health care process.<sup>1</sup> It is a specialty in breadth that integrates the biological, clinical and behavioural sciences. The scope of family medicine encompasses all ages, sexes, each organ and disease entity.<sup>3</sup>

The quality of continuity of care is determined by the degree with which a series of discrete encounters with health care professionals are coherent, connected, and consistent with the patient's medical needs and personal context.<sup>2</sup> Patient's medical records are basic clinical tools that should be used in every consultation<sup>4</sup> since they guide providers to the delivery of consistent care tailored for the individual patient. Apart from

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medical facts, medical records hold carers' considerations for future management and treatment of patients.<sup>5</sup> According to Saultz<sup>6</sup> continuity of care is one of the five pillars on which the specialty of family medicine is based. In fact, when continuity of care is present in healthcare, better outcomes are obtained<sup>7</sup> such as, higher patient satisfaction, improved delivery of medical services and lower hospitalisation rates. In addition to this, clinical records are the clinician's main defence if assessments, diagnosis and medical decisions are questioned.<sup>4</sup>

The Royal College of Physicians gives a detailed description of how good quality clinical records should be done and maintained. Some of the most relevant standards mentioned by the Royal College are listed below.<sup>8-9</sup>

- All contacts with the patient should be recorded
- Records should be made in an appropriate structure under the general headings: reason of contact, findings, action taken, conclusion and who was informed
- Every entry should be legible, dated, timed and signed
- Access to the medical records should be clearly defined and easy to obtain

## 2. *Family Medicine in Malta*

The beginning of primary health in Malta dates back to the 16<sup>th</sup> century when a system of provision of financial relief, food and free medicine to those in need was set up by the Order of St John. Primary health then continued to develop under the British rule and the first government dispensary was opened in 1832. Other dispensaries continued to open usually attached to the Local Police station. The current primary health care system started to shape itself in 1980 when free emergency polyclinic service was developed.<sup>10</sup>

Primary health care in Malta is provided by the private and the state sectors which operate independently of each other. The state offers services that include general practice in a number of Health Centres found throughout Malta (Floriana, Mosta, Birkirkara, Gzira, Paola, Bormla, Rabat, Qormi, Rabat – Gozo) and also provides services within the community at the local clinics (bereg) which are spread around forty different localities.<sup>11</sup>

The Health Centres mentioned above provide GP consultations within the clinic itself and as house visits, daily nursing care and emergency treatments/minor procedures. In these Centres one can also find various multidisciplinary and specialisation clinics being held such as physiotherapy services, well-baby clinic, medical consultant clinic, gynaecology services etc. In 2013 a total of 60,045 patients attended FHC for a GP consultation; during the month in which the study was

carried out, that is September 4,576 patients presented for a GP consultation.

## Methodology

The aim of the study was to assess the quality of continuity of care within FHC by assessing the percentage of patients that are given their medical records, by Healthcare Assistants, to be used during the GP consultation and the information that is documented in these records by the GP. The relevant institutional approval from the Primary Health Care Department was sought and granted. No Research Ethics Committee approval was required since the study did not involve individual patients.

Due to constraints related to time and resources, the study was carried out in only one health centre and a decision was taken to carry out the fieldwork on four separate weekdays and one Saturday or Sunday. The month of September 2013 was chosen and this month had four Saturdays, five Sundays and twenty-one weekdays. To minimise selection bias, the four weekdays were chosen at random by numbering twenty-one tickets according to the dates of the weekdays in September, placing the tickets in a paper bag and drawing four numbers at random. These numbers represented the weekdays dates when the data collection would be taking place. The same thing was done to select at random a weekend day out of the four Saturdays and five Sundays. The researcher ensured that there would be different Healthcare Assistants working during the different days of the study to ensure that any results were not linked to the practice of one Healthcare Assistant only.

In all, the medical records of 529 patients were reviewed by two doctors. The study focused on all the physician-patient encounters occurring in the GP consultation rooms between 8 a.m. and 5 p.m. This timeframe was chosen because it includes the majority of patient encounters occurring at the health centre during any one given day. The number of medical records which were given to patients was noted together with the total number of patients attending for a consultation. Patients who did not fall within the FHC catchment area should have been given a continuation sheet to document the encounter, which sheet is then posted to the appropriate Health centre. Such continuation sheets were also included in this study. The data was then divided in morning (8a.m. – noon) and afternoon (noon – 5p.m) so that the researchers could analyse the data and check for any trends in continuity of care during this eight hour period.

All the medical records given to GPs were then collected and assessed for quality of documentation by two different physicians independently, using a specific checklist which was compiled by the authors. The

checklist was informed by the guidance provided by the Royal College of Physicians and was structured to address a basic record keeping system. Any inconsistencies in quality of documentation in specific medical records were then brought into discussion. All data collected was inserted and analysed in a spreadsheet using Microsoft Excel 2010.

## Results

There were 411 patients attending the FHC for a GP consultation between 8a.m. and 5p.m. in four weekdays with an average of 102.75 patients per day (95% Confidence Interval (CI): 97.92 – 107.58 patients per day). On Sunday 118 patients attended for a consultation.

The number of medical records that were given to patients was recorded and illustrated in Figure 1. Overall only 23% of patients attending for a GP consultation during weekdays were given a file (Figure 2).

In addition to this, an average of the weekdays' performance was compared to a Sunday (Figure 3).

When comparing the number of medical records given in the morning (8a.m – noon) to those given in the afternoon (noon – 5p.m), a higher proportion of medical records were given during the morning 36.21% (95% CI: 31.38% – 41.04%) than during the afternoon 8.34% (95% CI: 3.51% – 13.17%) for both weekdays and Sunday (Figure 4). In two of the weekdays no medical records were given in the afternoon.

When the researchers reviewed the medical records which were given to patients, it emerged that the majority of GPs (75%) wrote a note in the patient's medical record (Figure 5).

The data which was present in the medical records was compared with the guidelines for good medical record keeping established by the Royal College of Physicians (Figure 6). There was a high percentage of GPs who inputted the date of the consultation, brief history, possible diagnosis, management plan/ treatment prescribed and signed their entrance. On the other hand, 36.9% (95% CI: 32.64% - 41.16%) of GPs who were given the patient's medical record did not insert a legible printed name in the documentation which might make it difficult to identify the physician for future reference. Time at which the consultation took place was not inserted by any of the GPs.

## Discussion

Patients' records are there to contribute a clear and concise picture of the management and treatment of patients and to help in providing the best possible clinical service.<sup>8</sup>

The Maltese Healthcare system does not yet allow patients to register with their own GP in the Health

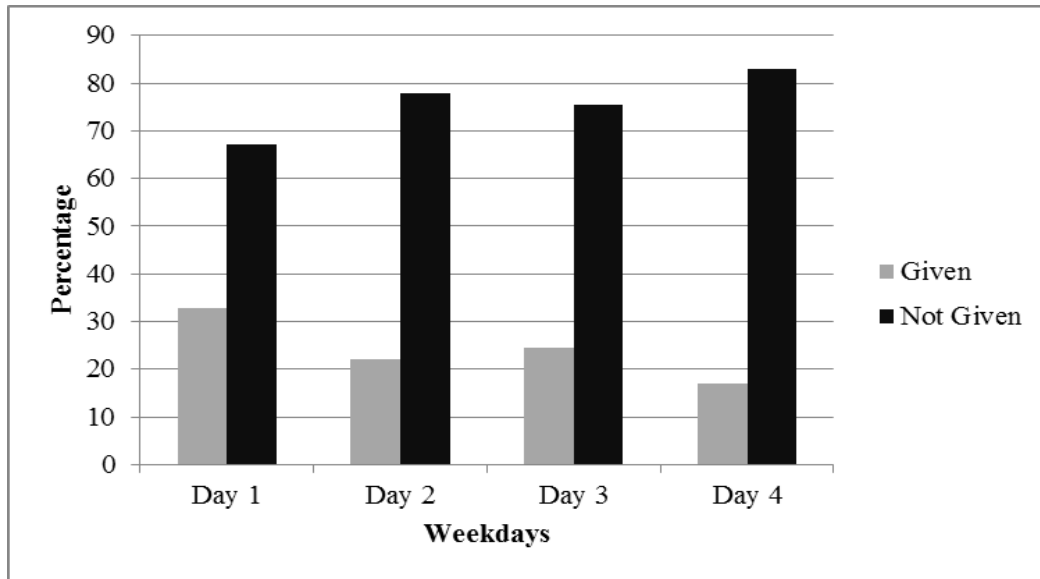
Centre. Therefore, patients are seen each time by a different doctor, and this emphasises the importance of keeping good patients' medical records in order to ensure proper continuity of care between one doctor and another.<sup>12</sup> In the absence of continuity of care, which refers to a developing relation between a GP and the patient, the next possible scenario is to have continuity of information, where despite the absence of a developing relation between a GP and patient, the necessary information is passed on between professionals and recorded.

One of the recommendations listed by the Royal College of Physicians is that "access to the folder should be clearly defined in local policies and procedures, but free access by the relevant user should be the usual practice"<sup>8</sup>; thus in our study we assessed whether medical records were being given to GPs during the consultation with the patient. In FHC, the common practice is that as soon as a patient enters the Health Centre s/he is registered at the reception after providing an Identification Card. The file is then retrieved by Healthcare assistants in the records, and the patient is provided with a file which s/he then presents to the GP during the consultation.

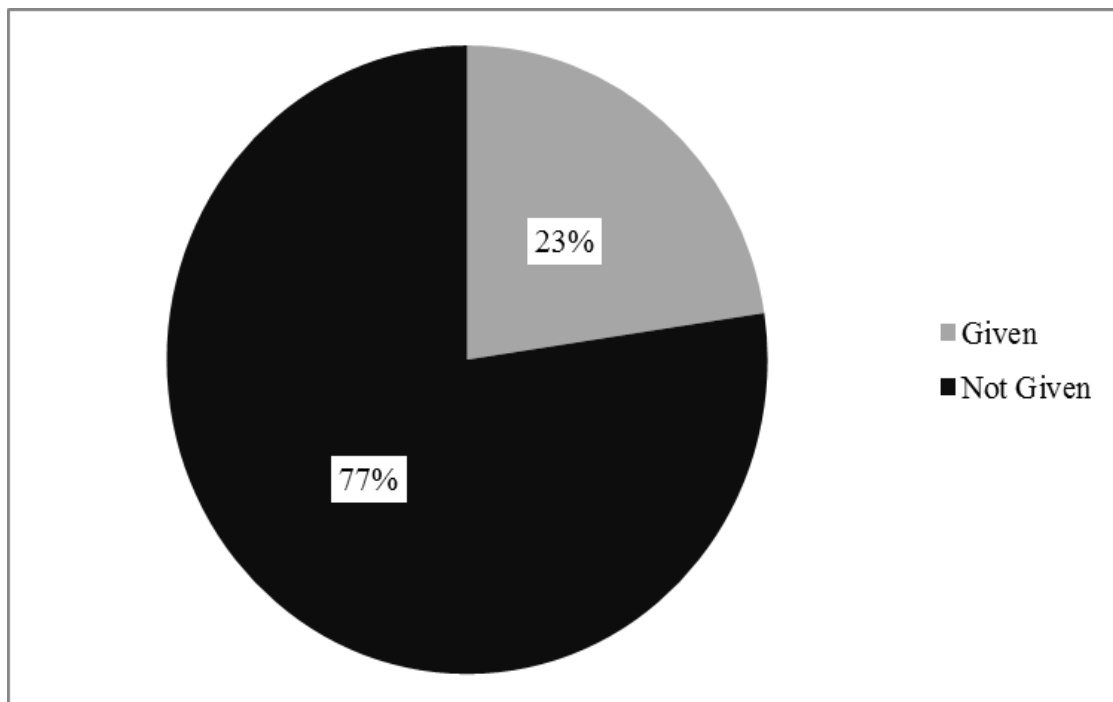
During the five days (8a.m – 5p.m) in which the study was carried out, 77% of the patients attending FHC did not receive their medical records and therefore the process of continuity of information did not even initiate. Additionally, there is a noticeable difference in the percentage of medical records which were given to patients in the morning (8a.m – noon) and in the afternoon (noon – 5p.m). This difference between morning and afternoon might be attributed to the start of recreational breaks of the healthcare assistants in the afternoon which leads to less staff on the shop floor to register patients, retrieve and distribute medical records.

We also assessed whether GPs wrote notes when medical records were provided. The Irish Ombudsman expressed his concern about the state of record-keeping and emphasised the importance of keeping clear and updated notes to improve patients' care and also to protect the doctor from medico-legal issues.<sup>13</sup> A positive result was registered when assessing percentage entrance of notes in medical records, with the majority of GPs inserting a note in the file when it was provided to them. Possible reasons for not inputting records might include pressure of work; lack of motivation to enter notes given the erratic nature of file availability, lack of appreciation of the importance of keeping good medical records; insufficient space in the file where to write down notes (continuation sheets are designed so that multiple entries are done on the same continuation sheet); and last but not least fatigue.

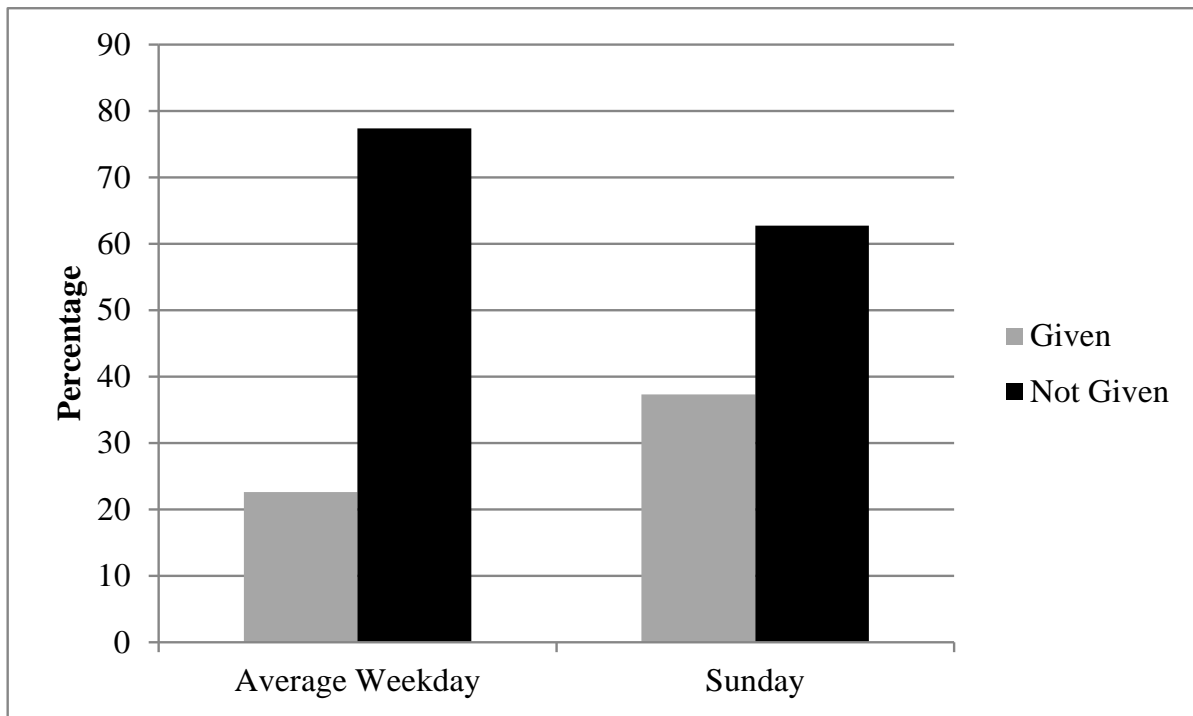
**Figure 1:** Percentage of total number of files which were given and not given to patients attending for a GP Consultation at FHC during weekdays



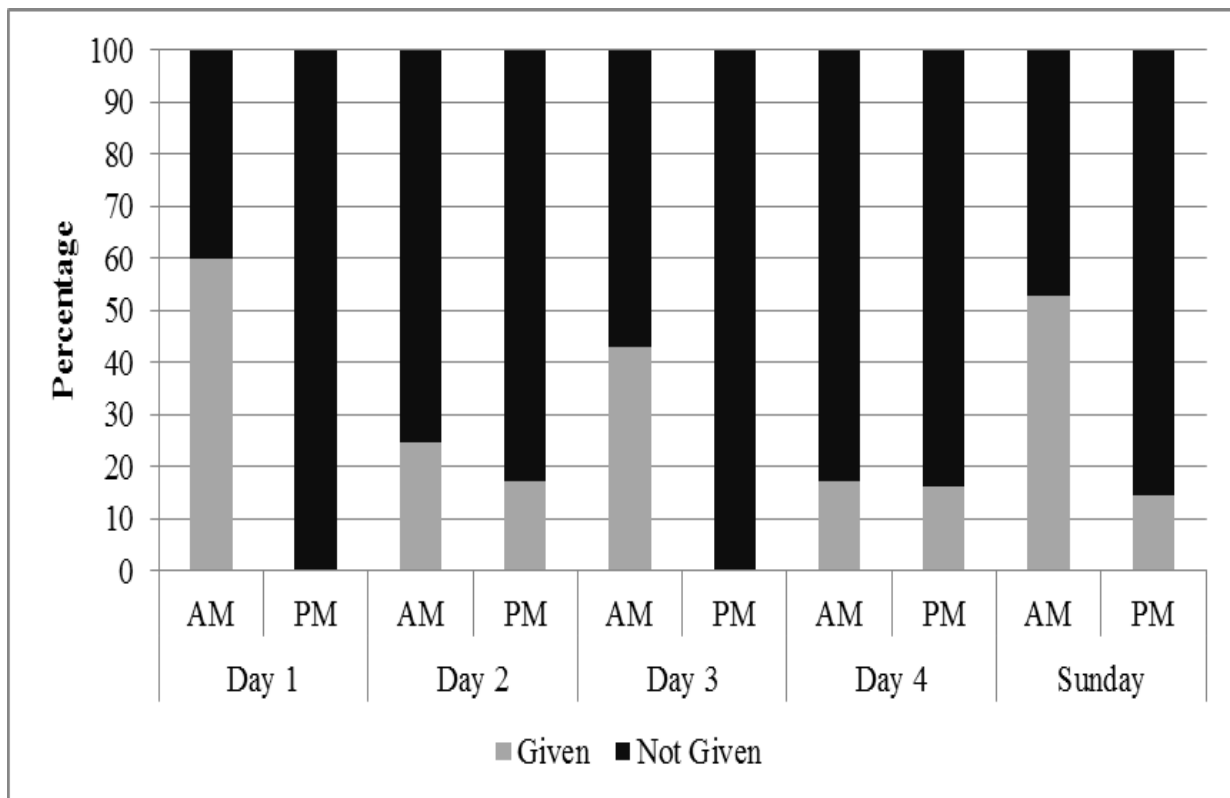
**Figure 2:** Average of the percentage number of files given and not given to patients



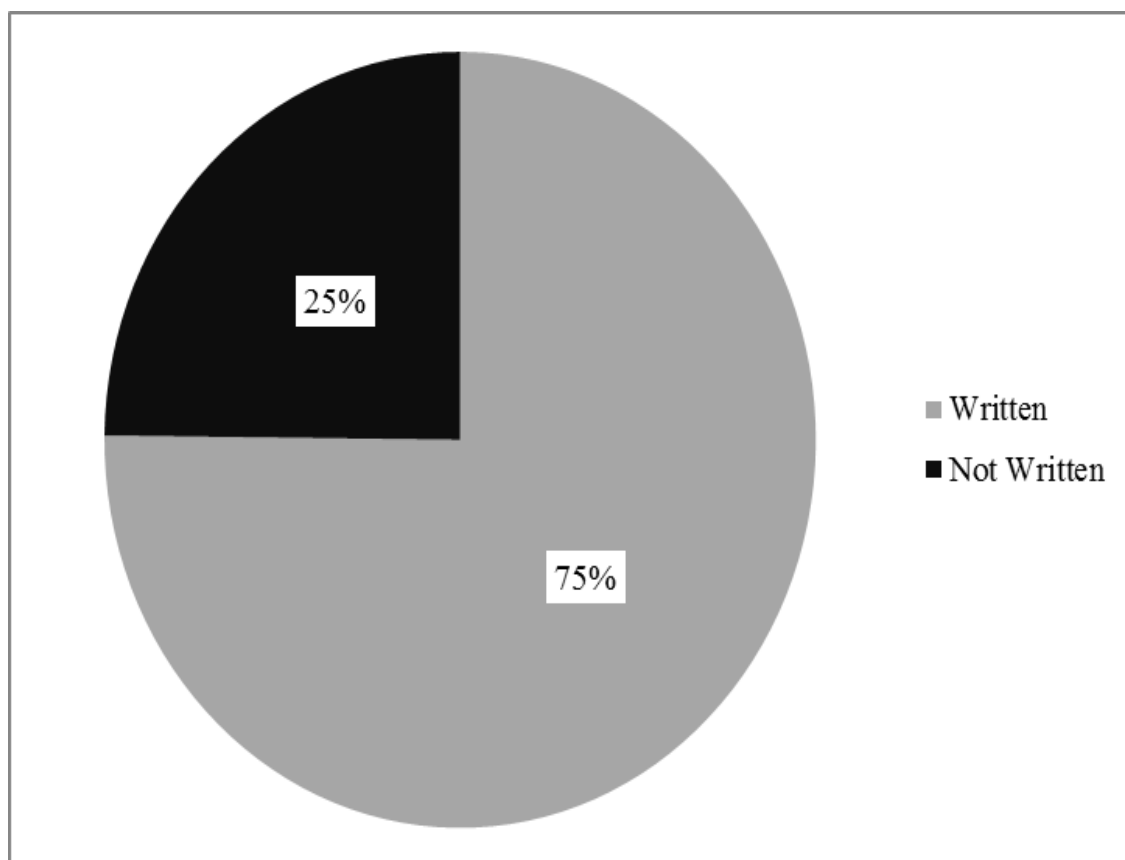
**Figure 3:** Comparison between the percentage number of files given and not given during weekdays and Sunday



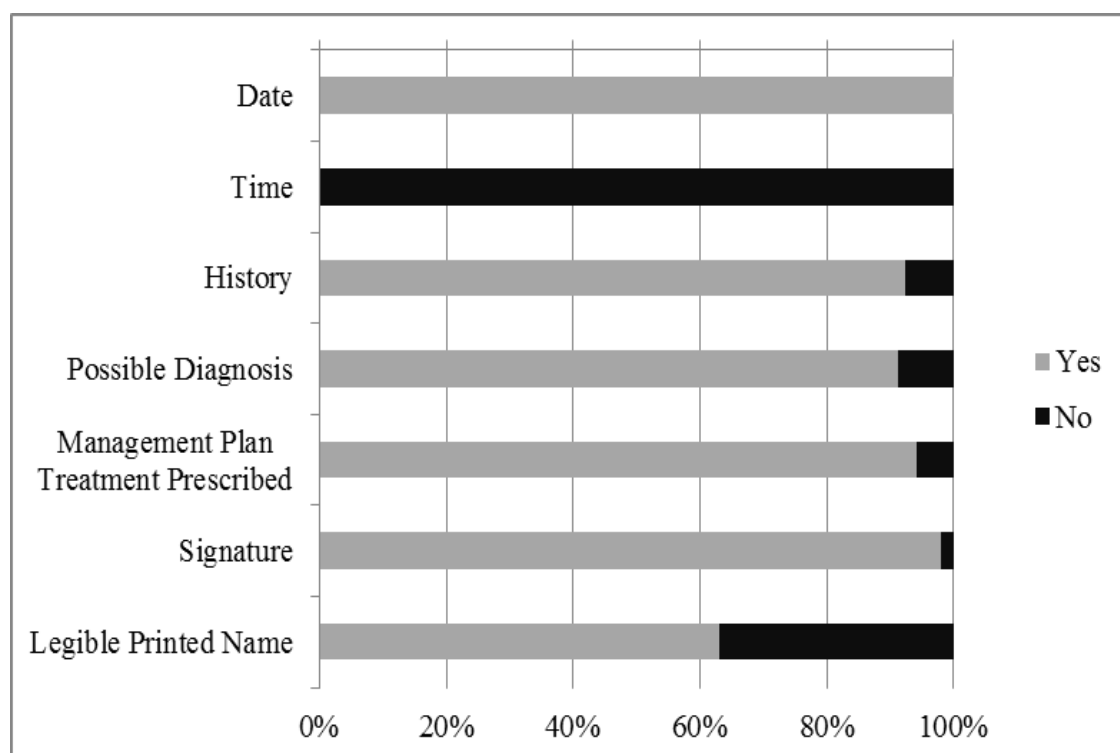
**Figure 4:** Percentage of the total number of files given and not given in the morning and the afternoon in five different days at FHC



**Figure 5:** Percentage of documentation which was written or not written by the General Practitioner when a file was provided



**Figure 6:** Quality of documentation inserted by the General practitioner in patients' files



The quality of the note written was also assessed and compared to record-keeping guidelines stipulated by the Royal College of Physicians. The majority of GPs inputted most of the fields found on the checklist but only a low percentage inserted a legible printed name in the documentation which might make it difficult to identify the physician for future reference. Time at which the consultation took place was not inserted by any of the GPs. Time is an important fact of documentation when medico-legal issues arise and also if the patient presents to the same Health Centre more than once within the same day with progression of his original complaint.

### Recommendations

The importance of maintaining continuity of care to optimise the quality of healthcare service given to patients and also to avoid medico-legal disputes should be explained to all healthcare professionals. If this concept is well understood arrangements can be done, for example when planning afternoon breaks, to increase compliance of distribution of medical records to the patient. Patient may also be educated in view of the importance of medical records so that they themselves ask for their medical records to be given to them at the reception.

In 'Guidelines of medical records in GP hospitals', Shaw states that each healthcare system should have an efficient system for finding and filing records so that they can be identified when needed. It also emphasises the need for sufficient space where medical records can be located easily.<sup>14</sup> Therefore, increasing space where medical records are stored and improving on the filing system so that medical records can be retrieved with greater ease, might also improve continuity of care.

Additionally, if the format of record keeping (the continuation sheet) is changed, the quality of the GP note might improve. Currently GPs have to document the consultation in a very limited space which restricts the amount of information on presentation of symptoms and future management plan inserted. Having to summarise and abbreviate information sometimes makes the documentation difficult to understand and to build upon in future consultations which are usually done by a different GP.

The necessity and benefits of electronic records has been highlighted in the literature. Electronic records are complete, integrated, and easily legible records, which can be accessed from multiple sites by different health care providers. This type of record-keeping can be used to generate risk alerts and reminders indicating that new information about the particular patient is available.<sup>8</sup> The Maltese Primary

Healthcare System might benefit from exploring and possibly investing in this area.<sup>5</sup>

In the absence of such development, another possible option to enhance continuity of care is to increase the number of visits by appointment. GPs could start having a regular appointment schedule, in addition to seeing walk-in-cases. This setting which is similar to the typical out-patient clinic scenario, will allow all visits to be planned and records made available beforehand. Presently at health centres this is done only for the speciality clinics.

One might also consider carrying out a study to analyse what are the attitudes of healthcare professionals towards medical record keeping, why they are not using them and what could be done to encourage them to use them. Carrying out consultations with healthcare professionals to assess their point of view is beneficial, since they are the ones using the system and if the system is something they want and agree with, there would be more cooperation with its implementation.

### Strengths and Limitation

The study was done over four days and a Sunday during which different Health Assistants' were operating, thus giving a good general overview of the overall picture and eliminating shift bias. The time frame chosen (8.am – 5p.m) allowed the researchers to focus their limited resources on the busiest part of the day at FHC. In addition, the quality of documentation inserted by the GP was reviewed by the researchers independently and consultation amongst the authors was done when there were inconsistencies thus eliminating personal opinion bias from the study.

One of the limitations of the study was lack of man-power. The medical records assessed were from 8a.m to 5p.m; the period of time in which the bulk of the GP-patient encounters occurs. This does not give any indication of quality continuity of care in the evening and at night. The study also focused on continuity of care during GP consultations in GP rooms which eliminated the assessment of continuity of care within the Treatment room and also within the Speciality clinics.

This study focused only on FHC which is one of the main health centres in Malta. Such study could be also carried out in the other two main health centres (Mosta and Paola) to get a more holistic picture of continuity of care in Primary Health in Malta.

### Conclusion

In conclusion, continuity of care is an important and essential element in delivering good quality



healthcare service to the patient. Continuity of care is not occurring to the desired level in FHC. With the increasing national and international emphasis on patient safety and patient rights, lack of appropriate documentation of patient visits is no longer tolerable and all efforts should be done to try to rectify the issue.

## Acknowledgements

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We would also like to thank Dr Amanda Saliba M.D., MSc, PgCert, a Higher Specialist Trainee in Public Health for proof reading and correcting this study.

## Conflicts of Interest

The authors are medical officers within the Healthcare Department. Permission was granted by the Primary Health Care department to carry out this study. No additional funding was provided.

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# Revisiting Plummer Vinson Syndrome – a report of three cases and review

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## Abstract

Plummer-Vinson or Paterson-Brown-Kelly syndrome (PVS) is characterised by a triad of cervical dysphagia, upper oesophageal web and iron deficiency anaemia. It is known to affect mostly white females, but cases have been reported from other ethnic groups in the literature.

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Exact data about epidemiology of the syndrome is not available, but the syndrome is extremely rare. It is considered as a premalignant condition associated with cancers of upper digestive tract.

Herein we report three cases of Plummer Vinson syndrome in Indian women, who presented with significant and long standing dysphagia, sideropenia and post-cricoid webs. Their esophagograms revealed the presence of webs at pharyngoesophageal junction. All the three patients were treated with oesophageal dilation of webs along with iron supplementation. The patients were under regular follow-up for three years after treatment and found to be with normal blood counts with no signs of recurrence and malignancy.

## Keywords

Dysphagia, Plummer Vinson syndrome, iron deficiency anaemia, oesophageal webs, deglutition disorders

## Introduction

Plummer-Vinson syndrome (PVS) is named after Henry Stanley Plummer and Porter Paisley Vinson, who were physicians on the staff of the Mayo Clinic. In 1912, Plummer reported a series of twenty one patients with long-standing iron deficiency anaemia, dysphagia and spasm of the upper oesophagus without anatomic stenosis, which was described as hysterical dysphagia.<sup>1</sup> In 1919 Vinson reported another case of 'angulation' of the oesophagus and attributed the first description of this entity to the earlier report of Plummer.<sup>2</sup> Another term is Paterson-Brown-Kelly syndrome, named after Donald Ross Paterson and Adam Brown- Kelly, who were the first to describe the characteristic signs and symptoms (including anaemia) of the syndrome independently in 1919. Paterson gave the fullest description but without reference to anaemia. He was also the first to draw attention to an association with post-cricoid carcinoma. Because of the constant presence of dysphagia associated with the characteristic mucosal lesions and evidence of diminished body iron stores usually associated with low serum iron values, Waldenstrom and Kjellberg introduced the term 'Sideropenic dysphagia' to describe this syndrome.

PVS is a manifestation of severe, long term iron deficiency anaemia causing oropharyngeal dysphagia

## Case Report

because of oesophageal webs. This article reports three cases of Plummer Vinson syndrome with significant long standing dysphagia and sideropenia and was treated effectively with dilation therapy and iron supplementation.

### Case-1

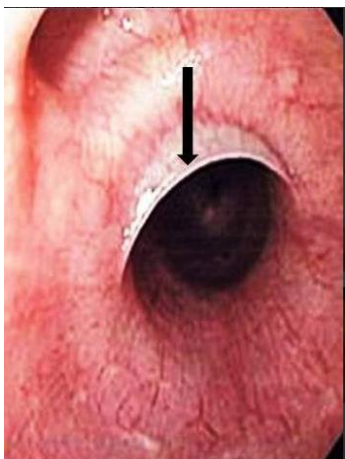
A 20 year old female presented to the outpatient clinic with difficulty in swallowing solids intermittently since eight years. For the past two years, she was unable to take even soft foods. She also had palpitations and breathlessness on exertion since two years. Physical examination revealed pale skin, eyes and oral mucosa with koilonychia and depapillated tongue [Figure-1].

*Figure 1: showing bald tongue and pallor skin*



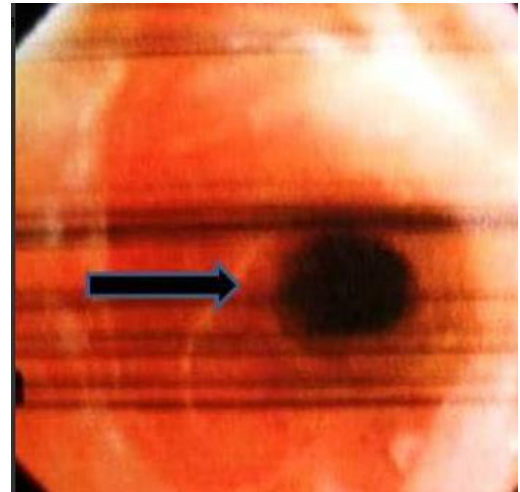
Investigations revealed hypochromic microcytic anaemia with haemoglobin (Hb) of 3.6gm%. Serum iron studies showed decreased serum iron of 25 µg/dl and increased total iron binding capacity of 525 µg/dl suggesting iron deficiency anaemia. Upper gastrointestinal endoscopy was done to assess the cause of dysphagia, which showed a post-cricoid oesophageal web [Figure-2].

*Figure 2: Esophageal endoscopy showing web*



Fulfilling the classical triad of dysphagia, iron deficiency anaemia and upper oesophageal web, PVS was diagnosed. During endoscopy, balloon dilation of the web [Figure-3] was performed which led to considerable improvement in her dysphagia. The patient was under iron supplementation for six months and follow-up examination showed normal blood counts.

*Figure 3: showing dilated web after endoscopy*



### Case-2

A 42 year old female presented with dysphagia, generalized weakness, anorexia and weight loss since three years [Figure-4].

*Figure 4: showing pallor skin with angular cheilitis*



On physical examination, pale skin, glossitis, angular cheilitis and spoon shaped nails were observed. All vital signs were found to be in normal limits. Haematological tests showed the presence of iron deficiency anaemia (serum Fe 30µg/dl, Hb 4.6gm/dl, Hematocrit 19%, Mean corpuscular volume 52fl). Peripheral blood smear revealed anisocytosis and hypochromic anaemia. However, liver and renal functions, enzyme levels and electrolyte levels were

## Case Report

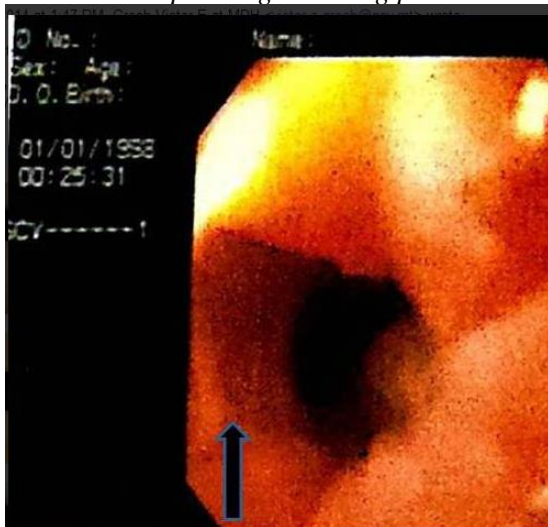
found to be in normal ranges. Barium swallow showed post-cricoid strictures [Figure-5].

**Figure 5:** Barium swallow showing esophageal stricture



The patient's oesophagogram revealed the presence of a web in the post-cricoid region, which was dilated with Savary Gilliard dilators [Figure-6] up to 12.8mm. The patient was given iron replacement therapy for six months until the haematological tests normalized.

**Figure 6:** Endoscopic image showing post dilated web



### Case-3

A 35 year old female came to the oral medicine department with a complaint of severely decayed teeth in the upper and lower quadrants of the jaw since three years. She also had difficulty in swallowing since two years. She looked emaciated with loss of weight and anorexia [Figure-7]. On physical examination, she showed signs of iron deficiency anaemia such as glossitis, angular cheilitis and koilonychia. Intra oral examination revealed multiple decayed teeth, dry mouth, stomatitis and glossitis.

**Figure 7:** showing pale skin, sunken cheeks and cheilitis



Lab investigations revealed haemoglobin 6g/dl, total leukocyte count (TLC) of 5500/ $\mu$ l, mean corpuscular volume (MCV) of 49fl, mean corpuscular haemoglobin (MCH) of 12pg/cell, serum iron 25 $\mu$ g/dl, and total iron binding capacity of 490 $\mu$ g/dl. A peripheral blood smear showed marked microcytic hypochromic anaemia. Barium swallow and oesophageal endoscopy was done to evaluate the cause of dysphagia. Barium swallow was suggestive of a web at pharyng-oesophageal junction [Figure-8].

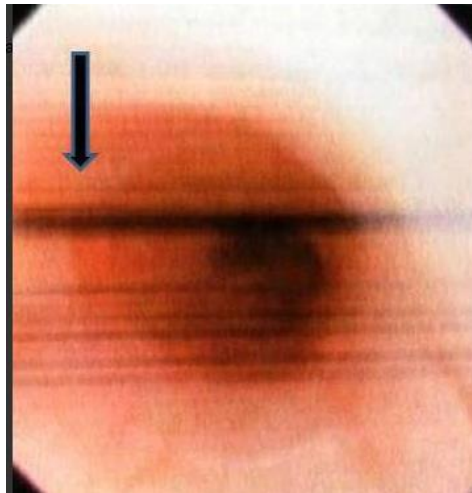
**Figure 8:** Barium swallow showing esophageal stricture



Endoscopic balloon dilation of the web [Figure-9] was done to relieve from dysphagia. She was prescribed oral iron supplements, sialogogues and transfused with packed red blood cells. On follow-up of 6 months, her blood counts normalized and she was referred for restorative procedures for all decayed teeth.



**Figure 9:** showing post dilated esophageal web



### Discussion

PVS is a manifestation of severe, long term iron deficiency anaemia causing oropharyngeal dysphagia because of oesophageal webs. Other features include glossitis, glossopyrosis, glossodynia, angular cheilitis, koilonychia, fragility, thinning of nails, and brittle hair, as presented in our cases. Symptoms secondary to anaemia such as pallor, fatigue, and weakness may also dominate the clinical picture.

PVS is most common in white females of 4<sup>th</sup> to 7<sup>th</sup> decade<sup>3</sup> but some cases in children and adolescents<sup>4</sup> are also reported. Most commonly, patients first have dysphagia to solids, but over time, symptoms can progress to dysphagia to liquids, as observed in our cases. Usually the dysphagia is painless and its progression can eventually lead to weight loss. In our cases, dysphagia was the main symptom that led all the three patients to seek medical help and dilation therapy. No exact data about the incidence and prevalence of PVS exist among Indians; only case reports have been published in the literature. Even though iron deficiency anaemia is prevalent among Indians, the incidence of PVS is rare, may be due to the improvement in nutritional status and better treatment of iron deficiency.<sup>5-6</sup>

The pathogenesis of this syndrome remains unclear, but possible etiopathogenetic mechanisms include iron deficiency, genetic predisposition or autoimmune disorder. It is reported that iron deficiency leads to the reduction of iron-dependent oxidative enzymes, which results in gradual degradation of muscles of the pharynx.<sup>7</sup> This may also predispose the patients to subsequent neoplastic change in mucosa (squamous cell carcinoma). Iron deficiency is believed to decrease the contraction amplitude of the oesophageal muscle resulting in motility impairment. Celiac disease, thyroiditis, large diaphragmatic hernia, gastric cancer, rheumatoid arthritis, Sjogren's syndrome, and pernicious

anaemia may predispose to PVS. All the reported three cases were not associated with any systemic disorder.

It is important that this syndrome be differentiated from other causes of dysphagia, e.g. malignant tumors, strictures, oesophageal burns, diverticula, motility disorders such as achalasia, spastic motility disorders, scleroderma, diabetes mellitus, gastric oesophageal reflux disease, heterotopic gastric mucosa or blistering skin disease, neuromuscular and skeletal muscle disorders.

The approach begins with laboratory evaluation of CBC count, iron and ferritin studies, antigliadin and antiendomysial antibodies (to rule out celiac sprue). Barium swallow studies and fluoroscopic evaluation suggest the diagnosis and the degree of stenosis. Oesophago-gastro-duodenoscopy helps obtain histological samples to rule out other disorders, confirms the diagnosis and also helps therapeutically in the dilation of webs. Previously mercury/tungsten filled bougies (Maloney/Hurst), bougienage dilators (bougie passed over guidewire; Savary Gilliard or American) and through the scope (balloon dilators) are the commonly used oesophageal dilators.<sup>8</sup> In most cases, one session of such dilation is usually enough for long term relief but, rarely, multiple sessions may also be warranted. All the three cases presented, were treated with dilation therapy (two cases with balloon dilators and one case with Savary Gilliard dilator) and iron supplementation.

PVS is considered as a precancerous condition and has been identified as a risk factor for developing post cricoid carcinoma of upper gastrointestinal tract.<sup>9</sup> 4 to 16% of the patients with PVS, mostly women between 15-50 years of age, have been reported to develop oesophageal or pharyngeal cancer.<sup>10</sup> In our cases no signs of recurrence or malignancy were found until three years and the patients are under regular followup as the minimum duration to detect malignant change in PVS cases is not less than five years.<sup>10-11</sup>

### Conclusion

We conclude that the patients presenting with symptoms of iron deficiency anaemia or with dysphagia should be investigated for PVS. Early diagnosis and prevention is necessary which would then depend ideally on the prevention of iron deficiency or, if iron deficiency occurs, on its early diagnosis and on the continued replenishment of the depleted iron stores. Moreover a careful otorhinolaryngological examination should be performed routinely in patients with PVS because of its premalignant potential.

### Conflicts of Interest:

The authors declare no conflicts of interest.

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# A Case report of fauntail treated with Alexandrite laser on an Amazigh girl in Tripoli

Ebtisam Elghblawi

## Abstract

A fauntail nevus is an abnormal lumbosacral hypertrichosis, and can be a marker for underlying spinal dysraphism. A fauntail is distinguished by an extensive, triangular or rhomboidal twisted patch of coarse terminal hair that is often several inches long. It is an exceptional finding, where the patient's psychological and social life is influenced negatively due to the cosmetic physical appearance.

This paper reports an 18-year old Amazigh girl, with a rhomboidal twisted hair tuft with terminal hair on the lumbosacral area, which she had since birth (Congenital Hypertrichosis). There were no neurological symptoms encountered. There was no abnormality on her spine X-ray and MRI screens. Furthermore, her general blood and hormonal investigations and abdominal ultra sound were normal.

Cosmetic improvement can be achieved with the help of Alexandrite laser, and it can be the method of choice for permanent hair removal due to its safety, effectiveness and ease of application.

The diagnosis was made on a clinical physical basis. The patient reported for cosmetic disability. The patient with her parent has been advised about the Alexandrite laser hair removal and she has already had good results from one application.

This case is reported for its clinical importance, significance and impact on the young girl's quality of life.

## Keywords

Fauntail, Hypertrichosis, lumbar, laser.

## Introduction

Hypertrichosis is the excessive growth of hair on the non-androgen dependent areas of the body. A fauntail nevus is a lock of coarse, terminal hair situated on the lumbosacral area (posterior midline of the lower back), which might hide a bony defect in the lumbar spine. Two forms can be described namely; Lumbar hypertrichosis which is described as silky down which presents as soft non-terminal hair, while a fauntail is a wide patch of coarse terminal hair, several inches long.

## Case report

An 18-year-old Amazigh girl presented with a big tufted hair growth over the lumbosacral (LS) region since birth. It was several centimeters long (Figure 1).

*Figure 1: Fauntail shape and hair*



Her mother had noticed the hairy patch with coarse hairs over LS region at birth, and she had shaved the lesion periodically. The dermatologic examination revealed a localized, 18x15cm sized, reverse triangular shaped (rhomboid) hair tuft on the lumbosacral region. Coarse to soft, dark, terminal hairs were observed (Figure 1).

The lesion had been present since her birth and had been growing ever since. The skin over the involved area was normal, and with normal sensation of touch, pain and pressure. There was no lower leg weakness and no urinary incontinence. Her past medical history was noncontributory except for vague neck pain. The girl has one older sister and two brothers and none have a similar

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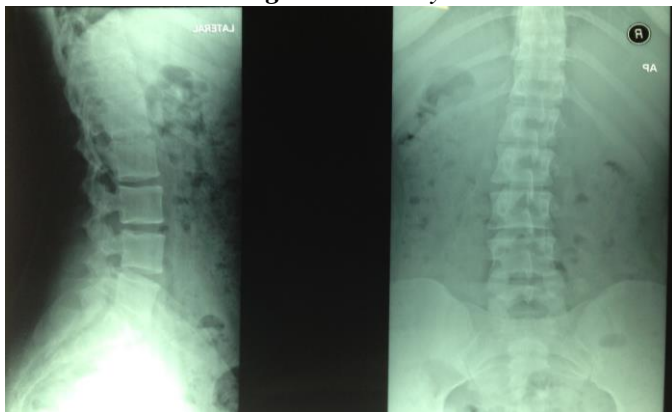
condition. Her developmental milestones were normal. She was the daughter of a consanguineous marriage and pregnancy and delivery were normal. No other member of family has similar history.

Her menarche was around 12 years old, and periods are regular. She weighs 74kg and her height is 133cm. this was the first time she was seen for a medical problem.

Neurological examination of the lower limbs was normal with no sensory or motor deficit. She had a normal gait with normal knee tendon jerks and the Babinski reflex was negative. Muscles revealed grade 5 power. She could perceive all modalities of sensations over the lower limbs. Lower back examination revealed nothing remarkable.

The only complaint she had was vague neck pain. Simple cervical and lumbosacral radiography showed no specific finding. However her cervical X-ray revealed neck spasm which the radiologist reported as possibly relevant to the complaint of neck pain (Figure 2).

**Figure 2:** X-ray



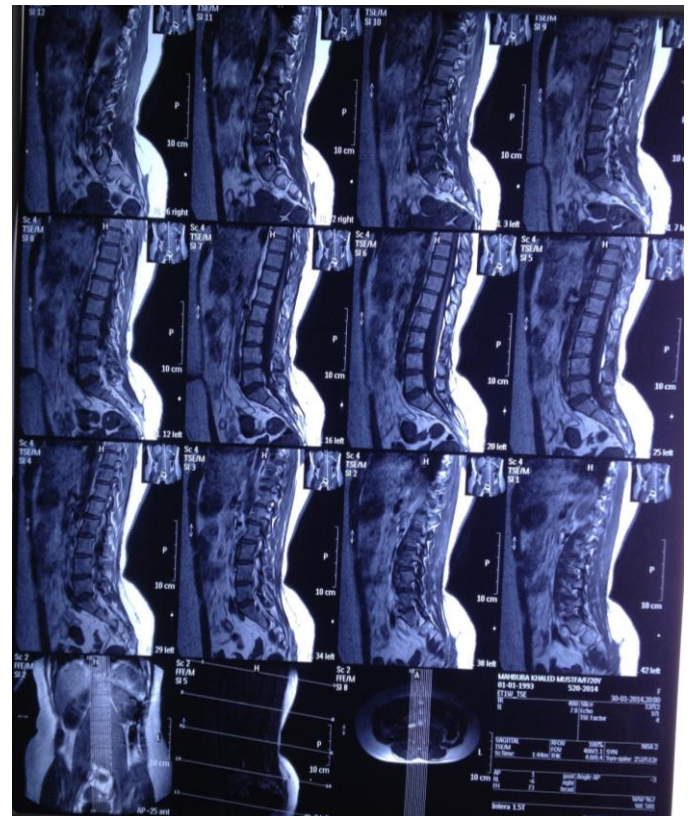
Further investigations included a magnetic resonance imaging (MRI) and abdominal and pelvic ultrasound. All were normal (Figure 3 and 4).

A punch skin biopsy was taken from the hypertrichotic patch, sent for histopathology and demonstrated normal epidermis. The dermis contained normal pilosebaceous structures and sweat glands. No diagnostic features seen in the dermis.

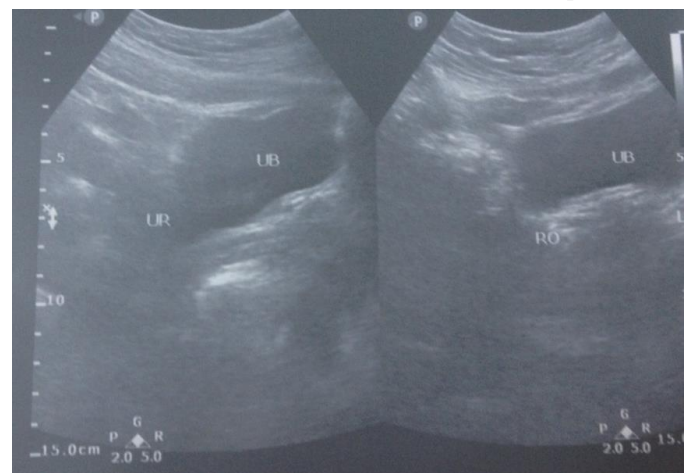
The blood investigations including, complete blood cell count, erythrocyte sedimentation rate and blood chemistry and hormonal levels were all within the normal ranges.

A clinical based diagnosis of fauntail without any underlying neurologic disease was made. The patient's main worry is about her physical embarrassment about the nevus as she is planning to get married soon and wants this problem sorted permanently.

**Figure 3:** MRI lower back



**Figure 4:** Ultrasound abdomen and pelvis



## Discussion

Fauntail refers to pointed ears with goat's leg and tail in Italian myths. It can be normal findings in certain ethnicity.<sup>1</sup> Fauntail is a rarely reported entity encountered in the medical setting. The patient may refer to a dermatologist primarily as in this case.<sup>1,2,5</sup>

The girl was Amazighen, which indicates a Berber root; an ethnic group indigenous to North Africa west of the Nile Valley, with their own languages and customs. Most of the reported cases in the literature were in the South Asia namely India.

Another observation on fauntail is that it is more prevalent in females (ratio 4:1).<sup>6</sup> All previous reported cases emphasized its association with underlying spinal



dysraphism. A delay in the diagnosis of this concomitant condition might incur irreversible neurological deficits. Currently laser hair removal is more acceptable as an effective efficient tool of hair removal as it targets mainly the melanin pigment in the hair follicle and selective destruction of hair follicle. Alexandrite laser has a deeper penetration to target darker hair follicles at wave length of 755nm.

The patient had two sessions of Alexandrite Gentlase hair removal with spot size 18 and energy fluence of 12 J/cm, with good results and tolerance.<sup>2</sup> There was neither hyperesthesia nor burning sensation at the low back area.

A good cosmetic and satisfying result was achieved with one session of laser hair removal and the patient came for another session after two months and she was happy about the results (figure 5).

**Figure 5:** Two months post Alexandrite laser



I report this case for its scarcity and the absence of any associated spinal anomalies. Also to emphasis a thorough work up is needed such as radiological and neurological examination to rule out any underlying associations.

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# Puerperal *Streptococcus pneumoniae* endometritis – A case report and literature review

Gabriel Galea, Rodianne Abela, Catriona Deguara, Paul Cuschieri, Mark Brincat

## Abstract

*Streptococcus pneumoniae* endometritis is an exceedingly rare clinical occurrence in the immunocompetent individual. This case report describes such an occurrence in an otherwise healthy woman 39 days post-normal vaginal delivery. The patient responded to prompt broad-spectrum intravenous antibiotics and made a full recovery. The clinical relevance of such a scenario, the likely pathogenesis of the event as well as a brief review of relevant clinical literature are discussed.

## Keywords

endometritis, female, puerperal infection, *Streptococcus pneumoniae*

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*Streptococcus pneumoniae* genital infection was a well-documented clinical entity in the pre-antibiotic era with a high mortality rate – 26% for localised infection and 74% for peritonitis and sepsis.<sup>1</sup> More recently, however, there have been only isolated reports of *Streptococcus pneumoniae* genital infection, with even less frequent accounts of this happening in immunocompetent individuals. In this report, we document a case of *Streptococcus pneumoniae* endometritis in a young, previously healthy female 39 days post-partum.

## Case Report

The patient, a 24 year old, dyslipidaemic gravida 4, para 3, Somali lady of Afro-American ethnicity, was electively admitted to the Central Delivery Suite at Mater Dei Hospital for induction of labour at 38<sup>+</sup><sub>4</sub> weeks of gestation due to intra-uterine growth retardation (IUGR); investigation prior to induction had revealed no obvious cause for the IUGR. Following two doses, 12 hours apart, of 1mg topical prostaglandin E<sub>2</sub> (Prostin E<sub>2</sub>®) placed in the posterior fornix of the vagina, and nine hours after artificial rupture of membranes, she delivered an apparently healthy boy weighing 2.23kg of Apgar scores 9 and 9 at one and five minutes, respectively. She enjoyed an uneventful postnatal period, and mother and son were found fit for discharge 48 hours after delivery.

She presented again 39 days later with a short history of severe, colicky epigastric and suprapubic pain radiating to the back. The pain was associated with chills, rigors and two episodes of vomiting.

Physical examination revealed a distressed patient with a temperature of 38.5°C, a blood pressure of 123/63mmHg, and a heart rate of 80 beats per minute. Her abdomen was tender on deep palpation suprapubically and in both flanks, with minimal signs of peritonism. Pelvic examination showed moderate cervical excitation, mild right-sided adnexal discomfort and a yellowish vaginal discharge. High vaginal and endocervical charcoal swabs were taken.

Three hours after presentation, her blood pressure dropped to 91/55 mmHg. Arterial blood gas examination performed at the time of this

haemodynamic deterioration revealed a pH of 7.39, pO<sub>2</sub> of 86.5 mmHg, pCO<sub>2</sub> of 36.0 and a lactate level of 2.8. Peripheral blood studies revealed a leucocytosis with neutrophil shift; inflammatory markers – erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) – were found to be raised. Amylase was normal and urine and peripheral blood cultures were eventually returned negative.

The patient was initially admitted to a surgical bed; intra-venous piperacillin-tazobactam (Tazocin®) was commenced.

Computed tomography scanning of her abdomen revealed an enlarged uterus with oedematous changes in the uterine wall and free fluid in the pouch of Douglas. She was transferred to a gynaecological bed. Treatment remained unchanged. Symptomatic improvement and gradual normalisation of ESR and CRP were seen and piperacillin-tazobactam was changed to oral co-amoxiclav (Augmentin®).

A pure culture of mucoid, Gram-positive diplococci with lanceolate morphology was obtained from the patient's endocervical swab. The presence of *Streptococcus pneumoniae* was confirmed by showing draughtsman colonies with weak  $\alpha$ -haemolysis on horse blood agar, sensitivity to ethyl hydrocuprein (optochin), and bile solubility. The presence of a polysaccharide capsule was confirmed by using the Phadebact® Pneumococcus Co-agglutination test. The isolate was sensitive to penicillins, macrolides and newer generation fluoroquinolones.

A final diagnosis of puerperal *S. pneumoniae* endometritis was made.<sup>2-3</sup>

After five days of oral antibiotic treatment, the patient was discharged home on a further 3 days of antibiotics. She remained well at an outpatient appointment follow-up 4 weeks later.

### Discussion

In the pre-antibiotic era, *S. pneumoniae* not infrequently caused female genital tract infections as a consequence of septic abortion, instrumental vaginal delivery and metastatic seeding of pneumococcal septicaemia.<sup>4</sup> However, primary pneumococcal infection of the female genital tract, as documented in this case scenario is, nowadays, an extremely rare occurrence.

Pneumococci are not components of normal vaginal flora<sup>5-6</sup>: in a literature review in 1990, Westh et al. described three studies where pneumococci were only cultured from 9 genital isolates out of a total of 1715 patients (0.5%)<sup>1</sup> while a further three microbiological studies gave no mention whatsoever of pneumococcus isolates from the female genital tract.<sup>7-9</sup> It is thought that pneumococci are unable to survive at normal vaginal pH; although it is postulated that changes in vaginal pH, as for example during pregnancy and the puerperium, may temporarily allow *S. pneumoniae* to exist as a

vaginal commensal.<sup>5-6</sup>

Risk factors for pneumococcal infection include antibody and complement deficiency, asplenia, neutropenia or impaired neutrophil function, steroid therapy, malnutrition, alcoholism, chronic medical conditions (renal failure, liver failure, heart failure, and respiratory pathology) and overcrowding.<sup>10-12</sup>

The organism possesses a number of virulence factors that aid in the pathogenesis of infection<sup>10-12</sup>:

1. *Polysaccharide capsule* – prevents opsonisation and phagocytosis. Different serotypes exhibit different severity of infection.
2. *IgA protease* – cleaves IgA1 and enables evasion of the protective function of this immunoglobulin isotype.
3. *Pneumolysin* – an intracellular membrane-damaging toxin released by autolysis. It serves to inhibit neutrophil chemotaxis, phagocytosis and respiratory burst, lymphocyte proliferation and immunoglobulin synthesis.
4. *Autolysin* - breaks the peptide cross-linking of the cell wall resulting in cell lysis and release of pneumolysin as well as cell wall fragments.

Most reports on pneumococcal female genital tract infections with or without secondary pneumococcal peritonitis suggest three possible mechanisms by which pneumococci can infect the genital tract or peritoneum.<sup>1</sup> These include:

- Infection via the external genitalia – following a change in vaginal pH, it is thought that *S. pneumoniae* can exist as a commensal. Pneumococcal Bartholinitis has been described as have ascending infections. The presence of an intra-uterine device, instrumentation of the uterine cavity, the use of tampons<sup>13</sup> and the puerperal period are all thought to facilitate ascending infection from the vagina.<sup>1</sup>
- Infections via the bloodstream – this is exceedingly uncommon nowadays and is associated with a high mortality (presumably secondary to metastatic pneumococcal infection and septicaemia and not specifically to genital tract involvement)
- Infection following orogenital sex – pneumococci are known commensals of the oropharynx and it has been postulated that orogenital sex can cause pneumococcal and *Haemophilus influenzae* genital tract colonization and possibly infection.<sup>13</sup> Paradoxically, Pitroff et al. in 2012 suggested that oral sex might actually be protective and decrease the risk of endometritis.<sup>14</sup>

Infection via the gastrointestinal tract and via transdiaphragmatic lymphatics have also been suggested as mechanisms of infections<sup>10</sup> but a literature search yielded no evidence confirming these theories.

Fernandez et al., in a 1993 prospective study on 1291 patients, suggested that a single 1.2g intra-venous

dose of co-amoxiclav at the onset of labour would decrease the risk of postpartum endometritis and also be cost effective.<sup>15</sup> While a comprehensive 2007 article on puerperal pyrexia by Maharaj suggests that high risk patients (those with previous spontaneous preterm delivery, history of low birth weight, pre-pregnancy weight less than 50 kg, or bacterial vaginosis in the current pregnancy) might benefit from prophylactic antibiotics in the second and third trimester of pregnancy, the author stops short of recommending the routine use of prophylactic antibiotics against postpartum endometritis.<sup>16</sup>

A 2007 Cochrane review of antibiotic choices for the treatment of established post-partum endometritis recommends the use of intravenous clindamycin and a once-daily dose of gentamicin, with no benefit seen with further oral antibiotics once clinical improvement is sustained for more than 24 hours<sup>17</sup>; this recommended combination was not used in this scenario due to a delay in diagnosis. The rationale behind these recommendations is based on the sensitivities of the commoner causative organisms of puerperal endometritis. Although *S. pneumoniae* endometritis is a highly uncommon aetiological agent for post-partum endometritis, no change to usual clinical practice is needed in view of the fact that an intravenous clindamycin-gentamicin combination would appropriately treat this rare scenario.

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# Chest wall reconstruction following a speedboat propeller injury

D. Sladden, A. Casha, A. Manché

## Abstract

Propeller blade injuries to the chest are uncommon but can result in devastating injuries. We describe a case of a 44 year-old male scuba diver who was dragged by sea currents into the propeller of a speedboat. He suffered extensive chest wall trauma but narrowly escaped damage to major organs and vessels. He was admitted directly to the operating theatre. There was significant loss of bone from the manubrium, costal cartilages, overlying skin and muscle which were stripped off in 3 horizontal bands. During reconstruction the bony fragments were anchored to the nearest stable sternal or costal cartilage entities using steel wires, to achieve stability. The overlying muscle and skin were sutured directly to its opposite edge in layers and in an interdigitating fashion following the shape of the propeller blade lacerations. The patient remained intubated for 3 days in ITU and was transported back to his home country. He required a small skin graft to one area of necrosis but eventually made a full recovery with only his scars as a reminder of his accident. There have been other cases of propeller injuries in Malta but this is unique in being a severe injury to the chest, in which the patient made a full recovery. This report highlights the importance of legislation in preventing propeller injuries by restricting swimmer zones and introducing propeller guards or jet drive systems.

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## Introduction

Propeller injuries are massively debilitating injuries with high mortality and account for 3.8% of all boating injuries in the US. In an average year there were 200-250 reported non-fatal propeller strike injuries<sup>1</sup>. Another 25-35 (12%) cases a year are fatal.<sup>1</sup> Such statistics may be under-reported by around 20%.<sup>2</sup> 72% of propeller injuries were the second or third event in an accident, the prior events being falling overboard or being hit by the boat itself prior to the propeller strike.

It is written in US federal law that all boating accidents involving the death or injury requiring medical attention of a person must be reported to the US coast guard and will be made available in public records<sup>4</sup>. No such records exist in Malta.

In a Canadian study 9 of 112 cases of propeller injury involved the chest and 2 of those 9 (22%) died. This is the second highest mortality classified anatomically after propeller injuries of the head, which are fatal in 40% of cases. The severity of propeller lacerations is such that several cases of complete limb amputation are described. Of the non-fatal chest injuries pneumothorax and lung contusions were the most common.<sup>3</sup>

## Case Report

A 44 year-old male on holiday in Malta was scuba-diving off Comino one August morning. While surfacing he experienced strong currents which pushed him into the moving propeller of his boat, which was not at maximal speed. The diver ascended into the propeller suffering injuries on the anterior aspect of his chest. His diving colleagues hoisted him onto the same boat and hastily made their way back to shore.

A member of his diving team was a cardiothoracic surgeon and provided first aid, covering the wound with a beach towel.

He was immediately taken to casualty by ambulance. On arrival he was conscious and breathing spontaneously. Analgesia was administered and he was intubated and ventilated and invasive arterial blood pressure monitoring was set up. Intravenous fluids were given until blood was typed and screened. At that stage he was haemodynamically stable.

The wounds were inspected and the right lung was visible protruding through the defect in the anterior chest wall. The wounds were covered with sterile large swabs

## Case Report

and the patient was taken directly to the operating theatre.

**Figure 1:** The injuries upon arrival to casualty. The white swab in the right side of the larger wound is covering herniating lung



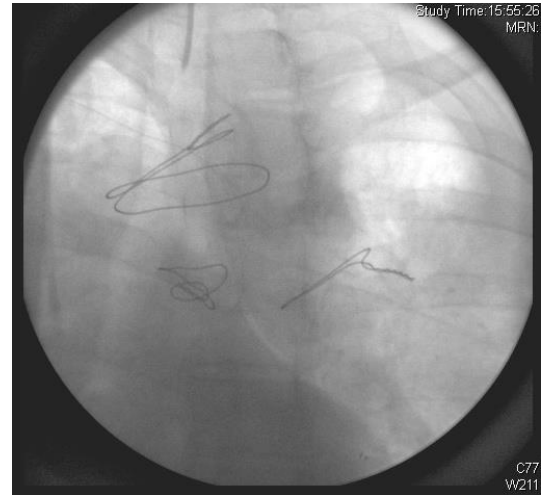
In theatre the wounds were cleaned from debris and sand. The chest was inspected and the lacerations were found to stop just short of the aortic arch and the brachiocephalic artery and vein in the superior mediastinum. Both lung apices were exposed and lung tissue was contused bilaterally but not lacerated. The pericardium was intact and no cardiac trauma was detected through the exposed anterior mediastinum.

The lower two horizontal musculo-cutaneous wounds were sutured in two layers as no deep structures were involved. The suturing was performed in an interdigitating fashion so as to match the edges of the wounds together. The shape of the propeller blades results in lacerations which are not straight but curved downward at one end and producing a zigzag configuration.

The superior wound was by far the larger and the damage involved the sternum and the upper costal cartilages. A portion of the manubrium was missing, leaving a defect slightly to the right of the midline. The sternum was separated with loss of the second and third costal cartilages on the left and the third and fourth costal cartilages on the right, also with some defect present due to tissue loss.

Stainless steel wires were used to anchor the detached middle sternum to the corresponding medial ends of ribs and clavicles bilaterally. The remaining upper sternum and manubrium was wired to the medial ends of the upper two right ribs. This defect was not closed as the edges could not be opposed. The gap was bridged by the wires, which stabilised the upper chest wall.

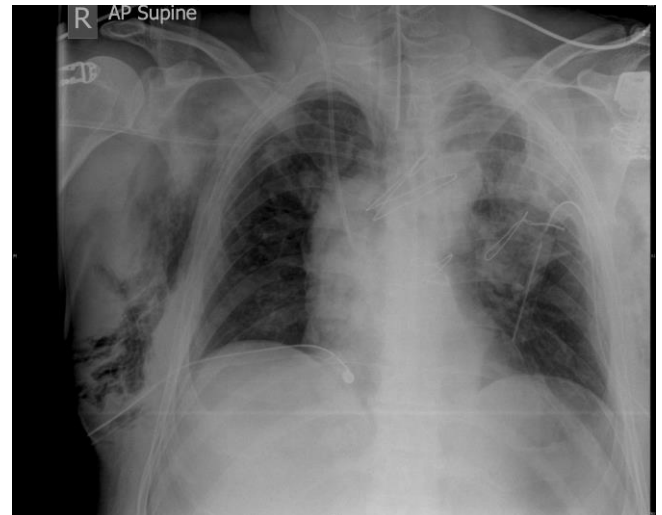
**Figure 2:** Post-operative chest x-ray showing the position of the steel wires



The overlying muscle was used to bridge defects in the ribcage, and was sutured with multiple single absorbable braided sutures and a subcuticular suture helped approximate the gaping wound. All skin closure was achieved using interrupted non-absorbable sutures. Bilateral wide calibre chest drains were inserted and the patient was transferred to the Intensive Care Unit where he was kept intubated.

The chest drains continued to bubble initially but this soon resolved and there was no persistent air leak. Despite bilateral lung contusions he maintained good oxygenation and was fit for extubation on the second day.

**Figure 3:** A chest x-ray on day 1 post-op showing surgical emphysema on the right, lung contusion on the left and 2 chest drains in situ



Extubation was however delayed as arrangements were made by the family for air-ambulance transfer back home. Once in his home country he was extubated within 48 hours and made a good recovery. He required a small skin graft to an area of skin necrosis in between the top and middle lacerations. At 3 months after the



## Case Report

injury he is returning back to a normal life and feels well.

**Figure 4:** photograph after 3 months. Note the diamond shaped area where the skin graft lies



**Figure 5:** photograph after 3 months from left side with arms raised



### Discussion

Malta's pre-hospital policy is that of scoop and run, with the aim of getting the patient to hospital as quickly as possible. A consultant emergency physician meets the patient at the site of the accident and begins procedures such as IV access and analgesia in transit.

Once in the resuscitation room a team-based approach following the European Trauma Course guidelines is followed. A quick overall survey is performed to identify any other occult and life-threatening injuries. The cardiothoracic surgery team were involved from the start of the resuscitation. The main surgical technique is that of damage control surgery. It involves the rapid control of haemorrhage and contamination in order to allow a survivable physiology to be established. In this case no major organs had been severely damaged and so a one-stage reconstructive

surgical procedure was performed. There are circumstances where delayed closure is advised, either to allow for eventual swelling or to limit operation time or to allow for continuous drainage of a contaminated wound. In this case the wound was contaminated however primary closure was still performed. This is because the chest cavity was opened and the lungs were protruding through the wound. This would have led to further problems since the patient was receiving positive pressure ventilation post-operatively.

Post-operatively the patient was covered with broad spectrum antibiotics because of the grossly contaminated wounds and the risk of pneumonia following lung contusions and intubation. Other preventative measures included the use of low tidal volumes to avoid barotrauma and adult respiratory distress syndrome (ARDS). The chest mechanics and stability were unpredictable and we were concerned about post-operative wound dehiscence on coughing. This did not occur and the chest remained intact.

In Malta there are 45 designated swimming zones where the use of propeller motors is not permitted<sup>6</sup>. There is no regulation on the imposition of propeller safety guards and neither is there a public registry of recreational boating injuries. Despite this lack of formal data most of these incidents are news items and a search of local newspaper online archives revealed other cases of propeller injuries.

In August 2012 a 44 year-old male was found dead on a reef with propeller injuries to the head cited as the cause of death<sup>7</sup>. Only 12 days before the case reported here, a 24 year-old swimmer suffered lacerations of both feet after being hit by a boat propeller. In 2008 a German holidaymaker was hit by a propeller causing transection of his brachial artery amongst other injuries.

### Conclusion

With water sports becoming ever more popular and the increasing number of holidaymakers in Malta, it is surprising that these accidents are not more common.

As shown, these cases are amenable to primary closure and this patient made a full recovery after one surgical repair. However propeller injuries can be devastating and their prevention is as important an issue as their treatment.

These injuries are not medically preventable but should still be safeguarded by public health legislation and boat design. There are many different suggestions to improve propeller safety, such as safety propellers with non-sharp edges, tunnelled drives where the propeller sits in a hollow part of the hull, sensors to stop the propeller when someone approaches, jet drives and propeller guards. The jet drives and propeller guards are the most often used, however jet drives are unable to power heavier craft and propeller guards have not been made obligatory due to a variety of objections. For

instance cage guards reduce efficiency and increase fuel consumption as well as the risk of debris getting caught in the cage and ring guards add the risk of getting trapped between the ring and the propeller and suffering worse injuries, besides reducing manoeuvrability.<sup>5</sup>

The size of the problem is unknown in Malta and a public registry needs to be made available in an effort to reduce these accidents.

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# Outcome of low back pain patients referred to orthopaedic outpatient clinic

Sarah Cuschieri, Stephan Grech, Joe Borg

## Abstract

**Background:** Musculoskeletal complaints are the commonest encounters in primary care. Low back pain management is commonly initiated by the family practitioner. Guidelines are limited as to when patients should be referred for specialist treatment by the orthopaedic department.

**Objectives:** Evaluate the justification of low back pain referrals to Orthopaedic outpatients (OOP), Mater Dei Hospital, Malta and assess whether these merited specialist consultation.

**Method:** Anonymous data was collected over a 3-month period, where 100 low back pain new case referrals were evaluated during OOP. Data collection was based on routine questions normally brought forward during a consultation and a management plan which was documented in a spreadsheet. Data was analyzed using the same software.

**Results:** Out of the total number of patients reviewed, 57 had been referred for the first time to OOP. Out of these, only 10 required an MRI with a scheduled follow up appointment. The remainder were referred for physiotherapy or pain clinic and discharged to follow-up in the community by the primary care physician. Out of 43 patients who had had previous OOP appointments complaining of lower back pain, 5 patients required an MRI and follow up appointment, remainder were discharged with physiotherapy or pain clinic appointments.

**Conclusion:** The majority of patients seen at OOP could have been managed in primary care. It reflects the importance of developing local management guidelines for low back pain, which would assist general practitioners. It is indicative that referral to OOP should only be triggered when all treatment options available in the primary care are exhausted. This would lead to patients achieving targeted treatment timely within the community, resulting in shorter waiting time for outpatient visits.

## Keywords

Back pain, Spine, Orthopedics, Primary Health Care, Referral and Consultation.

## Background

Musculoskeletal complaints including low back pain are among the commonest encountered in the primary health sector throughout the world. Malta is no exception with confirmation following a recent study.<sup>1</sup> The majority of patients that present with mechanical low back pain or disability, often have a short lived episode of low back pain and return back to their normal daily activities within 6 weeks, irrespective of any treatment administered.<sup>2</sup> It is not uncommon for patients that have undergone complete recovery from back pain to experience recurrence in the following 12 months.<sup>3</sup> On the other hand, a small number of patients go on to develop chronic back pain and disability that does not resolve within 12 weeks.<sup>4</sup>

It is common practice around the world that management of low back pain is initiated in primary healthcare. In order to assist the general practitioners, clinical practical guidelines have been issued internationally.<sup>4</sup> Guidelines are however limited when it comes to outline when patients should be referred to the orthopaedic specialists.<sup>5</sup> This might lead to inappropriate referrals to the orthopaedic outpatients.

Our study assessed the first successive 100 patients referred by their general practitioner in view of low back pain to Orthopaedic outpatients, Mater Dei Hospital, Malta over a period of 3 months. The management these patients received in the primary health sector was evaluated in order to see whether these patients could have been managed in the primary healthcare or a referral for specialist consultation was justified.

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## Method

The study was performed over a period of 3 months between June 2013 & September 2013. A total of 100 successive new case patient referrals with low back pain and lower limb radiculopathy referred by general practitioners to the orthopaedics outpatients at Mater Dei Hospital were taken in consideration. The data collected was gathered in an anonymous manner by the orthopaedic team who performed all the consultations of the patients in the study.

Data collection for this study was based on routine set of questions that are normally brought forward to all patients presenting with low back pain during an orthopaedic consultation. The management plan attributed to each patient was taken in accordance with the clinical judgment of the orthopaedic specialist taking in consideration any disability or pattern of pain the subject was in. Details on the pattern of pain were not recorded, as it was beyond the scope of this study. The data was documented in a spreadsheet document along with the management plan for each patient. The data was analyzed using the spreadsheet sorting and formulae functions.

Authorization was obtained from the Orthopaedic Department to use the anonymous data for this study. The team retained no personal details or performed extra clinical consultation procedures nor brought forward any sensitive questions, so no ethical approval was needed. Still informed consent was obtained from each patient, indicating clearly the main scope of the study.

## Results

### *Consultation*

A 3 month period was investigated, where a total of 100 patients (55 male, 45 female) were reviewed. These patients were all new cases presenting to orthopaedic clinic session led by an orthopaedic consultant. The referrals were divided into two categories (low back pain and radiculopathy) according to the general practitioner's working diagnosis. Radiculopathy incorporated all referrals that suggested any neurological symptoms as outlined by the general practitioner. Age ranges were from 15 to 87 years for the female study population while males' age ranged from 11 to 82 years. The major complaint was low back pain for both genders (males  $n=42$ , females  $n=38$ ) while radiculopathy was predominantly a male complaint (male  $n=13$ , female  $n=7$ ).

### *Analgesia*

Prescription or otherwise of any analgesics by the general practitioner was assessed. All patients complaining of low back pain were given analgesia, which varied from paracetamol to non-steroidal

(NSAIDs) medication. The majority were prescribed NSAIDs.

### *Previous Orthopedic Outpatient visits*

The study population was further evaluated to elucidate whether this visit was the first time encounter with the orthopaedic outpatients (OOP), or previous referrals for the same complaint were already done.

In the male study population, 63.6% ( $n=35$ ) were referred to the orthopedic outpatient for the first time. Out of these only 10.9% ( $n=6$ ) were in need for further investigation by means of an MRI and follow up orthopaedic consultations. Out of the patients who required MRI, 5 were referred due to radiculopathy while 1 complained of low back pain. 49% ( $n=27$ ) were referred for physiotherapy and discharged from the orthopaedic outpatients while the remainder 3.6% ( $n=2$ ) were referred to the pain clinic and discharged from the orthopaedic outpatients.

The remaining males (36.4% ( $n=20$ )) had already been seen previously by an orthopaedic specialist for the same complaint and were discharged from the orthopaedic outpatients to be managed in the community. Out of the patients who were re-referred to the orthopaedic outpatients, only 5.5% ( $n=3$ ) required further MRI investigations and follow-up. 23.7% ( $n=13$ ) were referred for physiotherapy and discharged while the remaining 7.3% ( $n=4$ ) were referred to the pain clinic and discharged from orthopaedic clinic. Table 1 shows a diagrammatic presentation of the distribution of the male study population management plan according to whether they had previous orthopaedic visits or not.

With regards to the female study population, 48.8% ( $n=22$ ) visited the orthopaedic outpatients for the first time due to low back pain or radiculopathy. 8.9% complained of radiculopathy, requiring an MRI scan. The majority, 33.3% ( $n=15$ ) were referred to physiotherapy and discharged from orthopaedic outpatients. The remainder were discharged, out of which 4.4% ( $n=2$ ) were referred to the pain clinic and 2.2% ( $n=1$ ) was prescribed analgesia.

Out of the total female study population, 51.1% ( $n=23$ ) had already consulted an orthopaedic specialist in the past. Only 4.4% ( $n=2$ ) were considered to be in need of an MRI and further follow up in view of their low back pain complaint. 28.9% ( $n=13$ ) were referred to physiotherapy as well as discharged and 17.7% ( $n=8$ ) were referred to the pain clinic and discharged. Table 2 shows a diagrammatic presentation of the distribution of the female study population management plan according to whether they had previous orthopaedic visits or not.

**Table 1:** Referred males under study and their management plan at orthopedic outpatient (OOP) clinic

Males	MRI & Follow-up	Physiotherapy & Discharge	Pain Clinic & Discharge	Total
First OOP visit	6	27	2	35
Previous OOP visit	3	13	4	20

**Table 2:** Referred females under study and their management plan at orthopedic outpatient (OOP) clinic

Females	MRI & Follow-up	Physiotherapy & Discharge	Pain Clinic & Discharge	Analgesia & Discharge	Total
First OOP visit	4	15	2	1	22
Previous OOP visit	2	13	8	0	23

## Discussions

The majority of the patients seen at the outpatient clinic could have been managed in the primary care setting. Our study shows that only 16% ( $n=16$ ) of all the study population merited further investigations and follow up. This reflects the importance of developing local management guidelines for low back pain, which would be of assistance to the general practitioners when it comes to managing low back pain. Such guidelines could possibly help identify the patients who merit a referral for a specialist opinion and those who can be managed in the community. Also reflects the need for better liaison between primary care and orthopaedic specialists in the management of low back pain in form of possible frequent 'GP update lectures' apart from local management guidelines.

When patients present to the general practitioner with back pain, it is important that a good clinical history is obtained to try to identify the origin of the back pain followed by a physical examination in order to elucidate any neurological symptoms. In a study<sup>5</sup> it was brought forward that cases of sub-acute low back pain with radicular symptoms as well as chronic back pain with symptoms of radicular pain should all be referred for specialist opinion. It is then up to the clinical judgment of the specialist to decide the management plan of the referred patient. In our study 20% ( $n=20$ ) of the referrals to the orthopaedic outpatients were due to radiculopathy, out of which 12% ( $n=12$ ) needed further imaging investigation and follow up.

Assessing the patient for red flags and yellow flags should be part of the general practitioner management guidelines for low back pain.<sup>6</sup> Table 3 and 4 give a list of red and yellow flags<sup>7</sup> respectively. These would give the general practitioner a general guideline on how to

manage the patient with low back pain. Patients presenting with red flags are to be referred immediately to the Accident and Emergency department or urgently to the orthopaedic outpatients depending on the seriousness of the spinal pathology elicited. On the other hand presence of yellow flags may require further assessment and possible referral to other professional members such as psychologist but rarely would need an orthopaedic referral. In our study, none of the patients had any red flags present but occasional elements of yellow flags criteria were evident.

When red flags are excluded, patients should be reassured and advised to keep as active as possible, with a target to increase in the levels of activity performed.<sup>4</sup> Bed rest should be discouraged as part of the management of low back pain. Some guidelines only permit a maximum period of 2 days bed rest in very severe pain.<sup>8-11</sup> In our study 15% ( $n=15$ ) of patients were advised by their general practitioner to undergo a period of bed rest, which does not follow the current guidelines.

The first management step for low back pain is analgesia which can be easily prescribed by the general practitioner. This would help the patient to remain active as well as manage the pain.<sup>7</sup> The first medication choice is paracetamol due to its low incidence of gastrointestinal side effects. The second step up the pain treatment ladder would be NSAIDs (unless contraindicated), which are used when paracetamol is insufficient to relieve the pain. Sometimes a short period of opioid containing analgesia and antidepressants may help the patient be relieved from the low back pain.<sup>4</sup> In our study, patients were either started on paracetamol and then moved to NSAIDs or else started on NSAIDs straight away.

**Table 3: Red flags in a patient presenting with acute back pain**

Red Flags <sup>7</sup>
Age less than 20 or more than 55 years
A recent history of trauma
Constant progressive pain – includes pain that is not associated with movement and not relieved with lying down
Thoracic pain
A past history of malignancy
Recurrent or prolonged use of corticosteroids
Immunosuppression and HIV
Substance misuse
Systemically unwell
Unexplained weight loss
Neurological symptoms such as weakness of the limbs
Structural deformity of the spine

**Table 4: Yellow flags in a person presenting with back pain**

Yellow Flags <sup>7</sup>
An inappropriate perception of back pain <ul style="list-style-type: none"> <li>a) The belief that back pain is harmful and disabling</li> <li>b) The belief that passive activity such as bed rest is better than staying active</li> </ul>
Lack of support at home and social isolation
Mental health problems such as depression, anxiety and stress
Problems at work such as job dissatisfaction
Claims for compensation and benefits

In general practice worldwide there appears to be mixed ideas as to who merits an imaging investigation, in fact in our study there were 36% ( $n=36$ ) who had x-rays performed. The general consensus among the guidelines present is that imaging does not show any benefits unless progressive neurological symptoms are present or else serious pathology is suspected.<sup>7,12,13</sup> As could be seen from our study, only 15% ( $n=15$ ) referred to the OOP needed further imaging. According to the European clinical guidelines, imaging is not recommended unless a specific cause is strongly

suspected. The guidelines state that plain radiography is the best option for structural deformities while MRI is best for radicular symptoms, discitis or neoplasm.<sup>14</sup>

According to United Kingdom guidelines, when the first line treatment consisting of analgesia fails to subside the pain or disability, the general practitioner should then refer the patient to physiotherapy, unless neurological symptoms arise, in which case referral to an Orthopaedic specialist is required.<sup>6</sup> In Malta, the state primary health care provides a free service of physiotherapists in all the major health centers found

around the island. General practitioners working with either the state or with private sectors are able to refer patients to these physiotherapy hubs. Patients should be directly referred to the physiotherapists by the general practitioner rather than referring the patients to orthopaedic outpatients when low back pain persists. Referrals to orthopaedic specialists when first line therapy fails are not indicated. Complying with this and preventing unnecessary referrals leads to a decreased burden on the outpatients waiting lists as well as preventing the delay in the management plan of low back pain patients.

Pain clinic referral should only be considered in patients in whom conservative treatment has failed and surgery is not indicated.<sup>6</sup> In Malta, pain clinic referrals fall outside the remit of the general practitioners. In practical terms this means that patients can access this service only after being referred to the orthopaedic outpatient clinic.

## Study Limitations

The study was performed over a short period of time assessing only the first 100 new referrals by general practitioners only, to one-consultant orthopaedic outpatient sessions. The management plan and assessment of each patient was based on the orthopedic specialist clinical judgment as well as on international guidelines. Clinical judgment may vary from one specialist to another, mostly depending on the exposure to the presenting complains. Only a small sample of patients with low back pain complaint was evaluated. Although this is suggestive of low back pain referrals in Malta, a larger population sample with the same complaint should be studied. Data obtained regarding previous orthopedic specialists encounter was obtained verbally during the consultation, therefore patient error may be present. No personal data of the patients visiting the OOP was kept making it impossible for any form of follow-up to be performed and so unable to close the audit loop. It would be suggested that a similar study would be performed with the aim to follow the cohort of patients to assess the long-term management plan. This was outside the scope of this current study, where the authors wanted to assess whether referrals to OOP were justified or not and to bring forward the correct management plan in accordance to the most recent guidelines.

## Conclusion

Low back pain is a common complaint, which is dealt with in the primary health care globally. This condition should not be lucidly referred for specialist review unless neurological symptoms are present. There is strong evidence that NSAIDs relieve low back pain<sup>15</sup> and this should be first line therapy. Patients should be advised to remain active, which should speed up the

recovery time and decrease the possibility of developing chronic disability. Muscle relaxants can be used to relieve pain but one needs to look out for side effects such as drowsiness.<sup>15</sup> If first line therapy does not relieve the pain, then the general practitioner should refer the patient for physiotherapy for a core strengthening exercise programme. Only when these steps fail should referral to the orthopaedic outpatients be considered depending on the patient's clinical evaluation. Our study shows that the majority of the cases referred to the orthopaedic outpatients were not indicated and the patient should have been managed in the community. Although this study was done over a short period of 3 months and assessed patients of only one consultant clinic, it is strongly indicative that referral to orthopaedic outpatients should only be triggered when all treatment in the primary health care system is exhausted. This suggests that there should be a better communication and management plans between the primary care and the orthopaedic specialists, possibly a beneficial exercise would be to have frequent lecture updates between the two departments on common orthopaedic encounters in primary care. General practitioners should have available local guidelines as to when to refer to OOP and when they can manage a low back pain complaint in primary care. Physiotherapy service is already available in the community making it easy and feasible for general practitioners to refer candidate patients with low back pain for physiotherapy without the need to refer to OOP. General practitioners unfortunately lack the access to refer patients to the pain clinic, something that may be of benefit to the patients if their family doctor has access to.

We believe that following this lower back pain management plan will lead to a better delivery of management of this common complaint. Patients would benefit from achieving targeted treatment timely with the added comfort of being managed in the community. It would undoubtedly result in shorter waiting time for an orthopaedic outpatient visit as well as result in more time and effort being spent on patients needing spinal surgery.

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# Cystic Lesions of the Pancreas

Neville Azzopardi

## Abstract

With the increasing use of abdominal imaging, cystic lesions of the pancreas are being more frequently detected. These lesions may carry a significant premalignant potential. Current guidelines recommend that mucinous cystic neoplasms, solid pseudopapillary neoplasms, main duct-intraductal papillary mucinous neoplasms and branch duct-intraductal papillary mucinous neoplasms (DB-IPMN) with "high-risk stigmata" for malignancy should be resected while asymptomatic BD-IPMN without mural nodules, no main duct involvement, and a size less than 30 mm can be followed up. Serous cystadenomas carry a very small malignant risk and are usually resected only if they cause symptoms. This review article highlights the common characteristics and recommended management of these cystic lesions of the pancreas.

## Keywords

cystic lesions of the pancreas, serous cystadenoma, intraductal papillary mucinous neoplasm, mucinous cystadenoma, solid pseudopapillary neoplasm

## Introduction

Cystic lesions of the pancreas (CLP) are relatively common and with the increasing use of high resolution computed tomography (CT) and magnetic resonance imaging (MRI) are being increasingly detected. The prevalence of CLP in autopsy series was as high as 24%<sup>1</sup> and high resolution CT identified these lesions in 2.6% of asymptomatic adults and in 8% of patients older than 80 years.<sup>2-3</sup>

Pancreatic cystic lesions include serous cystic adenomas (SCA), mucinous cystic neoplasms (MCN), intraductal papillary mucinous tumors (IPMN), solid pseudopapillary tumors (SPN), (which together represent 95% of all CLP) and also less common lesions such as cystic endocrine tumors and lymphangiomas. Distinguishing between these PCLs is extremely important because while some lesions are completely benign, other pancreatic cysts carry a significant premalignant potential and require close follow up or early surgical resection. In this review article, we describe the common characteristics and management of the most common pancreatic cystic lesions.

The prevalence of pancreatic cystic lesions appears to increase with age. In most cases, cystic lesions are detected incidentally by CT or MRI performed for other reasons.

MRI/magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasound (EUS) are considered to be complementary diagnostic tools. The added advantage of EUS is that in doubtful cases, cyst fluid analysis may be performed by carrying out a fine needle aspirate of the cyst contents. MRI should always be carried out before EUS as it identifies the number of cystic lesions (which may be multiple in IPMN), the relation of the cysts to the main pancreatic duct, and the size of the lesions. EUS is however superior in evaluating mural nodules (i.e. intracystic nodules arising from the cystic wall lining – these nodules are frequently precursors of malignant transformation and are an indication for surgical resection).<sup>4</sup>

The premalignant risk of CLP varies according to the type of lesion. While main duct-IPMN and MCN carry a significant premalignant risk, SCA are considered to have a very low risk of malignant transformation. A recent study by Rhim et al<sup>5</sup> has shown that patients with CLPs already have pancreatic cancer cells in their circulation before pancreatic tumours actually develop. In this study, circulating pancreas epithelial cells (CECs) in patient blood samples were detected and quantified. The authors identified >3 CECs/ml in 7 of 21 patients (33%) with CLP (predominantly IPMN) and no clinical diagnosis of cancer, in 8 of 11 patients (73%) with pancreatic adenocarcinoma, and in 0 of 19 patients without cysts or cancer (controls). This technique may

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in the future be used in risk assessment of CLPs.<sup>5</sup>

### Intraductal Papillary Mucinous Neoplasms (IPMN)

IPMN are more commonly found in the head of the pancreas (70%) with an equal gender distribution. They are commoner in the 6<sup>th</sup> and 7<sup>th</sup> decade and can be subclassified into main duct (MD)-IPMN and branch duct (BD)-IPMN based on imaging results and histology. All IPMNs appear to communicate with the main pancreatic duct and may be multifocal. Dilatation of the main pancreatic duct to >5mm on CT or MRI (without other causes of obstruction) suggests the presence of main duct IPMN with a main duct diameter of 5-9mm being considered a “worrisome feature” while a duct of 1cm or more is considered a “high-risk stigmata”. The presence of a mucinous cyst >5mm in diameter communicating with the main duct without causing main duct dilatation is strongly suggestive of branch duct IPMN. Mixed type IPMN have the criteria for both MD-IPMN and BD-IPMN. The difference between the two subtypes can be confirmed using EUS or intraductal ultrasonography. If these techniques are not available, histological analysis of surgically resected specimens can also distinguish between the two.<sup>6</sup>

MD-IPMN carries a very high risk of malignant transformation (57-92%)<sup>7-15</sup> while the risk with BD-IPMN is somewhat lower (6-46%).<sup>7-14</sup> MRI has a better sensitivity than CT scan in the detection of CLPs (19.9% versus 2.6%)<sup>2,16</sup> and for this reason is usually preferred in the classification of these lesions. In small cysts (<10mm in diameter), MRI follow up after 2-3 years is recommended. For cysts >10mm in diameter, pancreatic CT or gadolinium-enhanced MRI with MRCP are

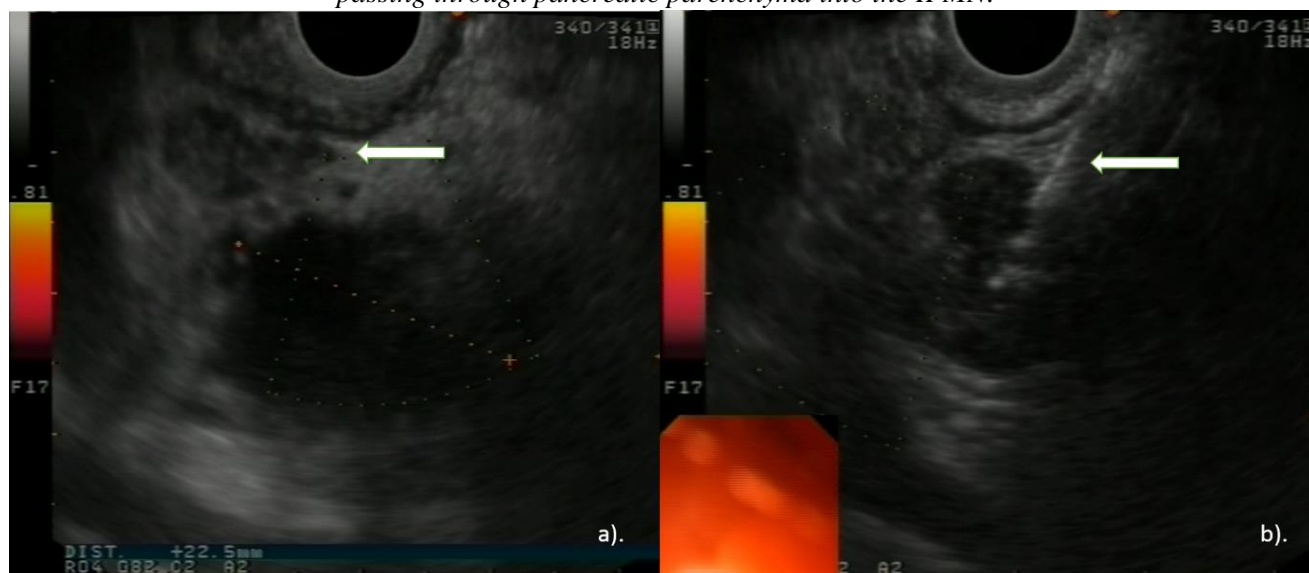
recommended, though MRI is better in identifying septae, nodules and duct communications.<sup>17</sup>

The 2012 international consensus guidelines for the management of IPMN<sup>6</sup> recommend that patients with “high-risk stigmata” on CT or MRI should undergo immediate surgical resection without further testing. These “high-risk stigmata” include obstructive jaundice in a patient with a CLP of the pancreatic head, enhancing solid component in the cyst and a main duct diameter >10mm. “Worrisome features” include cystic lesion >3cms in diameter, thickened enhanced cystic walls, main duct diameter 5-9mm, non-enhanced mural nodules, abrupt change in main pancreatic duct diameter with distal pancreatic atrophy and the presence of lymphadenopathy.<sup>18-22</sup>

These patients should be further evaluated with EUS, which further risk-stratifies the IPMN. In the presence of a definite mural nodule, if the main duct appears dilated or involved during EUS or if fine needle aspirate cytology from the cystic fluid is suspicious or positive for malignancy, the patient should be referred for surgery. In the absence of these features, follow up will depend on the size of the lesion. For cysts 1-2cms in diameter, yearly CT or MRI for 2 years with lengthening of the imaging interval if the cyst remains unchanged is recommended. For lesions which are 2-3cms in diameter, the guidelines recommend 3-6 monthly EUS with lengthening of the interval, alternating with MRI if there is no change. For cysts larger than 3cms, alternating MRI with EUS every 3-6 months is recommended. In young fit patients with cysts >2cms, surgery may be recommended early to avoid prolonged surveillance.

**Figure 1:**

- Endoscopic ultrasound view of a 22 mm branch duct IPMN in the head of the pancreas with no mural nodules and a small (<1cm), insignificant peripancreatic lymph node (arrow).*
- EUS-guided fine needle aspiration (FNA) of cystic fluid for biochemical and cytological analysis; arrow shows needle passing through pancreatic parenchyma into the IPMN.*





The main advantage of EUS over other imaging modalities lies in its ability to detect mural nodules and invasion, and is most effective in delineating the malignant characteristics of these lesions. In addition, it allows the acquisition of cystic fluid for cytological assessment and biological analysis of carcinoembryonic antigen (CEA) and amylase levels (Figure 1).<sup>23-25</sup> Elevated CEA (>192 ng/mL) is 80% accurate for the detection of mucinous cysts, though it provides no clue to the risk of malignancy.<sup>23,24,26</sup> Cyst amylase levels are not uniformly elevated in IPMNs

Molecular analysis of cyst fluid for KRAS (*Kirsten Rat Sarcoma*) mutations is still mainly an investigational tool; however KRAS mutations in cyst fluid are more in keeping with a mucinous rather than a malignant cyst.<sup>27-29</sup> In a study analysing sensitivity and specificity of KRAS mutation in identifying mucinous differentiation, KRAS had a specificity of 100% and sensitivity of 54% for mucinous differentiation. When stratified according to cyst type, KRAS had a sensitivity of 67% for IPMNs and 15% for MCNs.<sup>30</sup> New FNA/B (fine needle aspirate/biopsy) needles are now also able to obtain a histological sample of the pancreatic cyst wall providing higher diagnostic yields of cyst type than standard needles.<sup>31</sup>

### Serous Cystadenomas (SCA)

SCA represent 10-45% of all PCL and are much commoner in women (70%). They are more common in the body or tail of the pancreas (>80%) and they do not communicate with the pancreatic duct.<sup>32</sup> They may be either polycystic (microcystic), or oligocystic (macrocytic). Typically they present as single lesions with central calcification (in 20%) and high vascularity at EUS. If the diagnosis is still not clear, EUS-FNA may be used for biochemical assessment (Figure 2). SCA typically have low levels of both CEA (<5 ng/mL) and amylase and carry a very small risk of malignant transformation (3%).

Serous microcystic adenomas are glycogen-rich cystadenomas surrounded by fibrous capsules which separate them from normal tissue. CT or MRCP can frequently distinguish SCA from BD-IPMN because of their polycystic or honeycomb pattern. In their interior they form a honeycomb appearance with numerous small, closely packed cysts arranged around a central stellate, calcified scar.<sup>33</sup> Serous macrocystic adenomas are much less common and consist of fewer, larger cysts, typically >1cm in diameter.<sup>34</sup> They are more common in the pancreatic head and in view of their size may present with obstructive jaundice. Serous macrocystic adenomas may be associated with von Hippel Lindau disease.<sup>35</sup> In view of their small risk of malignant transformation, small (<4cms) asymptomatic SCA should undergo periodic follow up while larger, symptomatic cysts should be resected.

**Figure 2:** Endoscopic ultrasound view of a 17mm serous cystadenoma in the tail of the pancreas; note the honeycomb appearance with multiple small, closely packed cysts arranged around a central, calcified scar



### Mucinous Cystic Neoplasm (MCN)

MCN include mucinous cystadenomas and mucinous cystadenocarcinomas and account for 10% of PCLs. They are much commoner in women (>95%) and are more prevalent in the 4<sup>th</sup> and 5<sup>th</sup> decades. MCN are usually found as a single lesion in the body or tail of the pancreas and they do not usually communicate with the main pancreatic duct. At EUS-FNA, MCN amylase levels may be increased and CEA level is almost always increased. All young and fit patients with MCN should undergo surgical resection because of the elevated risk of malignant transformation and the need for prolonged surveillance. In a large series, up to 10% of MCN had invasive cancer at the time of resection.<sup>36</sup> MCNs <4cms in diameter have 15% risk of malignant transformation and such lesions may be followed up conservatively in elderly or frail patients.<sup>6</sup>

### Solid Pseudopapillary Neoplasm (SPN)

SPN represent 10% of all PCLs, and are predominantly found in young women. They may occur anywhere in the pancreas and may occasionally be very large. At EUS, these lesions may appear solid or mixed solid and cystic, with or without septations. SPN frequently undergo central haemorrhagic cystic degeneration with a pseudocapsule which may calcify.<sup>37</sup>

They have an indolent course but if left untreated, they may invade into adjacent organs and major vessels.<sup>38</sup> These tumors are usually very slow growing and carry an excellent prognosis once resected.

### Synchronous or metachronous malignant disease in extrapancreatic organs

Synchronous or metachronous malignancy in extrapancreatic organs occurs in 20-30% of patients with IPMN. Extrapancreatic malignancies appear to occur in different organs depending on the incidences of cancer in the general populations in different geographical regions.<sup>39</sup> While there are no current recommendations to screen extrapancreatic organs in patients with IPMN, a reasonable practice would be to carry out serum prostate specific antigen (PSA) assessment, mammography and colonoscopy in patients with these PCL.

### Conclusion

With the widespread use of abdominal imaging, PCLs are increasingly being recognised. In view of the premalignant potential associated with some of these lesions, they need to be accurately classified and followed-up or resected accordingly. MCN, SPN, MD-IPMN and BD-IPMN with "high-risk stigmata" for malignancy should be resected while asymptomatic BD-IPMN without mural nodules, no main duct involvement, and a size less than 30 mm can be followed up with a watchful waiting strategy.

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