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Table of Contents

Metabolically healthy obesity – is it time to lay the myth to rest?

Victor Grech

Metabolically healthy obesity (MHO) has been defined as a condition wherein obesity does not produce metabolic complications such as dyslipidemia, impaired glucose tolerance, or metabolic syndrome.[1-2] These individuals also have less visceral adipose tissue, smaller adipocytes, and a reduced inflammatory profile when compared to metabolically unhealthy obese individuals, and their cardiac and metabolic risk does not improve as a result of weight loss interventions.[1-3]

However, the latest studies suggest that so-called MHO individuals may still be at an increased risk of cardiovascular disease.[4-6] For example, a very recent study tracked the health of 90,257 women in the United States for up to 30 years. Those with excess weight were likelier to have a stroke or heart attack, even if they fit the criteria of MHO.[7] The researchers specified that this was an association rather than cause and effect, as this was mainly found in white women, so that these findings cannot be readily generalised to other ethnic groups or to men. However, the authors concluded that "healthy obesity is not a harmless condition".[7]

Furthermore, the study showed that women who were of normal weight but metabolically unhealthy were two-and-a-half times likelier to develop cardiovascular disease than women of the same weight who were metabolically healthy. And unsurprisingly, for women who were overweight and obese, the risk was even higher.[7]

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Perhaps it is indeed “finally time to dispel the concept of metabolically-healthy obesity?”[12]

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Cover Picture:
'Triton Fountain'
Woodburning
By Mark Schembri

Mark Schembri is a Consultant General and Vascular Surgeon. He has developed a special interest in Lower GI surgery after doing general and vascular surgery for a long part of his career. He also does Renal Transplantation. He is lead clinician for audits in the Surgical Department. He is a Visiting Senior Lecturer at the University of Malta.

Audit on testosterone therapy in adult males with testosterone deficiency

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Abstract

Introduction: Hypogonadism is estimated to affect between 2.1 and 12.8% of the adult male population.

Aim: The aim of this audit is to look at current practice and compare them with established guideline so as to identify areas which need improvement.

Method: A review of 235 patients suffering from hypogonadism was undertaken. Local standards of care were compare to the Endocrine Society Clinical Practice Guideline of 2010 (ESCG).

Results: Patients complained of 0, 1-4, 5-8 symptoms suggestive of hypogonadism in 17%, 67% and 16% respectively. 76.5% of the patients had repeatedly low testosterone. 20% suffered from primary hypogonadism. 77% suffered from secondary hypogonadism secondary. Karyotype was obtained in 35% and 5% of the patients suffering from primary and secondary hypogonadism respectively. Patients suffering from secondary hypogonadism had serum TSH (94%), prolactin (92%), cortisol (91%), GH levels (89%) and iron studies (43%) analysed. 77% of patients suffering from secondary hypogonadism had an MRI of the pituitary, with an abnormality reported in 53% of the patients. Prior to starting treatment 7% of the patients were assessed for prostate nodules and PSA was taken in 39% of the patients. Only 33% of the patients had bone mineral density (BMD) taken prior to starting testosterone treatment. Patients were reviewed 3-6 months (35%) and then annually (88%) after treatment was initiated.

Conclusion**:** This audit identifies the need for documentation of signs and symptoms. Testosterone levels should be repeated prior to starting treatment. It also highlights the need for karyotyping in patients with primary hypogonadism as well as the need to measure BMD and PSA before and after prescribing testosterone. Patients need review at 3-6months after initiation of testosterone supplementations.

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Key Terms

Testosterone therapy, hypogonadism, testosterone deficiency

Introduction

Testosterone deficiency is defined as sub-optimal serum testosterone levels with or without modified receptor *sensitivity* to androgens.[1] It may be further described as clinical hypogonadism (presence of signs and symptoms), or as subclinical hypogonadism (a biochemical deficiency with absence of symptom) and is estimated to affect between 2.1% and 12.8% of adult males.[2-3]

Testosterone deficiency can result from defects at different levels of the hypothalamus-pituitary-testes axis, ranging from abnormalities in the testes (primary hypogonadism), to pituitary or hypothalamic dysfunction (secondary hypogonadism).[4] Testosterone deficiency may also occur due to decreased bioavailability of the hormone (due to sex hormone binding variations) or androgen receptor alterations.[4]

Presentations includes sexual dysfunction, fatigue, mood disturbances, decline in bone mineral density (BMD) and change in body composition, erectile dysfunction, decrease morning erections and low libido being of greatest significance.[2,4-5] Due to its numerous influences on the endocrine and nervous system, testosterone deficiency is associated with a variety of co-morbidities including obesity, type 2 diabetes, hypertension, osteoporosis and cardiovascular disease. [1-2]

A definite diagnosis can be established after two morning total serum testosterone levels, with cut-off values depending on different methodology used.[2, 5-7] Treatment options for hypogonadism revolve around testosterone replacement therapy.[1-2, 6-7]

An audit was carried out with the aim of investigating patient demographists, clinical investigation, treatment and follow up of hypogonadal patients at Mater Dei Hospital. These findings were compared to the Endocrine Society Clinical Practice Guideline of 2010 (ESCG) regarding identification, diagnosis, investigations and managing patients with androgen deficiency syndromes.[7]

Aim

The aim of this audit was to review current practices in Mater Dei Hospital and compare them with established guidelines so as to identify areas which need improvement.

Patients and Methods

Sample

235 patients prescribed testosterone esters and listed on the Medical Approval Section covering entitlement for free medication from 2006 until February 2014 were included. Data analysis was carried out on 153 i.e. 65% of the cohort. In 29% of the cohort no data was available in their file while in 6% of the cohort the file could not be accessed. Case notes of adult males seen at Mater Dei Hospital who were on testosterone treatment were reviewed.

Methodology

This was an audit were medical notes and online documentation systems (Isoft® and PACS®) were used to collect data on the patients' diagnosis and management. The data collection form used was based on the ESCG.[7] Data collection was done using Microsoft Access® and then data analysis was carried out by using Microsoft Excel® using simple descriptive statistics. Analysis for concordance with ESCG recommendations was subsequently carried out.

Results

Patient demographic and symptomatology

Data analysis was carried out on 153 patients (*n*). 30% (*n*=46) of the patients were below 29 years of age, 57% (*n*=87) were between 30 and 59 years of age and 13% (*n*=20) were above 60 years of age (Figure 1).). 2 patients who suffered from hypogonadism secondary to multiple system atrophy and pituitary adenoma were over 70 years of age. The most common symptoms that the patients complained of were a decrease in spontaneous erections, reduced libido, small testes and reduced body hair (Figure 2). Patients complained of 0, 1-4, 5-8 symptoms suggestive of hypogonadism in 17% (*n*=26), 67% (*n*=102) and 16% (*n*=25) respectively (Figure 3).

***Figure 1**: Age when testosterone treatment was started.*

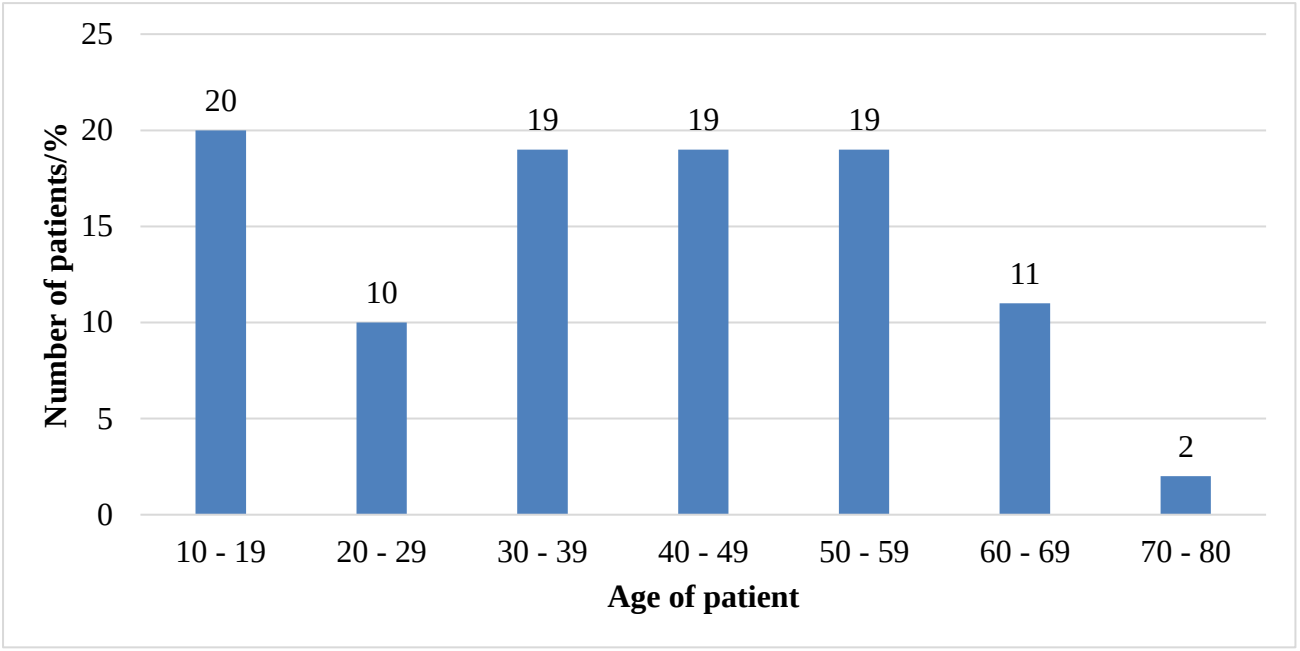


***Figure 2**: Symptoms and signs at presentation.*

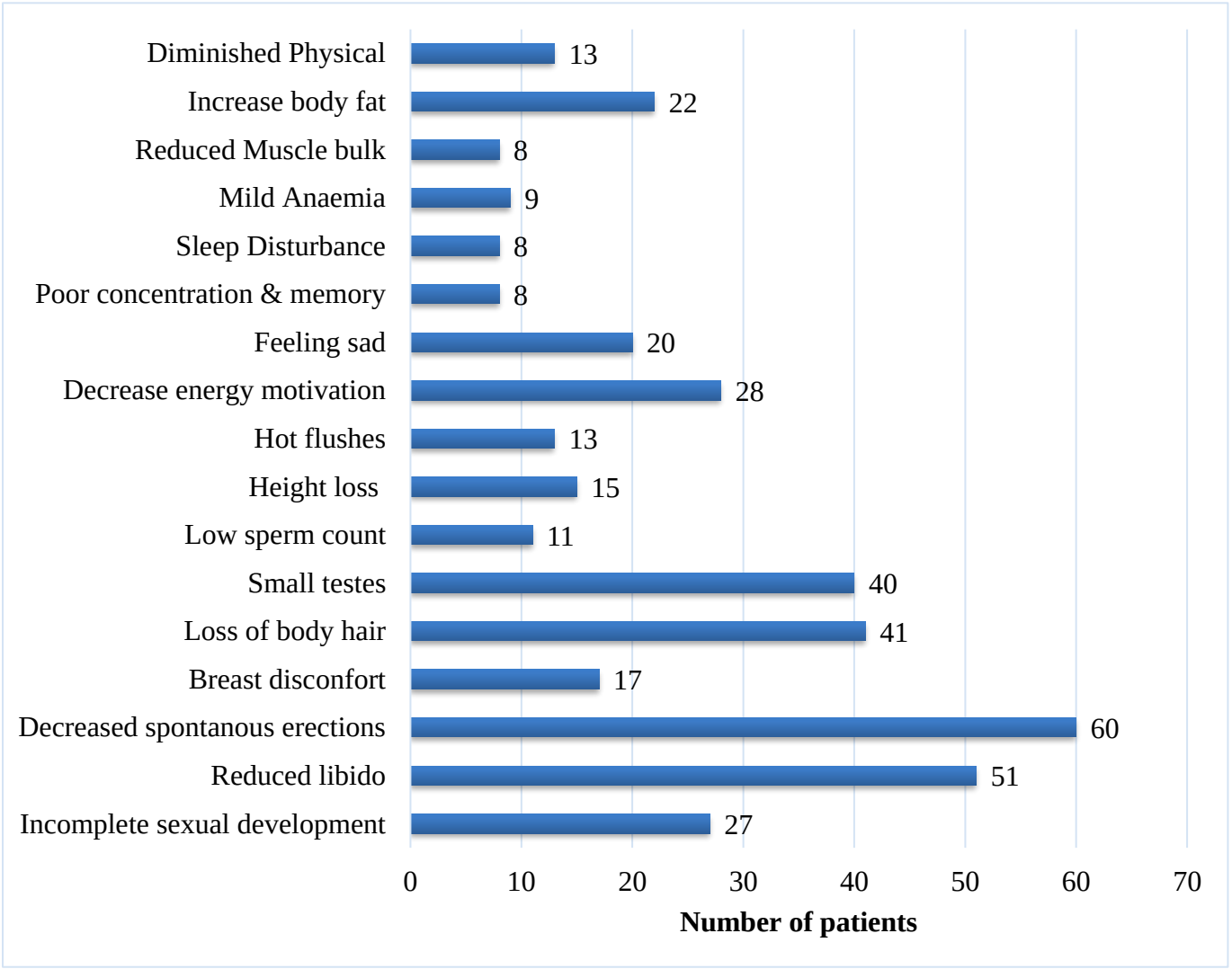
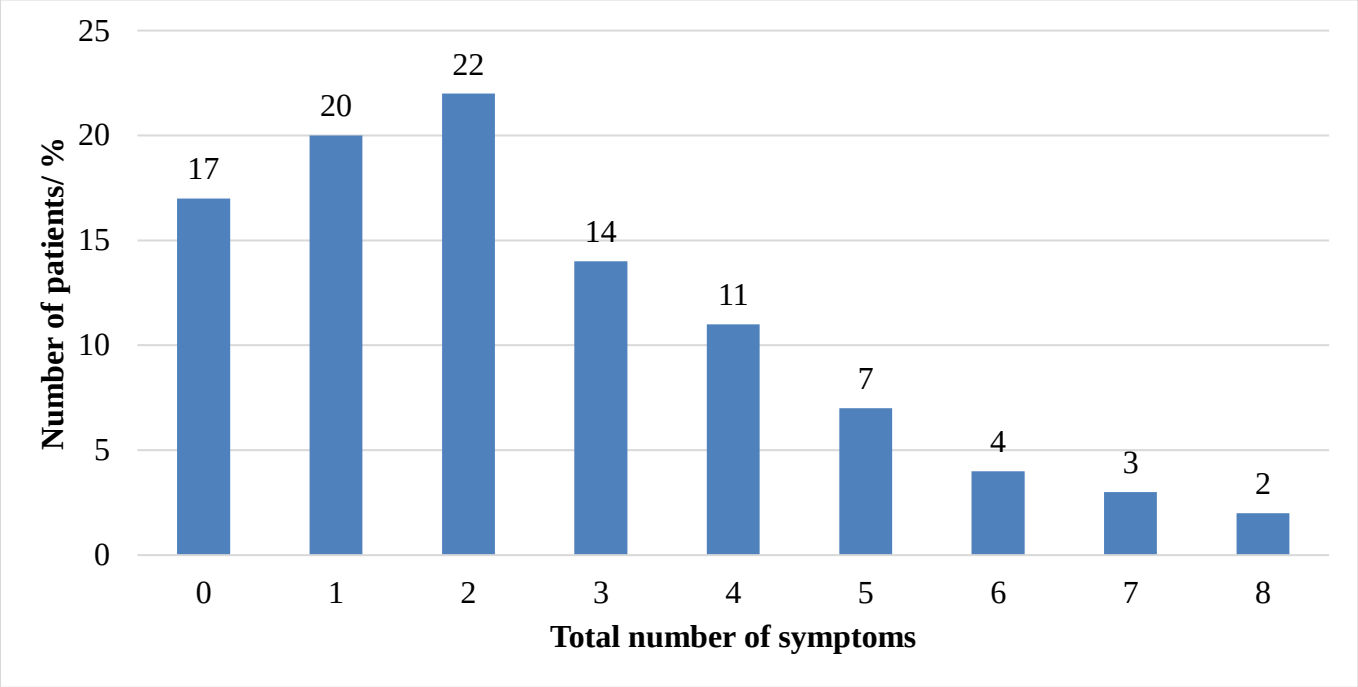


***Figure 3**: Percentage number of patients with 0 to 8 symptoms at presentation.*



Investigation

During data collection, testosterone levels were found to be below the lower limit of normal for the particular assay used. Different assays which were used over the years include enzyme–linked immunosorbent assay and chemiluminescent immunoassay. Due to the utilisation of different assays for total and/or free testosterone, different normative ranges were present over different time periods, hence graphical representations of these levels was not possible. However, 76.5% (*n*=117) of the patients had confirmation of low testosterone by repeat analysis prior to starting treatment. Sex hormone binding globulin (SHBG) was measured in 2 patients. However a number of patients (*n*=90) had conditions which could potentially affect SHBG concentration.

Karyotype was obtained in 35% (*n*=11) and 5% (*n*=6) of the patients suffering from primary and secondary hypogonadism respectively. Patients suffering from secondary hypogonadism had serum TSH (94%; *n*=110), prolactin (92%; *n*=108), cortisol (91%; *n*=107), GH (89%; *n*=104) and iron studies (43%; *n*=50) taken (Figure 4, 5). Of the 117 patients who suffered from secondary hypogonadism, 90 patients had an MRI of the pituitary, with an abnormality reported in 62 of the patients.

Diagnosis

20% (*n*=31) suffered from primary hypogonadism with Klinefelter's syndrome (5%; *n*=7) and orchidectomy (4%; *n*=6) being the most common causes (Figure 6). In 7 patients the cause was not found. 77% (*n*=117) suffered from secondary hypogonadism with pituitary adenoma (31%; *n*=47) and idiopathic hypogonadotrophic hypogonadism (14%; *n*=21) being the most common causes (Figure 7). 16 patients had no MRI done. 3% (*n*=5) of the patients could not be classified as suffering from primary or secondary hypogonadism since LH and FSH levels were not available.

Treatment and follow up

No patient had a past history of breast or prostate cancer. 78 of the patients were over 40 years old when testosterone treatment was started. PSA was tested in 42 (54%) of these patients. 23 of these patients had a PSA less than 0.6ng/ml. On the other hand, 19 of these patients had a PSA more than 0.6ng/ml with only half of these having a digital rectal examination performed.

Testosterone undecanoate and testosterone enanthate were the most commonly used testosterone esters. (Table 1)

Figure 4: *Percentage of patients with hypergonadotrophic hypogonadism with karyotyping and hormone profiles*

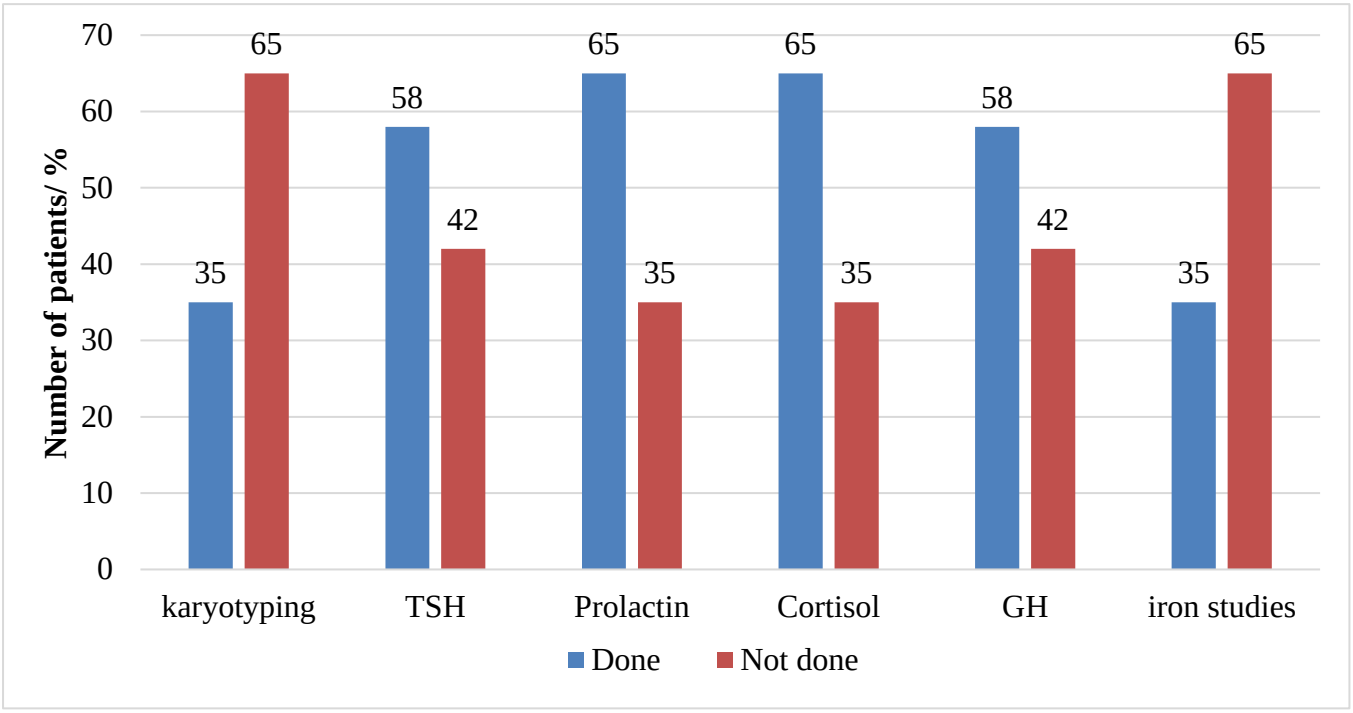


Figure 5*: Percentage of patients with hypogonadotrophic hypogonadism with karyotyping and hormone profiles*

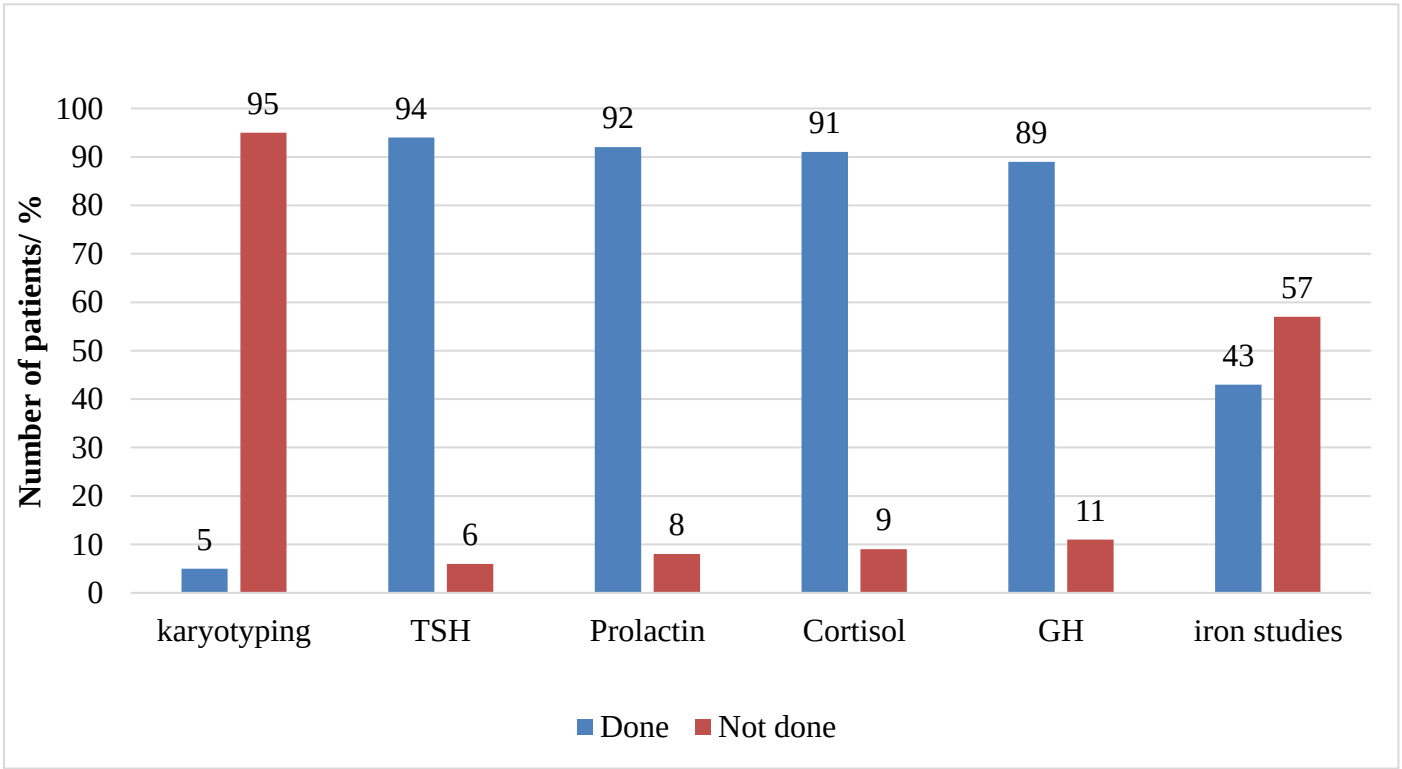


Figure 6: *Causes of primary hypogonadism (Hypergonadotrophic hypogonadism)*

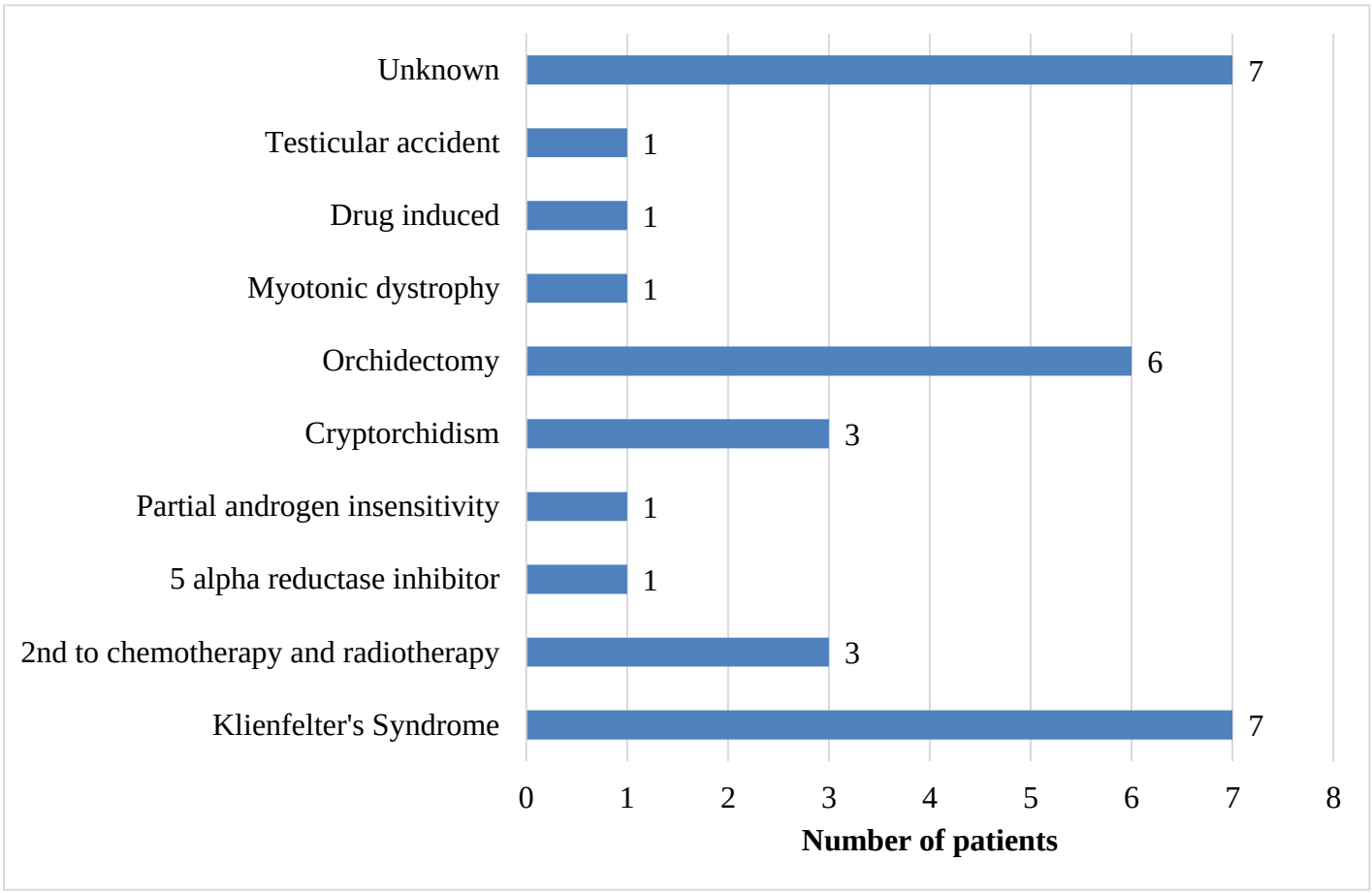


Figure 7: *Causes of secondary hypogonadism (hypogonadotropic hypogonadism)*

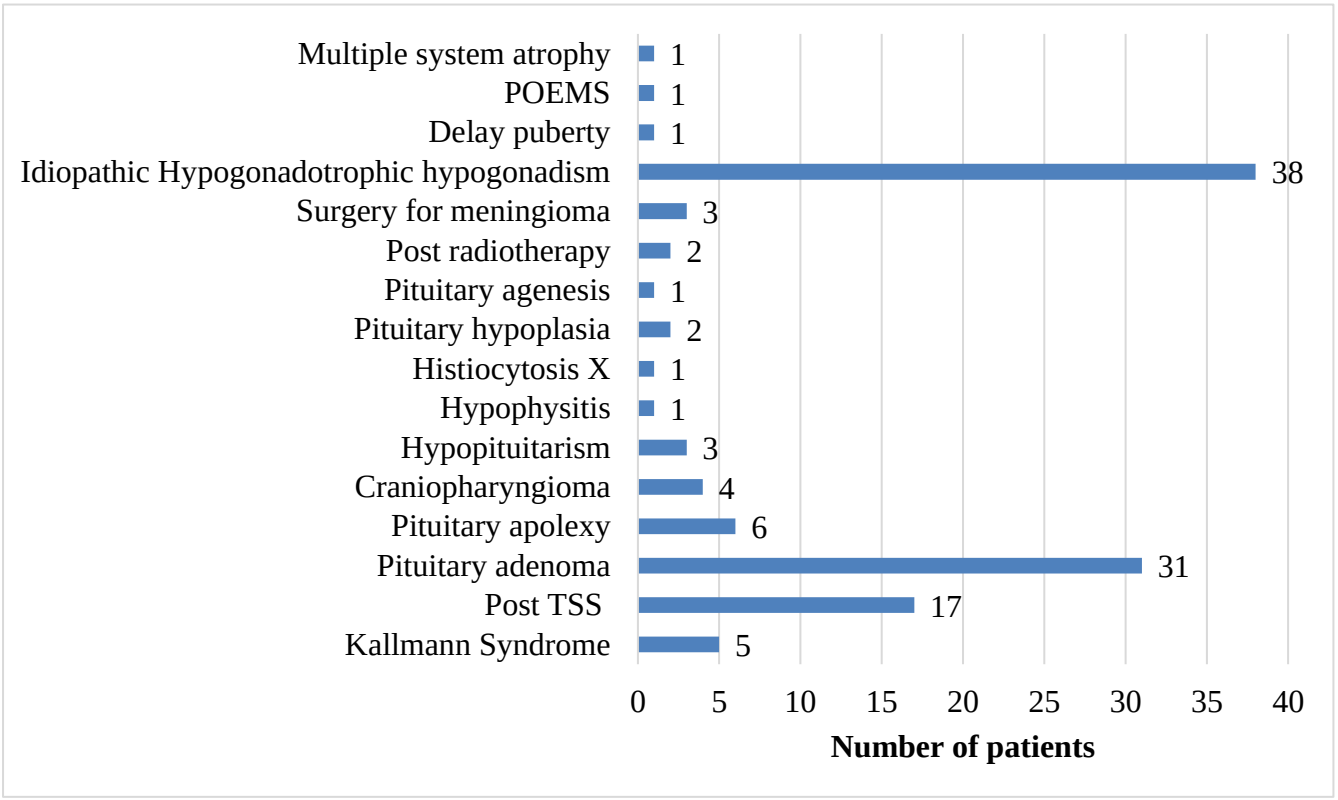


Table 1*: Type of testosterone esters used.*

Type of testosterone esters	Number of patients
Testosterone enanthate	91
Testosterone undecanoate depot	36
Testosterone undecanoate oral	4
Testosterone cypionate	1
Testosterone proprionate	1
Primotestosterone	10
Testogel	1
Not specified in notes	9
Type of testosterone esters	Number of patients
Testosterone enanthate	91
Testosterone undecanoate depot	36
Testosterone undecanoate oral	4
Testosterone cypionate	1
Testosterone proprionate	1
Primotestosterone	10
Testogel	1
Not specified in notes	9

Table 2: Bone mineral density results.

BMD at diagnosis	**Mean T score of the spine at diagnosis (+/- SD)**	**Mean T score of the spine after starting treatment (+/- SD)**	**Mean T score of the hip at diagnosis (+/- SD)**	**Mean T score of the hip after starting treatment (+/- SD)**
Normal (3pts)	-0.14 (+/- 0.61)	0.15 (+/- 0.23)	0.02 (+/-0.70)	-0.25 (+/- 1.36)
Osteopenia (9pts)	-1.59 (+/- 0.51)	-1.41 (+/- 1.18)	-1.15 (+/- 0.96)	-1.40 (+/- 0.41)
Osteoporosis (12pts)	-2.53 (+/- 1.27)	-2.71 (+/- 0.96)	-2.82 (+/- 0.57)	-2.46 (+/- 0.46)

Patients were reviewed at 3-6 months (35%; *n*=54) and then annually (88%; *n*=135) after treatment was initiated. Improvement of symptoms was documented in 50% (*n*=77) of the patients. 36 patients stated that they felt better after the treatment was started, with improved erectile function in 32 patients. 13 patients had improved libido and 19 patients had increased body hair.

80% (*n*=123) of the patients had annual haematocirt checked. All of these patient haematocrit value was less than 54% and so testosterone treatment was not discontinued for this reason.

33% (*n*=50) of the patients had BMD done prior to starting treatment with 16% (*n*=24) of these having follow- up BMD. BMD were carried out on either Norland and Hologic Bone Densitometers. BMD was assessed after starting treatment in 14% (*n*=22) of the patients. 20 patients were osteoporotic, 24 patients were osteopenic whilst 28 patients had normal BMD.

Table 2 displays patients who had BMD done at diagnosis and at follow up (16% of the patients). T score at the spine showed mild improvement in osteopenic and normal patients while slight deterioration was seen in osteoporotic patients. T score at the hip showed some deterioration in normal and osteopenic patients while there was an improvement in osteoporotic patients.

Discussion

This analysis of concordance with guidelines highlights areas which need to be improved when managing patients with hypogonadism at Mater Dei Hospital.

The gold standard methods to measure free testosterone values are liquid chromatography and mass spectrometry which are not available locally. Given this, total testosterone measurements are the best available option locally.[7-8] Free testosterone estimation would be preferred in scenarios were total testosterone levels are near the normal range and in whom altered sex hormone binding globulin (SHBG) levels are suspected (e.g. obesity, diabetes, hypothyroidism).[2,7] In our testosterone deficient patients, free and total testosterone serum levels were obtained at varying time points over the study period as a result of changes in the assays made available by the Pathology department at Mater Dei Hospital.

ESCG state that a diagnosis of hypogonadism is established after two separate measurements of morning total testosterone levels are low.[7] However results of the study show that 24% of patients diagnosed with hypogonadism had only 1 measurement. A retrospective cohort study in USA also showed lack of duplicate confirmatory testing, with only 40% of the 63,534 cohort population having 2 or more testosterone levels determinations.[9] However, all total testosterone serum testing was carried out in the morning, respecting testosterone's diurnal variation and adhering to guidelines.[7] This contrasts with a NorthShore University cohort study, were only 9% of men were tested in the early morning.[2] Barriers to guideline implementation include lack of awareness and familiarity with guidelines, patient non- compliance or environmental barriers (such as difficulty scheduling early morning testing).[2]

Karyotyping was not carried out in 65% of patients with primary hypogonadism. ESCG suggests that karyotyping is required to exclude Klinefelter syndrome (KS) in men with ''*primary testicular failure of unknown aetiology*''.[7] The incidence of KS is 0.1-2% of male neonates, being one of the commonest congenital disorders resulting in hypogonadism.[10] Due to significant variation in clinical presentation, only 10% of cases are identified before puberty and 25% up until adulthood, with the latter reported in a study using Danish patient registries.[10-11] Diagnosis should be made as early as possible in KS patients, as early treatment with testosterone helps improve their quality of life.[11] Although a combination of small testes and elevated gonadotrophins is present in the majority of KS patients, variable phenotypes, as well as mosaicism, make karyotyping essential in all patients with primary hypogonadism of unidentified aetiology.[10]

When diagnosing secondary hypogonadism; TSH, free thyroid hormone, prolactin, serum cortisol, IGF-1 and GH were assessed in the majority of patients (> 89%), whilst iron studies were documented in less than half of patients. ESCG suggest iron saturations be measured in all patients with secondary hypogonadism so as to exclude or confirm haemochromatosis.[7] The largest study on prevalence of hypogonadism in haemochormatosis reported a prevalence of hypogonadism of only 6.4%.[12] However, prevalence of hypogonadism may be decreasing due to earlier diagnosis of haemochromatosis.

Hypogonadism however still remains a significant complication and all patients with haemochromatosis should be screened for this.[12]

Testosterone enanthate followed by intramuscular testosterone undecanoate were the two commonest prescribed testosterone replacement treatment, and are recommended by ESCG.[7] However, oral forms (which include testosterone undecanoate) are associated with a high serum level variability and require multiple daily doses compared to other routes of administration.[13] This has significant implications with regards to compliance and efficacy. Intramuscular injections, subcutaneous implants, patches and gel have demonstrable better pharmacokinetics, better long term outcome and should ideally be available for patients use.[13-14]

With regards to patient follow-up, only 35% of patients were assessed at 3-6 months, whilst 88% were assessed annually, contrasting with the ESCG.[7] Canadian and other international guidelines for the management of hypogonadism also recommend these monitoring intervals.[1,4] This re-assessment should incorporate details of improvement of symptoms, possible therapeutic complications, patient adherence and biochemical monitoring (including testosterone level and PSA).[1,4] Shorter hospital outpatient appointment interval should therefore be recommended.

A limitation in our study was that we only had access to hospital files and some of the patients may have been followed up in the community. ESCG recommends assessing whether symptoms have ameliorated with treatment and if there is documentation of any adverse effects.[7] The BLAST study suggests that early sexual benefits and improvements can be effectively documented through use of the Ageing Male Symptom score.[5] A prospective study by Kovac et al. also revealed that satisfied patients reported more significant improvements in the areas of libido, concentration, mood and muscle mass higher than dissatisfied patients.[15] Adopting a standard method of symptom documentation on follow-up may help increase awareness for physicians, help identify patient complaints, and also indirectly increase treatment compliance and improve patient outcomes.

When considering complications of hypogonadism, 33% of patients had a documented baseline BMD, with only 16% of these having follow-up BMD monitoring. 14% of the total study population had BMD assessments after starting testosterone treatment. However the number of patients was very small, the bone densitometry utilised was not the same in all patients and there may have been other confounding factors making it difficult to draw up any conclusion from these figures.

In a randomized, double-blind, placebo-controlled study, Basurto et al showed how BMD in the lumbar spine significantly improved with testosterone treatment.[16] In a study done over 36 months on patients with hypogonadism and metabolic syndrome, Aversa et al showed an improvement in BMD in both lumbar spine and hip with testosterone replacement.[17] Treatment in hypogonadal men causes significant improvement in both hip and lumbar spine BMD, with significant effects on BMD reported after 6 months and an 8-10% increase over 3 years.[4-6,18] Due to the risk of decreased BMD and fractures in untreated hypogonadism, it is advisable to do bone densitometry at baseline (for future results comparison) and every 1-2 years of testosterone replacement.[1,6,8] This enables surveillance regard treatment compliance, and improvement of BMD with treatment, and subsequent appropriate dose adjustment if BMD measurements are unsatisfactory.[18] Other pathologies predisposing to osteopenia and osteoporosis should have been excluded prior to testosterone initiation.[18]

With regards to PSA testing and monitoring in patients older than 40 years, 54% of hypogonadal patients had a documented PSA at baseline prior to treatment. The association between testosterone replacement and prostate pathology is highly controversial.[19] Study by McLaren et al. revealed that continuation of testosterone replacement over a 2 year period did not raise PSA values, with minimal effect on prostate health.[20] However, a meta-analysis of randomized, placebo-controlled trials of 19 studies by Calof et al, deduced that rates of prostate cancer, significant increments in PSA levels and increases in American Urological Association/International Prostate Symptom Score scores were higher in testosterone treated men than the placebo group.[14] However, significant bias was noted in that testosterone treated patients were more likely to undergo prostate screening and biopsy than the placebo group.[14] A critical review by Jannini et al, concluded that whilst prostate cancer is androgen- dependent, no conclusive evidence for

increased prostatic cancer/ hyperplasia is available.[19] Therefore physicians should be cautious and monitor for prostate pathology.[19] The general consensus for screening includes PSA and a digital rectal examination before and during patient follow-up appointments.[1,7,21]

***Figure 8**: Algorithm in androgen deficiency patients*

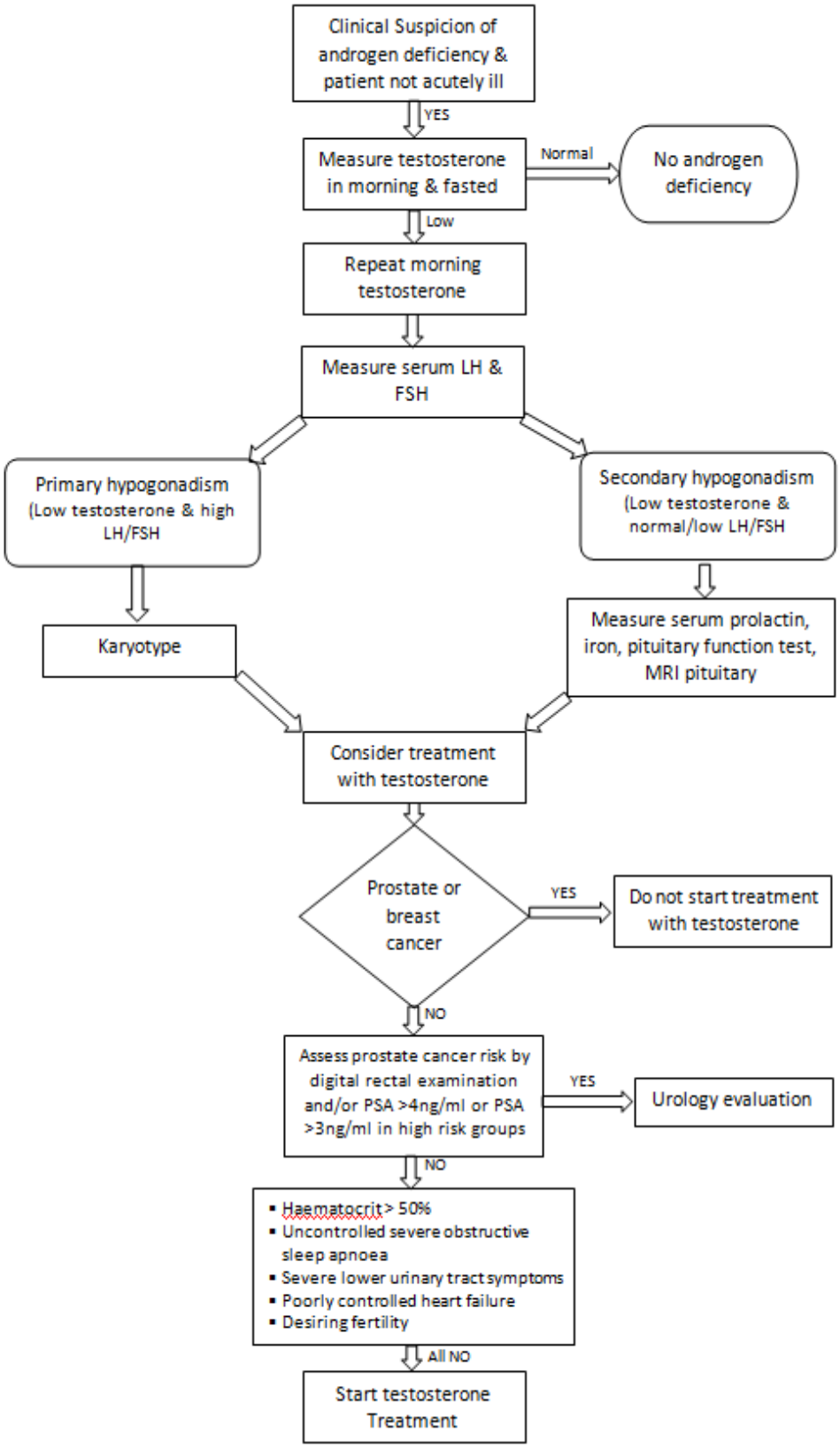
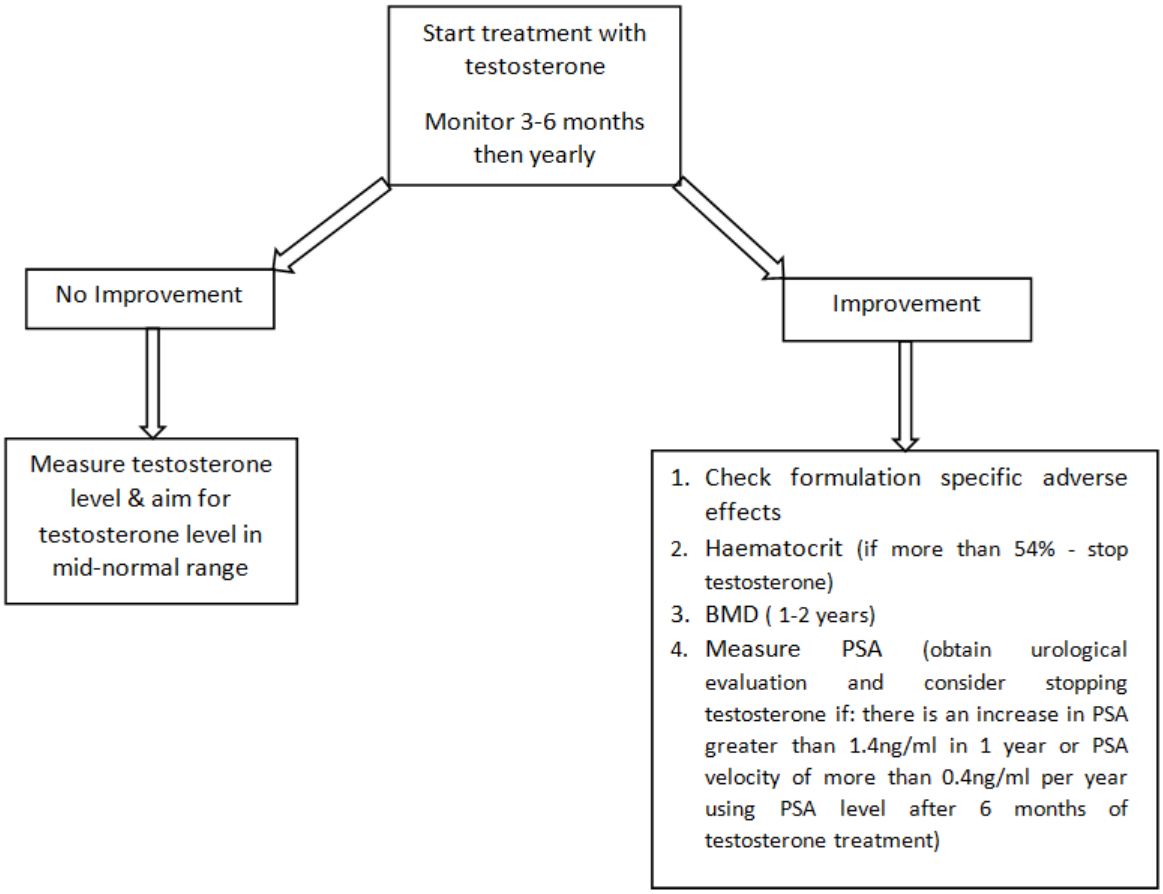


***Figure 9**: Algorithm regarding monitoring after starting testosterone treatment.*



Observations

Areas of good practice:

- Early morning measurement of total testosterone serum levels
- When diagnosing causes of secondary hypogonadism, a full pituitary hormonal profile was requested
- In a significant number of cases of secondary hypogonadism, a form of imaging modality was considered, generally CT or MRI
- No patient who was prescribed testosterone was known to have suffered from breast or prostate cancer.

Areas for improvement:

- Need for improved documentation of the signs and symptoms of hypogonadism
- Need for use of total testosterone testing as a primary diagnostic test, with 2 separate tests serving to confirm hypogonadism
- Karyotyping should be considered in the majority of testosterone deficient patients with primary hypogonadism
- Iron studies should be considered as part of the diagnostic investigations
- Need to take PSA prior to starting treatment in those over 40 years
- Need for shortened follow-up intervals following treatment intervention
- Need for improved documentation of patient symptom alleviation and treatment side effects on monitoring
- Need to perform BMD in all patients prior to starting treatment and follow up accordingly.
- Option to analyse steroids by liquid chromatography and mass spectrometry
- Need to have male normative BMD values for males

Recommendations

This analysis identified the need for documentation of the signs and symptoms and also to repeat testosterone levels prior to starting

treatment. It also identified the need for karyotyping in patients with primary hypogonadism. The results also show the need to measure BMD and PSA before prescribing testosterone. Regarding follow up, this audit recognizes the need for earlier review at 3-6 months with proper documentation of symptoms. Repeat BMD should be done at 1-2 years after treatment initiation. Figure 8 and 9 are two algorithms which one can use when considering testosterone treatment in patients with androgen deficiency. Finally, patients best served by review in a specialist clinic not in the community.

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Original Article

Patient Experience of Primary Health Care in Malta: A Quantitative Study

Jacob Vella, Liberato Camilleri, Philip Sciortino

Abstract

Background: Patient experience is an important factor in needs assessment in primary care provision.

Aim: The aim of the study was to assess patient experience of the Maltese primary health care (PC) and compare the public with the private sector.

Design and Setting: A quantitative, cross-sectional (observational) retrospective study was carried out. 240 participants were randomly selected from all 3 Maltese primary care department catchment areas. Participants were allocated into two equal groups: public and private groups according to their PC provider sector.

Method: Data was collected via telephone interviews using the Primary Care Assessment Tool (PCAT). PCAT computes 2 summative scores: the primary care score (PCS) and primary care extended score (PCES) with maximum score of 32 and 44, respectively. An adjustment model infered predictors of higher quality primary care.

Results: Overall (*n=240*), PCS and PCES registered 23.15 (72.34%) and 30.54 (69.40%), respectively, with a slight significant intersectoral difference in mean PCS with the public sector scoring the highest score (23.15 vs 22.99, *p=0.045*). No overall statistical difference is registered for the overall PCES. Better perceived health and the public care sector were the most significant predictors of better primary care scores.

Conclusion: The public sector scored higher than the private sector in patient-reported primary care experience. The most significant predictor of a higher score was good perceived health followed by having the public sector as main primary care provider. Both sectors equally showed low sensitivity to the cultural and cultural dimensions of primary care.

Further research, improved continuity of care and comprehensiveness of services would further improve the experience of the patient in a better coordinated system.

Keywords

primary care, primary care assessment tool, patient experience, patient satisfaction

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Introduction

Primary health care is the first level of care and most individuals in Europe satisfy their health needs with its services.[1]

Primary care (PC) in Malta is a dual system between the public and the private sector.[2] The public sector is run through walk in, 24-hour health centres.[2] The private sector is mostly offered by solo family doctors through community pharmacies or own clinics with varying services and availability.[2]

The aim of the study was to compare patient experience in both sectors and identify the factors and PC domains which lead to better perceived care through the Primary Care Assessment tool (PCAT).[3]

Methods

Research setting

Experience of primary care was analysed among members of the general public coming from the 3 geographical catchment areas designated by the Department of Health: the North, Central and South regions.[4]

Design and method

A quantitative, cross-sectional (observational) retrospective study was carried out. This format was deemed as mostly fitting the aim of the study that is to provide a picture of the current overall primary care experience in Malta.

Data was collected retrospectively via telephone interviews among participants from the 3 main catchment areas via the English (EN) and Maltese (MT) versions of the Expanded Version of the Adult Primary Care Assessment Tool (AE-PCAT). Participants who verbally consented to participate were given the choice of continuing the structured interview in either English or Maltese.

Research Tool

PCAT was developed[5] and validated[6] by the John Hopkins Primary Care Policy Center and it was concluded that it can be used as a quality measurement tool that assesses the adequacy of primary care experience. Azzopardi translated and validated AE-PCAT in Maltese. [7]

AE-PCAT computes the primary care score (PCS) and the primary care extended score (PCES). PCS, with a maximum score of 32, is summative of 8 core domains while PCES, with a maximum score of 44, includes an additional 3 derivative domains. The domains are the following:

Core Domains (8)

A) Extent of affiliation with a Place / Doctor
B) First Contact in terms of Utilisation
C) First Contact care in terms of Access
D) Ongoing Care
E) Coordination of Care
F) Coordination of Information Systems
G) Comprehensiveness of Services Available
H) Comprehensiveness of Services Provided

Derivative Domains (3)

I) Family Centeredness
J) Community Orientation
K) Culturally Competent Care

Study population and sampling

The study population, 240 in total, was randomly selected between June and July 2015 from the 2014 Malta electoral register[8] and stratified according to geographical area, sex, and put into either the public or private sector group (depending on their main primary care prodiver) as follows:

- Public sector *n=120* predominantly/exclusively using public service
  - Northern
  - Central 40 participants / region
  - Southern

- Private sector *n=120* predominantly/exclusively using private service
  - Northern
  - Central 40 participants / region
  - Southern

Individuals under 30 years of age were excluded in order to make sure that participants had enough PC experience and had seen a PC provider for at least 3 episodes of care. Gozo was also excluded.

Sample size was calculated via an online sample size estimator[9] based on differences of 2 reference intersectoral proportions for primary care experience from the 2008 National Health Interview Survey (NHIS).[10] A minimum of 100 participants per group were estimated to be needed to guarantee a satisfactory margin of error, assuming a 95% confidence level. Augmenting the sample size to 120 participants per group increased statistical power of the tests.

Ethical considerations and approval

Permission from authors to utilise the Maltese and English versions of the AE-PCAT was kindly granted by both.

The study was approved from the University Research Ethics Committee (UREC).

Verbal informed consent, anonymity and withdrawal at any time from the study were incorporated in the tool by its original author (Starfield et al., 2005) so that all potential participants are clearly informed of their rights.

Data Analysis

Raw data collection and descriptive statistics

were computed using Microsoft® Excel® while the Statistical Package for Social Sciences® (SPSS®) was used for inferential statistics.

Both overall PCS and PCES scores manifested right-skewed distribution and both the Kolmogorow-Smirnov and Shapiro-Wilk tests yielded p-values less than *0.001* indicating non-normal distributions. The Mann-Whitney U test was used to compare mean PCS and PCES scores between public and private sectors, where a *0.05* level of significance was adopted.

To accommodate the right skewed distribution of PCS and PCES, two generalised linear models (GLMs) were fitted to relate PCS and PCES to ten predictors which included geographical area, PC sector, sex, perceived health, chronic illness, employment status and sector, education level, number of breadwinners and age. Both models assumed a Gamma distribution and an identity link function.

Results

The overall reponse rate was 80% (*n=240*) with 55.4% female participants. Participant age ranged from 30 to 89 years and the overall mean age was 56 ± 16.3 years. There were no significant intersectorial differences for both sex and age.

Figures 1 and 2 show regional and national mean PCS and PCES, respectively, with univariate testing for significant differences between mean scores of both sectors . Overall (*n=240*), PCS scored higher as percentage of the full score when compared to PCES in all regions; overall mean PCS score was 72.34% (23 out of 32) while PCES scored lower with a mean of 69.48% (31 out of 44). Similar discrepancies were seen regionally.

Figure 1*: Mean Primary Care Scores (PCS). Maximum score for PCS is 32. Column length represents percentage score from the respective group. Overall (n=240) scores are represented in a darker shade. Statistically significant intersectoral p-values are in bold.*

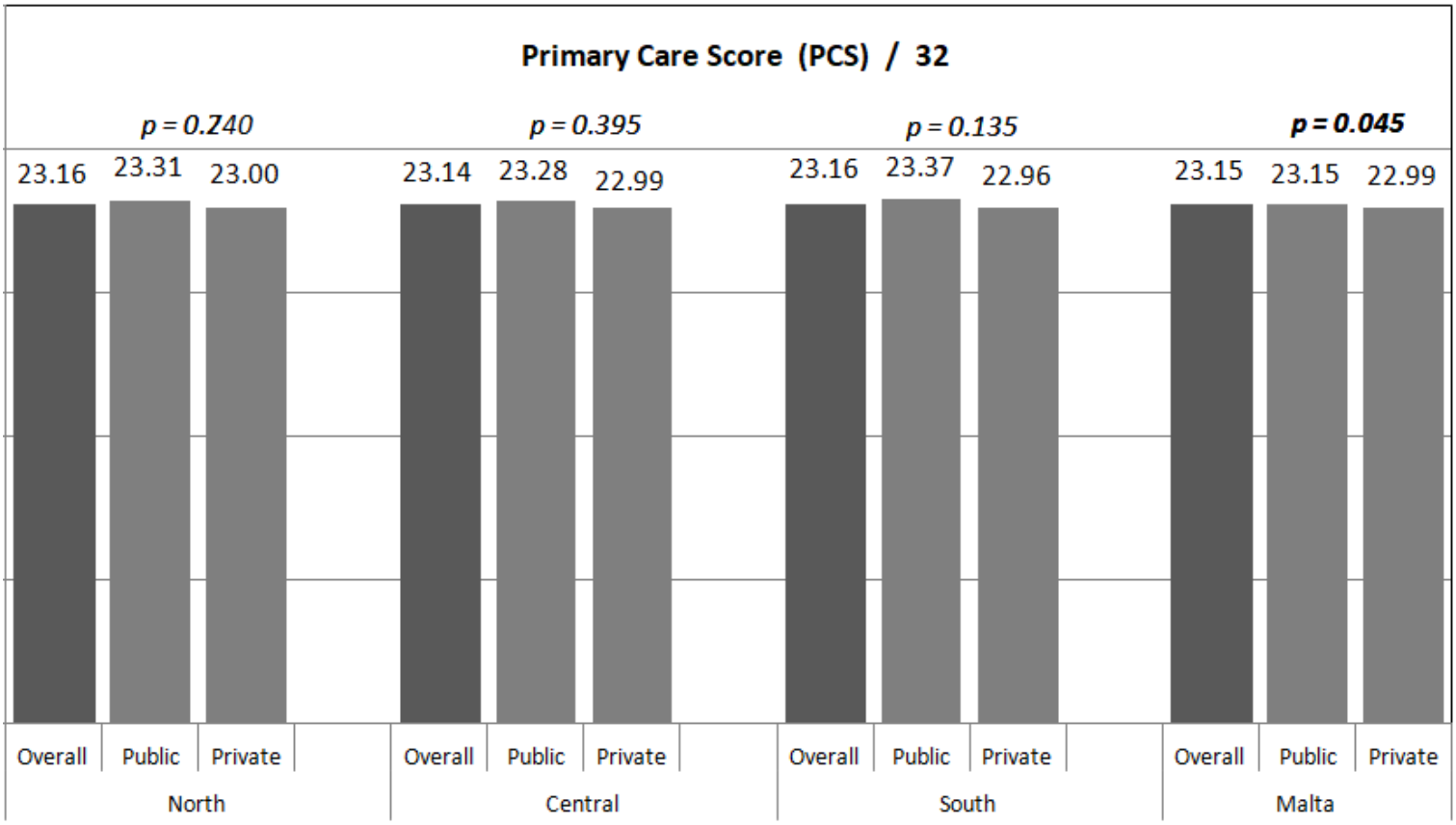

Figure 2: *Mean Primary Care Extended Scores (PCES). Maximum score for PCES is 44. Column length represents percentage score from the respective group. Overall (n=240) scores are represented in a darker shade.*

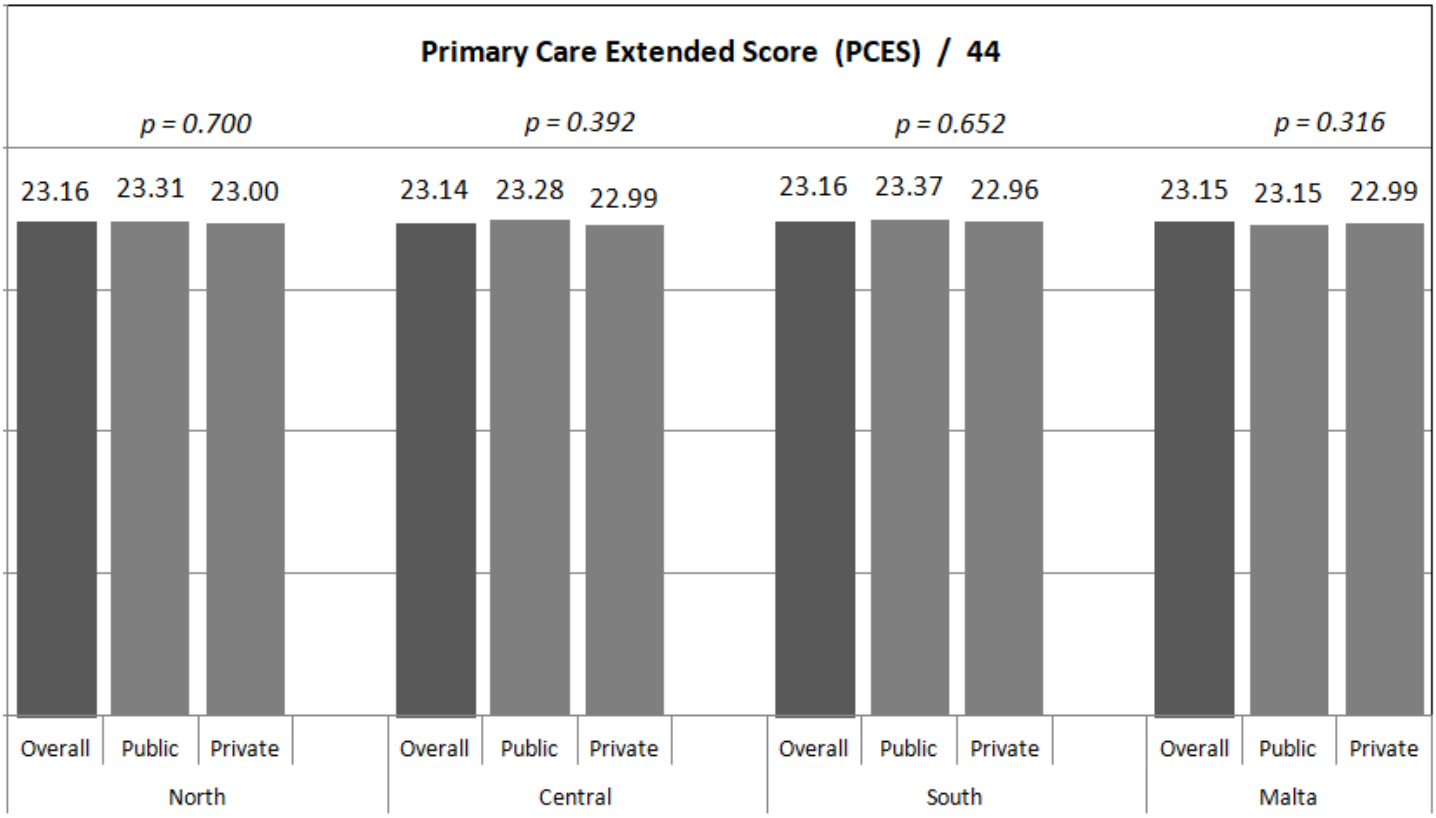

Table 1*: The test of model effects relating the national (n=240) Primary Care Score (PCS) to 10 demographic and socioeconomic predictors. Predictors are arranged in order of significance and statistically significant ones and their respective P-values are in bold for both initial and parsimonious models*

	Tests of Model Effects (Gamma distribution)		**Parsimonious model**	
Predictors	**Chi-Square**	**df**	***P*-value**	***P*-Value**
Intercept	*1885.361*	*1*	*0.000*	
Perceived Health	7.459	2	**0.024**	**0.040**
Primary Care Sector	3.782	1	*0.052*	***0.015***
Age	0.557	1	0.456	
Chronic Illness	0.349	1	0.555	
Employment Sector	3.771	5	0.583	
Employment Status	1.423	3	0.700	
Sex	0.068	1	0.795	
Education	0.618	3	0.892	
Geographical Area	0.400	2	0.819	
Breadwinners	0.145	2	0.930	

***Table 2**: Parameter estimates for the mean national (n=240) Primary Care Score (PCS) for perceived health and sector predictors identified as significant in the parsimonious model.*

Predictor	Parameter Estimates	Hypothesis Test	
		Chi-Square	P-value
Intercept	22.519	15622.262	0.000
Primary Care Sector (Public)	0.399	5.921	0.015
Primary Care Sector (Private)	0	.	.
Perceived Health (Excellent)	0.722	10.488	0.001
Perceived Health (Good)	0.478	5.929	0.015
Perceived Health (Poor)	0	.	.

Both unadjusted PCS and PCES registered similar results in all regions leading to insignificant differences between the public and private sector. However, when summating all regions together (*n=240*) PCS registered a statistical difference (*p=0.045*) with the public sector having the higher (23.15 vs 22.99) mean score. No overall statistical intersectoral difference was registered for the overall mean PCES.

Table 1 shows the results of the tests of model effects, where the 10-predictor model yielded one significant predictor of PCS. However, by using a backward procedure, the parsimonious model identified two significant predictors of PCS, which included perceived health (*p=0.004*) and PC sector (*p=0.015*).

Table 2 shows the parameter estimates and their corresponding p-values. The mean PCS for the public PC provider was 0.399 higher compared to the private counterpart and the difference was significant (*p=0.015*). Similarly, the mean PCS for an excellent and good perceived health rating were respectively 0.722 and 0.478 higher than a poor perceived health rating and both differences were significant (*p=0.001* and *p=0.015*, respectively).

The generalised linear model relating PCES to the 10 predictors identified no significant predictors.

Discussion

Strengths and limitations

A response rate of 80% indicates good representation of the general population and it can be confidently assumed that results can be generalised to the island of Malta. The researcher attempted to minimise overrepresentation of house wives, unemployed and the elderly by conducting telephone interviews between 1330 and 2100h during weekdays and between 0900 and 2100h during weekends.

The study carried a number of limitations which need to be taken into consideration when interpreting and correlating data.

Recall bias could have both occured in the study. Moreover, most Maltese citizens utlilise both public and private sectors[11] especially due to the absence of a registration system with a PC provider[2]. The interviewers could have been perceived as public service officials leading to considerable Hawthorne effect and desirability bias especially when reporting experience in the public sector.

There might have been an overrepresentation of housewives and elderly who invariable tend to respond to telephone calls since they would not be at home and the latter might also be less pressed for time. Mainly due to time and resource constraints, the island of Gozo was excluded from this study. No students participated and the study was limited to adults over 30 years of age; this excluded the paediatric and adoloscent populations which make up a considerable proportion of primary care encounters. No foreigners and refugees were included.

There is no data on the details of the primary care provider (PCP), for example the age of the clinician, year of graduation and whether the clinician underwent vocation training.

Summary

Both Primary Care Score (PCS) and Extended Score (PCES) scored similar results in all three regions. However, when combing data from all regions, PCS registered a slight statistical difference with the public sector having the higher mean score. PCES was lower than PCS in all regions and in both sectors with no significant difference in intersectoral and interregional mean score comparisons

Perceived health was the strongest predictor of high PC scores. PC sector was the only other significant predictor – this confirmed the result of unadjusted scores which showed better overall scores in the public sector. The reason behind having excellent or good perceived health as main predictor of a high PCS could be that people who truly are in good health tend to require less encounters with the healthcare system. Additionally, when they do, they would tend to have their demands met and achieve good outcomes with respect to individuals with multiple comorbidities and complex management.[12]

The small dimensions of the Maltese island could be the main factor leading to similar scores in all three regions.

Public sector users registered a slightly higher PCS when compared to private users possibly due to, as also suggested through national data[2], round the clock availability, better documentation and comprehensiveness of services in the public sector. A lack of services provided is one of the challenges in the private sector – most patients are referred to public PCPs or secondary care when it comes to blood investigations, suturing, plaster immobilisation and other services dependent on the availability of equipment. The private sector is mostly run by a solo general practitioner without nursing and reception staff, thus again limiting communication, logistics, and extent of services available.[2]

A low overall PCES suggests that the national PC service needs to address shortcomings in both sectors with regards to sensitivity to the cultural and community dimensions of PC. Despite no mention in local literature about this, it could be that such considerations might improve through the relatively recent introduction of the Specialisation Training Programme in Family Medicine and the concept of the biopsychosocial model of medicine in undergraduate medical education.

Comparison with existing literature

Both mean PC score (PCS) and extended score (PCES) were below 75%, which are in line with results from a European comparative study suggesting relatively weak PC economic conditions, worforce development, continuity of care and comprehensivess in Malta leading to an overall relatively weak score.[13]

Overseas studies vary considerably with regards to national health care systems, methodologies and primary care service structure. Despite similar methodologies, the complex cultural and geographical differences between Malta and other health care systems make any comparison doubtful with regards to validity.

Wong and colleagues compared public and private PCPs in Hong Kong among 1,000 adults using a modified version of the Chinese AE-PCAT via telephone interviews.[14] As most previous local studies[10,15], and contrary to this study, results showed that private PCP patients reported a better experience of primary care. Conclusively though, as in most Maltese adults, most patients in Hong Kong resorted to both public and private sectors and therefore the results might not be reflecting a true difference between both sectors.[14]

The European Health Interview Surveys (EHIS) conducted in Malta[10,15] and a recent study by Pullicino[11] are similar local studies regarding patient experience in primary care. None of them utilised the PCAT questionnaire. The 2002 EHIC showed that 83.1% of public sector patients, compared with 96.1% from the public sector, were satisfied with the care received.[15] The 2008 EHIC showed a lower proportion (78.3%) of public sector patients who were satisfied whereas a similar proportion (96.0%) of private sector patients expressed satisfaction of care experienced.[10] Similarly to this study, Pullicino, who interviewed 624 patients in 2014, found no significant intersectioral difference in patient experience.[11]

A steady improvement in the public sector, especially from the start of this decade, can be observed. Currently, the public and private sectors seem to equilibrate in terms of overall perceived quality.

Implications for research and practice

This study, when compared to other studies, showed a steady trend of improvement in the public sector. Despite the relatively good primary care

scores (PCS and PCES) in both sectors there are still large lacunae which are deterring holistic and appropriate primary care. It is therefore of no revelation that most adults resort to both sectors since none of them offer what patients expect.

Indeed the Maltese 2014 – 2020 National Health Systems Strategy (NHSS) is the document encompassing the ongoing health system reform in Malta.[15] The study goes in line with what the authorities are trying to foster, that is having primary care as the foundation for better health, increase trust in the public primary care system, having the family doctor acting as gatekeeper for secondary and tertiary care, and better communication between primary and acute care.[16]

The same document mentions the development of appropriate legal and regulatory framework to encourage the setting up of more group practices with financial and other incentives to support capital and other investments in the private sector.

The NHSS also mentions that patients will be encouraged to be affiliated with a regular primary care provider although there is no mention of how this will be implemented.[16]

Conclusion

The public sector scored higher than the private sector in patient-reported primary care experience. The most significant predictor of a higher score was good perceived health followed by having the public sector as main primary care provider. Both sectors equally showed low sensitivity to the cultural and cultural dimensions of primary care.

Further research, improved continuity of care and comprehensiveness of services would further improve the experience of the patient in a better coordinated system.

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Original Article

Ankle X-ray Use at Mater Dei's Accident and Emergency Department

Janice Abela, Sarah Cuschieri, Stephan Grech

Abstracts

Aim**:** To determine the amount of X-rays performed at the Accident and Emergency Department (A&E) at Mater Dei Hospital to investigate ankle injuries.

Objectives: A comparison between the X-ray report and the examining physician's request was also performed. The audit will propose the possibility of implementing a standard protocol of care for ankle injuries namely, based upon the Ottawa Ankle Rules.

Methods: A retrospective observational study was carried out between the 20th September and the 20th December 2015. All ankle X-rays performed at A&E during this period were analysed using the Picture and Archiving System (PACS).

Results: The commonest reason for requesting an X-ray following a traumatic event was to identify the presence of a fracture. Only 27.8% of these X-ray reports identified a fracture. X-rays were also requested for non-traumatic injuries very often due to swelling. Physicians' requests often contained minimal clinical details but only one request had no details whatsoever.

Conclusion: Ankle X-rays were most commonly performed to identify a fracture but very often no fracture was identified. Fractures were a relatively uncommon finding raising the possibility of inappropriate prescription of X-rays. Use of guidelines or an alternative investigation could be beneficial in order to reduce inappropriate radiography usage. Appropriately filled in request forms including clinical presentation would help the communication between the physician and the radiologist.

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Introduction

Ankle injuries are amongst the commonest encounters at the Accident and Emergency (A&E) department. The World Health Organisation estimates the use of radiation to amount to a total of 3.6 billion medical investigations such as X-rays, per year.[1] The use of ionising radiation, even if in small doses, may predispose to an increased risk of developing a malignant tumour. Age, gender, type of X-ray and area of the body being investigated affects the amount of radiation one is exposed to.[2]

In 2016, 15% of 117 million patients in the United States of America who presented to A&E had an ankle injury[3]. Most studies highlighted the fact that ankle injuries are very often associated with X-ray exposure.[4] Borg M. et al confirm that in 2008 in Malta, 95% of the patients who registered at St Luke's hospital A&E department for an ankle injury, were then exposed to an X-ray investigation.[5] This brings forward the importance of establishing guidelines to aid physicians in deciding when an X-ray needs to be requested. The latter is especially important to distinguish between bony and isolated soft tissue injuries.[3]

The development of the Ottawa Ankle Rules (OARs) by Stiell et al. helped clinicians to determine whether an X-ray investigation was required or not.[6] The latest version of the OARs state that an X-ray investigation should be requested by a physician if specific criteria are met.[6] As seen in Figure 1, bony tenderness elicited at specific

points around the ankle or foot confirms the need for an X-ray investigation. The OARs are known on an international basis since Silviera P.C. et al state that in the United Kingdom, United States of America and Canada, approximately 90% of emergency physicians are aware of the OARs.[7]

The aim of this audit was to establish the number of ankle/ankle-foot x-rays requested which proved to be beneficial. The study was carried out over a period of three months. The objectives included;

- To compare the radiologist report against the request put forward by the examining physician
- To verify the need of a protocol involving guidelines such as the Ottawa Ankle Rules
- Discuss other means on how to identify ankle fractures

Methods

This audit is a retrospective observational study carried out between the September 20th and the December 20th, 2015 at Mater Dei Hospital A&E Department.

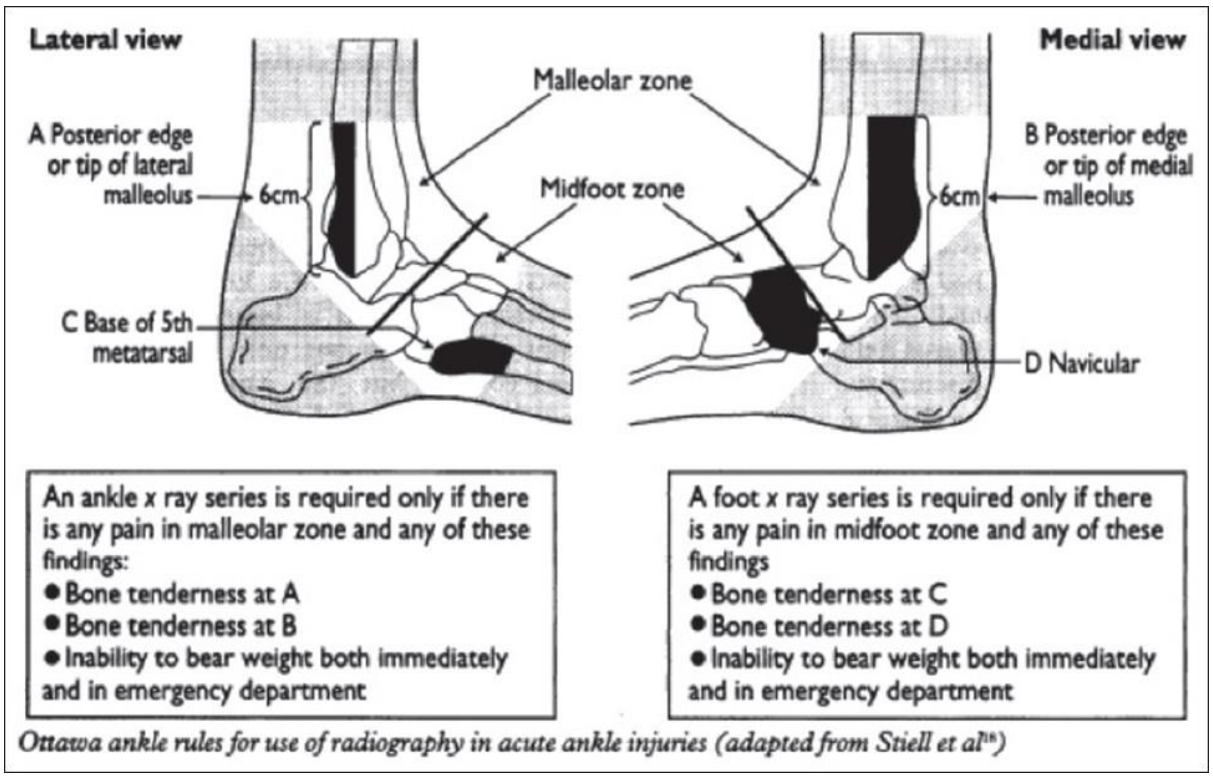
Inclusion and Exclusion Criteria

The minimum age chosen was 12 years and ages ranged up to 103 years. The cut off point of 12 years was chosen since bone ossification of the tibia, fibula and talus would have started by that age.[8] All ankle/ankle-foot X-rays requested by A&E physicians during the study period were included during data collection. All imaging records chosen were requested at the A&E department of Mater Dei hospital by physicians working in the different areas of the department including the Minor Care Clinic. Any radiological examination which had not been reported by a radiologist was excluded but records with incomplete information provided by the examining physician (e.g. no clinical examination details), were still included.

Data Collection and Analysis

Data was recorded on an excel sheet including the date, the different X-ray views performed (ankle/ankle-foot X-ray), age of patient, gender, reason for an X-ray request/clinical finding and the report provided by the radiologist. No identifiable data was recorded. Data was then analysed using the IBM SPSS statistics software (version 24). Statistical tests carried out were the chi-squared test where a p-value of <0.05 was considered as significant and the independent t-test.

Figure 1: *Description of the Ottawa Ankle Rules.*[6]



Ottawa ankle rules for use of radiography in acute ankle injuries (adapted from Stiell et al[18])

Permissions

Permission was granted by the Chairman (at the time) of the A&E department. Ethical approval was obtained by the University Research Ethics Committee. Data was recorded from the Picture Archiving Communication System (PACS) having been granted permission from the Data Protection Officer of Mater Dei Hospital.

Results

The total number of participants was 615 (male *n*=318, female *n*=297). The mean age for the study population was 45.8 years +/- SD 20.66 years. Figure 2 demonstrates the indication for an X-ray request by A&E physicians following a traumatic mechanism of injury.

The most common request (Figure 2) by the A&E physicians was to assess for the presence or the absence of a fracture in the foot/ankle region. Figure 3 shows the indication for an X-ray request by A&E physicians following a traumatic mechanism of injury by gender. Female population predominates in all mechanisms except in motor vehicle accidents where there is a significant difference between male and female participants (p=0.000). The most common reason for an X-ray for both males and females was to identify the presence of a fracture.

Figure 2: *Indication for X-ray requests following traumatic mechanism of injury*

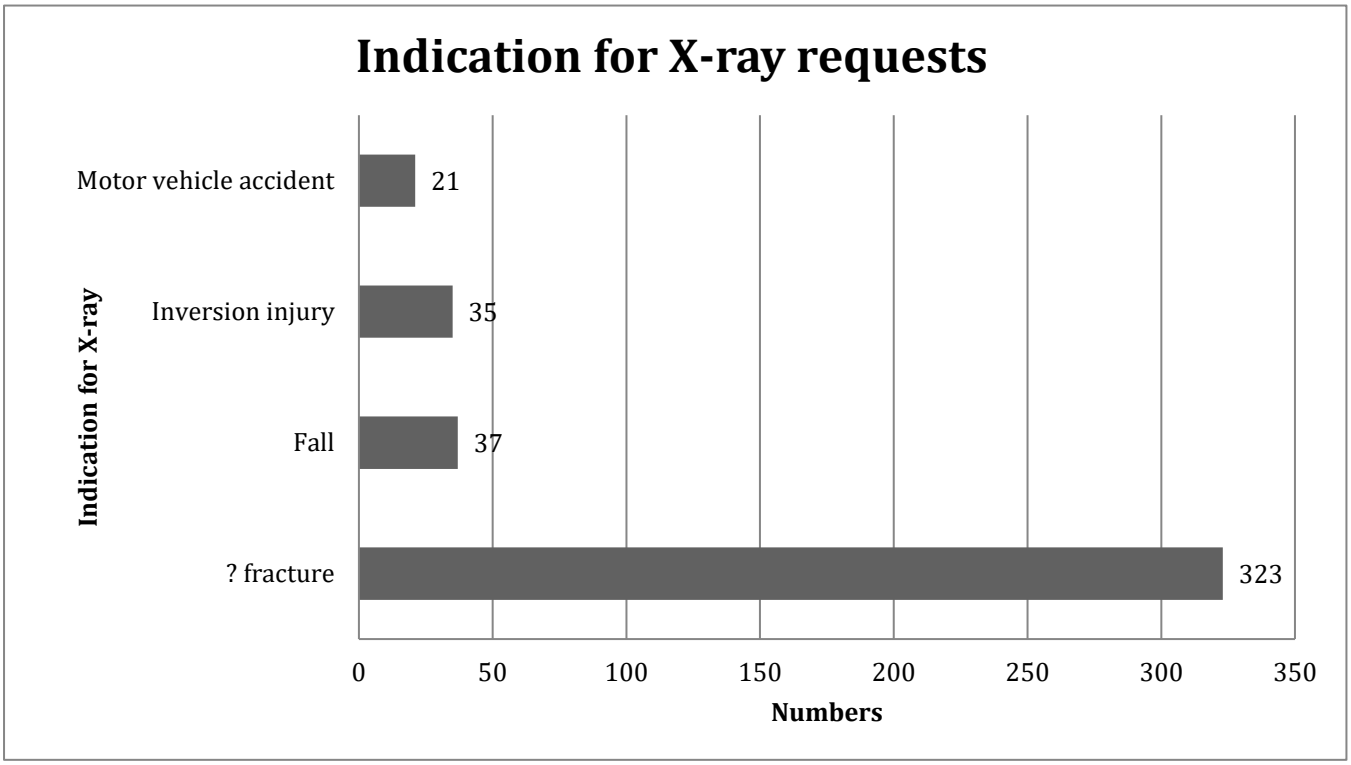


Figure 3: *Indication for X-ray request (mechanism of injury) and number of females and males per request.*

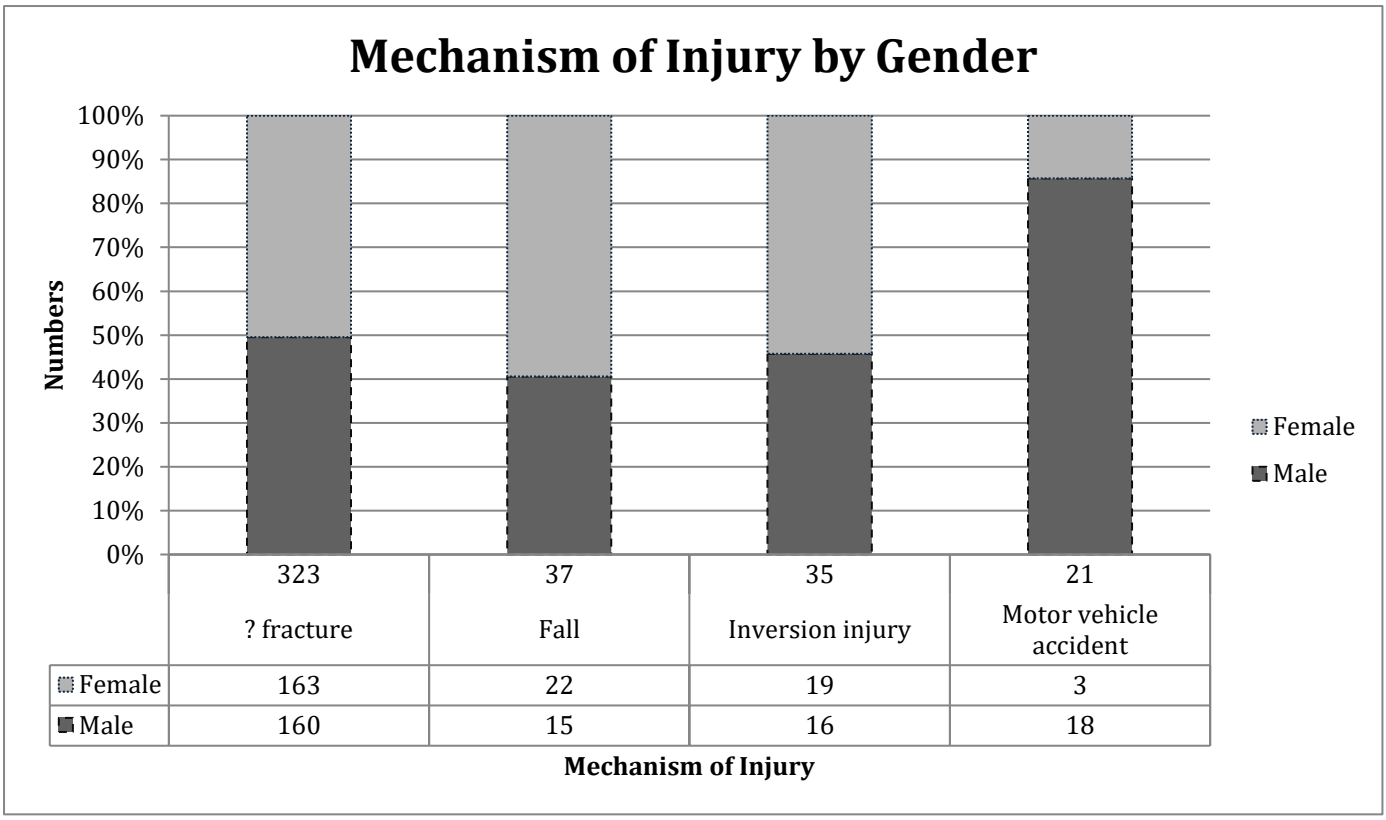


Figure 4: *X-ray requests following non-traumatic events by gender*

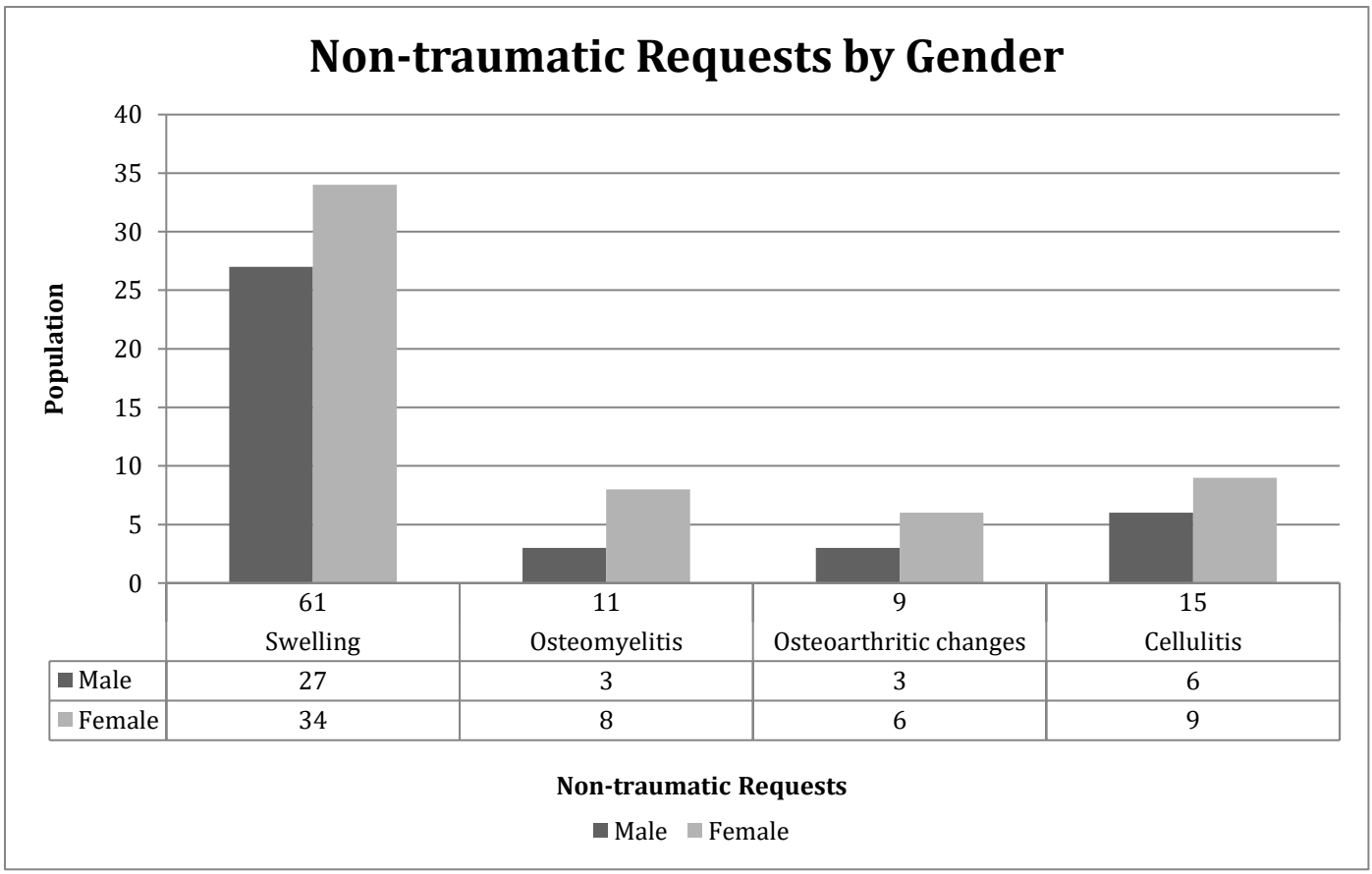
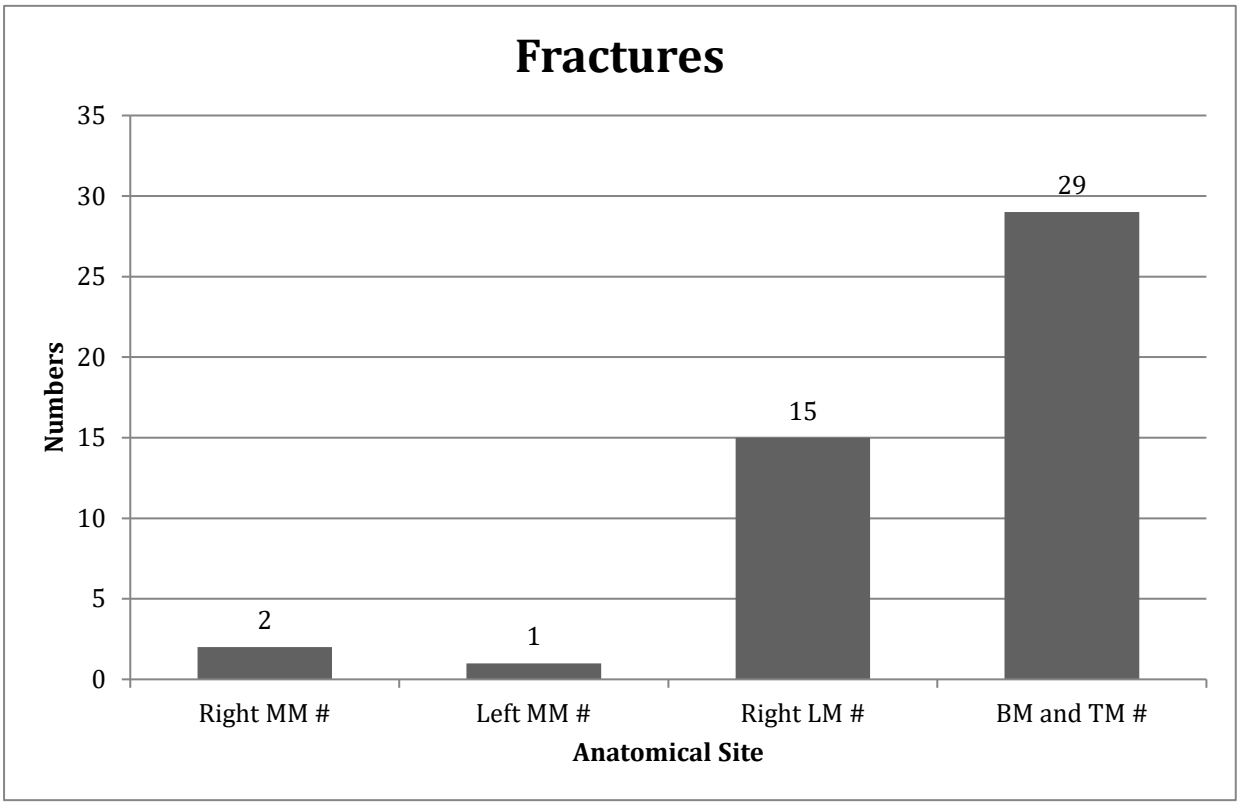


Figure 5: *Demonstrates the percentages of fractures identified by foot-ankle X-rays. MM – Medial Malleolar, LM – Lateral Malleolar, BM – Bimalleolar, TM - Trimalleolar and # - fracture.*



The audit also showed that ankle/ankle-foot X-rays were also requested for reasons which were non-traumatic, as seen in Figure 4. The presence of swelling was the commonest reason to request an X-ray, followed by cellulitis, osteomyelitis and finally osteoarthritic changes. Females predominate in all requests (*p=0.0001 respectively).*

Out of the 323 patients for whom their physician requested an ankle/ankle-foot X-ray, 76.4% did not have any fractures whilst 27.86% of patients were reported to have a fracture. The most common fracture was at the lateral malleolus with 15.7% (Figure 5). 10.5% of patients had a post reduction X-ray in plaster. As seen in Figure 5, the most common fractures occurred were complex fractures (bimalleolar and trimalleolar fractures).
Requests made by physicians were also analysed. It is important to note that age and gender are automatically filled in the request form by the software. These requests ranged from one-word requests ''*trauma, ffh*'' (fall from height) to more detailed requests such as *''57yr old fell from box own height complaining of pain at right ankle. Tender at base of 5th metatarsal and on inversion? #''*. Reports made by radiologists were all filled appropriately and the most common report was *''no #''*. The radiologists also reported back the presence of any incidental findings which may be present e.g. *''calcaneal spurs*''.

Discussion

This study shows that physicians prefer using X-rays in order to confirm their diagnosis especially when they need to rule out the presence of a fracture. Noteworthy was the fact, that during the period of the study, the least X-ray requests were to investigate any fractures following a motor vehicle accident even though statistics show that MVAs were increasing compared to the same period in 2014. This could be due to the fact that a trauma CT scan was requested instead.[9]

In Crosswell et al. 2014, they reported the fracture rates in patients who underwent an ankle/foot/ankle-foot X-ray.[10] They reported that physicians prescribed X-rays partly ro fullfill patients' expectations as well as to ease the patient load. They further state that X-rays are increasingly being used as a means of defensive medicine to avoid potential lawsuits for missed fractures. Crosswell et al. claimed that most X-rays were normal as was the case in our study in which only 27.86% reports confirmed the presence of a fracture.[10]

The use of X-rays can have a negative effect on the body by ionisation of molecules which results in free radical production. This may cause DNA damage and increase the risk of malignant transformation.[11] A proportion of X-rays were performed to supplement a clinical suspicion and this shows that guidelines might need to be implemented in order to help physicians identify situations where an X-ray would really be useful.

A means to avoid X-ray use was proposed by Shojaee M. et al.[12] They recommended the use of ultrasound as an alternative means of identifying ankle fractures. They state that the use of ultrasound is accurate as well as cost-effective and most importantly a means to reduce radiation exposure. In their study, sensitivity amounted to 98.9% whilst specifity was 86.4%. One of the limitations mentioned is the dependency on the operator's skills.[12] Barata et al. stated that ultrasound has high sensitivity and specifity for 'long bone fractures'.[13]

The Ottawa Ankle Rules are an ideal tool when it comes to selecting the right clinical scenarios requiring the use of radiological studies. These guidelines, as stated by Silveira et al.[7], are 'validated' and 'evidence-based' rules. Silviera et al., implemented a software tool which consisted of a questionnaire including the OARs and every physician had to fill this questionnaire on encountering a patient with ankle pain.[7] The questionnaire's score suggested whether an X-ray was needed or not. Following the implementation of this tool, use of OARs increased from 55.9% to 66.7%, clearly showing that physicians found this tool quite useful.[7]

Although most studies highly recommend the OARs, a study carried out by Ashurst J.V. et al. in 2014 contraversed this view.[14] In this study, researchers observed physicians during their encounter with their patient and noted whether a

radiographic investigation was requested or not. The researchers concluded, that even if the physicians involved were aware of the OARs, 58 out of 60 patients would still request an ankle X-ray. It also shows that physicians feel more 'secure' if they have an investigative confirmation on whether a fracture is present or not as physicians still felt uncertain about their clinical diagnosis.

However, since the OARs have a sensitivity of almost 100% and a reasonable specifity, Wang X. et al. in 2013 argued that physicians should rely more on these guidelines.[15] They do however also mention that the OARs can be quite subjective since they depend upon the depth of palpation of the physician as well as the patient's pain tolerance. Eliciting pain during palpation may be both due to bone tenderness as well as soft-tissue injury. Wang et al. clearly state that using the OARs can significantly decrease the use of unecessary X-rays and result in a more cost-effective approach without affecting the quality of healthcare.[15] They also suggest that the OARs should be introduced in developing countries where radiological facilities can be minimal.[15]

Another objective of this audit was to review the physician's X-ray request forms. A study carried out by Salazar L. et al investigated the rate of complete documentation of examination findings on patients with ankle/foot injuries at an emergency department.[16] The OARs were used as a standardised reference point. In this study complete documentation was considered if all components of the OARs were documented. Only 29% were noted to have complete documentation for ankle examination whilst 16% of patients had complete documentation for foot examination. It was also noted that some patients with incomplete documentation still had a radiograph obtained. The researchers concluded from their results that most documentation was incomplete regardless of whether a radiograph was requested or not. The researchers suggest that complete documentation would also be cost-effective apart from ensuring patient safety and avoidance of medico-legal issues.[16]

On comparing our study to the study by Salazar et al., it emerges that the majority of the physicians in Malta did not provide a detailed X-ray request form. As reported, filling the appropriate information would make it more cost-effective. In addition, lack of documentation can lead to disorganised communication, delay in care and also risk of medico-legal issues.[16]

Study Limitations

One of the main limitations is that a small population was used for this audit. This decreases the statistical power of the audit. Reports were limited to the main emergency department in Malta's Mater Dei Hospital only, further limiting the amount of requests which could be evaluated. Another limitation was the paucity of clinical details filled on the request form. This lack of information does not aid the reporting radiologist. It is suggested to repeat the study to assess the validation of X-ray requests. During these three months, a major incident occurred which might have led to an increase in X-ray requests.

Conclusion

This audit shows how common ankle X-rays are used in Malta's main emergency department. Unsurprisingly, the main reason for its use is to identify a fracture. Approximately a quarter of X-rays exhibited the presence of a fracture. This means that a proportion of the patients might have been exposed to X-rays unncessarily. Requests were also made for non-traumatic incidents, the most common request being for swelling. Guidelines such as the OARs could aid physicians when deciding which investigation would be most appropriate for the patient. Details on X-ray requests should be included in order to aid and inform the radiologist about all the clinical findings identified by the physician. Adequate requests would improve communication between the physician and the radiologist.

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Original Article

Management of fever in children under 5 years of age within paediatric emergency department

Nadine Anne De Battista, Valerie Said Conti

Abstract

Objectives: This audit aimed to (1) assess the management of children aged up to 5 years presenting with fever to the Paediatric Emergency Department (PED) at Mater Dei Hospital, and (2) assess the awareness of NICE guidelines on fever management amongst paediatric doctors and nurses.

Method: Data was collected from PED Assessment Sheets in January 2017. An online questionnaire based on the NICE guidelines for fever management in children under 5 years of age was completed by staff working within the Department of Child and Adolescent Health.

Results: 255 children aged up to 5 years presented with fever ≥37.5ºC at the Paediatric Emergency Department in January 2017. 22.7% of children were aged between 24 months up to 3 years. The average time for first medical contact was 51 minutes. 23.9% presented with fever of 1 day duration. Respiratory rate was not recorded in 62% of cases whilst blood pressure was only recorded in 19.1% where applicable. Antipyretics were given in 73.8% of febrile cases despite distress only being documented in 6.8%. NICE guidelines would recommend measurement of respiratory rate as part of routine assessment of children presenting with fever and blood pressure measurement in cases of abnormal heart rate or capillary refill time. Antipyretic use is recommended only in the presence of distress secondary to fever.

Conclusion: More education is required on proper antipyretic use and pre-discharge advice. Routine measurement and documentation of all parameters should be encouraged both on initial assessment and pre-discharge.

Keywords

fever, child, antipyretics, NICE guideline

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Introduction

Fever can be defined as an increase in body temperature above 37.5ºC. It is one of the commonest medical signs, with causes ranging from trivial to potentially life threatening, and usually indicating the presence of an underlying infection in the case of young children. In Malta, almost 50% of children admitted to hospital are less than 5 years of age, and of these 33% have fever with 32% suffering from respiratory tract infections and febrile convulsions.[1]

Fever in young children can be diagnostically challenging when it comes to elucidating the cause

despite overall progress in healthcare in recent years. Although trivial causes account for the majority of cases, potentially serious bacterial infections such as meningitis still need to be ruled out, and infection still remain the leading cause of death in children under 5 years of age. [2] Moreover, a significant number of febrile children have no obvious cause despite detailed assessment, presenting a further challenge to management. All this highlights the need to formulate guidelines in order to assist staff in improving recognition of potentially serious disease and to assist in the treatment of feverish young children.

The presence of fever often leads to widespread use of antipyretics by parents. [3] With parents often administering treatment unilaterally, the importance of advice on fever management from staff cannot be over-emphasised. Studies have shown that only 13% of paediatricians specifically cite child discomfort as a reason to administer antipyretics, with a large percentage administering treatment in an attempt to maintain normothermia. [4] Therefore, awareness of established guidelines on fever management amongst healthcare professionals working with children is of utmost importance in order to ensure proper use of antipyretics and fever management advice to parents.

Objectives

This audit aimed to assess the management of children aged 5 years or less presenting with fever to the Paediatric Emergency Department at Mater Dei Hospital, including the assessment of staff awareness of NICE guidelines on fever management in children in this age group. It specifically aimed to assess:

- Documentation of symptoms accompanying fever if present
- Documentation of parameters (temperature, heart rate, respiratory rate, capillary refill time) on presentation as part of routine assessment of a feverish child and documentation of blood pressure when applicable
- Repetition of parameters pre-discharge
- Types and indications for antipyretics when administered
- Documentation of fever management advice given to parents pre-discharge
- Awareness of NICE guidelines amongst staff working within the Department of Child and Adolescent Health focusing on proper temperature recording, parameter charting, antipyretic use and fever management advice

Guidelines

The guidelines used in this audit were the "NICE Guidelines Fever in Under 5s: Assessment and Initial Management", published in May 2013. Recommendations in this guideline against which the data collected was assessed are shown in Table 1.

Methodology

Permission to access records and carry out this audit was obtained from the Data Protection Unit, the Chairman of the Department of Child and Adolescent Health and from the Director of Nursing and Midwifery Services at Mater Dei Hospital. Data collected for this audit was obtained from two different sources:

A. Paediatric Emergency Department (PED) Assessment Sheets

Paediatric Emergency Department Assessment sheets for January 2017 were obtained from within the ED Records and the required clinical data was extracted and then compared to established NICE guidelines.

A proforma was used and data collected included:

- ID of patient
- Date
- Time of registration
- Time of triage
- Time of first medical contact
- Age
- Gender
- Presenting Complaint(s)
- Duration of fever pre presentation to casualty
- Temperature at presentation
- Heart rate recorded – yes/no
- Oxygen saturation recorded – yes/no

- Respiratory rate recorded – yes/no
- GCS/AVPU recorded – yes/no
- CRT recorded –yes/no
- Blood pressure recorded if abnormal HR/CRT – yes/no/not applicable
- Antipyretics given
- Reason for antipyretics if given
- Repetition of parameters pre-discharge
- Documentation of advice given to parents/carers

Inclusion criteria for data collection included:

- Children up to 5 years of age
- Children presenting with documented fever ≥37.5ºC at home or found to have fever on presentation to casualty
- Children who were discharged home after assessment
- Results for documented parameter charting were obtained solely from doctor assessment sheets. Parameters taken at triage were excluded.

Exclusion criteria for data collection included:

- Children admitted to hospital after initial assessment in casualty
- Children who were registered in the ED but failed to attend when called

B. Questionnaire distributed to staff working within the Department of Child and Adolescent Health at Mater Dei Hospital

An online anonymous questionnaire was sent to 74 doctors and nurses working within the Department of Child and Adolescent Health at Mater Dei Hospital in March 2017.

Questions were aimed to assess practices and awareness of:

- Proper temperature monitoring in children under 5 presenting with fever
- Vital parameters that should be recorded as part of routine assessment for young feverish children
- Scenarios in which blood pressure measurement would be applicable
- Proper administration of antipyretic agents and their indications for use
- Advice that should be given to parents/carers pre-discharge

Results

A. Data Collected from Paediatric Emergency Department Assessment Sheets

A total of 255 children aged up to 5 years who presented with fever ≥37.5ºC documented at home or in casualty were seen at the Paediatric Emergency Department between 1st January 2017 and 31st January 2017. The busiest day was the 7th January with a total of 16 children being assessed with fever, the least busy day being 5th January with only 3 children. 56.1% (143 children) of those assessed were males.

The average time taken for children to be assessed at triage once registered, was 21 minutes (median of 16 minutes, range of 0 waiting time to 1 hour 40 minutes). Time of triage was not documented on 3 triage sheets. The average time for first medical contact once triaged was 51 minutes (median 31 minutes, range 0 waiting time to 4 hours). The time of first medical contact was not recorded in 90 assessment sheets (35.3%).

Figure 1 demonstrates peak times for attendances for the month of January 2017 to the Paediatric Emergency Department. A peak in patient numbers can be seen at 19:00 hours, with the least amount of patients attending during the early morning hours.

The most common age group presenting with fever was children aged between 24 months up to 3 years of age (*n*=58 (22.7%)). The age of the child was not documented in 2 (0.8%) cases and there were no children aged less than 4 weeks.

The most common symptoms associated with fever were cough and upper respiratory tract symptoms (Figure 2).

Table 1: *Recommendations of NICE Guidelines Fever in under 5s: Assessment and Initial Management May 2013*

NICE Guidelines Fever in Under 5s: Assessment and Initial Management May 2013	
	Recommendations
Temperature Monitoring	Oral and rectal routes should NOT be routinely used to measure the body temperature of children aged 0–5 years. In infants under the age of 4 weeks, measurement of body temperature should be carried out with an electronic thermometer in the axilla. In children aged 4 weeks to 5 years, measurement of body temperature should be carried out by one of the following methods: ✓ electronic thermometer in the axilla ✓ chemical dot thermometer in the axilla ✓ infra-red tympanic thermometer.
Parameter Charting	Routine assessment of a child with fever should include measurement and documentation of temperature, heart rate, respiratory rate and capillary refill time Blood pressure should be measured if the heart rate or capillary refill time is abnormal and the facilities to measure blood pressure are available.
Antipyretic Use	Antipyretic agents do not prevent febrile convulsions and should not be used specifically for this purpose. Paracetamol or ibuprofen should be considered in children with fever who appear distressed. Antipyretic agents should NOT be used with the sole aim of reducing body temperature in children with fever. When using antipyretics: ✓ Should be continued only as long as the child appears distressed ✓ Changing to the other agent should be considered if the child's distress is not alleviated ✓ Both agents should NOT be given simultaneously ✓ Alternating these agents should only be considered if the distress persists or recurs before the next dose is due.
Advice Pre-Discharge	Advice to parents or carers looking after a feverish child at home should include: ✓ Offering the child regular fluids (where a baby or child is breastfed the most appropriate fluid is breast milk) ✓ How to detect signs of dehydration, to encourage their child to drink more fluids and consider seeking further advice if they detect signs of dehydration ✓ Warning signs such as a non-blanching rash and when to reseek medical advice ✓ Nursery/school advice

***Figure 1**: Number of children presenting to casualty against time*

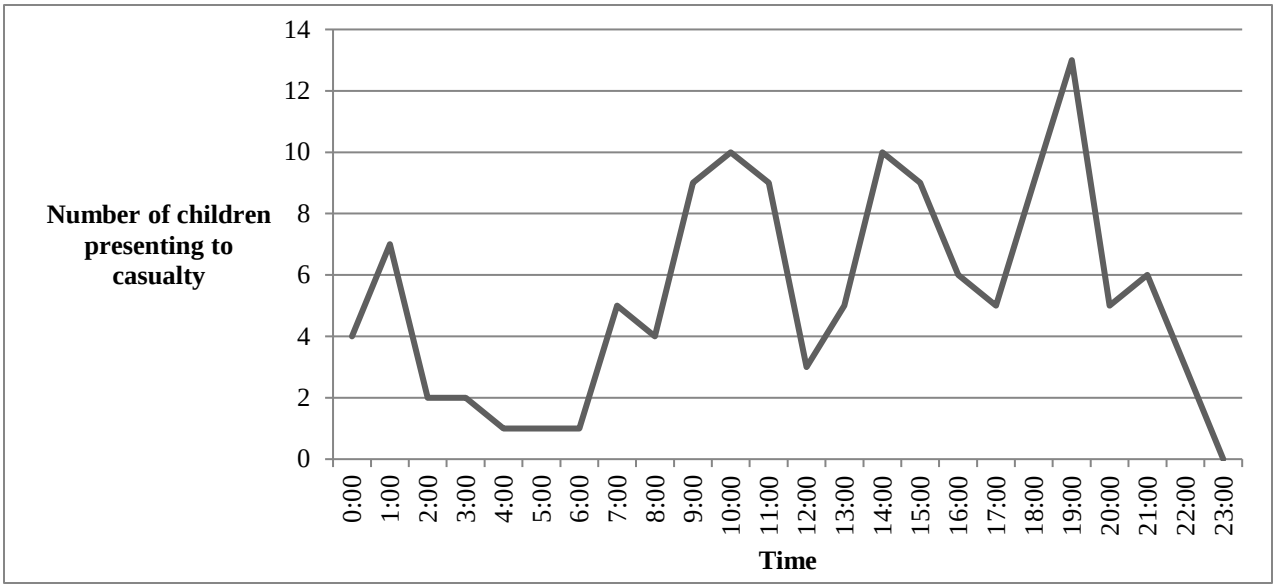
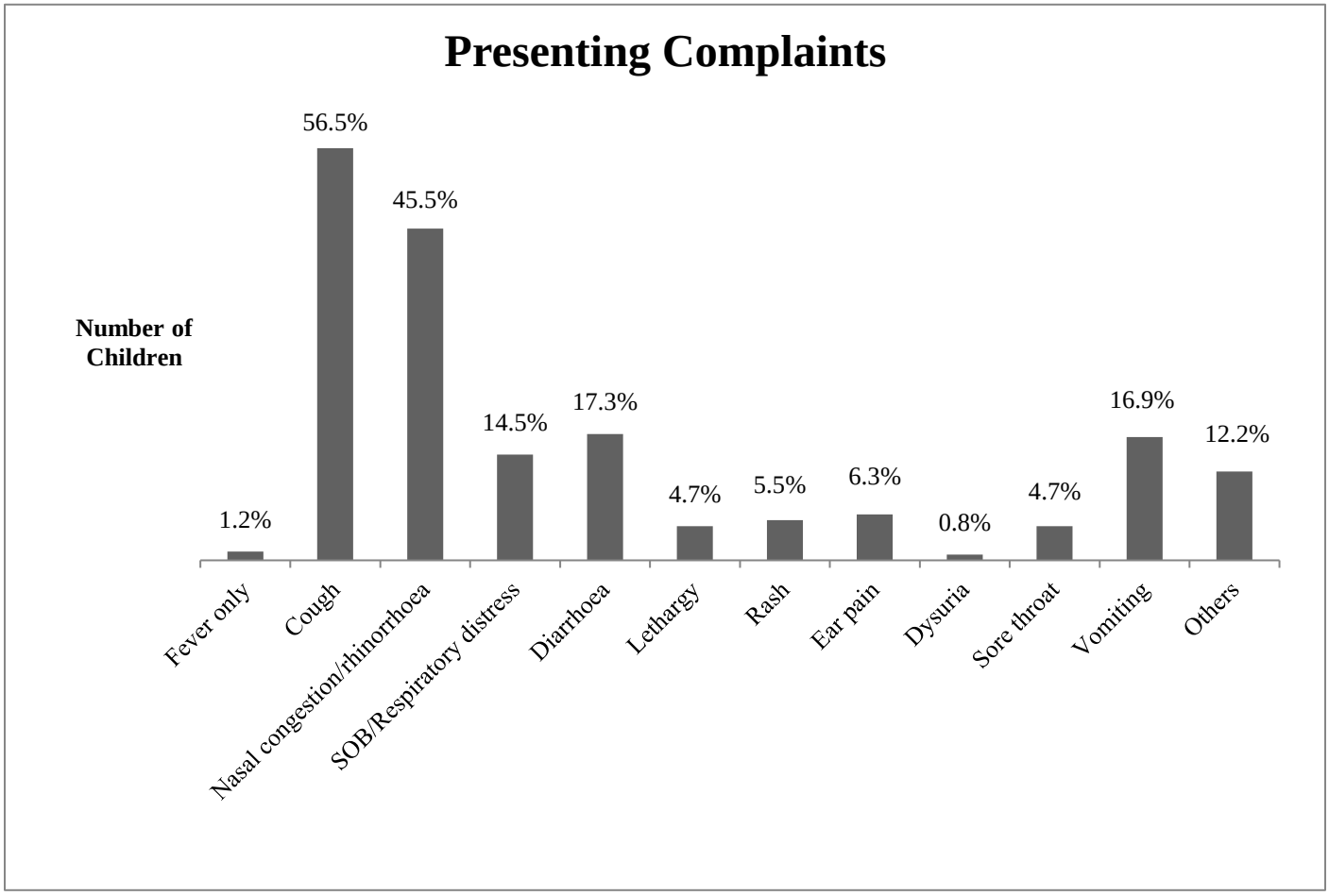


***Figure 2:** Associated symptoms for children presenting with fever to casualty.*



Most children (23.9%) presented with a fever of 1 day duration, followed by 15.3% presenting with fever of 2 hour duration.

45.5% of children presenting to casualty were afebrile on initial assessment. The temperature was not recorded in 1.2% of assessment sheets (Figure 3).

The NICE guidelines stipulate that routine assessment of a child with fever should include measurement and documentation of temperature, heart rate, respiratory rate and capillary refill time together with blood pressure measurement in cases of abnormal heart rate and CRT. Figure 4 shows documentation of these parameters on the doctor assessment sheets analysed in this audit. Figure 5 demonstrates results for blood pressure documentation should be performed in those with an abnormal heart rate and CRT.

Temperature was the parameter most commonly rechecked pre-discharge (67.6%), followed by oxygen saturation (14.1%), heart rate (12.7%) and respiratory rate (9.9%).

Antipyretic use and reasons documented for its administration were also assessed. No antipyretics were administered in casualty in 65.5% of cases (Figure 6) since these children were afebrile. In two cases, it was specifically documented that antipyretics had already been given by the parents/carers at home a few hours before bringing the child for assessment, at which point the next dose of antipyretics was not yet due.

Advice given to parents or carers re warning signs to look out for whilst caring for the child at home was documented in 64.3% of cases. Regular antipyretic use purely for fever control, irrespective of the presence or absence of distress in the child was given in 22% of cases. Parents were advised to administer antipyretics only if the child appeared to be distressed, as per guidelines, in just 6.7% of cases. Fluids were only encouraged in 14.9% (Figure 8).

Figure 3: *Duration of fever before presentation for doctor assessment*

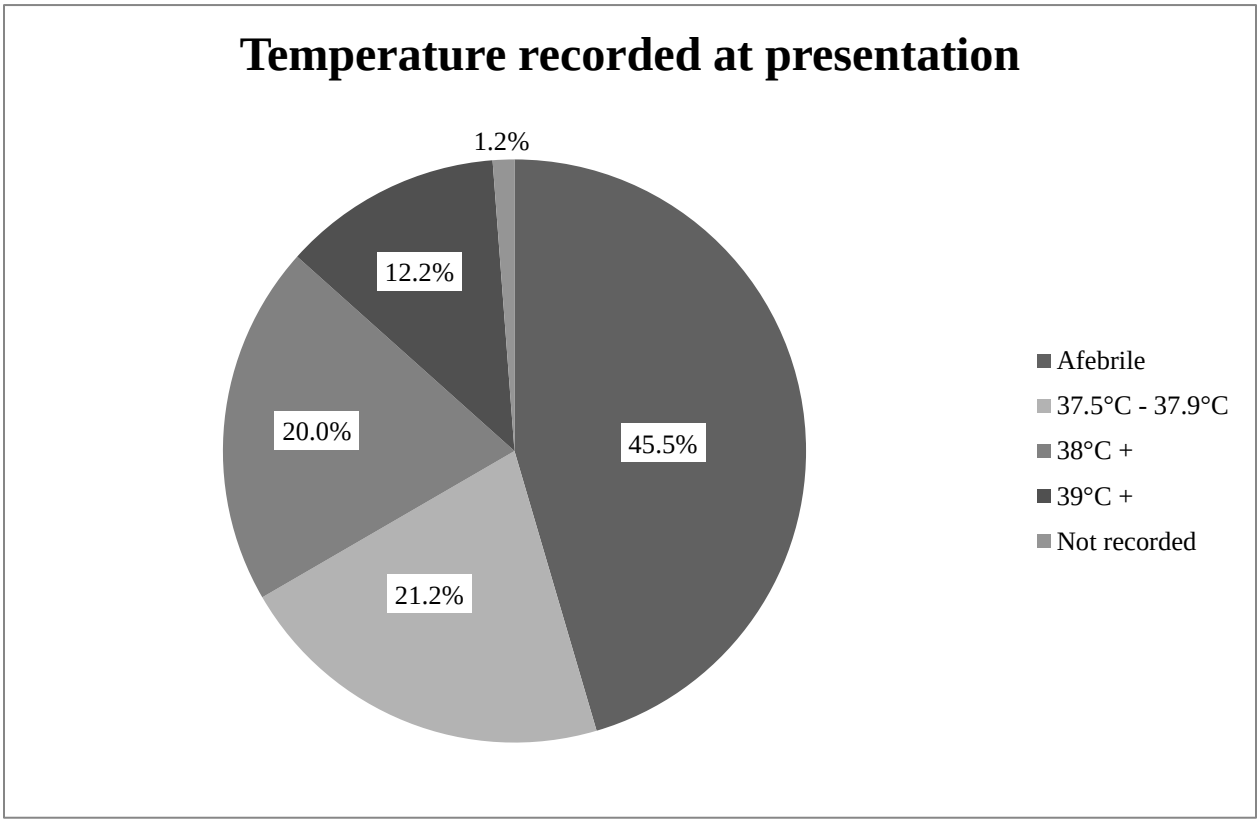


Figure 4: ***P****arameters recorded by doctors on initial assessment*

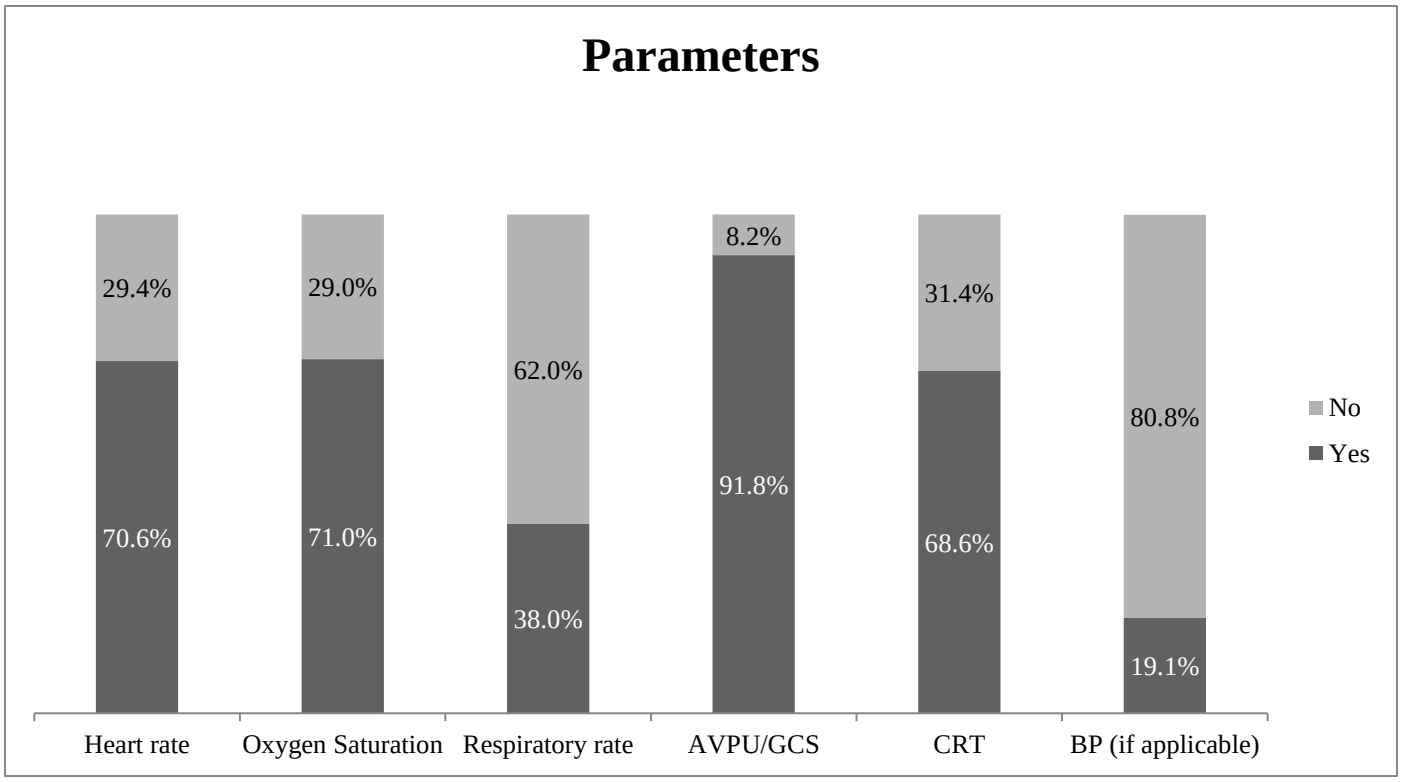


Figure 5*: Blood pressure measurement and documentation*

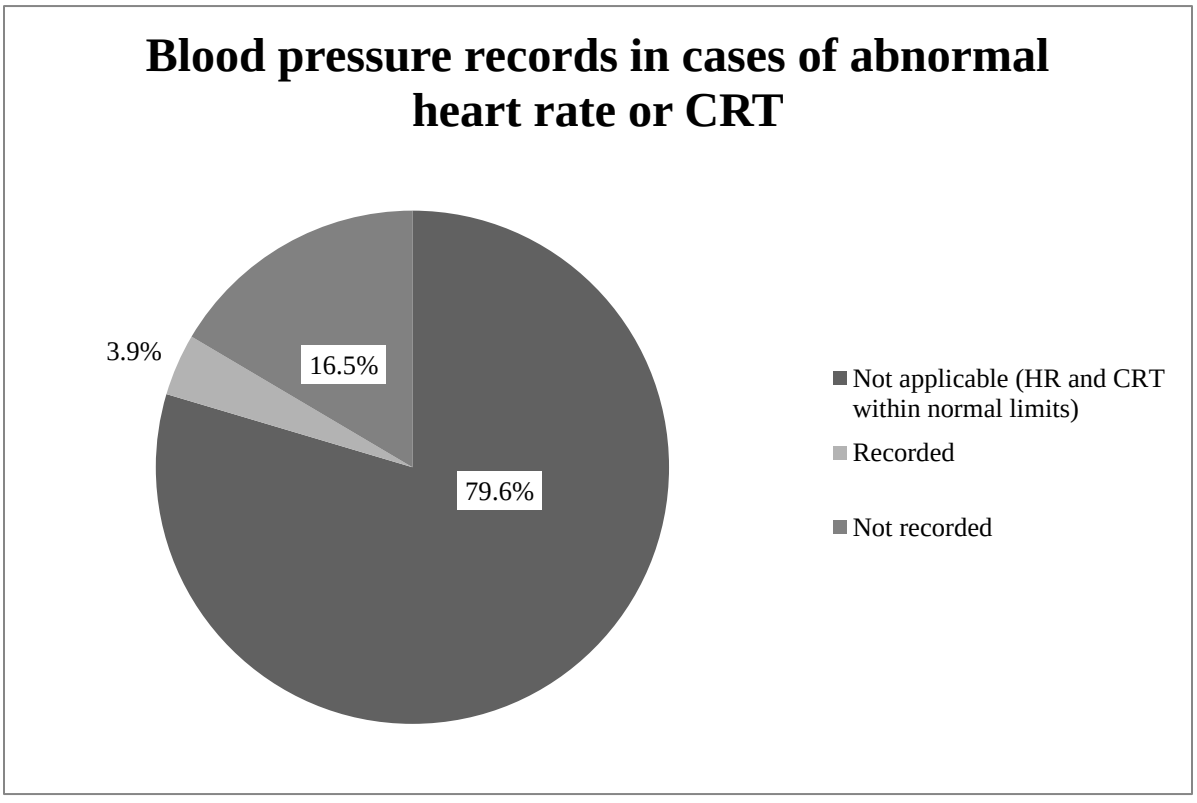


***Figure 6**: Antipyretic use within the Paediatric Emergency Department*

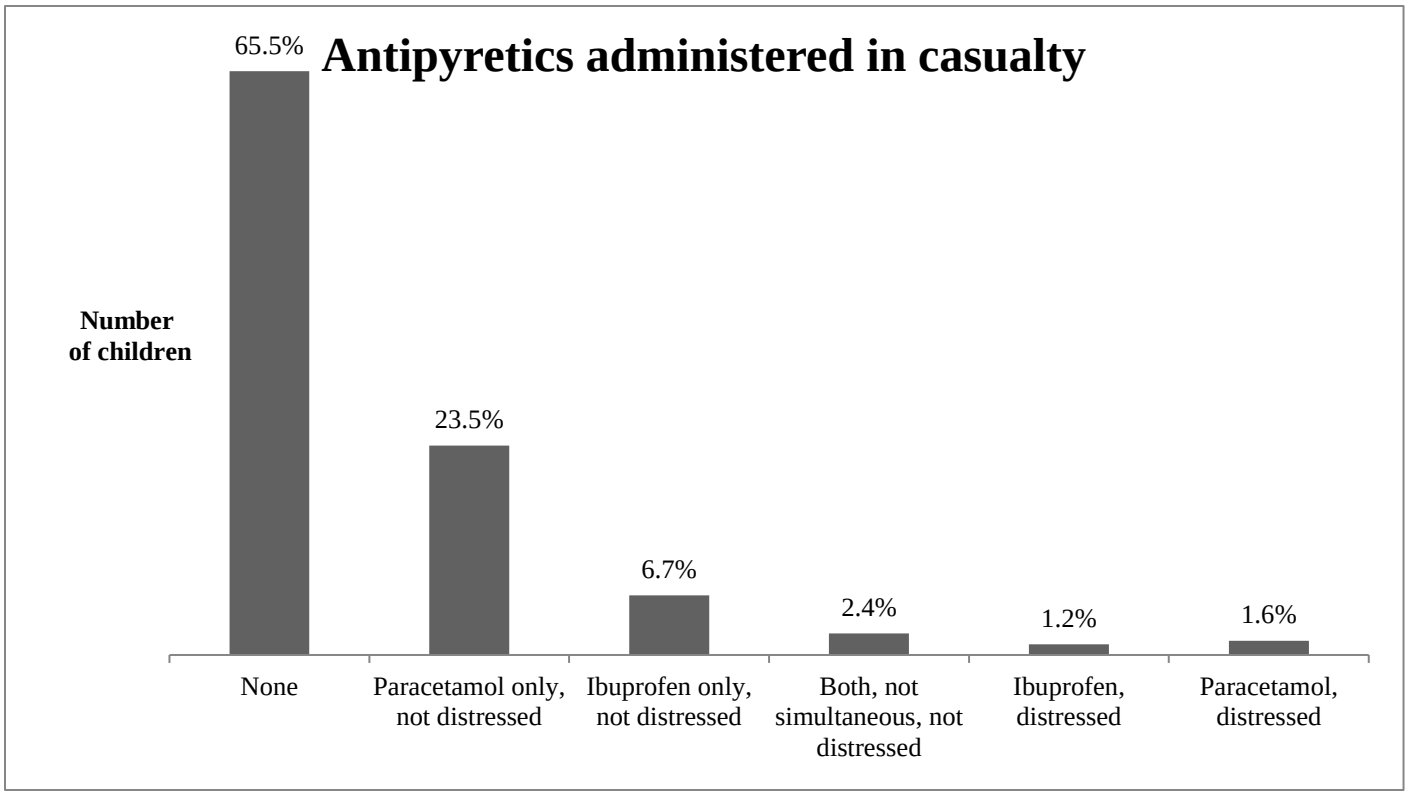


***Figure 7:** Reasons for antipyretic use*

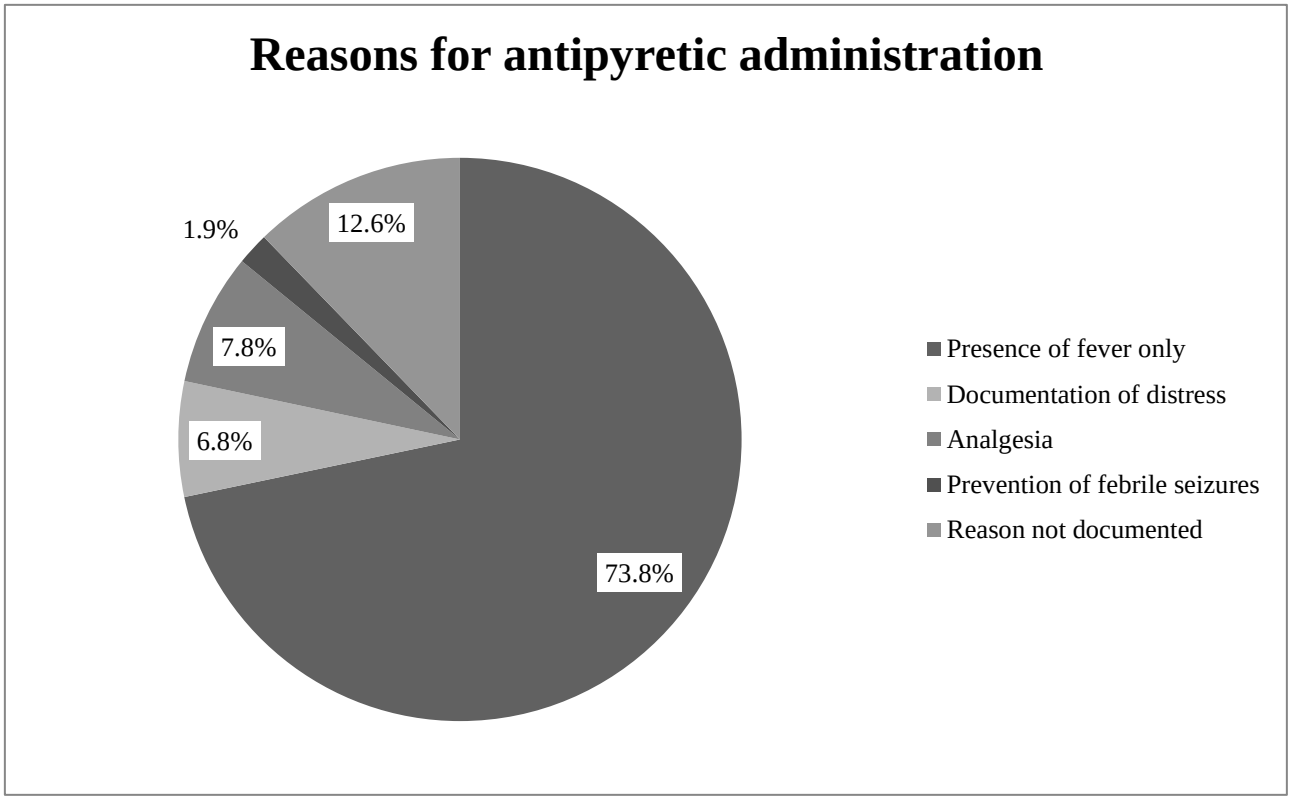
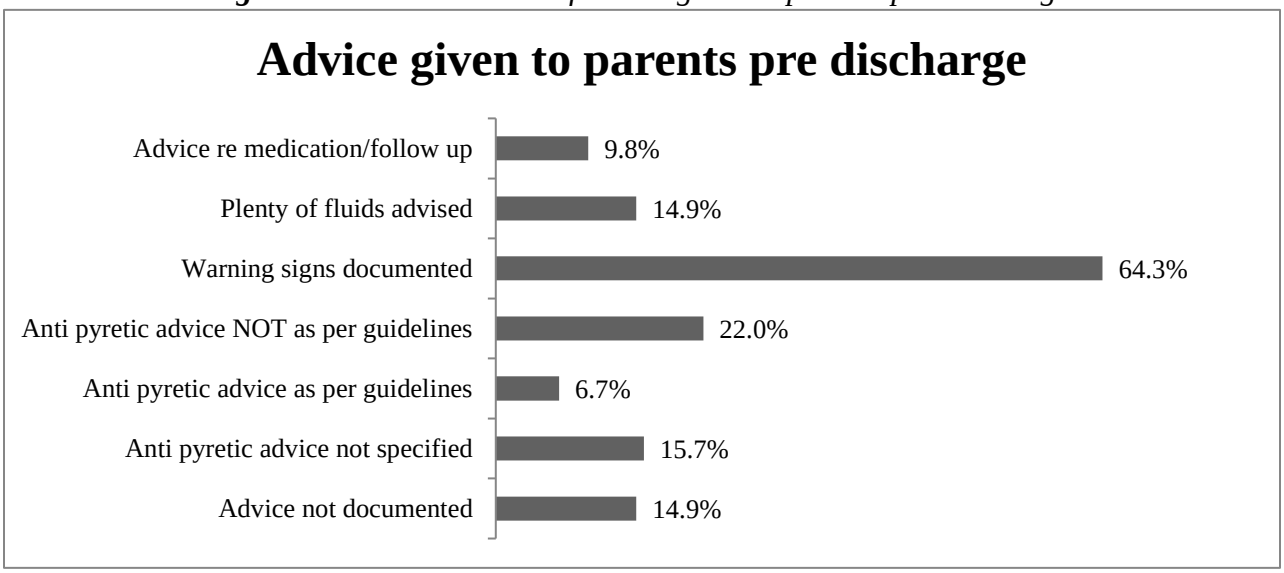


Figure 8: *Documentation of advice given to parents pre-discharge*



B. Data collected from questionnaires distributed to doctors and nurses working within the Department of Child and Adolescent Health at Mater Dei Hospital

An online questionnaire was distributed to 74 doctors and nurses working within the Department of Child and Adolescent Health at Mater Dei Hospital. 40 staff members participated in the study (10 consultants, 3 resident specialists, 6 HSTs, 6 BSTs, 7 foundation doctors and 8 paediatric nurses) giving a response rate of 54%. They were questioned regarding methods of temperature measurement, vital parameters routinely monitored in a feverish child, indications for antipyretics and advice for home care pre-discharge.

97.5% (*n*=39) of participants correctly identified the axilla as an appropriate route of temperature measurement in children under 5 years of age. Correct choice of thermometer type (electronic thermometer) was also identified by the majority of participants for the different age groups (83% for infants less than 4 weeks of age and 90% for infants between 4 weeks up to 5 years).

Heart rate (97.5%, *n*=39) was identified as a routine vital parameter that should be measured in a feverish child, followed by temperature (87.5%, *n*=35) and respiratory rate (77.5%, *n*=31). Capillary refill time was only mentioned by 37.5% (*n*=15) of respondents followed by blood pressure monitoring (22.5%, *n*=9). 72.5% (*n*=29) identified abnormal CRT as an indication for blood pressure measurement, followed by 65% (*n*=26) for abnormal heart rate.

72.5% (*n*=29) identified distress secondary to fever as the only indication for antipyretic use, whilst 5% (*n*=2)opted for antipyretic administration as long as fever beyond 38°C is present and another 5% irrespective of temperature grade.

Use of multiple antipyretic agents in cases of distress recurring before the next dose is due, or distress not alleviated by one agent was correctly chosen by 57.5% (*n*=23) and 52.5% (*n*=21) respectively. 35% (*n*=14) advised multiple antipyretic use in cases of fever not being alleviated by one agent or fever recurring before the next dose is due (20%, *n*=8).

All participants identified the importance of encouraging parents to increase oral fluids in feverish children. The identification of a non-blanching rash (95%, *n*=38) together with detecting signs of dehydration (90%, *n*=36), were also popular pre-discharge advice. Nursery/school advice was mentioned in 77.5% (*n*=31) of cases. Tepid sponging and over/underdressing advice was interestingly mentioned by 32.5% (*n*=13) and 42.5% (*n*=17) respectively.

Discussion

The high-impact on healthcare systems brought about by young children presenting with feveris undisputable. With fever being one of the commonest complaints of young children presenting to the paediatric emergency department[5], the importance of guideline awareness amongst staff and ensuring proper public education is of utmost importance. It is well known from various studies,that inconsistent fever management approaches are still found even within the most established paediatric emergency departments.[6-7]

This study aimed to assess fever management within the paediatric emergency department at Mater Dei Hospital covering both aspects of documentation and awareness of NICE guidelines amongst paediatric staff. It also sought to explore patterns in the presentation of young children with fever in an attempt to better understand and improve our current healthcare system.

The average time for first medical contact was 51minutes, ranging from no waiting time to a waiting time of 4 hours. This might reflect recent attempts to reduce waiting times to a maximum of 4 hours, including the introduction of a computerised patient tracking system, in order to ensure reasonable time frames for review. The wide difference in waiting times might be a reflection of both differences in staff availability and peak attendances to casualty. In fact, further detailed analysis shows longer waiting times between 11am and 2pm and also between 10pm and midnight, mirroring peak attendance times taking place at 10am and 7pm respectively. Such peak attendances especially in the early evening, possibly correlate to more convenient times for parents to bring their children for review after school or work, and this is also reflected in the low number of attendances observed during the early morning hours. Longer waiting times were recorded for weekends especially Sundays, possibly suggesting lack of availability of community physicians and paediatricians during the weekend.

The commonest age group of children presenting with fever was as expected - that between 24 months and 3 years of age (22.7%), when children start nursery and school and there is increased contact with other children. Upper respiratory tract symptoms followed by symptoms of gastroenteritis were the commonest associated symptoms, reflectingtheir easy transmission. This was also the finding in a study in England by Nademi *et al.* in 2001, who reported 71% of children presenting to casualty with fever from a trivial viral infection, with tonsillitis and gastroenteritis being amongst the commonest diagnosis.[8]

23.9% of children had a fever of only 1 day duration, followed closely by 18.3% presenting with a 2 hour history of fever possibly reflecting parental anxiety, and might warrant further study into possible lack of awareness on proper fever management and recognition of warning signs amongst carers of children within the community. 45.5% of children assessed were afebrile, however it was difficult to determine whether this was due to previous administration of antipyretics at home, as information regarding the time of last antipyretic administration was only recorded in 2 cases. In view of this, antipyretics were not administered in casualty in 65.5% of cases.

Paracetamol was the commonest drug administered (23.5%) followed by ibuprofen (6.7%), sincemost presented with low grade fever. Antipyretics were administered by staff in 73.8% of children whilst distress was specifically documented in only 6.8% and were only withheld in 12.6% of cases. 35% of staff opted for use of multiple antipyretics in persistent fever irrespective of distress. Possible explanations for this might be either lack of documentation of distress in the child or an attempt to alleviate parental and possibly also staff concern.

Heart rate, oxygen saturations and CRT were documented in over 70% of assessments, possibly reflecting the ease with which these parameters can be quickly obtained using available equipment. In contrast, respiratory rate was not recorded in 62% of cases and this was surprising given the fact that the majority of children presenting with fever had upper respiratory tract symptoms. However, analysis of data obtained via

the questionnaire distributed to staff showed that 77.5% included respiratory rate as part of their routine assessment. Possible explanations for such inconsistencies may be the effort and time it takes to measure respiratory rate in distressed children. Moreover, one must consider that the paediatric emergency department at Mater Dei Hospital is run by basic specialist trainees, foundation year doctors and nurses, and the returned questionnaires were largely not representative of this group. Therefore, such data might be reflecting differences in awareness in different cohorts of staff.

Temperature was the most common parameter to be repeated pre-discharge (67.6%) in contrast to heart rate (12.7%). This might reflect the misconception by staff that response to antipyretic therapy helps in categorizing seriously ill children from those who are not, a common misconception also highlighted by other studies.[9]

Blood pressure was not recorded in 80.8% of cases with abnormal heart rate or CRT. This was further reflected in the questionnaires - only 22.5% of staff recognized blood pressure as being one of the vital parameters to record in young feverish children, thus emphasizing the need for more awareness in this regard.

Misconceptions regarding temperature control were also mirrored on analysis of advice given to the parents by staff pre-discharge. Whilst warning signs were documented in 64.3% of cases, regular antipyretics were advised in 22% versus 6.7% who advised antipyretic use only in cases of distress as per guidelines. Encouragement of oral fluid administration was documented only in 14.9% despite 100% positive responses in the questionnaire distributed, which again might reflect management differences in staff cohorts.

Limitations

The data on which this study is based was obtained over a one month period. Data obtained over a longer period would allow better assessment of changes in patterns of both presentation and clinical practices within the department including seasonal changes. Moreover, the response rate for the questionnaire was 54% - a higher response rate would ensure more representative data.

Conclusion

This study showed that whilst there is good overall staff awareness of NICE guidelines on fever management in young children, there is room for improvement when it comes to implementation of such practices. Whilst the recent introduction of an educational leaflet on fever management aimed at parents within the PED is a step in the right direction, further continuing medical education is required on indications for antipyretic use and proper pre-discharge advice. Measurement of parameters especially blood pressure should be encouraged and documented both on initial assessment and pre-discharge.

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Original Article

The Value of Multiple 2D Ultrasound Scanning Views in the Detection of Congenital Heart Disease in the Second Trimester (18 to 24 weeks)

Maria Spiteri, Simon Attard Montalto, Victor Grech

Abstract

Antenatal detection for Congenital Heart Disease (CHD) is poor, but may be improved by adding views to routine ultrasound scanning.

From June 2014-July 2015, 600 randomly selected women between 18 to 24 weeks of pregnancy, had a routine 4-chamber ultrasound scan at Mater Dei Hospital view (Basic 4CV). In addition, they completed an Extended Cardiac Ultrasound Examination (ExCUSE) including the left outflow tract, right outflow tract, 5-chamber view and 3-vessel view. All views were timed. The results obtained from the 600 women who received Basic and the ExCUSE scanning were followed-up clinically after delivery of the infants. Validity testing of both 4CV and ExCUSE views was carried out, and the detection rate of CHD compared.

During the 12-month period, 61 cases from a total of 4,200 children up to 1 year of age were diagnosed with CHD by Paediatric Echocardiography. 19 were included in the 600-study cohort, of which 12 were detected antenatally, 1 via the 4CV alone, 4 by both the 4CV plus at least 1 of the ExCUSE views and 7 by 1 or more of the ExCUSE views alone. On average, ExCUSE views took approximately 6 minutes longer, yet there was a significant difference between the detection rate of CHD by the 4CV compared with the ExCUSE views (χ^2=0.031, p=0.05). Sensitivity and specificity of the 4CV were 31.6% and 100%, respectively, and 63.1% and 100%, respectively for ExCUSE views.

Antenatal diagnosis of CHD is improved with additional ultrasound views, but this will necessitate staff training and adjustments in clinic schedules to accommodate increased scan time.

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Keywords

congenital heart disease, detection, antenatal scanning

Introduction

Congenital heart disease (CHD) represents the most common type of congenital malformations,[1] with an estimated incidence of about 4-13 per 1,000 live births.[2-3] In Malta, there were 48 neonates with CHD out of 4,435 live births in 2015, resulting in a prevalence of CHD in Malta of 11.2 /1,000 live births in 2015.[4] Despite the high incidence of CHD in newborns, the rate of antenatal detection CHD is very low, ranging from 15 to 20% of all cases diagnosed shortly after or within a few weeks of birth.[1] This would translate into an average of 6 or 7 cases in Malta. An improvement in antenatal detection of this condition could lead to better prenatal and postnatal care that may significantly

reduce neonatal morbidity and mortality.[3] Routine surveillance using 2-dimensional (2D) antenatal ultrasound scanning for CHD had been introduced in 1958 by Ian Donald and rapidly became established as the standard of care in the United States (US) and most European countries.[5] Initially, these scans employed a four-chamber view (4CV) alone, showing the two atria and ventricles, atrial and ventricular septum and atrioventricular (AV) valves, with real-time images of valve function.[7] The 4CV was appropriate for the detection of anomalies of the atria, ventricles, AV junctions and atrial and ventricular septa, but less effective for lesions involving the outflow tracts, great arteries and visceral and atrial situs. Hence, lesions such as transposition of the great arteries (TGA), Tetralogy of Fallot (TOF), severe pulmonary stenosis, pulmonary atresia, double outlet right ventricle (DORV) and common arterial trunk (CAT) were missed by the 4CV alone.[6]

The implementation of additional, multiple scanning planes to the routine anomaly 2D ultrasound scan have improved antenatal detection of CHD.[7] These usually include the evaluation of the left and right outflow tracts (LOT and ROT views), the aorta, pulmonary artery and superior vena cava (the three-vessel view, 3VV) and the aortic root (the five-chamber view, 5CV).[6,8] For the purpose of this study, these views, when performed in conjunction with the 4CV of the heart, are referred to as the 'Extended Cardiac Ultrasound Examination', whilst the 4CV, when taken as a stand-alone evaluation of the foetal heart, is being referred to as the 'Basic Cardiac Examination'.

In many countries, the extended examination comprising multiple views has been the standard approach for several years. Therefore Malta, where the solitary 4CV was still in use in 2014, was arguably falling short of the accepted standard practice. Indeed, at this time, out of approximately 40 CHD cases per annum, only 6 or 7 cases of CHD were being diagnosed antenatally.

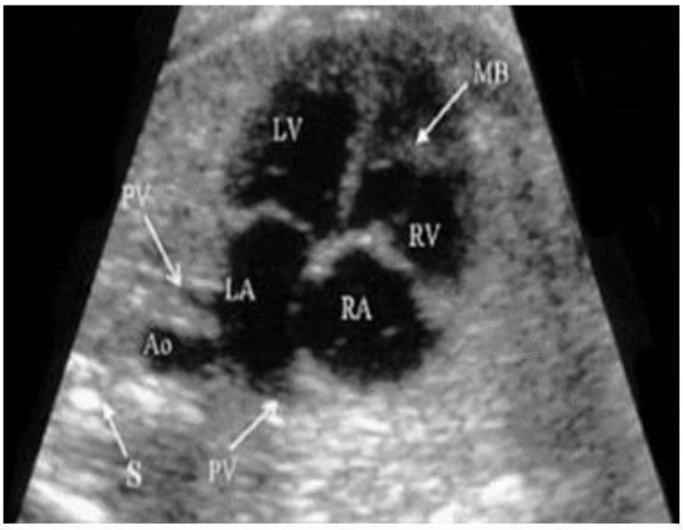
This study assessed whether there was any significant increase in antenatal detection of CHD in Malta by implementing ExCUSE scanning routinely. Furthermore, the feasibility and increase in scanning time by ExCUSE was also determined.

Methodology

Data Collection

Data collection spanned July 2014 to June 2015 with permission from all relevant parties. Furthermore, ethical approval was granted by the University Research Ethics Committee and access to health records allowed by the Directorate of Health Information and Research. Women between 18-24 weeks of gestation were recruited sequentially on attendance for their routine antenatal scan. They were given an information sheet explaining the research and, if willing to participate, were asked to sign the informed consent form. The following data was collected: gestational age, mother's age, mother's Body Mass Index (BMI) and foetal gender. The entire study sample of 600 women was scanned by the same researcher using the conventional 4CV and four additional views, namely the left outflow tract (LOT), the right outflow tract (ROT), the five-chamber view (5CV) and the three-vessel view (3VV), as shown in Figures 1 to 5. The composite scan including all views was denoted as the Extended Cardiac Ultrasound Examination (ExCUSE). All ultrasound scans were timed. Firstly, the routine 4CV standard anomaly scan was performed and timed, this representing the actual scan time for a routine anomaly ultrasound scan in Malta. Thereafter, all the above-mentioned extra views comprising ExCUSE were performed and timed separately.

Figure 1: *The four chamber view*

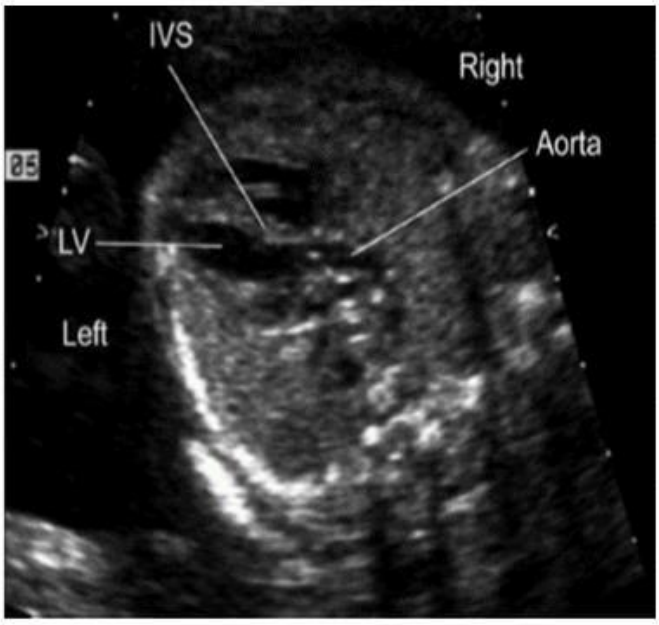


Legend: Ao – Aorta; LA – Left Atrium; LV- Left Ventricle; MB – Moderator Band; RA – Right Atrium; RV – Right Ventricle; PV – Pulmonary Veins; S – Foetal Spine

Figure 2: *The right outflow tract view*

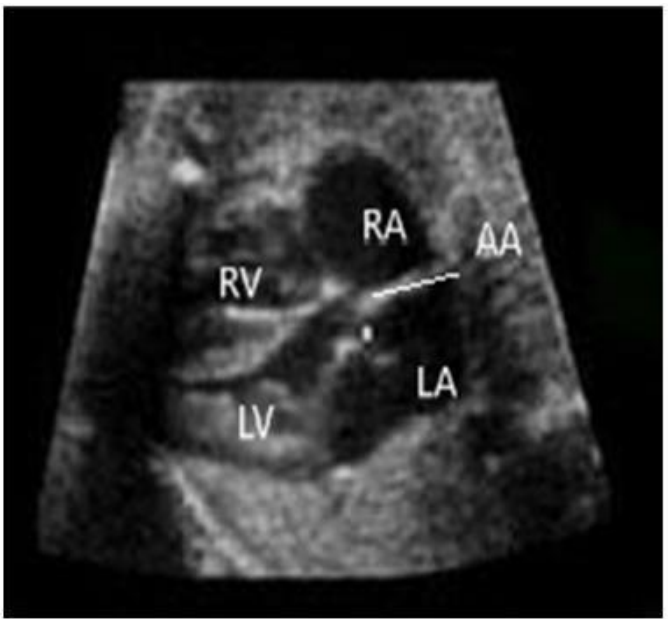
Legend: RA – Right Atrium; RV – Right Ventricle

Figure 3: *The left outflow tract view*



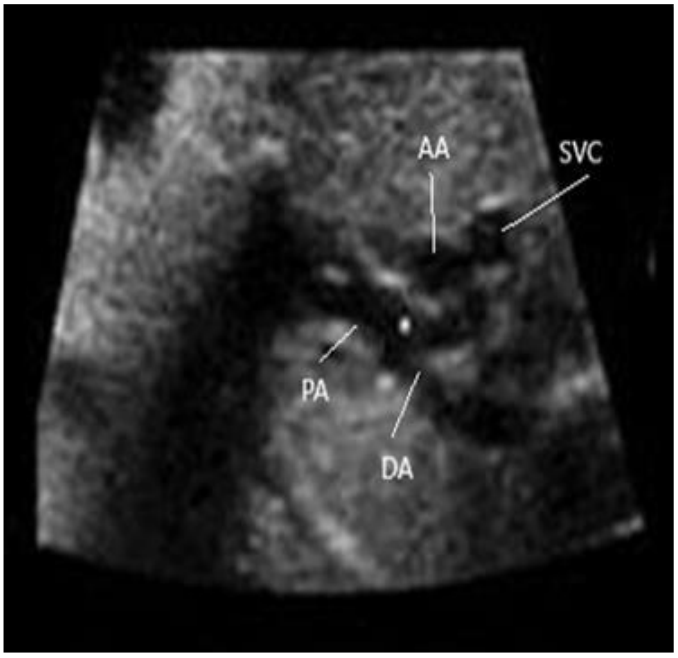
Legend: LV- Left Ventricle; IVS – Inter-Ventricular Septum

Figure 4*: The five-chamber view*



Legend: AA – Ascending Aorta; Ao – Aorta; DA – Ductus Arteriosus; LA – Left Atrium; LV- Left Ventricle; MPA – Main Pulmonary Artery; RA – Right Atrium; RV – Right Ventricle; SVC – Superior Vena Cava

Figure 5*: The three-vessel view*



Legend: AA – Ascending Aorta; DA - Ductus Arteriosus ; MPA – Main Pulmonary Artery; PA - Pulmonary Artery; SVC – Superior Vena Cava

Inclusion and Exclusion Criteria

All mothers 18 to 24 weeks pregnant of all ages residing in Malta with a doctor's referral for an elective or urgent antenatal ultrasound appointment were included, whereas those with an Intra-Uterine Death (IUD), refusal to sign the Consent form and non-resident pregnant females were excluded.

Outcomes

The outcome of the study sample group of mothers that gave birth to neonates with or without CHD was followed prospectively. The results obtained by the Basic 4CV and ExCUSE scanning were then confirmed clinically after the delivery of the infants. All infants were then followed up for a further twelve months, in case of any late diagnoses of CHD, thereby significantly reducing the incidence of false negatives.[9] Any infant with a suspicion of CHD underwent postnatal echocardiography, as per current, routine practice. The actual clinical and echocardiographical findings of newborns found to have CHD were compared to the results of the antenatal ultrasound scan, thus confirming or refuting whether the cardiac malformation had been detected accurately or not, and if so, by which view had it been detected.

Statistical Analysis

Demographic data was compared with data from the National Statistics Office (NSO, Demographic Review, 2015). Validity testing was performed to obtain the sensitivity and specificity of ExCUSE scanning. The definitive confirmation of CHD was taken on the basis of the result of a postnatal echocardiogram. Chi-Square Test (χ^2 test) using SPSS® was used to check for any significant difference between the 4CV as a stand-alone view and the ExCUSE scan. McNemar χ^2 test was used for 'Agreement Analysis' in the event of marginal homogeneity. A p-value of ≤ 0.05 was taken to represent a significant difference.[10]

Results

600 mothers were recruited with no mother refusing to sign the consent form. Since they were all residing in Malta at that time all were eligible for the study.

Statistics concerning the demographics of the population sample were carried out to determine how representative the study sample was of the general population. The mean age of the population sample was 29 years compared with 30-34 years of age for the national cohort,[11] whereas the mean BMI for the population sample was 24.9 which compares well with that of the whole national pregnant population since 53.2% of the female population in Malta had BMIs equal to or more than 25.[12] Out of 600 subjects, there were 291 mothers with male foetuses (48.5%), 291 mothers with female foetuses (48.5%) whilst in 18 cases, i.e. 3% of the cases, the foetal gender could not be determined. The latter was mainly due to high mothers' BMI which reduced image quality due to decreased resolution therefore making it difficult to determine foetal sex by ultrasound scanning.

During the 12-month study period there were 61 cases of children of up to 1 year of age who were diagnosed with CHD by definitive postnatal Paediatric Echocardiography. There were 25 (41%) male children versus 36 females (59%) with CHD. The types of CHDs varied from simple ASDs and VSDs to TGAs, TOFs and coarctation of the aorta.

Of these, 19 were born to mothers who formed part of the study cohort of 600. A diagnosis of some type of CHD was made by antenatal scanning in 12 of these 19 cases, 1 via the 4CV alone, 4 by both the 4CV plus at least 1 of the ExCUSE views and 7 by 1 or more of the ExCUSE views alone (that is, where the 4CV was normal), as shown in table 1. This meant that there was a significant difference between the detection rate of CHD by the 4CV compared with the ExCUSE views (χ^2=0.031[a]; p=0.05). The sensitivity of the 4CV was found to be 31.6% and its specificity was calculated to be 100%, whilst the sensitivity and specificity of the ExCUSE views (that is, the 4CV plus all the other views) were found to be 63.1% and 100%, respectively. These denominators included all CHD babies since all forms of CHD that were present in these 19 subjects could have been potentially detected and in which an early diagnosis would have been helpful in the management of the CHD. Furthermore, all CHD babies detected antenatally were subsequently born, that is, there were no intra-uterine deaths.

Furthermore, as shown in Table 2, on average anomaly scanning that included the ExCUSE views took approximately 6 minutes longer to perform.

***Table 1**: Number of cases with CHD detected by 4CV and ExCUSE views*

CHD only picked up	Number
4CV	1
4CV + at least 1 ExCUSE view	4
1 or more ExCUSE view whilst 4CV appeared normal	7

***Table 2**: Timing for 4CV and ExCUSE views*

View	Time (mean, in minutes)
4CV	1.16
LOT	1.14
ROT	1.16
5CV	1.12
3W	1.15

Discussion

This study set out to objectively show the necessity of implementing change using local data so as to be wholly relevant to Malta. Despite multiple studies abroad, whereby antenatal foetal ultrasound scanning routinely employ the application of several scan views, Malta was still lagging in this regard in 2014. Hence, it was important to make a case for change in the health service in Malta, so as to include the extra views when assessing the foetal heart. Moreover, this study had not been previously undertaken in Malta, and no local data was available to support or refute the use of multiple images in order to augment the pick-up of foetal CHD in Malta. In this regard, this study was original, unique and comprehensive, and also included the variable of time.

The demographic results obtained showed that the population sample compared well to the general pregnant population in terms of age, BMI and foetal gender since the results obtained were very similar to those of the general population according to the National Statistics Office (NSO) for the Demographic Review published in 2015.

The study did show that, even within the health service framework in Malta, additional antenatal ultrasound scan views do increase the detection of congenital heart disease during this critical period, thereby facilitating the planning of care and intervention for these children. The study highlighted the need for an enhanced protocol that is required to standardise the approach to the diagnosis of CHD antenatally using the Extended Cardiac Examination views as well as the routine 4CV. It would also recommend that training in foetal cardiac scanning is needed to ensure a standard approach and improve the diagnostic acumen for CHD of 'obstetric' ultrasonographers. In order to achieve this, sonographers should have achieved a certain level of expertise (a minimum of 3 years as full-time sonographers), and be performing this on a full-time basis. Diagnostic yield would also be enhanced with the routine use of other and/or new techniques such as the use of Doppler, transvaginal (TV) scanning and 3-Dimensional (3D) Echocardiography that all increase diagnostic reliability of ultrasound scanning in the case of the foetal heart.

In this study, the aortic arch view was not included in the recommended extra views since it frequently proves difficult and time-consuming. However, it must be pointed out that it is essential in the diagnosis of aortic arch malformations that, albeit rare, tend to be life-threatening and require urgent intervention. Therefore, early pick-up is very important. In fact, whenever it proved possible, whilst scanning the 600 subjects, the aortic arch view was included in the sequence of extra views. However, due to time constraints, this was only done when it did not prove too problematic to obtain.

This study had limitations. Ultrasound is operator-dependent, and this may have influenced the effectiveness of using the Extended Cardiac Examination as a screening tool since, apart from training, operator-dependency is highly reliant on the experience of the sonographer(s) in question.[13] Since there was only one principal researcher performing all 600 cases, there was the risk of operator-bias. However, this ensured that all views were performed in a standardised manner.

Time-constraints and cohort size limitations (one researcher scanning a cohort of 600 patients in one year) made it impossible to include a strict control group in the population sample. The study cohort was compared to historical data rather than an age and demographically matched control group. Furthermore, the ultrasound machine used (Siemens Sonoline G50) was older than 10 years. As a result, since over time, image resolution decreases due to normal wear and tear, image quality (and diagnostic potential) may have been adversely affected. The

importance of the suitability of the equipment being used and its maintenance cannot be stressed enough since it can be a major limiting factor in scanning the foetal heart.

It was decided that the babies scanned antenatally would be followed up until they would be one year of age. However, there may have been some cases where no clinical symptoms presented in this period, albeit uncommonly. Hence, limiting follow up to just 12 months may have resulted in some cases of CHD being missed (although very few, if any).

Finally, implementation of the study recommendations would increase the workload in the antenatal ultrasound clinic, and increase the scanning time for each patient. Hence, a new, extended protocol for antenatal scanning using ExCUSE views would need to be taken into consideration and accommodated.

Since completion of this study, dedicated list of anomaly scans are being performed by personnel using the afore-mentioned views.

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Case Report

Oral ranula – report of a case with review of literature

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Abstract

Ranula is a soft bluish translucent swelling that occurs in floor of mouth usually causing mild discomfort to the patient. Ranula can be categorized as simple or plunging. Simple ranula manifests as bluish colored swelling in the floor of the mouth whereas plunging ranula spread through the facial plans posterior to the mylohyoid muscle into the submandibular and neck spaces. The authors have presented a case of 28- year-old female patient with simple ranula the classical clinical features of simple ranula have been described in detail. The surgical management of the case has been comprehensively described. A detailed discussion of the literature published in recent articles on oral ranula is also presented in the case report.

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Keywords

ranula, sublingual gland, floor of mouth

Introduction

The term ranula used for a bluish translucent swelling in the floor of mouth is derived from the Latin word rana, denotation used for belly of a frog.[1] There are two possible etiological theories proposed for the development of ranulas. One theory suggests that ranulas progress as a result of mucus extravasation, whereas the other theory states that ranula is formed due to mucus retention.[2] Though the exact information regarding the prevalence of ranula is unclear some researchers have reported it at the prevalence rate of 0.2 cases for every thousand individuals. [3] Females are more commonly affected than males with a male-to-female ratio of 1:1.4.[4] In most of the reported cases the patient is in the second and third decades of life, however cases have been reported individuals ranging from the age of 3 years to 61 years. [1] Considering this background information the authors intend to present a case of oral ranula involving floor of the mouth in a 28-year-old female with comprehensive treatment and 6 month follow-up.

Case report

A 28-year-old female of Ethiopian origin reported to the clinic with complaint of a swelling under the tongue since a period of 3 months. The patient reported of discomfort while chewing food and speaking due to the swelling. The patient stated that moderate pain originating from the swelling was felt during consumption of food. There was no positive history of fever or discharge from the site of swelling. On examination was pinkish–blue in color and hemispherical in shape [Figure 1]. The approximate diameter was around 3 centimeters and capillaries were visible on the surface of swelling. On palpation the swelling was soft in consistency and fluctuant. There was no evidence of fixity to

underlying structure. There was no indication of any extraoral swelling. An occlusal radiograph was made to rule out any calcific duct obstruction. Based on the history and clinical features a provisional diagnosis of ranula was made. After routine preoperative investigations, excision of ranula was carried out under local anesthesia [Figure 2]. A clear white color discharge came out after de-roofing of the swelling confirming there is no infection or pus in the lesion. Surgical closure was done using 3-0 sutures [Figure 3] which insuring suturing the lesion lining membrane with the floor of the mouth mucosa to avoid recurrence. The patient was reviewed 10 days after the surgery to remove the sutures and healing was satisfactory. Patient was reviewed further after a period of six months, no evidence of recurrence was observed.

Figure 1: *clinical photograph showing the clinical features of oral ranula*

Figure 2*: intraoperative photograph showing exposed surgical site*

Figure 3*: Post operative photograph showing surgical site with suture placement*

Discussion

Ranula is basically mucocele involving the sublingual salivary gland and is formed due to the salivary extravasation from any one of the 20 ducts of the sublingual salivary gland.[5] Apart from the two theories suggested for the etiopathogenesis of oral ranula; certain other factors have also been suggested. Higher prevalence of ranula in certain ethnic population groups like Maori and Pacific Island Polynesians, have been observed suggestive of possible congenital factors in the formation of ranula.[6] A Study conducted in Zimbabwe showed high prevalence of ranula in Human immune virus (HIV) patients giving rise to a possibility of HIV salivary gland disease causing ranula.[7] The prevalence of oral ranula is about 0.2 cases per 1000 persons.[8] Clinically they appear as a blue, dome shaped swelling in the floor of the mouth around 3-6 centimeters in size.[5] in the present case similar clinical feature was observed and the size of the swelling was around 3 centimeters. Ranulas are differentiated as simple and plunging variety based on their extension.[9] Plunging ranulas characteristically extend posteriorly beyond the free edge of the mylohyoid muscle intruding the sub-mandibular and sometimes even the parapharyngeal spaces.[9,10,11] In the present case the swelling was restricted to the floor of the mouth and hence was classified as simple variety. In most of the reported cases, ranulas were observed on the lateral side of floor of the mouth.[10] In the present case similar site of occurrence was observed. In the present case the patient was a 28-year old similar age related feature has been reported by several other authors with highest incidence being reported in the second and third decade of life.[11-13] Slight gender predilection favoring the female population was reported in

reviews although the difference was not significant.[13] In the present case oral ranula was reported in a female patient. Differential diagnosis for oral ranula include other lesions occurring in the floor of the mouth such as lipoma, dermoid cyst, abscess, salivary gland lesions and vascular lesions.[5]

There are no precise diagnostic tests to diagnose ranula. In majority of the cases simple ranula presents as a cystic fluctuant swelling which gradually increases in size gradually. Biochemical analysis of contents of ranula have revealed higher salivary amylase and protein content compared to serum therefore suggesting that ranula originate from sublingual gland which produces saliva with higher protein concentration as compared to submandibular gland.[14] Although the diagnosis of ranula is often simple because of its classical clinical feature a wide range of investigative modalities have been used ranging from invasive procedures like Fine Needle Aspiration Cytology (FNAC) to non-invasive imaging techniques like occlusal radiograph and Magnetic resonance Imaging (MRI). [12] In the present case occlusal radiograph was made to rule out ductal calcifications. Several treatment modalities have been used for oral ranula which includes sclerotherapy, marsupialization, excision of the pseudocyst, and excision of the sublingual gland. in the present case surgical excision was carried out in the presenting case.[17] The common complications reported secondary to surgical management of ranula include recurrence of the lesion, sensory deficit of the tongue, damage of the duct post-operative hematoma and infection.[18]

The recurrence rates of ranula vary as per the treatment modalities that have been used. recurrence rate for ranulas treated with incision and drainage ranges from 70% to 100%, for ranulas treated with marsupialization recurrence ranges from 36.4% to 80%, for ranulas treated with surgical excision recurrence ranges from 18.7% to 85%, for ranulas treated with excision of ranula along with sublingual salivary gland the recurrence rate ranges from 0% to 3.8%.[18]

No complications were reported in the present case and no clinical evidence of recurrence was noticed for a period of six month post-surgical intervention.

Conclusion

Identifying the important clinical features of ranula is an important aspect in the diagnosis of ranula. Investigative modalities can be useful in cases of plunging ranula or to rule out differential diagnosis. The authors have made an attempt to highlight the key clinical features of ranula along with the detailed treatment and follow-up details.

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Case Report

Adenomatoid tumour of the epididymis in a torsion testis: a histopathological surprise!

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Abstract

Testicular or paratesticular adenomatoid tumours are benign swellings of the human genital tract. Although benign, they prove a challenge to diagnose clinically, and thereafter treat appropriately. Often, an adenomatoid tumour can be mistaken for a testicular malignancy, causing a patient to undergo an orchidectomy. When symptomatic and diagnosed preoperatively, a testis sparing surgery can be performed in these patients. We report a patient who underwent an orchidectomy for torsion testis, and incidentally was found to have an adenomatoid tumour of epididymis. Though this patient had dull aching pain of the left testis for a significant time, he failed to seek medical help, which if he had done, would have helped him to save his testis! A detailed literature review has been done.

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Key words

Torsion, testis, orchidectomy, adenomatoid, tumour, epididymis.

Introduction

Adenomatoid tumours are benign neoplasms which occur in both sexes. Common locations are paratesticular parenchyma in males, and uterus and fallopian tubes in females. They are the most common paratesticular tumours, accounting for 30% of all paratesticular masses.[1] Epididymis is the most frequently involved site. It usually presents in males in the third or fourth decade, as a non-tender paratesticular swelling. Due to its rarity, it is often misdiagnosed, and leads to unnecessary orchidectomy.[2] Physical examination and sonographic features may be helpful in distinguishing an adenomatoid tumour from a malignant tumour of the testis. A preoperative diagnosis aids in organ preservation, as the adenomatoid tumour can be managed by a surgical excision without orchidectomy.[3] This seems to be the first ever case where in an incidental adenomatoid tumour has been reported in a patient who underwent orchidectomy for torsion testis.

Case history

A 36-year-old male presented to the emergency triage with sudden pain and swelling of the left side of the scrotum of 10 hours duration, for which he was seen at a local hospital and was prescribed analgesics, with no pain relief. There was no history of trauma, fever, dysuria or perurethral discharge. On general examination, he was in severe pain, febrile and had tachycardia (120 beats/min). Local examination revealed an enlarged left side of scrotum, tender testis, minimal hydrocele with no transillumination. Left sided cord structures were tender and thickened. Also, there was a 4x3 cm firm swelling on the epididymis. A clinical diagnosis of torsion testis was made. Blood investigations revealed neutrophilia. Scrotal doppler was performed and revealed total cut-off of blood

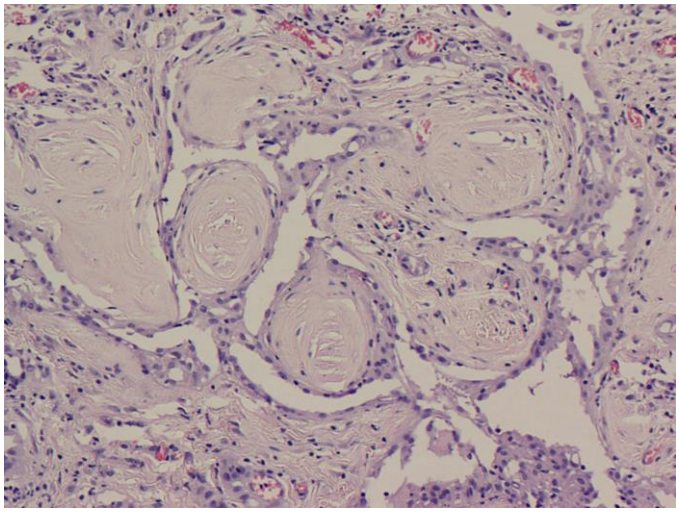
supply with non-viability and suspected gangrene of left testis with no presence of any tumor. At surgery, the left testis was gangrenous with a firm epididymal lump (Figure 1). He underwent left orchidectomy and right orchieopexy. The postoperative period was uneventful and he made a good recovery. The final histopathology was reported to be testicular gangrene with adenomatoid tumour of the epididymis (Figure 2). Patient has been kept under follow-up and at the end of 6 months, is doing well.

***Figure 1**: Orchidectomy specimen with epididymal mass.*

Discussion

Golden and Ash, in 1945, published a study of 15 cases of a tumour of male and female genital tract and proposed the term 'adenomatoid tumour' because of its epithelial nature and gland like spaces seen on histology. They confirmed the benign nature of the tumour based on its low mitotic activity, absence of local tissue invasion and metastasis.[4] Though it was a significant contribution in the understanding of the nature and development of this tumour, they could not comment on its cell of origin. Delahunt et al investigated the histological origin of paratesticular adenomatoid tumour by using immunohistochemical (IHC) markers that included IHC staining of sections of 12 cases and concluded that the tumour originated from mesothelial cells.[5]

***Figure 2**: Photomicrograph showing a tumour composed of cells ranging from flattened to cuboidal epithelial like appearance with moderate to abundant eosinophilic cytoplasm, few cells showing vacuolation, lining numerous channels simulating vascular spaces along with intervening collagen fibers, proliferating congested capillaries and infiltrating lymphocytes (H&E, X400).*



Most adenomatoid tumours involve paratesticular tissue, although extragenital tumours have also been reported.[6] The first case of intratesticular adenomatoid tumour was documented by Horstman et al.[7] Since then, many cases of adenomatoid tumour of testis have been reported.[8-10] These tumors typically occur in the third till fifth decade, but can also present as early as the first year of life.[10] They are usually small, firm and asymptomatic mass, which most often confine to the lower pole of the testis. In spite of the benign nature of these tumours, they are often subjected to radical organ resection surgery. This occurs due to uncertain preoperative diagnosis.[3]

Ultrasonography (USG) is the standard imaging modality used for assessing testicular tumours. Kassis retrospectively analysed ultrasound findings of 22 patients with testicular tumours that included 6 patients with adenomatoid tumours and concluded that isoechoic nodules are unlikely to be malignant. However, hypo or hyperechoic lesions can be either benign or malignant. They advocated that in such conditions it is prudent to opt for an inguinal approach to perform biopsy and frozen section, before executing radical orchidectomy.[11] Other studies have also found that USG cannot accurately differentiate all benign lesions from malignant tumours, hence, an inguinal approach and

histological diagnosis is preferable before performing an orchidectomy.[9] A fine needle aspiration cytology (FNAC) can assist in preoperative diagnosis of the tumour but a confirmed diagnosis can only be made after histopathological examination of the excised tumour.[8]

Surgical excision of the tumour is the treatment of choice, and an organ sparing surgery can be performed without a risk of recurrence.[10] In cases of adenomatoid tumour of tunica albugenia, radical orchidectomy has been performed in the past due to doubtful preoperative diagnosis.[6] However, recent trend has been towards local excision and frozen section biopsy in order to preserve fertility.[9] A detailed literature search has not revealed any recurrences so far in operated patients.

Albeit the diagnosis of an adenomatoid tumour is benign and treatment being simple, the possibility of undertreating a testicular malignancy is the real concern. The vice versa is also true, that the worry of a testicular malignancy causes us to over treat a benign condition. Even though there is abundant literature about this neoplasm, a definitive diagnostic modality is yet to be determined. If diagnosed early, a testis sparing surgery can be offered to the patient.

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