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EDITORIAL

MMJ: new instructions to authors

Simon Paul Attard Montalto

Readers and contributors to the Malta Medical Journal will be aware that the MMJ has had significant administrative problems relating to the final processing of manuscripts prior to their publication on-line.[1] As a result, and in tandem with ever-increasing manuscript submissions, the MMJ has accrued a large backlog of completed papers awaiting publication that, in some instances, has exceeded eighteen months. Following discussions with personnel from Administration within the Faculty of Medicine and senior members within the Marketing, Communications and Alumni Office at the University of Malta measures have now been taken to address this crisis. Whilst we welcome the new help and thank those who have made this possible, we have started to work on the backlog and hope that time intervals from submission-to-publication will start to reduce. Indeed the last three issues have been finalised and turned around in a relatively short period of just a few months.

Prof Simon Attard Montalto
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COVER PICTURE

'Bagheera dreams' - *Oil on canvas board with painting knife*

Victor Grech is a consultant paediatrician with a special interest in paediatric cardiology. He finds photography and painting relaxing pastimes. He lives in Pembroke with his family, as well as three Siamese cats with the Kiplingesque names Shanti, Mowgli and Shere Khan. This painting depicts these felines' predecessor, beloved Bagheera who crossed the Rainbow Bridge - missed but not forgotten (1994-2011).

The MMJ Executive Board has also reviewed the Journal's acceptance policy. Most importantly, the MMJ will continue to accept manuscripts based on original research, but case reports will only be considered if exceptional and strongly associated with Malta or relevant to Maltese Healthcare. Reviews and updates will only be accepted by 'invitation' from the Editor. These increasingly stringent criteria for acceptance are designed to restrict papers that are of less interest to the readership, concentrate peer-review time, reduce turnaround times and improve the overall standard of the MMJ

Concomitantly the MMJ Executive Board has made changes to the 'Instructions to Authors' (ITA). Many sub-sections have been clarified and, most importantly, a detailed section on Ethical approval in relation to scientific submissions and publications has been included. In this regard, the MMJ board is grateful to Dr Ian Baldacchino for his input and advice.[2-6] **All authors are strongly encouraged to read 'The Instructions to Authors' in full and comply with all requirements before submitting a manuscript.** In future, the MMJ will adopt a return-to-sender policy for those manuscripts not compliant with ITA, and this will simply delay the whole process for individual papers, primarily at the expense of the authors whilst not taking up any more of the MMJ administrative time. In practice, this commonly applies to references cited in an incorrect format: authors will no longer be asked to correct these at a final, pre-publication stage but will receive their manuscript for correction before the peer review process even commences.

The MMJ is experiencing a considerable amount of work-in-progress, and significant strides have been undertaken to reduce the backlog of completed papers 'pending' publication. Nevertheless the latter is considerable and we would ask our readers for patience whilst the MMJ 'catches up'!

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REVIEW ARTICLE

Early Intervention for Infantile Capillary Haemangiomas at Mater Dei Hospital

Victor Grech

Infantile capillary haemangiomas (strawberry nevus) are common, benign vascular tumours that appear in infancy, typically within the first few weeks to months of life. While many of these haemangiomas undergo spontaneous regression, some may present challenges due to their size, location, or associated complications. Early intervention is crucial to prevent potential disfigurement, functional impairment, or other complications, especially when lesions affect critical areas such as the face, particularly near the eyes or nasal bridge. Propranolol is highly effective in arresting progression and inducing regression of these lesions. This paper describes the problems and issues that may arise from infantile haemangiomas and alerts the local medical community to this service at Mater Dei Hospital since early referral for prompt evaluation and treatment, if necessary, ensures optimal functional and cosmetic outcomes.

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Infantile capillary haemangiomas (strawberry nevus) are common, benign vascular tumours that appear in infancy, typically within the first few weeks to months of life. They are red, maculopapular haemartomatous benign neoplasias of endothelial cells. These lesions may appear anywhere with a propensity (50%) for the head and neck. Haemangiomas occur in 1-2% of all children.[1]

Some grow rapidly in the first 2 years of life in size, depth, and elevation above the skin surface in the proliferative phase, but then regress, with 60% disappearing by 5 years of age, and in over 90% of cases by 9 years age in an involutional phase.[2]

They are commoner in females (5:1) and in Caucasians and treatment when necessary was traditionally surgical, or with laser, or medical therapy including high dose corticosteroids, alpha-interferon, and vincristine.[3,4] In 2009, an infant with a large nasal haemangioma who was treated with corticosteroids developed iatrogenically induced hypertrophic obstructive cardiomyopathy (HCM). On commencing propranolol, the standard treatment for HCM, rapid involution of the haemangioma was noted, prompting the successful treatment of a series of children (who received up to 5 mg/kg/d), which led to the acceptance of this modality of treatment as first line.[5]

While many of these haemangiomas undergo spontaneous regression, some may present challenges due to their size, location, or associated complications. Early intervention is crucial to prevent potential disfigurement, functional impairment, or other complications, especially when lesions affect critical areas such as the face, particularly near the eyes or nasal bridge.

TREATMENT OPTIONS

Treatment for infantile capillary haemangiomas has evolved significantly over recent years. Observation is critical as a significant proportion of these lesions resolve without intervention. However for those requiring treatment, early intervention is crucial, and this involves simple propranolol which is available in both syrup and tablet form. This non-selective beta-blocker has emerged as a cheap, simple and highly efficacious frontline treatment for problematic infantile haemangiomas and demonstrates remarkable efficacy in promoting rapid regression, particularly when initiated early.[5]

Topical timolol maleate, a topical beta-blocker, has also shown promise in certain cases, particularly for smaller, superficial haemangiomas.[5] Laser and surgical therapy are beyond the scope of this short paper.[5]

Formerly due to the high rate of spontaneous resolution, treatment was limited to those lesions that impaired senses, such as the eyes or that impaired function of vital organs.[5] However the safe and widespread use of this drug for these conditions has led to its use in the setting of haemangiomas also for cosmetic reasons.[6,7]

AT MATER DEI

Propranolol is commonly used in paediatric cardiology, typically for the suppression of arrhythmias, for the prevention of cyanotic spells in tetralogy of Fallot and for the management of hypertrophic cardiomyopathy. Since paediatric cardiologists are most familiar with propranolol, it has devolved to paediatric cardiology at Mater Dei Hospital to treat these patients. The first patient treated was a Libyan child in 2011 with an ulcerating haemangioma on the latter aspect of the arm, with rapid resolution.[8] Since then, over 50 children have been treated with oral propranolol. The clinic also provides a platform to educate parents and caregivers about infantile haemangiomas, including signs to watch for and the importance of early intervention.

RATIONALE FOR EARLY CLINIC INTERVENTION

The establishment of a dedicated clinic several years ago (within the paediatric cardiology outpatient clinic) for infantile capillary haemangiomas at Mater Dei Hospital addressed the critical need for early assessment and intervention. By identifying and treating these haemangiomas promptly, complications may be prevented, such as obstruction of vision with the potential for amblyopia, airway compromise, or deformation of facial structures. Haemangiomas at risk of trauma and bleeding are also effectively treated, for example on the extensor surfaces in toddlers, on the fingertips, and on the buttocks which are enclosed in nappies. Trauma in the latter location in the sitting infant may result in skin rupture and infection.

Early intervention can also minimize the long-term cosmetic impact of haemangiomas, especially when they affect highly visible areas like the face, neck, and upper torso. An example is shown in **Figure 1**, before treatment at 8½ weeks of age, and **Figure 2** at 10

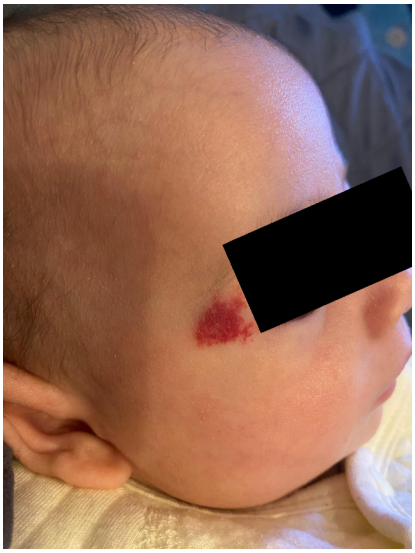

Figure 1 *Haemangioma at 8½ weeks of age, with treatment*

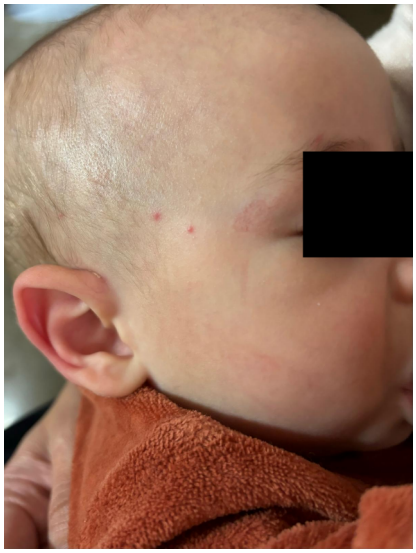

Figure 2 *Same lesion at 10 weeks of age*

weeks of age. A more dramatic example is shown in Figure 3 before treatment at 2 months of age, and Figure 4 after treatment at 10 months of age.

TREATMENT

The approach is simple. Patients who have lesions deemed worth treating have baseline weight, blood pressure and heart rate measured. These are typically infants weighing four to six kilograms, so propranolol is started gradually, incremented over several weeks to approximately 1mg/kg per dose, thrice daily, with monitoring of the aforementioned parameters at each visit.

Results are generally almost dramatic, with a swift reduction in lesion tenseness, and a decrease in redness, which progresses over several months.[7]

CONCLUSION

Medicine is replete with serendipitous discoveries, such as the accidental discovery of penicillin, as well as minoxidil for promotion of hair growth and sildenafil for erectile dysfunction, both drugs having been developed initially to treat hypertension.[9]

Propranolol is effective and safe and results in a better response when treatment is commenced early, in infants under the age of three months.[7] Indeed there are suggestions that premature infants have superior responses to propranolol than term infants.[10] Propranolol has also been safely used in the presence of complicated haemangiomas, i.e., those with co-morbidities such as hypothyroidism and heart failure.[11]

The purpose of this paper is meant to alert the local medical community to this service at Mater Dei Hospital since early referral for prompt evaluation and treatment, if necessary, ensures optimal functional and cosmetic outcomes.

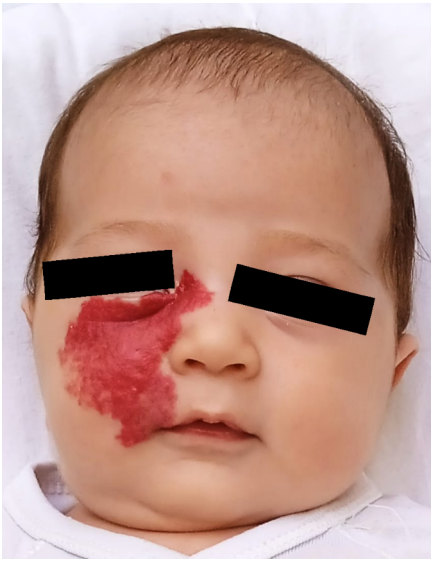

Figure 3 *Haemangioma at 2 months of age*

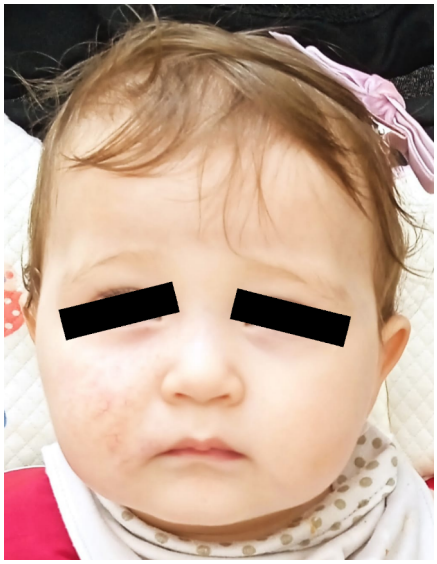

Figure 4 *Same lesion at 10 months of age, with treatment*

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ORIGINAL ARTICLE

Good practices for childhood obesity prevention in kindergartens and primary schools in Malta

Jason Attard, Martina Portelli, Charmaine Gauci

Background

Obesity is a worldwide and chronic disease with significant morbidity and mortality which often begins in childhood. Kindergartens and schools are unique settings that may contribute towards the prevention of childhood obesity through ensuring a safe and supportive environment and the development of personal life skills. The aim of this study was to identify good practices, as defined by the Joint Action across Europe on Nutrition and Physical Activity (JANPA), that are effective and sustainable for childhood obesity prevention in kindergarten and primary schools in Malta.

Methods

This descriptive study design involved the development of an online questionnaire using the nine core criteria of the JANPA toolbox. An operational definition of fulfilling six core criteria was used to qualify an initiative as a good practice. The questionnaire was sent to the Heads of School of all kindergartens and primary schools in Malta. Two researchers independently of each other reviewed the replies for each initiative and assigned one point for each fulfilled core criteria. The total sum of points produced a JANPA core criteria score for that initiative.

Results

The response rate for this study was 21.9%. 24 out of a total of 39 initiatives achieved the operational JANPA core criteria score of 6. Initiatives were grouped into nutrition only, physical activity only, and combined nutrition and physical activity good practices and were described.

Conclusion

This study identified several good practices that can be extended to other schools across Malta. The survey tool can also be used when designing and implementing new initiatives.

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Obesity is a worldwide and chronic disease, with significant morbidity and mortality from cardiovascular, neurological, and oncological sequelae. Obesity often begins in childhood and is an important predictor for adult obesity.[1] Obesity in childhood may result in difficulty in breathing, increased risk of bone fractures, the emergence of the metabolic syndrome, and psychological sequelae.[2] Prevalence data for 7–9-year-old children in 2015-2017 shows that 29% of boys and 27% of girls were overweight or obese. The prevalence of obesity was 13% in boys and 9% in girls.[3] Prevalence data in 2018 for 11-, 13-, and 15-year-old children showed that one in five adolescents were found to be overweight or obese.[4]

In 2015/6, a National study on childhood's Body Mass Index (BMI) approximately 40% of school-aged children in Malta were either overweight or obese.[5] In a recent WHO report, the age-standardised prevalence of overweight and obesity among 5–9-year-old school-aged children (2016) in Malta was 43.3% in boys and 36.4% in girls. The prevalence of obesity stood at 19.7% in boys and 14.2% in girls. The age-standardised prevalence of overweight and obesity among 10-19-year-old adolescents (2016) in Malta was 37.8% in boys and 32.5% in girls. The prevalence of obesity in this age cohort was 13.9% in boys and 9.6% in girls.[6]

The latest WHO report states that a life course approach is critical in reversing the obesity epidemic.[6] Children spend several years in kindergartens and schools. They are unique settings that may contribute towards the prevention of childhood obesity through ensuring a safe and supportive environment and the development of personal life skills.[7] Several Maltese national policies, strategies and action plans capitalise on this, describing school-based action measures that promote healthy eating and physical activity.[8–11] These include measures encouraging fruit and vegetable consumption such as the School Fruit Scheme, promotion of healthy eating in schools through clear guidance on the age-appropriate content of lunchboxes, the introduction of healthy breakfast clubs, restricting sale of unhealthy food from school canteens, promotion of plain water consumption, and measures that promote physical activity.

According to Joint Action across Europe on Nutrition and Physical Activity (JANPA), a good practice is an initiative that has been proven to work well (i.e., process evaluation) and produce good results (i.e., output and outcome evaluation), and is therefore recommended as a model. It is a sustainable and efficient experience, with clear objectives and clearly defined target groups that is aimed to be empowered. Its activities use existing structures, and it has a broad support among the target population, thus deserves to be shared so that a greater number of people can adopt it. A prime example of a best practice that was developed in Malta is 'The Schools on the Move' project. This peer-led, participatory action initiative led to increased physical activity during recess in secondary schools.[12] Furthermore, in an EU Joint Action Chrodis Plus project (2017-2020), the Health Promotion and Disease Prevention Directorate (HPDP) within the Ministry for Health showcased the ToyBox Programme. ToyBox is a multi-component kindergarten-based family-involved intervention focusing on drinking, eating, snacking, physical activity, sedentary behaviour, and oral health, which was implemented in church and independent schools in Malta and Gozo.[13]

The aim of this study is to identify good practices that are effective and sustainable for childhood obesity prevention that were carried out or are currently being carried out in year groups K2-Y6 in Maltese kindergarten and primary schools.

METHODOLOGY

A questionnaire was developed aiming at identifying effective and sustainable school-based initiatives for preventing childhood obesity that were carried out in schools. The questionnaire was developed using the JANPA framework of good practice criteria spanning across three categories, namely intervention characteristics, implementation, and monitoring and evaluation. The JANPA toolbox consists of 48 criteria, nine of which are considered core criteria needed to be fulfilled to qualify an initiative as good practice. Only these nine core criteria were used to develop the questions for the tool.[14]

The tool consisted of a quantitative-qualitative questionnaire which was validated using a face validation method. The tool was discussed with the Lead of the Health Promotion Unit within the Health Promotion and Disease Prevention Directorate, the Lead of the Strategy Development and Implementation Unit within the Office of the Superintendent of Public Health, and senior manager within the Directorate for Research, Lifelong Learning and Employability. Questions were checked for clarity, simplicity, and adequacy. Feedback was used to amend the tool (see **Table 1**). Whilst there are nine core criteria that need to be fulfilled to qualify a programme or policy as good practice, an operational definition of six core criteria was used for this study.

Table 1 *JANPA good practice core criteria*

JANPA	Good Practice Core Criteria	*Modified Good Practice Core Criteria*
1. Programme characteristics	Are the objectives of the programme SMART (Specific, Measurable, Achievable, Realistic and Time-bound) and clear?	*Are the objectives of the initiative SMART (Specific, Measurable, Achievable, Realistic and Time-bound)?*
	Is the target group clearly defined (including age, gender and socio-economic status)?	*Is the target group clearly defined? (including age, sex, general education students, students with a statement of needs, etc.)*
	Is the approach you use proven to be successful and effective in practice (has had a positive impact on individuals and/or communities)?	*Is this intervention proven to have a positive impact on individuals and/or communities? (From evidence-based research in the literature, good practices from other countries, first-hand evaluation of the initiative, etc.)*
2. Implementation	Is the aim to empower the target group by enhancing its knowledge, skills and competences so that its members can make decisions independently?	*Is the aim of the initiative to empower the target group by enhancing its knowledge, skills and competencies so that its members can make decisions independently?*
	Are the activities using/integrating existing structures?	*Are the activities using/integrating existing structures? (Curriculum, PE lessons, human resources such as an on-site home economics teacher, home economics labs, parent-teacher associations, formal inter-ministerial collaborations, etc.)*
	Is there a broad support for the intervention amongst the intended target populations?	*Is there a broad support for the intervention amongst the intended target populations? (Do the students/ teachers/parents like the intervention?)*
	Are the financial and human resources in place for evaluation?	*Does the school have the human and financial resources to evaluate this initiative?*
3. Monitoring and evaluation	Have the planned activities been performed and have most of the objectives been reached?	*Are the objectives of the initiative being reached?*
	Has the outcome or impact evaluation showed significant contribution to the target behaviour or its determinants?	*Has the outcome or impact evaluation shown significant contribution to the targets knowledge, attitudes, or practices? (Has the intervention shown an improvement in healthy eating and physical activity?)*

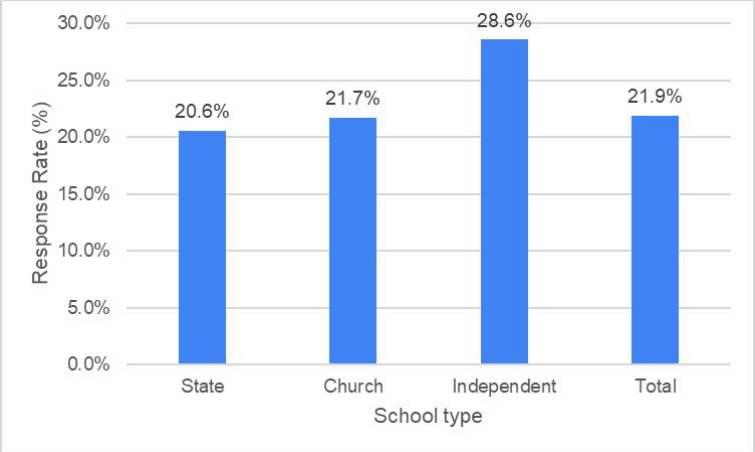

Figure 1 *Response rates by school type*

The online questionnaire was sent to the Heads of School of all kindergartens and primary schools in Malta who were invited to participate in the study in July 2021; reminders were sent in December 2021 and January 2022. The Head of School or their delegate were requested to provide information about one to three initiatives that were carried out in their school that they felt are most effective and sustainable for childhood obesity prevention. It was made clear that participation in the study was entirely voluntary and that they were under no obligation to participate. Submitting the online questionnaire was considered as acceptance to participate in the study. For each initiative, the Head of School or their delegate was asked several questions including nine yes or no questions related to the nine core criteria. For each yes answer, the Head of School or their delegate was asked to provide a brief explanation. The results of the report were anonymised with the data accessible only to the research team. The data collection phase closed in February 2022.

Two researchers independently of each other reviewed the replies to the questions for each initiative in March 2022. Each fulfilled core criteria were given one point. The total sum of points given for the nine core criteria for each initiative produced a JANPA core criteria score with a minimum of 0 and a maximum of 9. Discrepancies were resolved by discussion. An operational definition of six core criteria was used to decide which initiatives would be considered good practices and included in the results of this study.

Permission to administer questionnaires to Heads of School or their equivalent was approved by the MEDS Research Ethics Committee. The research project always abided the General Data Protection Regulations.

RESULTS

A total of 128 (68 State, 46 Church and 14 Independent) schools were invited to participate in this study. This study resulted in responses from 28 schools with an overall response rate of 21.9%. Figure 1 illustrates the differing response rates across school types. The response rates were Independent>Church>State schools.

A total of 39 initiatives were submitted by 28 schools. Just over one half of initiatives (56.4%) were submitted by State schools. Many initiatives either had a nutrition only focus.[17] or a combined nutrition and physical activity focus.[15] Figure 2 shows the number of initiatives by intervention focus and school type.

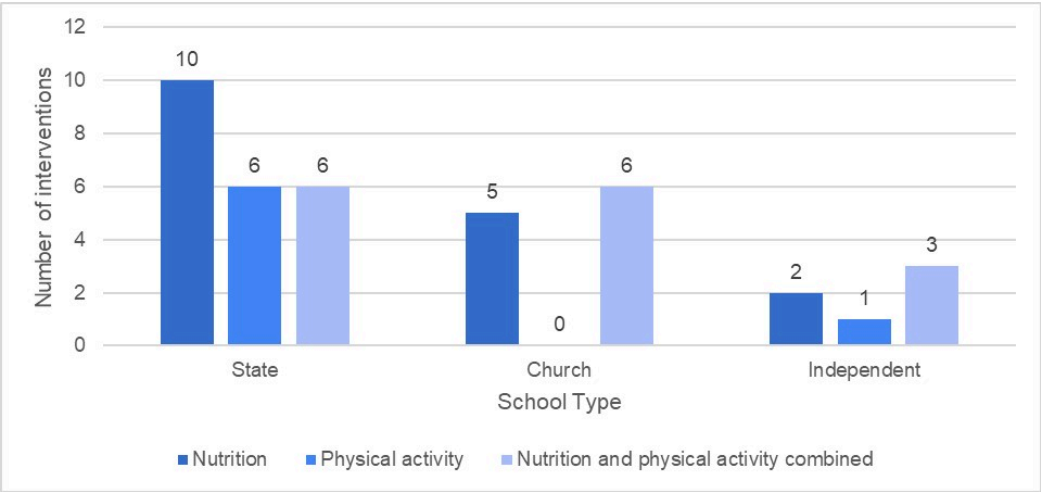

Figure 2 *Number of initiatives by intervention focus and school type*

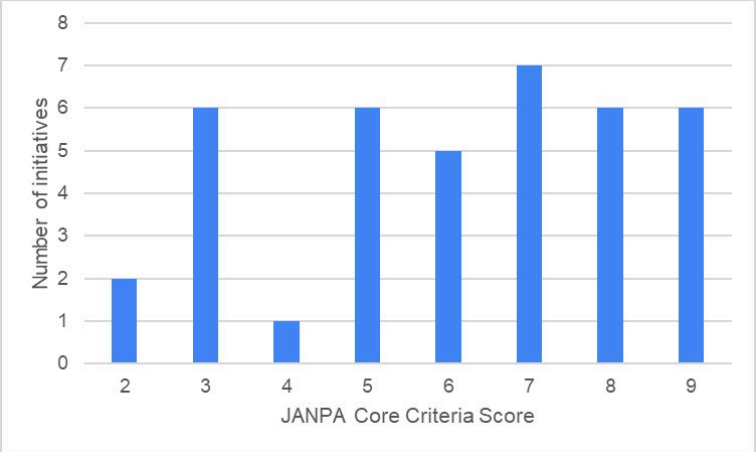

Figure 3 *Number of initiatives by JANPA Core Criteria Score*

The average JANPA core criteria score across all initiatives was 6.1, with a median score of 6.0. The distribution of the number of initiatives by JANPA core criteria score is depicted in **Figure 3**.

A total of 24 initiatives achieved the operational JANPA core criteria score of 6 or more. Some of these good practices were common or very similar across schools and were grouped together. These good practices are described below.

Nutrition Only

Healthy Eating Policy

Seven schools stated that they are following a healthy eating policy. Some schools stated that parents are given a set of policies at the beginning of the scholastic year included a booklet on healthy lunches and permissible foods including plain drinking water. One school stated that they have a reverse osmosis system so that fresh water was always available on demand and that a water fountain for the whole school was also installed. Some schools stated that the rationale for the healthy eating policy is explained to the students through a variety of educational fora.

Fruit/Vegetable Break

Two schools stated that they actively encouraged students every day to eat one fruit or vegetable during the school lunch break by promoting intake through curricular approaches such as through lessons such as social studies, English, mathematics, Physical Education, and the Home Economics Centre and monitoring by the teachers and the senior management team. This was carried out, and monitoring. One of these two schools rewarded a compliant student with small tokens. One school stated that they observed an increase in fruit consumption from 55% to 83% increase after their intervention.

Food Lab: Healthy Recipes

One school stated that they have an initiative where classes cook a healthy recipe at least once a month.

Book: "Ikel Frisk mill-Iskola" (Fresh Food from School)

One school stated that they produced a recipe book with healthy recipes as part of their Ekoskola activities. The recipe book required the use of fresh local produce promoting sustainable buying of local products. The recipe book was targeted to both children and their parents. The recipes were prepared and photographed by the school, and then published. The proceeds from the book sales went to a charity fund.

Training in food and nutrition for Primary school educators: a hands-on approach

One school held a professional development session done in collaboration with the Home Economics Seminar Centre, within the Directorate for Learning and Assessment Programmes. The aim was to support Primary School educators in planning and facilitating interactive food and nutrition related activities such as basic cooking skills, by improving their theoretical and practical knowledge and skills.

Online Nutrition Programmes

One school had two online nutrition programmes: one for Year 3 students and another for Year 5 students. The online programmes for the Year 3 and 5 students were facilitated through a 40-minute session by support teachers from the Home Economics Seminar Centre on a class basis. The sessions were held five times to meet al classes. The Year 3 programme focused on the importance of having a daily healthy breakfast. The Year 5 programme encouraged positive attitudes towards the consumption of vegetables and fruit.

Physical Activity Only

Daily Mile

Three schools stated that they carry out the Daily Mile initiative in their school. The daily mile is an initiative that involves students either walking or jogging for up to 30 minutes daily. The Daily Mile was considered quite simple and not resource intense to implement. One school stated that a physical education teacher supervises the run-a-mile initiative just after assembly. Another school stated that the Daily Mile gave space for the students to take a break from their class. Two schools stated that the Daily

Mile initiative could not be implemented during the COVID-19 pandemic as to maintain class bubbles.

Active Fridays

Two schools stated that they organise Active Fridays. One school stated that they organised games whilst another school stated that they organised Fun Fit Football Sessions in collaboration with the Malta Football Association and the National Literacy Agency Sports and Literacy Leaders. The Active Friday's initiative was very well received by both children and parents. Educators felt that students practiced various games during the rest of the week.

Activity Days

One school stated that they organise Activity Days. Activity Days were held two or three times per scholastic year and varied according to the year group of the students. Generally, one or two of the Activity Days were carried out on-site at the school and one of the Activity Days was carried out off-site. Activity Days consisted of different planned cross curricular activities including informative treasure hunts on flora and fauna, keep fit sessions, and the science of movement. The on-site Activity Days engaged the parents, various educators including peripatetic teachers, and collaborations with the local governance. The school stated that the Activity Days had very strong support from students, parents, and educators and its' absence during the COVID-19 pandemic was felt.

Combined Nutrition And Physical Activity

The Outside Classroom

One school stated that they have an Outside Classroom initiative. This is a cross-curricular activity that involves the active participation of students, particularly those in kindergarten, in school gardening such as planting seeds, watering plants, and study of insects.

Healthy Lifestyle Week

Two schools stated that they carry out Healthy Lifestyle Weeks. Healthy Lifestyle Weeks incorporate various cross-curricular activities such as student visits to the Home Economics Centre for talks and doing their own breakfast, talks to the whole school including parents, information sessions about the healthy food plate, balanced diet and nutrition, distinguishing between healthy food and fast foods, trying out different foods, the fruit basket initiative where students take a fresh fruit out of a basket placed in a central place in the school entrance, and daily exercises and sports.

Let's Move

One school stated that they participated in an EU funded Erasmus+ programme to promote health lifestyle. This project included a conglomerate of initiatives including staff training, having a fruit break every morning, online seminars and nutrition sessions with parents and pupils, and physical activities.

Integrated Learning about Health Living

Two schools stated that they integrated learning about healthy living, such as the importance of healthy food choices and exercise, throughout various subjects. One school did this through the Personal, Social and Career Development, Physical Exercise and Science subjects. The other school did this through a dedicated topic on healthy living.

DISCUSSION

The most quoted initiative by respondents was the Healthy Eating Policy. The school food environment is an important contributor to childhood obesity. Evidence from a recent meta-analysis shows that restriction of sugar sweetened beverages and unhealthy snacks reduced their intake by 0.18 servings per day and 0.17 servings per day, respectively [15] Whilst school meal standards increased fruit intake by 0.76 servings per day, it did not statistically significantly increase vegetable and fruit and vegetable intake.[15]

Several innovative teaching approaches were described such as the online nutrition education programmes, experiential learning, and cross-curricular approaches such as the Food Lab and Outside Classroom, parental involvement, and contingent reinforcement through token economy. According to a systematic review and meta-analysis of the literature\(2015\), the most effective approach to reduce food consumption and energy intake and improve nutritional knowledge, and to a lesser degree, fruit and vegetable consumption or preference in primary school students, was through experiential learning. Other, albeit less effective, approaches include cross-curricular approaches and enhanced curriculum interventions.[16]

School-based physical activity initiatives in primary school-aged children can either be integrated into the average school week (Daily Mile and Active Fridays) or carried out occasionally throughout the scholastic year (Activity Days and Healthy Lifestyle Week). Some initiatives are very easy to implement (Daily Mile) whereas others require more effort

(Active Fridays, Activity Days and Healthy Lifestyle Week) or may require additional funding (Let's Move). Some of the described initiatives have an established evidence base. For example, the Daily Mile is a simple, easy to implement, physical activity initiative that has been shown to be effective at promoting physical activity, reducing physical inactivity, and at improving fitness and body composition.[17] Irrespectively, long-term school-based physical activity interventions have been shown to improve body composition among primary school students in a recent meta-analysis.[18] and should be consistently implemented in schools. The education sector also stands to benefit from increasing physical activity in schools as classroom-based physical activity, in-turn, may lead to positive academic outcomes including classroom behaviours, cognitive function and academic achievements [19]

This study is not without limitations. An important limitation that needs to be taken in consideration when interpreting the results of this study is that it was carried out during the COVID-19 pandemic. This could have influenced the response rate and possibly the responses themselves in view of the school restrictions in place at the time, such as the mandatory quarantine of both staff and students. Another limitation of this study was in the quality and depth of the responses from the respondents. Respondents sometimes did not focus on a single initiative or did not provide strong evidence supporting their affirmative replies to the core criteria. This required significant interpretation on behalf of the two researchers when reviewing the replies to the questions for each initiative. This issue could have been averted through follow-up face-to-face interviews with the respondents. However, this could not be done as it was not taken into consideration when obtaining permission to administer the questionnaires to Heads of School or their equivalent by the MEDS Research Ethics Committee. This methodological choice was partly influenced by the full deployment of the main researcher to the National Maltese COVID-19 Public Health Response Team. Therefore, the results of this study cannot provide definite good practices using the previously described definition and core criteria.

This study serves as a good starting point on what practical actions can be implemented. Firstly, some of the less resource intense initiatives can be easily taken up by other schools. Secondly, it is highly recommended that an audit of the Whole School Approach to Healthy Lifestyle: Healthy Eating and Physical Activity Policy and Healthy Eating Lifestyle Plan is carried out. Thirdly, the JANPA toolbox core criteria should be central to the design and implementation of effective future interventions. This validated tool can be disseminated to schools through information sessions and workshops. Importantly is critical to convey the message that thorough documentation is needed for an initiative, including a description of the initiative itself and evidence for all core criteria, especially when it comes to monitoring and evaluation, to assess if an initiative is a good practice. Further research is needed to be able to qualify those initiatives as good practices more strongly and to identify more initiatives that are being carried out in Maltese kindergartens and primary schools.

SUMMARY BOX

What is already known about this subject:

- The prevalence rates of school-aged children in Malta who are either overweight or obese are among the highest in the WHO European Region.
- Kindergartens and schools are unique settings that may contribute towards the prevention of childhood obesity.

What are the new findings:

- Many of the less resource intense good practices can be easily extended to other schools across Malta.
- The validated survey tool can be used when designing and implementing new initiatives.

CONCLUSION

This study describes good practices that are effective and sustainable for childhood obesity prevention in Maltese kindergartens and primary schools. The good practice with the most support relates to food restrictions in the school food environment. Its' implementation in other schools across Malta could be assessed in the future through an audit. Other good practices that address nutrition and or physical activity were also briefly described. These can be extended to other Maltese kindergarten and primary schools. The validated survey tool can also be used when designing and implementing new initiatives.

ACKNOWLEDGEMENTS

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ORIGINAL ARTICLE

A short survey about drug deprescribing

Doriella Camilleri, Francesca Farrugia, Marise Gauci, Peter Ferry

Aim

The main purpose of the survey is to discover practices about deprescribing of potentially inappropriate polypharmacy among doctors working within the Department of Geriatric Medicine in Malta.

Methods

An online questionnaire was distributed via electronic mail to all doctors more senior than foundation year 1 working within the mentioned department between August and September 2021.

Results

A response rate of 54% was obtained. Just over half of the participants admitted to deprescribe at every opportunity, with psychiatric medications being mostly deprescribed. One of the commonest reasons for deprescribing included medication not indicated. Lack of knowledge about the reason for prescription and being prescribed by others were primary barriers to deprescribing. The role of a clinical pharmacist and need for a guideline was reflected in the results.

Conclusion

The importance of deprescribing is appreciated by many doctors working in geriatrics in Malta, but there is still room for improvement.

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Potentially inappropriate polypharmacy (PIP) is a growing concern particularly among older adults (>65 years) who have multiple co-morbidities. PIP implies that more drugs are prescribed than is necessary, having unacceptable side effects, wrong dosages, and/or having harmful interactions.[1]

Deprescribing is defined as the process of withdrawal of PIPs with the goal of reducing pill burden, and improving clinical outcomes.[2] There is lack of evidence about whether effective deprescribing is cost-effective.[3] There are various deprescribing tools including the STOPP criteria, STOPPFrail Beers Criteria and Bruyère Research Institute Deprescribing Guidelines.[4-7]

This survey was carried out in order to obtain more insight into the practice and perspectives of deprescribing among medical doctors working in the Department of Geriatric Medicine in Malta.

METHODOLOGY

Approval was obtained from the research committees of Karin Grech Hospital (KGH) and Saint Vincent de Paul long term care facility (SVP). An electronic survey was distributed to all second year foundation doctors, basic specialist trainees, higher specialist trainees, resident specialists, general practitioners and consultants working within the Department of Geriatric Medicine between August and September 2021. It included doctors working at KGH, SVP, orthogeriatric section at Mater Dei Hospital (MDH) and community. A total of 63 doctors were invited to participate. A second reminder was sent via electronic mail the following week.

RESULTS

Thirty-four out of 63 doctors accepted the invitation resulting in a response rate of 54%. All the results obtained were anonymous.

Table 1 The number of respondents from each professional group

Grade	n	Number of responses	% response
Consultant	18	14	78%
Resident specialist General Practitioner	7	4	57%
Higher Specialist Trainee	14	7	50%
Basic Specialist Trainee	5	2	40%
Foundation doctor	19	7	37%

Table 1 shows how the majority of respondents were consultants (41%).

A total of 53% of the respondents were male whilst 41% were female. A total of 6% of the participants preferred not to reveal their gender. (Table 2)

The age of the respondents is demonstrated in Table 3.

Figure 1 shows the different workplaces of the respondents. Several respondents are employed across different work settings within the geriatric department as shown below. A total of 7 respondents work both in KGH and in SVP.

Figure 2 shows how the majority of the respondents (52.9%) deprescribe at every opportunity. None of the respondents claimed that they never deprescribe.

Figure 3 shows how psychiatric medications including benzodiazepines and antipsychotics are commonly deprescribed. Around 85% (29) of the participants mentioned benzodiazepines as commonly deprescribed while 59% (20) of the respondents quoted antipsychotics as well as medications with anticholinergic properties, pro re nata basis (PRN) medications and antihypertensives as commonly deprescribed as well. Antidepressants, treatment for

Table 2 *The gender of the respondents*

Gender	n
Male	18
Female	14
Prefer not to say	2

Table 3 *Age groups of the respondents*

Age range	n
21 - 30	14
31 - 40	4
41 - 50	4
51 - 60	11
61 - 70	1

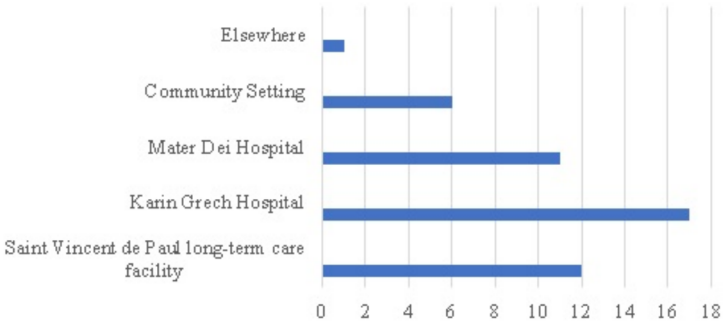

Figure 1 *Workplaces of the respondents*

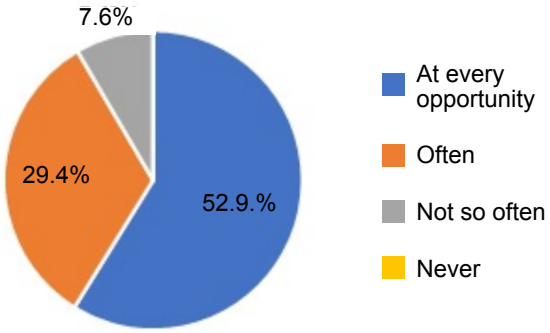

Figure 2 *Reported frequency of deprescribing attempts*

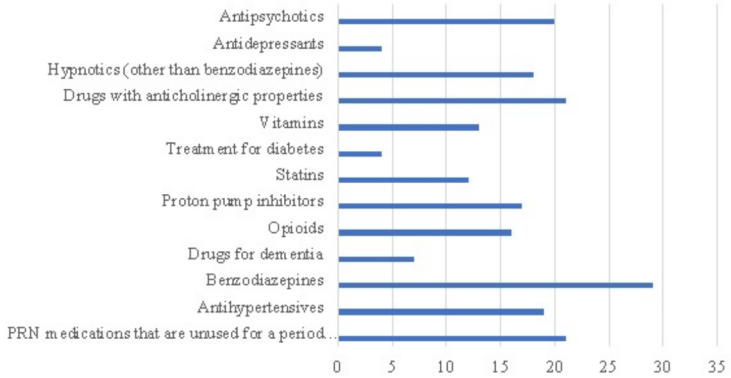

Figure 3 *Commonly deprescribed drugs*

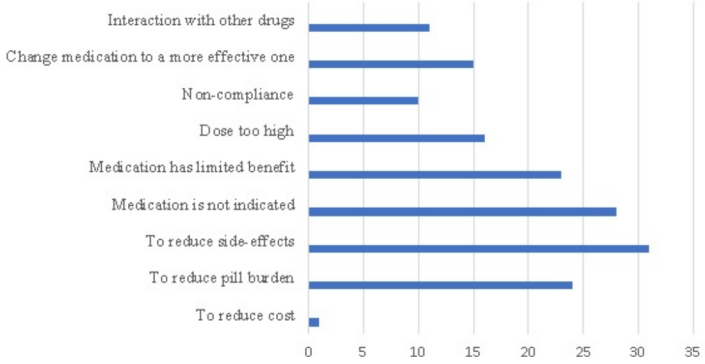

Figure 4 *Reasons for deprescribing*

diabetes and drugs for dementia were the least commonly deprescribed drug classes locally.

Figure 4 reveals some of the most common reasons for deprescribing, including to reduce side effects, when the medication is no longer indicated and to reduce pill burden. Cost of drugs seems to be the least common reason for deprescribing possibly reflecting the local system for free medications.

Figure 5 shows some of the barriers to deprescribing. A total of 8% of the participants do not understand the reasoning behind deprescribing. Not knowing why the medication was introduced, resistance from the patient or being prescribed by someone else are common barriers in Malta.

Figure 6 indicates how clinical pharmacists and guidelines about deprescribing may encourage doctors to deprescribe.

Figure 7 demonstrates how having a clinical pharmacist on the ward, having more deprescribing tools and teaching are keys for improvement. Of note clinically is that at present clinical pharmacists are only present at KGH.

Several comments from individual respondents were submitted in the survey. These are included in **Table 4.**

DISCUSSION

The survey had a very good response rate considering that 54% answered the questionnaire. This is better than quoted response rates in a study about deprescribing among geriatricians where only 26% answered.[8]

In this survey all the respondents answered that they all attempt to deprescribe at some point, with more than half trying to do so at every opportunity available and 29% do so often. There were, however, around 8% of respondents who did not do so regularly. The most commonly deprescribed drugs are benzodiazepines, drugs with anticholinergic properties, antipsychotics as well as medications which are prescribed on a PRN basis and rarely administered. Antihypertensives are the most deprescribed medication other than psychiatric medications.

The main reasons for deprescribing were to reduce the side-effect profile of medications, when the medication is not indicated, to reduce the medication burden and if the medication has limited benefits. This was also reflected in the study by Goyal et al carried out in 2018.[8]

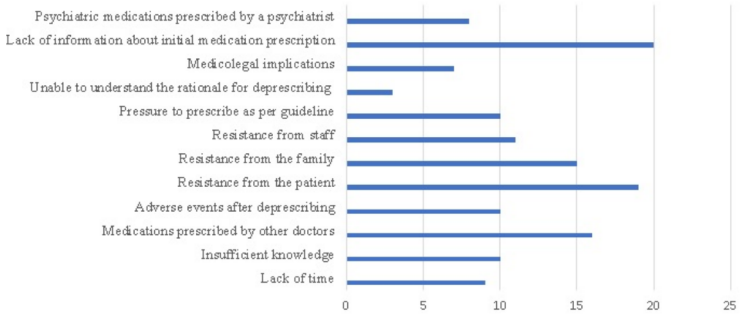

Figure 5 *Barriers for deprescribing*

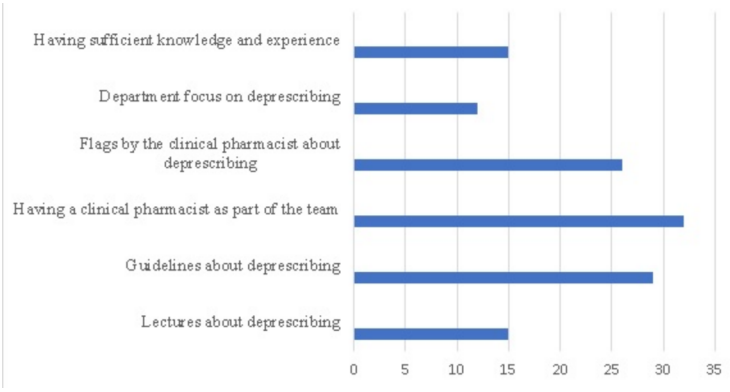

Figure 6 *Factors that encourage deprescribing*

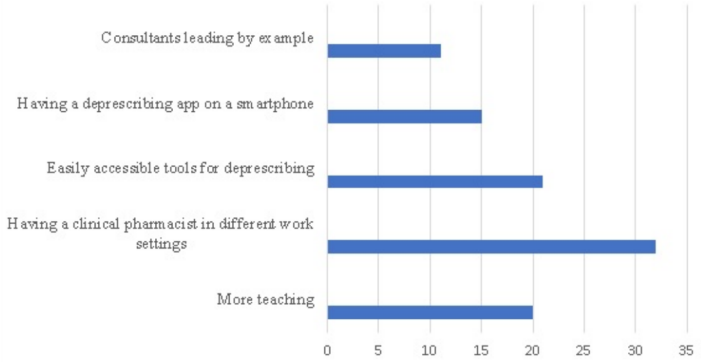

Figure 7 *Suggestions for improvement*

The most commonly encountered barriers to deprescribing were a lack of information of why and when the medication was prescribed and resistance from the patient to stop medications. The first two factors mentioned here were reflected in a study carried out in Singapore.[9] These scenarios are very common within the Maltese geriatric setting. Patients are referred to the geriatric team after being under the care of other professionals both in the acute setting as well as in primary health care and medical documentation may not always be available or up-to-date. Patients may not always remember the circumstances as to when and why certain medications were prescribed in the first place. Some patients may not be under the care of a general practitioner but rather resort to primary health care in times of need only, so geriatricians are very often in a difficult position where the patient has different medications prescribed by different doctors and an unclear drug history. Lack of time was not commonly quoted in the Maltese study, while this was one of the main barriers quoted by Nadarajan et al.[9]

The respondents of this survey feel that the role of the clinical pharmacist within the team is vital and important for deprescribing. This was also reflected in a study carried out by Kuntz et al.[10] The latter study also highlighted the importance of patient education, which was not highlighted in this study. The presence of a clinical pharmacist on the ward, the pharmacist role within the team to facilitate deprescribing and the availability of guidelines regarding deprescribing have proven crucial for the respondents.

The areas for improvement for the deprescribing efforts within the Maltese geriatric department according to the respondents include the presence of the clinical pharmacist in different work settings within the local geriatric field, easily available tools for deprescribing and more teaching. Several respondents of the survey also noted the importance of having senior doctors of the department leading

Table 4 *Comments*

Comments
The need to study the pharmacology of the drugs that the prescriber frequently prescribes.
The current trend of overprescribing, sometimes prescribing medications to counter the side-effects of other drugs.
The presence of a clinical pharmacist in different work settings, including in long- term care for guidance to doctors at both prescribing and deprescribing would be greatly beneficial.
To perform deprescribing during ward rounds of stable cases as deprescribing in acute scenarios may be impractical.
Drugs are not candy.

by example and the availability of deprescribing electronic applications on smart phones.

A deprescribing guideline is currently being adapted for use in Malta and will serve the purpose of having a readily available tool for medical professionals. Other online tools such as smart phone apps may be developed in the future, allowing a more widespread availability of updated resources regarding deprescribing across different work settings.

CONCLUSION

The results obtained from this survey are very important and shed light on the practices amongst doctors working within the Department of Geriatric Medicine in Malta. This is the first national survey which is crucial for the development of further quality improvement in Maltese practice. Whilst it is very encouraging that the vast majority of doctors within the department try to deprescribe drugs frequently, doctors to this day still face daily challenges in doing so during every clinical encounter.

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ORIGINAL ARTICLE

Preoperative Factors affecting TURP Postoperative Outcomes

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Objectives

To determine whether preoperative patient specific characteristics, presenting symptoms, renal status, medical treatment and patient comorbidities have an effect on TURP outcome by looking at postoperative variables such as trial without catheter (TWOC) success, long term catheter dependence, complication rate and follow-up duration.

Methods

Data was collected retrospectively from patients >40 years who underwent TURP and were followed up postoperatively between January 2014 and March 2015 in Malta's state hospital. Preoperative and postoperative variables were collected and compared using Fisher's exact test, independent sample t-test and one-way ANOVA.

Results

A total of 141 males were included, with 85 patients (60.3%) being catheter free with no or mild lower urinary tract symptoms reported in their last follow-up visit. Statistical significance was noted between indication of surgery and catheter dependence postop (LUTS vs AUR p=0.029; LUTS vs CUR p=0.003; LUTS vs any retention p=0.003). Poor preoperative renal status prior to surgery also increased the risk of remaining catheter dependent (p=0.008) and of having failed postoperative trial without catheter (p=0.004).

Conclusion

Patients undergoing a TURP locally had an overall successful outcome. Late presentation for TURP and a diminished renal function are associated with a poor postoperative outcome.

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Transurethral resection of the prostate (TURP) is a common endourological procedure for the treatment of obstructive urinary symptoms secondary to benign prostatic hypertrophy (BPH).

Literature shows that obstructive urinary symptoms are attributed to BPH, and are linked to aging with a resulting poor quality of life [1] Malta has an ageing population and the number of TURPs performed annually is expected to rise. Catheter failure rates and urinary incontinence following TURP have been associated with increasing age.[2,3]

Indications for having a TURP mainly include LUTS (lower urinary tract symptoms), acute urinary retention (AUR), chronic urinary retention (CUR). Studies show that patients presenting with urinary retention have a poor outcome.[4,5] Painless retention further increases the risk of having a failed trial without catheter (TWOC) success postoperatively.[6] Predictors of TWOC success will help prioritise patients for surgery.[7,8]

High bladder volumes increase the risk of bladder hypotonia, renal insufficiency and subsequent poor outcome. Overuse of medical treatment and delaying surgery has increased the prevalence of such presentations.[9,10] Medications such as alpha-antagonists, 5-alpha reductase inhibitors and a combination of the latter improve symptoms in a safe cost-effective manner.[10-12] Furthermore studies showed that BPH progresses faster in patients suffering from diabetes.[13,14]

The purpose of this study is to evaluate whether preoperative patient specific characteristics, presenting symptoms, renal status, medical treatment and comorbidities have an effect on TURP outcome during their postoperative follow-up by looking at TWOC success, long term catheter dependence, complication rate and follow-up duration. This will help with better resource allocation and patient prioritisation to improve outcomes of surgery.

METHODS

A retrospective review was conducted for men >40 years of age undergoing a TURP from January 1st 2014 to March 31st 2015 (16 months) for whom at least one postoperative recording was available. These dates were selected to have at maximum 5-year follow-up period from the date of surgery to the date of data collection. Data collection for each patient stopped at the time of their last follow-up. Patients who passed away by the time of data collection were excluded from the study since their records could not be accessed. All TURPs were performed under the supervision of five full time consultant urologists, who provide urological care in the Maltese islands. Data was collected from a database stored in the department of urology at Mater dei hospital (MDH) which listed all patients who underwent a TURP between January 2012 and December 2019.

Data was collected over a period of 8 months which started on the 5th March 2020 and ended on the 27th November 2020. Using the local health care software system (iSOFT and patient dashboard), discharge summaries and inpatient/outpatient records in MDH and Gozo General Hospital. Patients who underwent TURP for BPH only were included in this study.

Preoperative variables for patients who underwent TURP included patient demographics, indication for surgery, bladder residual volume at presentation, uroflowmetry, urinary tract ultrasound imaging, renal profile, catheter status at time of operation, medical treatment together with its prescribed duration, and patient comorbidities. The postoperative course was evaluated in terms of length of stay, uroflowmetry, TWOC failure, catheter status on discharge and at last follow-up, final operation outcome, medical treatment needed after surgery and follow-up duration.

Statistical analysis was performed using Fisher's exact test for categorical variables. Independent sample t-test and one-way ANOVA analysis was used for continuous variables. Results were considered significant if $p < 0.05$. IBM SPSS Statistics (Version 26) was used for data analysis. Approval for this study was obtained from the University of Malta Research Ethics Committee FREC number- UREC-DP2112004MED.

RESULTS

A total of 141 patients were included in this retrospective analysis. Mean age was 69.5 years (SD 7.6 years) with the most common age group being between 60-69 years. Mean LOS was 3 days (SD 1.3) and mean follow-up post-TURP was 1149 days (SD 851 days). Common indications for surgery include LUTS (n=61 (43.3%)) and retention i.e. AUR and CUR (n=75 (53.2%). Out of 141 patients, 85 patients (60.3%) were catheter free with no or mild LUTS reported in their last follow-up visit. The commonest early complication was bleeding requiring readmission (5 (3.6%)). Preoperative and postoperative variables are listed in Table 1 and Table 2 respectively.

Table 1 *Variables of measured TURP preoperative and postoperative variables*

Retention status	Residual urine >500ml n= 118	53 (37.6%)
	Painful urine retention n= 141	30 (21.3 %)
	Mean residual urine volume at presentation (ml) n= 120	635.39 (694.51)
Renal status	Hydronephrosis at presentation n= 96	25 (17.7%)
	Atrophy at presentation n= 96	4 (2.8%)
	AKI[1] at presentation n= 140	37 (26.2%)
	Mean eGFR at presentation (SD) n= 140	75.36 (26.18)
Catheter status	Failed preoperative TWOC[2] n= 141	38 (27.0%)
	Catheter in situ at TURP[3] n= 141	63 (44.7%)
Comorbidities (n= 141)	Diabetes n= 141	38 (27.0%)
	CVA n= 141	4 (2.8%)
	Parkinsons n= 141	2 (1.4%)
	Neurological condition n= 141	5 (3.6%)
Medication (n= 141)	Preop medical treatment for BOO[4] n= 141	95 (67.4%)
	Mean duration of treatment preop in months (SD) n= 85	16.39 (24.03)
Indication (n= 141)	LUTS[5]	61 (43.4%)
	Refractory urinary retention	22 (15.6%)
	Chronic retention without catheter	14 (9.9%)
	Chronic retention with catheter	39 (27.7%)
	Intractable prostatic bleeding	4 (2.8%)
	Bladder stones	1 (0.7%)

[1]Acute kidney injury, [2]Trial without catheter, [3]Transurethral resection of the prostate, [4]Bladder outlet obstruction, [5]Lower urinary tract symptoms

Table 2 *Variables of measured TURP preoperative and postoperative variables*

Retention status	Mean residual urine after successful TWOC[1] (ml) n=141	69.59 (111.64)
	Mean residual urine volume at follow-up (ml) n=102	47.14 (109.50)
Catheter status n= 137	Failed inpatient TWOC	18 (12.8%)
	Catheter free at last follow-up	124 (87.2%)
	Catheter dependent at last follow-up	13
	Mean days postoperatively with catheter	5.10 (8.03)
Postoperative complications n= 141	Bleeding requiring re-admission	5 (3.6%)
	Bleeding requiring re-operation	1 (0.7%)
	Sepsis	4 (2.9%)
	Readmission with retention	2 (1.4%)
	Stress urinary incontinence	1 (0.7%)
	Urethral stricture	4 (2.9%)
	Prostate regrowth- LUTS[2]	2 (1.4%)
	Prostate regrowth- re-TURP[3]	3 (2.1%)
	None	118 (84.0%)
Outcome n= 141	Catheter free- no or mild LUTS	85 (60.3%)
	Catheter free- LUTS (conservative treatment)	3 (2.1%)
	Catheter free- LUTS (medical treatment)	30 (21.3%)
	Catheter free- LUTS (re-TURP)	6 (4.3%)
	Long term catheter	3 (2.1%)
	Intermittent self catheterisation	10 (7.1%)
	Did not turn up for follow-up	4 (2.8%)

[1]Trial without catheter, [2]Lower urinary tract symptoms, [3]Transurethral resection of the prostate

Table 3 *Catheter dependence at last follow-up is related to mode of presentation*

Outcome Indication	Catheter free at last follow-up	Catheter dependent at last follow-up	*p*-value
LUTS[1] vs AUR[2] n= 80	57	1	*0.029*
	19	3	
LUTS vs CUR[3] n= 110	57	1	*0.003*
	42	10	
AUR vs CUR n= 74	19	3	0.743
	42	10	
LUTS vs Any retention n= 132	57	1	*0.003*

[1]*Lower urinary tract symptoms,* [2]*Acute urinary retention,* [3]*Chronic urinary retention*

The mean age of men who were catheter free at last follow-up was 69.2 years compared with the 71.9 years for men who were not catheter free ($p = 0.159$). Only 5 patients were never catheter free post-TURP (mean age of 75.1 years). No statistical difference was noted when comparing catheter free rates with age groups ($p = 0.543$).

Table 3 shows that when compared to patients with LUTS, patients with AUR and CUR prior to surgery have a higher risk of remaining catheter dependent (LUTS vs AUR $p = 0.029$; LUTS vs CUR $p = 0.003$). Patients with any type of retention are also more likely to remain catheter dependent postoperatively when compared to LUTS ($p = 0.003$). There was no statistical significance in patients presenting with painful retention and outcome of surgery ($p = 0.364$). Furthermore there was no relationship between preoperative post-void residual (PVR) urine volumes and postoperative outcomes ($p = 0.3$).

Patients presenting with hydronephrosis were associated with a higher rate of failed TWOC (($p = 0.004$) and catheter dependence ($p = 0.008$) postoperatively. A failed postoperative TWOC (P 0.012) and poor outcome (P 0.003) were linked to a lower mean eGFR levels as seen in Table 4.

Table 4 *Effects of hydronephrosis and renal status on postoperative outcome*

Variable	Hydronephrosis n= 96		*p*-value	eGFR n=136	*p*-value
	Yes	No			
Failed postoperative inpatient TWOC[1]	8	5	*0.004*	60	*0.012*
Successful TWOC	17	66		77	
Catheter free at last follow-up	18	66	*0.008*	77	*0.003*
Catheter dependent at last follow-up	7	3		54	

[1]*Trial without catheter*

The majority of patients (95 (67.4%)) were on medical treatment prior to surgery. Mean age of patients on medication and those not on medication was 69.8 and 69.9 respectively (p = 0.48). Mean duration of medication was 16.4 months. Patient follow-up (p = 0.207) and outcome (p = 0.835) were not affected by preoperative medication.

Diabetic patients did not have an increase in the rate of postoperative complications (p = 0.980), poor outcome (p = 0.940), re-TURP (p = 0.741) or length of follow-up (p = 0.584).

Preoperative Qmax was calculated in 13 patients (9.2%) while postop Qmax was calculated in 18 patients (12.8%).[1] One patient received a transfusion during the perioperative period.

DISCUSSION

Our study did not show a relationship between age and catheter free rates. In a prospective study, Losco et al[2] determined that age does influence the risk of postoperative catheter dependence. The latter also recommended that TURPs should be recommended in context of anaesthetic risk and long-term disability of these patients. Other minimally invasive surgeries such as GreenLight laser vaporization, Holmium laser enucleation and transurethral needle ablation of the prostate were recommended in elderly individuals however all of the latter are not commonly performed locally.[2]

Our results revealed that 53 patients (37.6%) present late in states of retention. Khan et alconcluded that mode of presentation heavily determines the postoperative outcome.[4] Painful or painless retention should be specified during preoperative assessment. This retrospective analysis failed to show a link between painless retention and a failure to TWOC postoperatively. Literature shows that painless retention is highly indicative of bladder dysfunction and is less likely to improve with a TURP[15] Other factors which influence the risk of a failed TWOC and poor surgical outcome include prostate mass (>50g), severe LUTS according to International Prostate Symptom Score (IPSS) and high preoperative PVRs (>1000ml).[7]

Hydronephrosis was a common feature in patients presenting for a TURP in our cohort. This may be related to a delay in surgery due to a heavy reliance on pharmacological treatment for BOO with many patients presenting in states of retention and hydronephrosis resulting renal insufficiency.[10-11] Studies recommend starting patients presenting with AUR on an alpha blocker with an eventual plan for TWOC and TURP since it increases the chance of having a successful outcome postoperatively.[16]

Contrary to the above results, literature shows that patients with diabetes are susceptible to more postoperative complications and have a higher risk of re-TURP.[13]

The European Association of Urology recommends that uroflowmetry be performed prior to undertaking medical or surgical treatment. This will help monitor postoperative treatment outcomes.[1] Our study showed that preoperative Qmax was only documented in 13 patients preoperatively.

Smith et al[17] does not recommend routine crossmatch since it is classified as a low-risk procedure. Patients should be candidates for cross match taking in the presence of a coagulopathy and if Hb is <10g/dl.[17] This idea is reinforced above since only one patient required perioperative

SUMMARY BOX

What is already known:

- Catheter failure rates and urinary incontinence following TURP have been associated with increasing age
- Studies show that patients presenting with urinary retention have a poor outcome
- High bladder volumes increase the risk of bladder hypotonia, renal insufficiency and subsequent poor outcome.
- BPH progresses faster in patients suffering from diabetes

What this study adds:

- Age has no affect on postoperative catheter status
- Patients with any type of retention are more likely to remain catheter dependent postoperatively when compared to LUTS
- Patients presenting with hydronephrosis were associated with a higher rate of failed TWOC and catheter dependence postoperatively
- Diabetic patients did not have an increase in the rate of postoperative complications (p = 0.980), poor outcome (p = 0.940), re-TURP (p = 0.741) or length of follow-up (p = 0.584).

administration of blood products. Avoiding routine cross match taking will improve cost cutting significantly.

Being a retrospective study, data collection was only limited to data which could be gathered from patients' medical notes. Our population number was limited to patients who were alive at the time of data collection since patients who passed away could not have their records accessed. Last day of follow-up was considered as their last visit to a urology clinic irrespective to whether this visit was related to their TURP follow-up. This led to some patients having longer follow-ups which do not reflect their true postoperative follow-up. Human error during data collection was limited as much as possible by creating standardised data collection models.

CONCLUSION

In conclusion, this study showed that TURP remains a successful procedure for all age groups and it is still the gold standard surgical treatment for LUTS/BPH Our findings support the hypothesis that patients presenting with retention and hydronephrosis have a less favourable result after postoperative TWOC and should be prioritised to prevent progression of disease. Such patients should be informed preoperatively that their chances of failure to void after TURP is greater.

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ABBREVIATIONS

TURP	Transurethral resection of the prostate
BPH	Benign prostatic hypertrophy
LUTS	Lower urinary tract symptoms
AUR	Acute urinary retention
CUR	Chronic urinary retention
TWOC	Trial without catheter
MDH	Mater dei hospital
PVR	Post void residual
AKI	Acute kidney injury
BOO	Bladder outlet obstruction

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ORIGINAL ARTICLE

Discharge documentation for febrile children in the Paediatric Emergency Department: how can it be improved?

Ruth Farrugia, John Xuereb, Christopher Micallef, Victor Calvagna

Background

A high turnover of patients is the norm at the paediatric emergency department, which inadvertently affects the documentation of patients' encounters.

Methods

This retrospective study involved two audit cycles, performed over six-week periods at a one-year interval, to assess discharge documentation for febrile children in the paediatric emergency department. Documentation for the following fields was assessed; diagnosis, treatment prescribed, drug doses, advice given, legibility and follow-up plan. A number of deficiencies in documentation were identified following the first cycle. Three interventions were implemented: presentation of initial audit to doctors, setting-up of a follow-up clinic for febrile children and designing a handout for carers about caring for febrile children. Chi-squared test was used, with a p-value of <0.05 considered as significant.

Results

386 and 380 children were included respectively in the first and second audit. Diagnosis was documented in 84% (n=324) and 80% (n=304) respectively (p=0.09). No significant change in documentation of the prescribed treatment was noted, 73% (n=285) versus 79.4% (n=302). However, there was a significant positive trend in documentation of actual drug doses ($p<0.0001$). Documentation of advice given to carers rose significantly from 11% to 48.6% ($p<0.0001$). A significant improvement in documentation for follow-up plan was documented, 32% (n=122) to 40% (n=153) (p=0.01). Legibility was the only parameter to show a worsening trend ($p<0.0001$).

Conclusions

This study looks at the effectiveness of three interventions on the level of documentation for discharge planning of febrile children from the paediatric emergency department. In spite of the marked gains, there is room for improvement.

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The paediatric emergency department (PED) is a hectic place with a very high turnover of patients. Time pressures, frequent interruptions and incomplete information may place further pressure on the attending physician, and documentation often suffers in this environment. The PED sheet provides the only lasting record of the details of care provided to each patient. Complete documentation of any patient encounter is of paramount importance, both to provide a clear picture of what has been done and also as evidence should things go wrong – it alters medicolegal risk.[1] The discharge process is one of the critical periods during the doctor-patient interaction, when clear communication is important and documentation of what has been said is essential. Furthermore clear instructions and adequate information should be given upon discharging patients home.

An initial audit assessing discharge documentation for febrile children presenting to the PED was performed at Mater Dei Hospital in Malta in 2015. Since fever is a very common presentation in the PED, the documentation for febrile children who are discharged home was deemed to be a good representative of overall discharge documentation from the PED. The audit had highlighted a number of deficiencies in documentation of the emergency department discharge plan for febrile children. Subsequently the following interventions were implemented: presentation of initial audit findings to all doctors working in the PED emphasising the areas needing improvement, the setting-up of a follow-up clinic for children with pyrexia (to provide a pathway for early follow-up when required) and the design of a handout for carers which contained information about caring for the febrile child (including when to seek urgent medical advice). A second audit was repeated during the subsequent year in order to assess for changes in the adequacy of discharge documentation.

The aim of this study was to examine the effectiveness of the above interventions on the documentation of discharge plans for febrile children under the age of 16 years presenting to the PED at Mater Dei Hospital in Malta with pyrexia. The outcome was to improve both discharge documentation and discharge planning for febrile children in the PED.

MATERIALS AND METHODS

This retrospective study was performed over a six week period during December and January for two consecutive years, with a number of interventions being introduced following the first audit cycle.

The study involved children attending the PED at Mater Dei Hospital with fever and subsequently being discharged home. Mater Dei Hospital in Malta is a regional centre providing secondary and tertiary paediatric services. The PED is manned by second year foundation doctors and trainees in family medicine and paediatrics, under the supervision of two paediatric emergency consultants. Patient encounters are documented manually by the attending medical officer.

Patient record sheets for paediatric attendances were manually selected from amongst the sheets of all patient attendances to the emergency department during both study periods. Inclusion criteria were children aged up to 15 years and 11 months whose presenting symptom at casualty reception was fever, those for whom 'fever' was written at triage assessment and all children found to be febrile at triage. Patients who discharged home against medical advice were also included. Children who left the PED before being seen by a doctor, as well as those needing hospital admissions, were excluded. Written permission was obtained from the chairperson of the paediatric department.

Documentation for the following fields was assessed; diagnosis, treatment prescribed and drug doses, advice given, legibility and follow-up plan. There were no formal guidelines or standards for documentation of discharge plans, so these criteria were chosen as being the most relevant for medico-legal purposes following discussion with the clinical departmental chair and the hospital lawyer.

Criteria Being Assessed For Documentation

1. Diagnosis recorded

This field referred to whether the patient's diagnosis was documented or not, without assessing whether the diagnosis fit in with the history. Illegible inconclusive or irrelevant diagnoses which did not refer to the underlying source of fever were recorded as 'no diagnosis'.

2. Treatment prescribed

This field was classified as a 'yes' or 'no' answer. For a positive score, drug name had to be specified in the treatment section or in the discharge note, with the exception of antipyretics, in which case 'antipyretics as prescribed' was included as positive.

3. Doses recorded (if treatment is documented)

There were four possible answers in this field: 'Yes' when all drug doses were documented; 'No' when no

drug doses were documented; 'Mixed' where some were documented (typically the antibiotic dose) and some weren't (typically the antipyretic doses); and not applicable (N/A) when there was no documentation of the treatment prescribed (previous outcome) and therefore no doses could have been written.

4. Advice given

Advice involves any warning signs which should prompt the patient or carer to seek immediate medical advice and not wait for the formal follow-up which would have been recommended. Three possible answers were chosen. When the full advice was documented, or in cases where 'handout given' was written, this was graded as 'yes'. 'No' referred to instances where the advice was not documented. Where the term 'warning signs explained' was written, without any further details, this was graded separately an intermediate grade 'WS'. The handout was produced following the first audit cycle and therefore was only available during the second audit cycle.

5. Legibility

Legibility was scored as a 'yes', 'moderate' or 'no', depending on the degree of handwriting clarity.

6. Follow-up plan

An acceptable follow-up plan involved one of three options: 1. A formal referral for follow-up; 2. Advice for General practitioner (GP) follow-up in a specific time-frame; 3. Objective signs given regarding need for medical advice – for example to seek medical advice if fever persists more than 48 hours. Where 'to return as needed' or 'to return if deteriorates' were written, these were not counted as follow-up plan, since these are subjective signs which parents might miss.

We included the specific diagnosis in order to have a clear picture of the range of diagnoses involved in this audit. For further analysis, the diagnoses were divided into those of viral origin and those of bacterial origin. Upper respiratory tract infections, gastroenteritis (unless specified as bacterial), pharyngitis and viraemia were included as viral infections. The bacterial infections included tonsillitis, bacterial enteritis, lower respiratory tract infection and otitis media.

Interventions

Three interventions were carried out based on the results from the initial audit. These interventions were executed in the six months prior the second cycle. The interventions included:

1. Presentation of the audit findings to trainees working in the PED at Mater Dei Hospital in order to increase awareness of the importance of full documentation of discharge planning
2. Issuing of a new handout containing useful information for the carers of febrile children, including general warning signs
3. A follow-up clinic for children with pyrexia was launched within the PED, to ensure the provision of adequate follow-up for those children deemed to need close follow-up after presenting to the PED with fever after discharge home

Data Collection

We aimed for a cohort of 380 patients for each audit cycle. The sample size was calculated to be representative of the whole population of children who visit the PED in one year, based on the findings of a previous study that 2269 children attended the PED at Mater Dei Hospital over a time period of three months.[2]

Data was collected by the same two foundation year doctors for both cycles, who also scored the parameters. 10% of the sheets were independently reviewed by a consultant paediatrician, in order to ensure consistency. There were no disagreements regarding the assigned scores.

The data was entered into an excel spreadsheet. Percentages were used to illustrate proportions for each of the assessed parameters for both audit cycles. Chi squared test was used to test for significance, with a p value of <0.05 being considered as significant.

Electronic medical records (EMR) capabilities are not currently available at our institution.

RESULTS

A total of 386 children who fit the inclusion criteria were included in the first audit cycle. These patients were seen in the paediatric emergency department over a period of five weeks, between the 5th December 2015 and 10th January 2016. For the second audit cycle, 380 children were included over a period of six weeks, between the 4th December 2016 and 15th January 2017.

Diagnosis was documented in 84% (n = 324) and 80% (n = 304) for the first and second audit cycles respectively (p = 0.09). The majority of patients with recorded diagnosis had viral infections (n = 536); 85%, with just over half of these patients having a viral infection involving the upper respiratory tract.

There was no significant change in documentation of the prescribed treatment, with rates at 73% (n = 285) versus 79.4% (n = 302) during the two audit cycles. However there was a significant positive trend in documentation of actual drug doses amongst the patients for whom the treatment was documented ($p < 0.0001$).

Documentation of the advice given to carers rose significantly from 11% to 48.6%, including instances where 'handout given' was documented in the notes (p < 0.0001). There also was a significant improvement in documentation for follow-up plan, from 32% (n = 122) to 40% (n = 153) of cases overall (p = 0.01). Unfortunately documentation of follow-plan was lacking in more than half of those patients diagnosed with bacterial infection, namely 72% (71/99) during the first audit cycle and 55% (24/40) in the second cycle.

Legibility was the only parameter to show a worsening trend during this audit. The trend was significant (p < 0.0001), with a drop from 84% (n = 324) to 70% (n = 266) of notes deemed completely legible and doubling of the rate of illegible discharge plans from 2% (n = 6) to 4.5% (n = 17).

DISCUSSION

Doctors spend an average of 11.6 minutes of charting per patient visit.[3] However there are several deficiencies in documentation of patient encounters, including the management plan.[4] Our initial audit in 2015 highlighted a number of deficiencies in discharge planning for febrile children from the PED We then researched the most effective methods to improve documentation of discharge planning whilst also enhancing patient care, mainly focusing on advice given to parents prior to discharging patients home.

A significant proportion of patients and parents will either not understand or not follow discharge instructions upon returning home from the emergency department. Waisman et al[5] found that only about 75% of parents understood their child's diagnosis. The parents suggested that a discharge nurse would facilitate their understanding of discharge instructions, with their second favourite option being the use of discharge instruction sheets related to their child's specific diagnoses.

When questioned, parents ask for understandable written and verbal instructions, self-management plans and clear instructions regarding follow-up.[6] These are important elements of the discharge plan for which documentation has been shown to be lacking.[7] Even written discharge documentation can still be inadequate.[8] It is important to keep these instructions simple [9] and to aim at a comprehension level which will be understood by the general population, since discharge instructions may inadvertently be at an inappropriately high reading level.[10]

Following discharge from the emergency department, less than half of parents correctly record the treatment prescribed for their child.[11] Parents may also fail to obtain the prescribed medications and default from the scheduled follow-up visits with their physician[12], especially primary-care follow-up.[13]However attendance rates for follow-up visits improve if these are scheduled in the emergency department.[14]

Isoardi and colleagues[4] assessed the impact of formal teaching on medical documentation by interns in an

Table 1 *Pre and post intervention audit results*

Parameter	Quality of Documentation Initial Audit (n = 386)			Quality of Documentation Re-Audit (n = 380)			Chi	pvalue	Trend
	Complete	Partial	None	Complete	Partial	None			
Diagnosis	324	N/A	62	304	N/A	76	2.85	0.09	
Treatment prescribed	285	N/A	101	302	N/A	78	3.40	0.07	
Doses prescribed	114	40	131	149	97	56	58.01	*<0.0001*	Improving
Advice given	44	243	99	185	107	88	140.27	*<0.0001*	Improving
Follow-up plan	122	N/A	264	153	N/A	227	6.24	*0.01*	Improving
Legibility	324	56	6	266	97	17	21.9	*<0.0001*	Worsening

emergency department and also found significant deficiencies in documentation of discharge planning in their audit. Their pre-intervention data collection showed some deficiencies in documentation which were similar to the results obtained in our initial audit, namely in medication ordered (34%vs 27.3%) and advice given, which was inadequate in 79.2% of cases in their study and in 89% in our initial audit.[4] However they had a better rate of documentation of referrals or follow-up (75% vs 32%) and of diagnosis (100% vs 83.9%). Formal teaching did not lead to any significant improvement in the quality of documentation for treatment prescribed, discharge instructions and referrals.[4] However a systematic review by Lorenzetti et al[15] showed that the use of audits and provision of feedback have a significantly positive impact on documentation in the emergency department.

Following the first audit cycle, we proposed a number of interventions based on our findings and the other studies mentioned above, namely a discharge information sheet, a follow-up clinic and a formal presentation to departmental trainees. The discharge information sheet was aimed at carers of children with fever, when these are discharged home from the emergency department and included information for carers, warning signs and instructions when to seek medical advice. A follow-up clinic was set up in order to facilitate early follow-up for selected patients with pyrexia. Apart from leading to an improvement in documentation for follow-up plans, the clinic provided a niche for planning care for selected patients needing close follow up and therefore also improved patient service. Our findings were also presented to all doctors working in the PED in order to increase awareness of the importance of documentation and to explain about the handout and set up of the follow-up clinic.

The results from our second audit cycle show a significantly improved performance in most of the parameters which we have used to measure documentation when compared to the initial audit performed in 2016. Legibility was the only parameter showing a negative performance, but we are unable to explain this. Electronic medical records would be another intervention which can help with improving legibility. Apart from this, EMR can also help improve documentation in the other fields studied by having standardised fields which one can fill in at discharge documentation.

The audit was performed during the same time period for both years, during the busy months of December and January to try to emulate the same conditions for both assessments and eliminate sources of bias.

SUMMARY BOX

What is already known about this subject:

- Complete documentation of any patient encounter is of paramount importance.
- The discharge process is one of the critical periods during any doctor-patient interaction.
- The high patient turnover at the paediatric emergency department may inadvertently affect the documentation of patient encounters.

What are the new findings:

- Our pre-intervention data identified deficiencies in most areas of discharge documentation, which improved with our three interventions.
- The improvements in documentation of treatment and drug doses prescribed may be attributed to the presentation of the initial audit findings to the doctors working in the department.
- The significant advances made in documentation of advice given to parents, was mainly due to the fever handout, containing all the relevant warning signs, which was introduced after our first cycle.
- The introduction of the early follow-up clinic, apart from raising the percentage of documentation for follow-ups; meant an improvement in the services provide by our department.

Our pre-intervention data collection identified deficiencies in documentation for these areas: 'treatment prescribed' (73% documented), 'dose of medication prescribed' (40% documented), 'advice given' (11%) and 'follow up plan' (32%). All of the 3 implemented measures seem to have impacted on the improvement in these areas of documentation for febrile children who are discharged home from the PED The gains in documentation of treatment (6.3%) and drug doses prescribed (8.8%) may be attributed to the presentation of the initial audit findings to the doctors working in the PED The most significant advance was made in documentation of advice given to parents, which more than quadrupled (from 11.4% to 48.6%) and this is mainly due to the fever handout, which contains all the relevant warning signs. By writing 'handout given' doctors are automatically

including these warning signs in their notes. The follow-up clinic, which marked the introduction of a new service, has made it easier to provide follow-up for those who need it and has raised the percentage documentation of follow-up by 7.7%.

The limitations of the study include that we did not create any standardised form for documentation criteria for the department. Also Group consensus or Delphi technique in the creation of the standards for documentation of discharge planning would have provided a stronger methodological approach, apart from the essential input from the clinical chair and hospital lawyer. EMR are not available at present in our institution, which could have been an essential tool to help keep track of discharge documentation and in improving documentation across the board. For Legibility moderate legibility was not defined, therefore between chart auditory there could have been a wide variability in interpretation. Our interventions, although focused to mark improvements in discharge documentation, were focused on some practical deficiencies noted by our peers, for example the lack of clear pathway for early follow-up for discharged children. This led to the setting up of the early follow-up clinic, therefore provided a route for early follow-up and indirectly thereafter improving discharge documentation.

CONCLUSION

Discharge planning is a critical area, both in terms of patient care and communication and in terms of possible future medicolegal consequences. This study looks at the effectiveness of three interventions on the level of documentation for discharge planning of febrile children from the PED In spite of the marked gains in some areas of documentation, there is room for further improvement. Ongoing measures are necessary to maintain and increase the level of documentation for all discharge plans from the PED.

ACKNOWLEDGMENTS

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ORIGINAL ARTICLE

Improvement in pain and patient comfort during injection of local anaesthesia with the use of sodium bicarbonate

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Background

The beneficial effect of adding 8.4% sodium bicarbonate ($NaHCO_3$) to local anaesthesia, making it less painful to inject, is documented in the literature. However, few doctors actually put this knowledge into practice. With this study, we quantify this effect in the Maltese population and justify its use in our day to day practice. In addition, we take this opportunity to elaborate on the additional factors that improve patient comfort when injecting local anaesthesia.

Method

A total of 150 patients having a procedure under local anaesthesia at the Plastic Surgery and Burns Unit, at Mater Dei Hospital, Malta, were included in this study. 75 patients were injected with lidocaine alone and another 75 patients were injected with lidocaine mixed with 8.4% sodium bicarbonate.

Results

The commonest age group was the 70-79 age group in both cohorts. The minimum pain score was 0 in both groups. The highest score was 9 in the group without sodium bicarbonate and 8 in the group with sodium bicarbonate. The mean pain score was 3.93 in the cohort without sodium bicarbonate and 2.55 in the cohort with sodium bicarbonate. The median value was 4 in the group of patients injected without sodium bicarbonate and 2 in the group injected with sodium bicarbonate. The *p-value* was <0.05, making these results statistically significant.

Conclusion

Alkalinisation of local anaesthetic solutions improves the pain of infiltration of the local anaesthetic at a minimal cost. This increases patient compliance and patient comfort and thus allowing more surgeries to be performed under local anaesthesia.

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The beneficial effect of adding 8.4% sodium bicarbonate ($NaHCO_3$) to local anaesthesia, making it less painful to inject is documented in the literature. However few doctors actually put this knowledge into practice. In some cases, the pain during injection of local anaesthesia is so severe, that although it is short lived, deters the patient from doing any future surgery under local anaesthesia.[1-8] This increases the risks from general anaesthesia and also the financial burden on the hospital. With this study, we quantify this effect in the Maltese population and justify its use in our day to day practice. In addition, we take this opportunity to elaborate on the additional factors that improve patient comfort when injecting local anaesthesia.

METHOD

Approval to proceed with this study was obtained from the Chairman of Surgery, the CEO, the Legal Officer and the Data Protection Officer at Mater Dei Hospital Malta where it was carried out. Ethical clearance was obtained and all the patients gave verbal consent to be included in the study. The patients were approached to be included in the study only after the procedure was done so as to avoid possible effects resulting from patient/doctor power dynamics. A total of 150 patients having a procedure under local anaesthesia at the Plastic Surgery and Burns Unit at Mater Dei Hospital Malta were included in this single-blinded study. 75 patients were injected with lidocaine alone and another 75 patients were injected with lidocaine mixed with 8.4% $NaHCO_3$. The patients did not know in which arm of the study they were part of. The mixture that the second cohort were injected with, was composed of 9mls of lidocaine and 1ml of 8.4% $NaHCO_3$. The patients included in the study were consecutive patients that had surgery done under local anaesthesia. There were no exclusion criteria. The local anaesthetic was injected by a CT1 grade or higher, small needles were used and the anaesthetic was injected slowly. The temperature of the anaesthetic was brought up to body temperature as much as possible. After the surgery, the patients were asked the same formulated question, asking them to quantify the pain of injection of the anaesthetic, excluding the insertion of the needle with which the anaesthetic was given. This was done with the help of the visual analogue scale shown in **Figure 1.**

The data obtained included: gender, age, area injected, presence of diabetes or fibromyalgia, other comorbidities affecting perception of pain including previous surgery at same site, expertise of injector, pain score and whether the anaesthetic was mixed with 8.4% $NaHCO_3$ or not. This information was inputted anonymously in an excel sheet and analysed using a one tailed, two sample, unequal variance t-test.

RESULTS

Seventy-five patients were considered in each cohort – local anaesthetic with $NaHCO_3$ was injected in one group while subjects in the other group received local anaesthetic without $NaHCO_3$. The commonest age group was 70 – 79 in the cohort with local anaesthetic without $NaHCO_3$, while the commonest age range of the other group was 60 - 69 years. **Table 1** summarises the characteristics of all included subjects, namely gender, age, comorbidity and pain score. Three of these characteristics – gender, age and pain score – were found to be statistically significant in relation to the local anaesthetic solution used with *p*-value <0.05 indicating that local anaesthetic with bicarbonate addition has a direct relationship to gender, age and pain score.

The average pain scores for **Figure 2** exhibits mean and 95% confidence intervals (CI) achieved from the

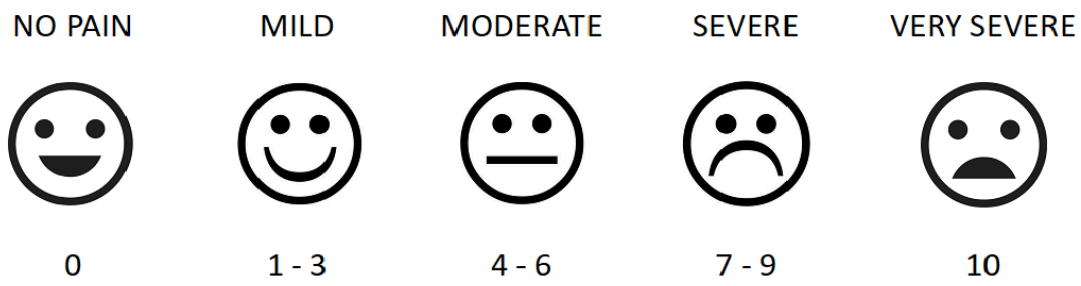


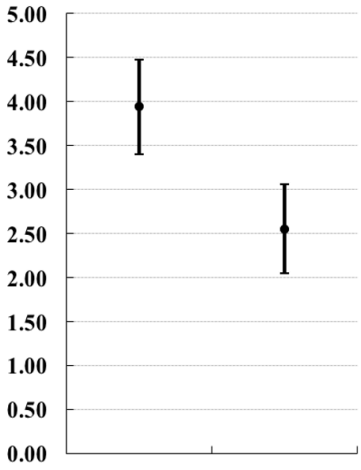
Figure 1 *Pain Visual Analogue Score*

Table 1 *Characteristics of subjects including gender, age, past medical/surgical history and pain score. P values correspond to overall comparison of row variables (Gender, Age, Past Medical/Surgical History, Pain Value) in comparison to column variables (use of local anaesthetic with or without bicarbonate). Values do not represent comparison of specific groups within each variable.*

	Without bicarbonate	With bicarbonate	*p* value
Gender			
Male	39	44	*<0.00001*
Female	36	31	
Age (years)			
0 – 9	0	0	*<0.00001*
10 – 19	4	2	
20 – 29	6	8	
30 – 39	4	10	
40 – 49	8	8	
50 – 59	12	9	
60 – 69	14	13	
70 – 79	19	16	
80 – 89	7	8	
90 – 99	1	1	
Past Medical/Surgical History			
Diabetes Mellitus	6	7	0.37
Fibromyalgia	1	0	
Stroke affecting site of surgery	0	1	
Previous surgery at same site	2	5	
Others: Stage 2 lymphoma, Multiple sclerosis	2	0	
Nil	64	62	
Pain Value			
0 (least)	9	18	*0.018*
1	4	9	
2	9	15	
3	7	12	
4	11	2	
5	19	11	
6	5	4	
7	6	3	
8	4	1	
9	1	0	
10 (most)	0	0	

two cohorts. Table 2 further explains the median, standard deviation, minimum and maximum in both groups. The *p*-value from this data is also <0.05, confirming the difference between the two cohorts to be statistically significant.

The average pain scores of specific age groups, gender and medical conditions with or without bicarbonate are exhibited in Table 3.



	Without bicarbonate	With bicarbonate
Upper 95% CI	4.47	3.05
Mean	3.93	2.55
Lower 95% CI	3.40	2.04

Figure 2 *The mean and 95% CI for both cohorts*

Table 2 *The mean, median, standard deviation, minimum and maximum for both samples*

	Without bicarbonate	With bicarbonate
n	75	75
Mean	3.93	2.55
Median	4.00	2.00
Standard deviation	2.34	2.18
Minimum	0.00	0.00
Maximum	9.00	8.00

DISCUSSION

Local anaesthetics are basic solutions that have a pKa which is similar to the normal extracellular pH of the human cells. Lidocaine has a pKa of 7.9, which compares well to the normal extracellular pH of 7.4. This solution exists in two forms: The charged form (BH^+) and the basic uncharged form (B), as shown in the equation below.

$$BH^+ \longleftrightarrow B + H^+$$

Half of the drug is in the charged form and the other half is in the uncharged form, when the pH is equal to the solutions' pKa. Only the uncharged lipophilic

Table 3 *Average pain scores for gender, age and patients' comorbidities for use of local anaesthetic with or without addition of bicarbonate*

	Without bicarbonate	With bicarbonate
Gender		
Male	3.77	2.41
Female	4.11	2.74
Age (years)		
0 – 9	N/A	N/A
10 – 19	5.50	3.00
20 – 29	3.83	1.67
30 – 39	3.50	3.00
40 – 49	4.00	3.00
50 – 59	3.42	3.00
60 – 69	3.86	3.00
70 – 79	4.89	3.00
80 – 89	2.63	3.00
90 – 99	0.00	3.00
Past Medical/Surgical History		
Diabetes Mellitus	3.17	4.43
Fibromyalgia	6.00	N/A
Stroke affecting site of surgery	N/A	8.00
Previous surgery at same site	4.50	4.20
Others: Stage 2 lymphoma, Multiple sclerosis	7.00	N/A

form will diffuse across lipid barriers, such as the perineural sheath and the cell membrane. The charged hydrophilic form will move across tissue fluid barriers, such as interstitial fluid.

The local anaesthetic acts at the cytoplasmic end of the sodium channel that is present in the cell membrane. The molecules move from the outside of the cell and across the nerve cell membrane in the uncharged form (B), to then re-equilibrate on the inside of the cell, within the cytoplasm. This allows both of the forms (B and BH^+) to be present again. Then the charged form (BH^+) attaches to its receptor on the cytoplasmic end of the transmembrane sodium channel. This results in a conformational change in the channel protein which blocks the passage of sodium ions into the cell. When enough length of an unmyelinated nerve is impaired by this action, an action potential in that axon is inhibited. For a myelinated nerve, on the other hand, the sodium channels are found at the nodes of Ranvier. The sodium channels in many nodes of Ranvier situated near each other along the axon, need to be inhibited so as to stop the transmission of an action potential.

Commercially available local anaesthetic drugs have a pH typically between 3.5 and 5.5. This is to increase their shelf life to around three to four years.[6] This pH level helps to slow down aldehyde formation, photo degradation, and other reactions that affect the non-ionized molecules.[2] Hydrochloric acid is put in the anaesthetic solution to obtain this low pH Local anaesthetic solutions with adrenaline are usually at a lower pH than the solutions without adrenaline and so, they are more painful to inject. This is because the adrenaline is more stable at a lower pH.[6]

By neutralising these acidic solutions with 8.4% $NaHCO_3$, the pain during injection of the local anaesthetic is improved, without affecting the duration of anaesthesia.[2] This occurs because buffering the anaesthetic solution, brings the pH closer to the physiological level of pH 7.0 to pH 7.4.

The non-ionized form of the amide local anaesthetic solutions is only slightly hydrophilic, limiting how basic the local anaesthetic solution can be, before it precipitates.[5] Precipitation has occurred when the solution becomes cloudy. Precipitation also increases with time so the solutions should be freshly prepared. The recommended mixture of amide anaesthetic and 8.4% $NaHCO_3$ is shown in Table 4.[4,6]

Table 4 *Dosage for alkalinisation of anaesthetic solutions*

Anaesthetic Solution	Volume of 8.4% $NaHCO_3$ to be added to 10mls of anaesthetic
Lidocaine 1% or 2%	1ml
Bupivicaine 0.25% or 0.5%	0.05mls

SUMMARY BOX

What is already known:

- It is well documented in the literature that the addition of sodium bicarbonate to local anaesthetic makes it less painful to inject.
- This practice is not widely used among non-anaesthetic doctors in Malta.
- Many surgeries are done under local anaesthetic.

What are the new findings:

- Adding sodium bicarbonate to local anaesthetic makes it less painful to inject also in the Maltese population.
- This practice makes our patients more comfortable and more complaint.
- Adding sodium bicarbonate to our local anaesthetic is financially justifiable in our day to day practice.

In addition to adding 8.4% $NaHCO_3$ to local anaesthetic, there are many other cumulative factors that can make local anaesthetic injection less painful. These include: applying an anaesthetic cream prior to injection, using a regional nerve block technique, using a small needle, injecting the local anaesthetic slowly, warming up the local anaesthetic to body temperature prior to injection[5], antegrade infiltration, puncturing the skin at 90 degrees to intersect less nerve endings and injecting a bolus of anaesthetic subdermally before infiltration. This alleviated the pain coming from the needle being in the skin.[8] Moreover one should inject subdermally rather than intradermally when possible and use the smallest volume of anaesthetic possible.[7] Perception of pain is influenced by the patients' anxiety level.[5] Thus it is also of utmost important to make the patient feel at ease prior to injecting.

An entire local anaesthetic operating list consisting of around 10 patients, can be done utilising only one or two 10ml vials of 8.4% $NaHCO_3$ at the cost of around ten Euro each. Mixing the local anaesthetic with the 8.4% $NaHCO_3$ did not increase the time taken to finish the operating list.

The antibacterial properties of lignocaine have also been documented. Moreover the addition of 8.4% $NaHCO_3$ increases this antibacterial effect that has been described for lignocaine on its own.[9] Thus it might be that at times, we are unable to culture organisms from tissue specimen sent for culture because the tissue was exposed to lignocaine that was alkalinized with $NaHCO_3$.

Limitations of this study include the fact the it is single blinded and that the data collection was carried out by the same doctors caring for the patients.

CONCLUSION

Alkalinisation of local anaesthetic solutions with 8.4% $NaHCO_3$ significantly improves the pain of infiltration of local anaesthetic solutions at a minimal cost. This increases patient compliance and patient comfort and thus allowing more surgeries to be performed under local anaesthesia.

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ORIGINAL ARTICLE

Audit on Oxygen prescription and administration in adult inpatient wards at Mater Dei Hospital

Darren Borg, Craig Muscat, Sumaya Elsadi, Ariaga Anderson, Stephen Montefort

Background

Oxygen is one of the most common therapeutic agents utilised in both hospital emergency department (ED) and medical wards, therefore correct administration is paramount. The primary aim of this audit was to assess current local implementation of guidelines on oxygen prescription in the ED and medical wards, along with adequate documentation in treatment charts or plans.

Methods

This audit involved data collection for a total of 5 weeks (in the months of November 2021 to December 2021) from patients who were being assessed at ED and then subsequently admitted to medical wards in Mater Dei Hospital (Malta).

Results

300 patients were recruited over the period of 5 weeks, all having a presenting complaint of 'shortness of breath'; oxygen was administered to 82.7% (n=248) of patients. 260 were given a plan on oxygen administration, out of whom 253 had an oxygen prescription written in the management plan (only 92 also had documentation on the treatment chart as well).

Regarding the oxygen delivery being delivered in the ward, only 163 (62.7%) matched with the latest plan, whilst 86 (33.1%) did not match and 11 (4.2%) were started on NIV. When comparing the data to the audit performed in 2011, the greatest differences were regarding the lack of oxygen prescription in the treatment chart (35.4% in this audit, compared to 51.8% previously) and correct oxygen administration, being much higher (62.7%) when compared to the older values (7.1%).

Conclusion

Oxygen should be clearly mentioned in management plans and correctly written on treatment charts, the lack of which could lead to inappropriate oxygen administration. A designated oxygen prescription sheet could be utilised for possible improvements.

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Oxygen is one of the most common therapeutic agents utilised in both hospital emergency department (ED) and medical wards. According to the British Thoracic Society guidelines[1], oxygen should be prescribed on concentrations adequate to achieve target saturations of 94-98% for acutely ill patients, or 88-92% in those patient who are at increased risk of hypercapnic respiratory failure. Therefore appropriate prescription, Oxygen Saturation (SpO_2) charting, and management of oxygen delivery is very important as both hypoxia and excess oxygen supply may be harmful.

The primary aim of this audit was to assess current local implementation of guidelines on oxygen prescription in the ED and medical wards, along with adequate documentation in treatment charts or plans. This served to identify any relationship between good documentation of prescribed oxygen in treatment charts and eventual correct oxygen delivery.

MATERIALS AND METHODS

This audit involved data collection for a total of 5 weeks (in the months of November 2021 to December 2021) from patients who were being assessed at ED and then subsequently admitted to medical wards in Mater Dei Hospital (Malta). The data was audited in accordance with British Thoracic Society guidelines, collected through review of treatment charts, notes at the emergency department and the patient's file once admitted in the medical ward, along with assessment of the actual oxygen delivery in the ward setting.

A self-constructed data collection form was used to maintain full confidentiality and no possible patient identification. The data collected was then compared to international data and previous audits carried out locally[2,3] with the aim of improving local guidelines on oxygen prescription and delivery.

An anonymized data set was kept on a private Mater Dei Hospital intranet network which can only be accessed using an authorized government account. Only investigators were able to access the data collected and this was kept until statistical analysis was performed and was deleted once analysis was performed.

The patients were not contacted at any stage of the data collection, analysis and study reporting.

The data included:

- Age
- Gender
- Admission date
- Diagnosis
- Smoking History
- Admission Ward (Medical/Surgical)
- Admission on Normal Bed/Telemetry/Monitor
- SpO_2 at ED (on Room Air and on Oxygen)
- Arterial Blood Gases at ED (on Room Air or on Oxygen)
- Oxygen delivery at ED (type of mask used and flow rate)
- Oxygen prescription in management plan
- Whether there was Oxygen prescription in treatment chart
- Whether there was SpO_2 charting ordered in admission plan
- Ward oxygen administration (mask used and flow rate)
- Repeat Arterial Blood Gases ordered

The following were the inclusion criteria included in the dataset:

- Patients admitted to medical inpatient wards with the following conditions (and had a presenting complaining of 'Shortness of Breath'):
  - Exacerbation of congestive heart failure
  - Acute Coronary Syndrome
  - Asthma exacerbation
  - COPD exacerbation
  - Pneumonia/ Bronchitis
  - Pleural effusions
  - Pulmonary Fibrosis
  - Lung Malignancy
  - Pulmonary Embolism
  - Shortness of Breath (SOB) requiring oxygen.

The following exclusion criteria were applied:

- Patients admitted to intensive care unit (ICU)
- Patient with age less than 16 years
- Patients positive for SARS-CoV-2

RESULTS

300 patients were recruited over the period of 5 weeks, all having presenting complaints of "shortness of breath". Table 1 shows the different

Table 1 *Diagnoses of patients along with frequency of SpO2 documentation at the ED*

Diagnosis	% of Total Patients	SpO_2 Documented (% of patients)
ACS	0.3% (n=1)	1 (100%)
Asthma	8.7% (n=26)	24 (92.3%)
CHF Exacerbation	30% (n=90)	84 (93.3%)
COPD Exacerbation	21.3% (n=64)	48 (75%)
Lung Fibrosis	2% (n=6)	4 (66.7%)
Lung Malignancy	1.7% (n=5)	5 (100%)
Pulmonary Embolism	2.7% (n=8)	7 (87.5%)
Pleural Effusion	1.7% (n=5)	5 (100%)
Pneumonia	25.7% (n=77)	67 (87%)
Unclear Diagnosis	6% (n=18)	17 (94.4%)
Total Number	300	262

ACS: Acute Coronary Syndrome, CHF: Congestive Heart Failure, COPD: Chronic Obstructive Pulmonary Disease

diagnoses in this patient group as well as the frequency of whether SpO_2 was documented at the ED

Figure 1 summarises SpO_2 documentation at the ED on whether there was specification of the oxygen delivery device or if taken on room air; a total of 262 patients had this documentation in their notes.

Oxygen was administered to 82.7% (n=248) of patients, out of whom 83.9% (n=208) had an arterial blood gas (ABG) taken. With regards to the patients who had an ABG taken, 60 (28.8%) were on room air, 139 (66.8%) were on oxygen and in 9 (4.3%) this was not specified. Hypoxaemic (type 1) respiratory failure was predominant in ABGs comprising 73.6% (n=153) of results, with hypercapnic (type 2) respiratory failure evident in 23.1% (n=48) and normal values in 3.4% (n=7).

A total of 248 (82.7%) patients were administered oxygen at the ED, 238 of whom (96%) had oxygen flow rate documented in the "treatment given" section of the notes, 4 (1.6%) were given nebulisers only and 6 (2.4%) had no documentation at all. 11 patients (4.4%) were given oxygen when this was not indicated, the latter was determined by the presence of an SpO_2 on room air of more than 94% (or more than 88% in hypercapnic respiratory failure).

With regards to oxygen prescription, 260 were given a plan on oxygen administration, out of whom 253 had an oxygen prescription written in the management plan. As demonstrated in Figure 2, from the latter 253 patients, only 92 also had documentation on the treatment chart as well. Seven patients had documentation on the treatment chart only.

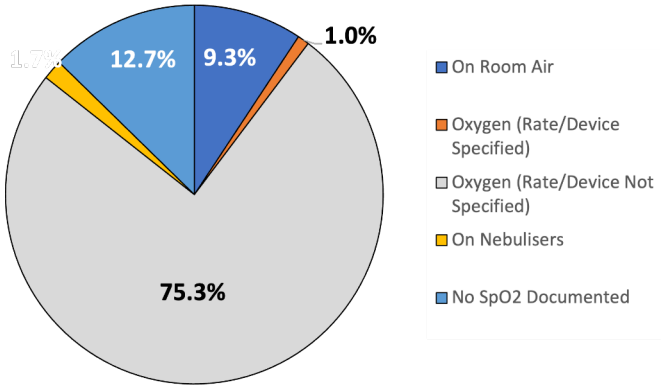

Figure 1 *Documentation of SpO2 depending on oxygen delivery device or on room air (at the ED)*

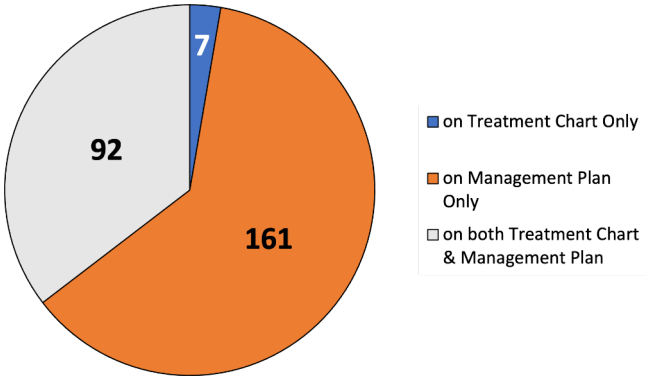

Figure 2 *Oxygen prescription documentation, demonstrating the number of patients in each*

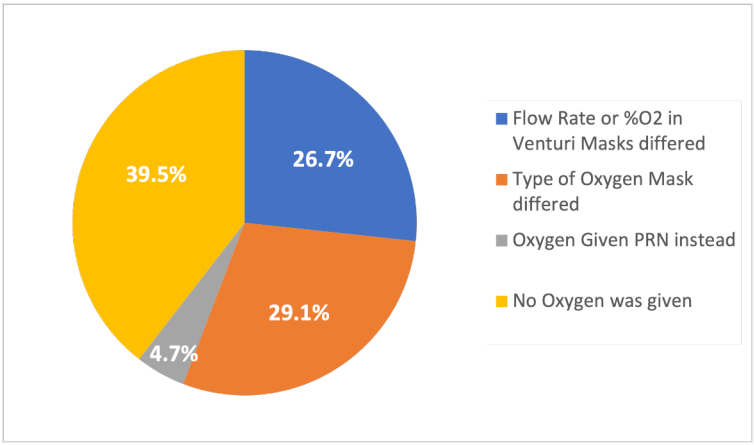

Figure 3 *Patients whose Oxygen delivery was not matching with the last management plan and/or treatment chart*

283 (97.7%) patients had SpO_2 monitoring as part of their management plan, and in 58 (19.3%) repeat ABGs were requested.

When comparing those 260 patients who had an oxygen administration plan (in the latest management plan and/or treatment chart), and the oxygen delivery being actually delivered in the ward, only 163 (62.7%) matched, whilst 86 (33.1%) did not match and 11 (4.2%) were started on NIV in the ward. The reasons for why those 86 patients' oxygen delivery did not match to the latest prescription is summarised in Figure 3.

DISCUSSION

In the data collection period for this audit, the majority of the cohort were admitted for CHF exacerbation, COPD exacerbation and pneumonia (in total comprising 231 patients, therefore 77% of the total). Indication for oxygen was defined as the recording of an SpO_2 on room air of less than 94% (or less than 88% in those who had a history of chronic hypercapnic (type 2) respiratory failure); a total of 248 (82.7%) patients were administered oxygen. 11 of the latter (4.4% of those given oxygen) did not have an indication for oxygen, but this was still unfortunately administered; whilst the number may seem low, it should be clear that both hypoxia and hyperoxaemia are related to increased mortality(4), the latter of which is less often recognized.

Documentation is paramount in inpatient management, especially in the acute setting. Regretfully from the data collected during this period, 38 patients (12.7%) had no documentation of saturations prior to admission to an inpatient ward; this could have led to an inaccurate representation of whether patients had oxygen indicated or not from the initial time of their admission. More so, from the patients who had a documented SpO_2, in 75.3% (n=226) this was taken on oxygen with no flow rate or device being specified, whilst only 3 patients (1%) had a specified mask or rate whilst on oxygen. Only 28 patients had documentation of SpO_2 while on room air.

Titration of oxygen could be done only if there is proper documentation of the flow rate and delivery mask from initial assessment, especially in those who had arterial blood gases obtained (n=208). In reference to the latter, 9 patients (4.3%) had no documented oxygen flow rate which was administered at the time of sampling. Data was however better with regards to the documentation of oxygen flow rates and devices in the section where "treatment given" was written, with 96% (n=239) being documented.

It is clear that more attention needs to be addressed with regards to oxygen prescription in treatment charts, with only 99 patients (38.1% of those who were prescribed oxygen for the inpatient stay) having this. Clear Oxygen prescription in both treatment charts and management plans would also allow nursing staff to administer oxygen more accurately, as evidenced by the data in this audit with 86 patients (33.1%) having a different oxygen prescription compared to the treatment chart and/or latest management plan (34 of these patients having no oxygen given). It is important to note that a reason for patients not being administered oxygen was possibly the fact that there was no clinical indication (that is having normal saturations on room air); however, this should be made clear by updating the latest management plan and treatment chart, since this would avoid inadequate administration of oxygen.

When comparing this data to a previous local audit performed in the same hospital with regards to oxygen prescription[2,3], values differed significantly. The audit performed in 2011[2] recruited 248 patients, compared to 300 patients in this audit. Table 2 summarises the differences in data when comparing the two audits.

Several striking differences can be noted when comparing the data to the audit performed in 2011, particularly the lack of oxygen prescription in the treatment chart (35.4% in this audit, compared to 51.8% previously). However correct oxygen administration was noted to be much higher (62.7%) when compared to the older values (7.1%), although this is still not ideal. Improvements such as having a separate prescription sheet for oxygen in the file of all patients admitted to hospital could lead to better outcomes, as well as possibly having a designated

Table 2 *The differences in data collected between an audit performed in 2011 and the current audit*

	Audit in 2011	Current Audit
Number of Patients	248	300
SpO2 documentation on admission	92.7%	87.3%
ABGs taken	93.5%	69.3%
Oxygen prescribed on treatment chart	51.8%	38.1%
Oxygen prescribed in management plan	34.1%	50.6%
Oxygen correctly administered in the ward	7.1%	62.7%

area for oxygen prescription in online documentation (which has become much more utilised from the ED since the start of the COVID-19 pandemic).

Several limitations can be identified, first of all having patients from a short period of time (5 weeks) and the fact that these were not randomly selected.

CONCLUSION

Oxygen should be clearly mentioned in management plans and correctly written on treatment charts, the lack of which could lead to inappropriate oxygen administration. A designated oxygen prescription sheet could be utilized for possible improvements.

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ORIGINAL ARTICLE

Knowledge and Use of Contraception among Women in Malta

Justine Pearson, Jacob Vella

Background

The aim of this cross-sectional study was to assess knowledge of contraception among women of reproductive age by testing for a statistically significant difference in awareness between women with different demographics and according to the type of contraceptives they had ever used.

Methods

151 women, aged 16 to 50 years, who visited Primary Health Clinics in the Northern Catchment Area, participated in the study by filling in an anonymous questionnaire. Demographic data and 12 statements related to the safe use of contraceptives were included and could be marked as either True, False or Don't Know. Statistical analysis was performed using the unpaired t-test and the Chi-Square test.

Results

Participants with a tertiary level of education were more knowledgeable about contraception. No statistically significant difference in awareness between Maltese and foreign women was found. Participants who used the OCP were more aware than their counterparts of increased risk of thromboembolic events related to its use.

Conclusion

It is suggested that national efforts be directed at improving sexual education in the Minimum Curriculum. It is recommended that Family Doctors adopt the role of educating women about the risks associated with the use of the OCP and protection against STIs.

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The safe and effective use of birth control methods is key in the holistic practice of reproductive health.[1] When counselling women on the ideal contraceptive method to be opted for, healthcare professionals are to consider efficacy in preventing pregnancies, transmission of sexually transmitted infections (STIs) and most crucially, the past medical and drug histories of the patient with subsequent reference to the UK Medical Eligibility Criteria for Contraceptive Use (UKMEC).

The aim of this cross-sectional study was to assess knowledge of contraception use among women of reproductive age residing in the Northern Catchment Area of the Primary Health Care Department. The fact that the vast majority of healthcare is delivered at a Primary Setting puts General Practitioners at the forefront when it comes to advocating for the safe use of contraceptives. Hence determining the extent of such awareness was deemed essential to guide Family Doctors in providing thorough counselling when discussing birth control methods with their patients as to date, local data on contraception is very limited.

MATERIALS AND METHODS

The research project was approved by the Data Protection Officer of the Primary Healthcare Department who did not suggest an Ethics Committee Board approval as the study did not involve the collection of data that could jeopardise anonymity, did not involve any intervention and did not impinge on either provided or perceived healthcare provision. Patients were only to be invited to participate at the end of a consultation.[2]

Participant selection was done through convenience sampling whereby female patients seen at the Health Centre were invited to fill in an anonymous questionnaire at the end of the consultation if they satisfied the inclusion criteria in Table 1.

Participants had the option of answering the questionnaire in either Maltese or English. Data collection took place between September and November 2021.

The first section of the questionnaire was aimed at collecting demographic data including level of education. Participants were also asked whether they had ever utilised any type of contraception. The second section consisted of 12 statements, listed in Table 2, which could be marked as either True False or Don't Know. The statements were constructed using lay language and mostly with the scope of assessing awareness about the effectiveness, side effects and contraindications to the oral contraceptive pill (OCP) and the Levonorgestrel Intrauterine System (LNG-IUS). A brief pilot study was conducted before distributing the questionnaire to ensure that the statements were comprehensive.

After voluntarily opting in to participate and once completing the questionnaire, the candidates were given a copy of the questionnaire marked with the correct answers. It also contained a Quick Response (QR) Code to access further information relevant to them from a UK online patient portal.[3]

The demographics (country of origin, age group and educational level) and any type of contraceptives used were identified as variables. Analysis was carried out by stratifying the data according to these variables to assess for a statistically significant discrepancy in the knowledge between these groups. Statistics were then calculated using Microsoft Excel and an online processor for the Chi-squared test (https://www.socscistatistics.com/tests/chisquare2/default2.aspx).[4] The p-value cut-off for statistical significance was <0.05 for both t-tests and Chi-squared tests.

Table 1 *Inclusion Criteria*

Inclusion Criteria
Female Patients
Age between 16 and 50 years
Able to understand the written questionnaire in either Maltese or English

Table 2 *Statements in the questionnaire*

	Statement
1	Some contaceptive methods are 100% effective
2	**Throwing up can make the OCP less effective**
3	**Mood swings are a side effect of the OCP**
4	**The OCP can ease painful and heavy periods**
5	**Some contraceptives should not be used by those with a history of blood clots**
6	Once placed, implants make contraception life-long
7	The Mirena® protects against sexually transmitted infections
8	Natural contraceptive methods are reliable in women with irregular menstrual cycles
9	Emergency contraceptive pills are available over the counter in Malta
10	**Smoking increases health risks when using certain pills**
11	**Weight gain increases health risks with certain types of pills**
12	Condoms are the only contraceptives protecting against sexually transmitted infections

RESULTS

A total of 151 women filled in the questionnaire. Approximately two-thirds (66.9%), answered the questionnaire in English whereas 33.1% preferred to answer the questionnaire in Maltese.

Demographics

Table 3 shows the demographic data of the study.

Table 3 *Demographic Data*

Demographic Feature	Number / n	Percentage / %
Country of Origin		
Maltese	116	76.82
Foreign	35	23.18
Age		
16 - 20	14	9.27
21 - 25	19	12.58
26 - 30	26	17.22
31 - 35	32	21.19
36 - 40	26	17.22
41 - 45	19	12.58
46 - 50	15	9.93
Education		
Primary	2	1.32
Secondary	44	29.13
Tertiary	105	69.53

Average Scores

When calculating the score out of 12, the 2 modal average scores achieved by the participants were of 8 and 9. Only 9 participants obtained full marks as shown in Figure 1.

The overall average score obtained was of 63.2% with Figure 2 depicting how those aged between 21 and 25 years fared best with an average score of 69.3%, followed by the 46 to 50 year band (69.1%). On the other hand, the lowest average score (60.5%) was obtained by participants aged between 41 and 45 years.

Correlation Of Knowledge With Demographics

Statistical significance between the mean scores achieved by participants who had a primary or secondary level of education (57.6%) versus those with a tertiary level (65.7%) was tested for using the unpaired t-test. A p-value of 0.04 was obtained suggesting a statistically significant difference. Conversely when the unpaired t test was used to compare the mean score achieved by the Maltese participants (63.8%) with that obtained by the foreign recruits (60.9%), the p-value was found to be that of 0.5. The difference was not found to be statistically significant.

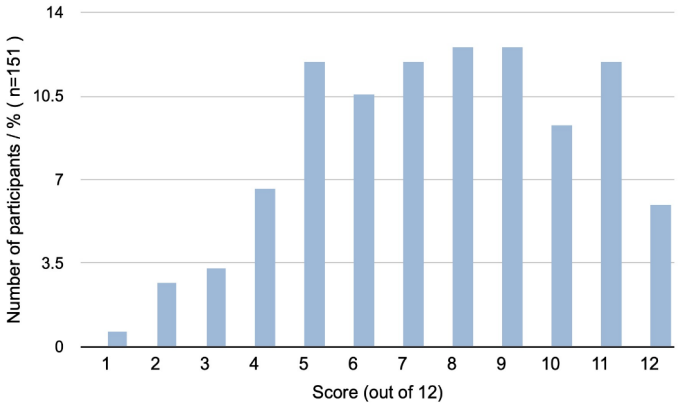

Figure 1 *The frequency in percentage of each total score (maximum score 12)*

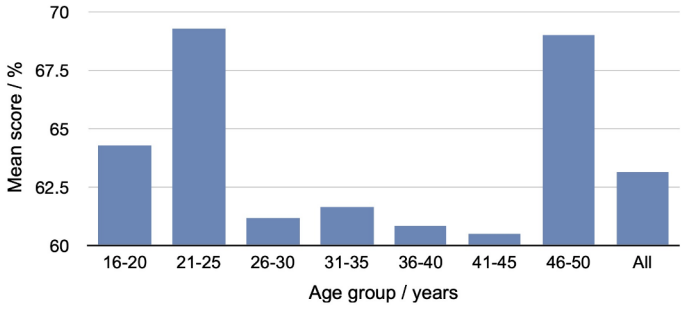

Figure 2 *Mean score according to age group*

Contraceptive Use Among The Participants

Of all participants surveyed, 80.1% used at least one type of contraceptive. The most common types of contraceptives used were the condom and the pill as demonstrated in Figure 3.

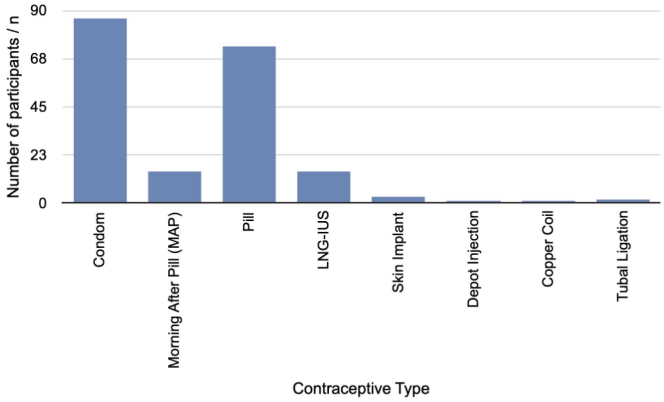

Figure 3 *Contraceptive Type Frequency*

Table 4 *The percentage of women who have ever used a birth control method versus those who never used any according to age group*

Age Group / years	Ever used a birth control method?	
	Yes (%)	No (%)
16-20	64.29	35.71
21-25	89.47	10.53
26-30	80.77	19.23
31-35	71.88	28.13
36-40	88.46	11.54
41-45	68.42	31.58
46-50	100.00	0.00

Table 4 shows that all participants aged between 46 and 50 years have used at least 1 type of birth control method. In comparison, only 64.3% of the 16-20 years cohort had ever used contraception up till the period of data collection.

Knowledge Related To OCP and LNG-IUS Use

The Chi-Squared Test was used to assess whether there was a statistically significant difference when comparing the knowledge related to the statements highlighted in bold in Table 2, between patients who have ever used the OCP and those who have never used it.

Table 5 provides a summary of the Chi-Squared values obtained for each tested statement.

On analysing the values, one can deduce that the only statistically significant difference in knowledge between those who have ever taken the OCP and those who have never taken it lies in question 5 ($p = 0.03$ therefore, <0.05). This confirms that participants who were on the oral contraceptive were more aware of venous thromboembolic event (VTE) risk when taking the OCP.

Similarly no statistically significant difference (Chi-Squared $p=0.24$) was found between participants with a LNG-IUS and those without on asking whether intrauterine devices conferred protection against transmission of STIs.

Table 5 *Statement Numbers and their corresponding Chi-Squared Value*

Statement Number	Chi-Squared Value
2	0.57
3	0.39
4	0.66
5	*0.03*
10	0.15
11	0.54

DISCUSSION

Barrier methods of contraception remain one of the commonest types of birth control methods which women in Malta resort to. A local study conducted in 2012 showed the upward trend in barrier contraception use from 12% in 1971 to 39.3% in 2010.[5] According to this study, conducted 10 years later, the use of barrier methods has increased further as 57% of our respondents admitted to having used condoms at least once. Similarly in a recent study among Singaporean women, the condom also emerged as the commonest method of contraception.[6]

This study shows that there is a statistically significant difference in knowledge about contraception between women with a tertiary level of education and those with either a primary or secondary level, with the former cohort faring better. On the contrary, the difference in awareness between Maltese and foreign women was not statistically significant. Similarly, two studies, one in Serbia[7] and one in Yemen[8], showed correlation between knowledge on contraception and level of education.

Participants who used the OCP were more aware than their counterparts of increased risk of thromboembolic events related to its use. Conversely there was no difference in knowledge with regards to the effect of vomiting and the risks associated with smoking and obesity. This might suggest that prescribers should dedicate more time to discuss such association. The United Kingdom Faculty of Sexual and Reproductive Healthcare (FSRH)

considered obesity and smoking as risk factors making the combined hormonal contraceptive pill (CHC) contraindicated in certain instances [9]

Having almost 3 out of 4 participants (72.2%) of participants aware that condoms are the only contraceptives conferring protection against STIs might be deemed as reassuring. On the other hand, only 52.31% of those surveyed knew that the LNG-IUS does not prevent STIs. Therefore more efforts should be directed at improving the Maltese population awareness on STIs and how to protect oneself against them.

The main limitation of the study is the small sample size mainly attributed to the short period of data collection. Another limitation is that only participants residing in the Northern part of Malta were included.

CONCLUSION

In conclusion, future studies could therefore increase both the size and geographical spread of the sample population. We also suggest the implementation of reforms in the education system to improve the delivery of sexual education in the National Minimum Curriculum.

SUMMARY BOX

What is already known

- Barrier methods are among the commonest types of birth control methods used in Malta.
- A past personal history of blood clots is a contraindication to the use of the OCP
- Smoking and obesity increase health risks in women on the OCP

New findings

- Participants who used the OCP were more aware than their counterparts of increased risk of thromboembolic events related to its use.
- OCP users were not found to be more knowledgeable than their counterparts about the increased risks posed by smoking and obesity whilst taking the OCP
- Merely 52.31% of the participants knew that the LNG-IUS does not confer protection against STIs.

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ORIGINAL ARTICLE

Assessment of Urinary Albumin-Creatinine Ratio in the Diabetic Patient: A Retrospective Study

Martina Mifsud, Roberta Mifsud, David Coppini

Background

Microalbuminuria is one of the earliest markers of diabetic kidney disease. Hence, the National Institute for Health and Care Excellence (NICE, NG18) recommends screening diabetic adults, children and young people on an annual basis with urinary albumin-to-creatinine ratio (ACR) for the early detection of diabetic kidney disease. Timely detection of a positive urinary ACR leads to earlier intervention, better glycaemic control and surveillance.

Method

Patients over the age of 18 attending the Diabetes Clinic at Mater Dei Hospital over a 1-week period in June 2021 were identified. Data regarding order requests and test results of urinary ACR was collected from iSOFT Clinical Manager System and iLab Laboratory Information System in liaison with the Clinical Chemistry Lab.

Results

A total of 168 patients were identified for the purpose of this study. The majority (45.2%) had a new case appointment and were excluded. Results show that despite urinary ACR was requested by the reviewing physician (90.2%), only 49.4% of these test samples were submitted to the laboratory services. The median average urinary ACR was found to be 13.9mg/g.

Conclusion

There is appropriate knowledge amongst doctors caring for diabetic patients regarding the importance of checking urinary ACR yearly. Suboptimal sample submission rate highlights the lack of awareness amongst patients about its underlying use of detecting kidney disease. Hence, improved patient education and logistical planning are required to ensure detection and timely intervention.

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Moderately increased albuminuria (formerly known as 'microalbuminuria') is one of the earliest markers of diabetic kidney disease. The 24-hour urine collection has been the "gold standard" test. However the spot urinary albumin-to-creatinine ratio (ACR) is able to provide a more convenient way of assessment whilst still correlating accurately with 24-hour collections.

The National Institute for Health and Care Excellence (NICE) 2015 and 2021 recommends screening adults, children and young people with diabetes (type 1 or type 2) on an annual basis with urinary ACR for the early detection of diabetic kidney disease.[1,2] Timely detection of moderately increased albuminuria (ACR range 30-300mg/g) reduces the risk of progression to severe diabetic nephropathy by alerting both the physician and the patient to the need for better glycaemic control and surveillance.

The use of an early morning urine sample is recommended to mitigate the risks of a false positive result. If the initial test is suggestive of moderately increased albuminuria then the result should be confirmed on 2 separate samples of early morning urine, prior to performing further investigations or instituting treatment.[1]

This study aims to assess whether urinary ACR is being requested and performed on an annual basis in the diabetic patient as recommended by NICE guidelines.

METHODOLOGY

The audit was carried out over a 1-week period in June 2021. A retrospective analysis of the use of urinary ACR in the preceding year was carried out for all patients attending their diabetes clinic visit in the designated 1-week period.

The patient cohort was identified through the Central Patient Administration System (CPAS) lists. Recruitment criteria were used to assess eligibility (Table 1). Data regarding order requests and test results of urinary ACR as well as HbA1C and renal function tests was collected from iLab Laboratory Information System (LIS), in liaison with the Clinical Chemistry laboratory at Mater Dei Hospital. The datasets evaluated are presented in Table 2.

During this study, there was no patient contact. No experiential or patient identifiable data was extracted or utilised. Permission was obtained from all the consultants in the Department of Diabetes as well as the Head of Department. Clearance from MDH data protection team was also sought.

Table 1 *Recruitment criteria*

Inclusion criteria
Age between 18-100
Under regular review by a Diabetes consultant at Mater Dei Hospital
Exclusion criteria
Being a new case referral
Failing to attend for two consecutive years
Gestational diabetes

Table 2 *Datasets*

Dataset
Age
Gender
Number of HbA1C tests performed by the laboratory over the past 1 year
Average HbA1C result per patient over the past 1 year
Number of ACRs requested per patient by the caring physician over the past 1 year
Number of ACR tests per patient performed by the laboratory
Number of renal profiles requested per patient by the caring physician over the past 1 year

RESULTS

A total of 168 patients were identified through the CPAS lists. 76 of these patients were excluded from the study. The main reason for exclusion was being a new case appointment (Table 3). There were more males (n = 54) than females (n = 38) with a median age of 61.5 years and an inter-quartile range (IQR) of 21.3 years. Also whilst urine ACR was requested by the reviewing physician (90.2%), only 49.4% of these test samples were submitted to the laboratory services.

Table 3 *Reasons for exclusion*

Reasons for exclusion	Number of patients
Being a new case appointment	39
Failing to attend the past 2 diabetes clinic appointments	34
Having gestational diabetes	2
Undergoing dialysis	1

Table 4 *ACR, HbA1c and renal profile descriptive measures*

Test	Requested/year			Performed/year		
	Total	Patients (%)	Per patient*	Total	Patients (%)	Per patient*
ACR	147	83 (90.2%)	1 (1 - 4)	57	41 (49.4%)	1 (1 - 3)
HbA1c	143	87 (94.6%)	1 (1 - 3)			
Renal Profile	149	86 (93.5%)	1 (1 - 4)			

**Mode of average requests per patient with range in brackets.*

Further descriptive measures for the laboratory results are presented in Table 4 and Table 5.

DISCUSSION

This study was able to assess whether diabetic patients are having a urine ACR checked on an annual basis as part of their diabetes care. The study was based on investigations requested and performed over a one-year period during which the COVID pandemic was ongoing. This might have affected patient's willingness to engage with medical services for investigation and management of their diabetes. In addition, the short assessment period of 1-week may have also been a limitation in this study. The patient cohort obtained (n=92) after applying exclusion criteria however allows for generalizability.

The study focused on ACR tests requested by diabetes physicians. Henceforth ACR requests and results by other specialties were not considered. Although most diabetes doctors ordered urinary ACR tests for their patients, 10% of the patient cohort did not have this test ordered. This statistic needs to be further evaluated.

Worryingly 50.6% of the patient cohort did not submit a urine ACR despite this test being requested. This might be due to communication failure or logistical issues. Diabetes care in Malta is historically either tertiary based (at Mater Dei Hospital) or community based with often little overlap or communication between the two. Urine ACR is often ordered prospectively for the next diabetes visit. Patients then receive a letter reminding them to have their blood tests taken at a phlebotomy clinic prior to their diabetes appointment. There is however no specific reminder for urine sample submission to pathology services.

Table 5 *Test results in patient cohort*

Test	Median	Range	Inter-Quartile Range
HbA1c (%)	7.2	4.9 – 13.7	2.15
ACR (mg/g)	13.9	0 – 4788.5	31.9
Creatinine (µmol/L)	75	37 – 493	31.1
eGFR (mL/min/ 1.73m^2)	89.3	11 – 207.6	45.8

CONCLUSION

Despite there being appropriate awareness amongst diabetes doctors regarding the need of an annual urine ACR check, half of the tests requested were not submitted to laboratory services. This highlights the need for improved doctor and patient awareness, as

SUMMARY BOX

What is already known about the subject?

- Moderately increased albuminuria is one of the earliest markers of diabetic kidney disease.
- Annual screening of diabetic patients with urinary ACR leads to timely detection and intervention.

What are the new findings?

- There is appropriate awareness amongst diabetes doctors regarding the need for a yearly urinary ACR check.
- Patients should be educated regarding its importance and purpose of detecting diabetic kidney disease. Further strategies for its submission should be implemented.

well as better logistical planning for submission of urine ACR samples. The following recommendations are made:

1. to educate patients regarding the importance of an annual urine ACR check during the diabetes consultation
2. to highlight the need for a urine ACR check in the appointment letter
3. to consider random submission of urine ACR as opportunistic screening in clinic (whilst being aware of the risk of a false positive result).
4. to introduce paper notices at Outpatients to continue raising awareness amongst doctors about the importance of requesting a urine ACR.

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ORIGINAL ARTICLE

Evaluation of referrals to the Migraine Clinic at Mater Dei hospital

A Clinical Audit

David Degaetano, Malcolm Vella, Ruth Galea

Background

The recently established migraine clinic at Mater Dei hospital in Malta has been receiving a steady stream of referrals from a number of sources for the investigation and management of patients with suspected migraine headaches. This necessitated the need for a retrospective analysis and clinical audit to determine the appropriateness of referrals to the migraine clinic.

Methods

Data was collected retrospectively from tickets of referral and migraine clinic notes from patients' medical records over an 18 month period.

Results

A total of 63 new case referrals were received with an appointment being given within an average of 18 weeks from the date of referral; 74.6% were female and 25.4% were male with a mean age of 35 years. Six discrete sources of referral were identified including General Practitioners (GP) 25.4%, Accident and Emergency (A&E) 15.9%, inpatients 11.1%, ophthalmology emergency 9.5%, ENT emergency 3.2% and outpatients 3.2%; Attendance rates to the first appointment were 65.1%; 55.1% of patients received a diagnosis of primary headache, of which migraine with aura was the most common (63.0%); 49% of attending patients were referred appropriately with 37.5% of these being referred by GPs and 29.2% being referred from the emergency services.

Discussion

Just under half of referrals to the new migraine clinic are appropriate, necessitating the need to improve the quality and accuracy of referrals by defining a clear pathway for referral as well as improving the management at the primary care level by educating both providers and patients in the way of diagnosing and managing headache disorders.

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Being one of the most debilitating headache disorders in the young, working population, migraine has a significant impact on patients' quality of life, productivity and socioeconomic status.[1] Local data on the epidemiology of migraine are few, with prevalence rates being largely inferred from an international study conducted by the Global Burden of Diseases, Injuries, and Risk Factors (GBD) study, 2016.[2] The migraine prevalence rate is estimated to be between 18,000 and 19,000 per 100,000 population, making the mean total prevalence of migraine in Malta around 80,226 individuals (17.4%) at the time.[3] Furthermore, a European health survey conducted in 2008 ranked migraine as the 5th commonest health condition experienced in Malta (morbidity rate of 14%) with medicines for headache and migraine being the most commonly used over-the-counter medicines at 46.8%, doubling from 2002.[4,5] The socioeconomic impact of migraine in Malta is therefore expected to be significantly large, especially when considering both the direct (health service use) and indirect costs (reduced productivity and social activities)[6], as well as the global increase in rates of years lived with disability (YLDs) due to migraines.[7]

The need for a dedicated specialised clinic to manage the burden of migraine on the local healthcare system as well as the general neurology clinics is therefore self-evident. Since its establishment in January 2019, the migraine clinic at Mater Dei has been receiving a steady stream of referrals from both primary and secondary care specialists. The aim of this audit is to determine the appropriateness of these referrals as well as to collect and analyse data on patient demographics, sources of referral, attendance rates, investigations, diagnoses and disposition. This will also provide useful information on the local migraine population epidemiology and efficacy of the clinic; as well as identifying the need to establish and implement a national migraine referral guideline to streamline and maximise appropriate referrals so that specialist care may reach those most in need.

METHODS

Qualitative and quantitative data were collected retrospectively from consecutive patients newly referred to the migraine clinic over a period of 18 months from the date of the first clinic on the 3rd of June 2019 till the 7th of December 2020. Data were obtained from patients' physical medical records, tickets of referral (TOR) as well as electronic medical records from Mater Dei hospital IT systems including iSOFT clinical manager and Electronic Case Summary (ECS) programs. These data were recorded and analysed using the Microsoft Excel program. Appropriateness of referral was determined using two objective criteria in order to reflect those factors defining patients most likely to require specialist care. These were (i) the headache diagnosis obtained after attendance to the migraine clinic and (ii) the long-term follow up status (long-term follow up being considered as two or more follow up appointments). Patients who fulfilled only one of the above criteria were excluded, therefore this includes patients correctly diagnosed with migraine but not requiring long-term follow up as well as patients diagnosed with any headache other than migraine who may have received long-term follow up for whatever reason.

RESULTS

The first referrals to the migraine clinic were received in late January 2019 with the first clinic being held five months later, on the 3rd of June 2019. A total of 63 new case referrals were received over a period of 21 months, with an appointment being given within an average of 18 weeks (range 5 - 35 weeks) from the date of referral. Of these cases, 47 were female (74.6%) and 16 were male (25.4%), with ages ranging from 16 to 70 years (mean of 35 years). The majority of patients were Maltese nationals at 76.2% with foreigners comprising the remaining 23.8%.

Six discrete sources of referral were identified (Figure 1), which in order of decreasing percentage of total referrals were as follows: General Practitioners (GP) 25.4%, Accident and Emergency (A&E) 15.9%, inpatients 11.1%, ophthalmology emergency 9.5%, ENT emergency 3.2% and outpatients 3.2%. The largest proportion of referrals however (31.7%) had an unidentified source due to either incomplete or missing TORs.

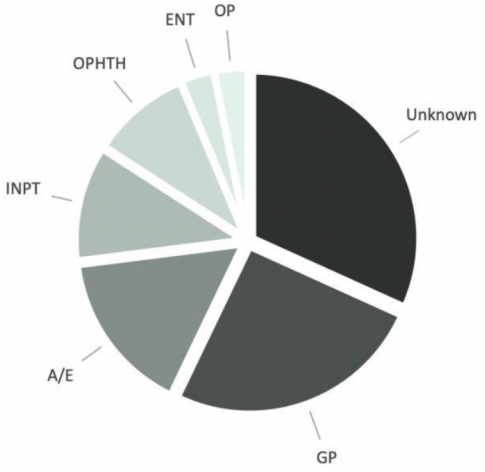

Figure 1 *Pie chart showing the distribution of referral sources to the migraine clinic*

Attendance rates to the first appointment were 65.1% with the remaining 34.9% not attending. Of those not attending their first appointment, 14 (63.6%) were discharged and 8 (36.4%) were given a re-appointment. Of those attending their first appointment, one patient (2.4%) was discharged immediately, 11 patients (26.8%) were discharged after the second appointment and the remaining 29 patients (70.7%) received longer term follow up. Attendance rates to follow up appointments were 70.7%, with the remaining 29.3% not attending.

Twenty seven patients (55.1%) attending the migraine clinic received a diagnosis of primary headache, of which migraine with aura was the most common (63.0%), followed by migraine without aura (18.5%), Tension Type Headache (TTH) (11.1%), coital headache (3.7%) and primary stabbing headache (3.7%). Three patients (6.1%) were diagnosed with a secondary headache, of which two were due to Medication Overuse Headache (MOH) and one patient had an intraparenchymal haemorrhage. Eleven patients (22.4%) had a mixed cephalgia which were composed of various combinations of migraine with/without aura with TTH and/or MOH. Four patients (8.2%) were still awaiting diagnosis at the time of data collection with a differential including probable migraine with aura, hemicrania continua and migraine. A further four patients (8.2%) had a neurological problem other than headache including diabetic polyneuropathy / cervical myelopathy, non-specific visual disturbance, L5/S1 radiculopathy and musculoskeletal pain (see Figure 2, Table 1).

The data show that 24 patients (49% of attending patients; 38.1% of all referrals) were referred appropriately. Furthermore, of the appropriate referrals, 37.5% were referred by GPs, 29.2% were referred from emergency services (including ENT and ophthalmology emergencies), 16.7% were referred from an unknown source, 12.5% from inpatient referrals and 4.2% from outpatient referrals (see Figure 3).

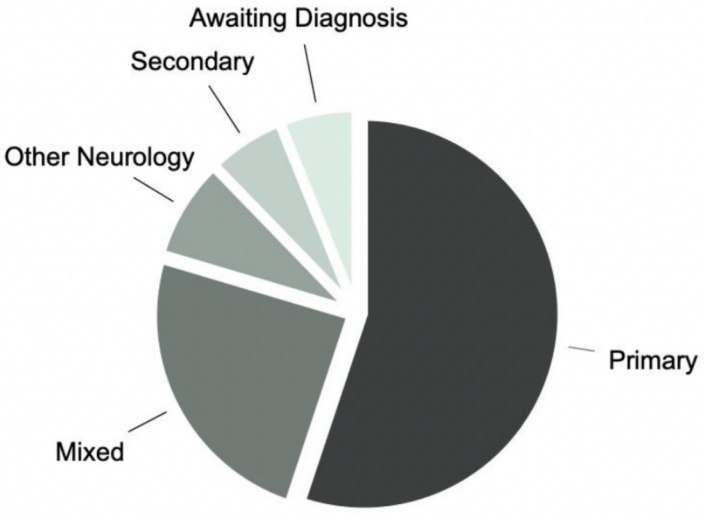

Figure 2 *Pie chart showing the distribution of headache disorders diagnosed at the*

Table 1 *Headache diagnosis*

Diagnosis	Number
Primary (n = 27)	
Migraine with aura	17
Migraine without aura	5
Tension Type Headache (TTH)	3
Coital headache	1
Primary stabbing headache	1
Secondary (n = 3)	
Medication Overuse Headache (MOH)	2
Intraparenchymal haemorrhage	1
Mixed (n = 11)	
Migraine with aura / TTH	5
Migraine without aura / TTH	3
Migraine without aura / MOH	2
Migraine without aura / TTH / MOH	1
Awaiting Diagnosis (n = 4)	
Probable migraine with aura	2
Hemicrania continua / Migraine	1
Probable cluster headache	1
Other Neurology (n = 4)	
Diabetic polyneuropathy/Cervical myelopathy	1
Non-specific visual disturbance	1
Left L5/S1 radiculopathy	1
Musculoskeletal pain	1

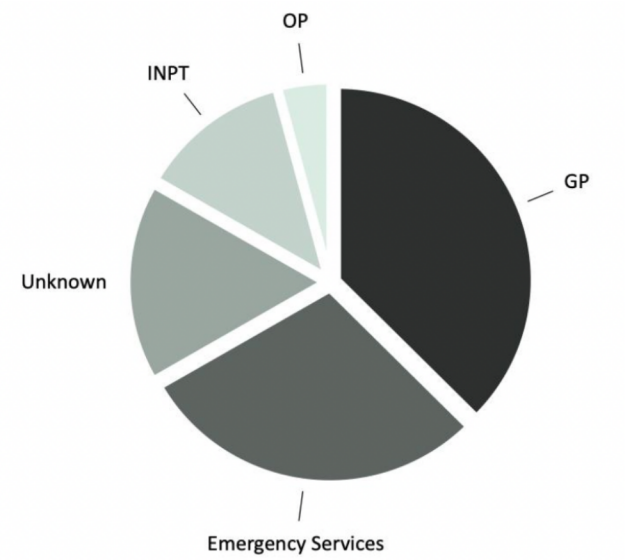

Figure 3 *Pie chart showing distribution of appropriate referrals by source of referral*

DISCUSSION

This clinical audit provides the first data on the recently established migraine clinic allowing for the identification of the various referral sources and their appropriateness as well as patient demographics and the overall distribution of headache disorders according to the International Classification of Headache Disorders, 3rd Edition (ICHD-3).[8] Although three quarters of patients referred to and attending the migraine clinic were confirmed to have a diagnosis of migraine, just under half of the referrals were found to be appropriate using the criteria stipulated above.

The demographic data obtained on patients attending the migraine clinic over an 18 month period have shown a concordance with observations in other primary and secondary care clinics that manage headaches in Europe.[9-12] Three quarters of the patient cohort were middle aged females with a quarter being male. A similar proportion were of Maltese and foreign nationality respectively.

Excluding the referrals of unknown origin, which unfortunately comprised a significant proportion of the results obtained, most referrals were independently received primarily from general practitioners working in health centres (25.4%). Considering however, the combined referrals from the emergency department together with those from ophthalmology emergency as well as otorhinolaryngology (ENT) emergency, a greater percentage of referrals were received overall (36.5%). Inpatient and outpatient referrals were comparatively minimal. This highlights the importance of targeting the former two primary sources when implementing any future referral pathways. More than one third of patients (34.9%) failed to attend their first appointment with the majority (63.6%) being discharged without reappointment. Reasons for non-attendance remain unknown, however one study on Did Not Attend (DNA) rates in a neurology outpatient clinic suggests that most common reason is that patients simply forget.[14]

Over half of attendees (55.1%) were diagnosed with a primary headache of which 81.5% were diagnosed with a form of migraine. Together with the mixed cephalgias comprising 22.4% of diagnoses, these patients were the most likely to benefit from referral to the migraine clinic, except that just over half may have well been managed in the primary care setting as long-term follow ups were not given. These results are in line with those of other studies.[9,15] and reflect poor management of headache disorders in the primary care setting as well as incorrect referral to secondary care services where resources are limited and costs are greater.[17]

Studies have shown that patients with headache disorders may be safely managed in the primary care setting, and that the majority of referrals to specialised clinics were unnecessary.[9,12,13] As the burden of migraine disorders on patients, society and the economy is becoming more apparent[2] and an increase in the incidence and prevalence of the disabling disease progresses globally[16], we forecast a proportional and exponential increase in referrals to specialist secondary care. Given the lack of clearly defined referral pathways locally and based on the reasonable assumption that a specialised clinic such as the one under study should receive patients with chronic or treatment refractory migraines, we would like to propose the development and implementation of a national migraine referral guideline. This will have a threefold impact including to (a) streamline and maximise appropriate referrals, (b) minimise referrals of other primary headaches and (c) guide referrers in selecting migraine sufferers most in need of specialised care.

This audit has encountered several limitations which were beyond the control of the authors, particularly relatively low new-case referrals within the 18 month data collection period. We strongly suspect that this was related to the start of the SARS-CoV-2 pandemic in April 2019 as the migraine clinic is currently running double the amount of clinic sessions than the previous year. Another limitation was data accessibility and data quality (e.g. missing TORs), both of which may impact the findings of this audit.

CONCLUSION

Our findings suggest that just under half of referrals to the new migraine clinic are appropriate, necessitating the need to improve the quality and accuracy of referrals by defining a clear pathway for referral as well as improving the management at the primary care level by educating both providers and patients in the way of diagnosing and managing headache disorders.

ACKNOWLEDGEMENTS

We would like to thank Ms. Stephanie Galea for patiently procuring the majority of the patient's physical medical records as well as the Mater Dei Hospital MOP3 staff for their kind help and support.

ETHICAL APPROVAL

Data protection approval obtained from MDH data protection on 3/1/21 together with approval from MDH CEO and the clinical chair of the MDH department of neuroscience, Dr Norbert R Vella.

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CASE REPORT

Kimura disease of submandibular gland

Submandibular Kimura disease

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Kimura disease (KD) is a rare benign chronic inflammatory disorder of unknown aetiology prevalence in young adult Asian males. Head and neck region especially salivary gland and cervical lymph node are the most commonly affected. In contrast to parotid gland, submandibular gland involvement is rarely reported. Diagnosis is always challenging due to variable presentations that may mimic other inflammatory or neoplastic conditions, and non-specific imaging, cytology, and histopathology findings. Generally, there was several treatments modality reported but showed variable response with high recurrence rate. The treatment for submandibular gland KD specifically is not well describe due to its rarity. We present a case of KD with submandibular gland and cervical lymph node involvement in elderly man that mimic malignancy and highlight the challenging in management.

Kimura disease (KD) is a rare chronic inflammatory disorder of unknown aetiology and was first described in Chinese language literature in China 84 years ago.[1] It is become well known as KD in 1948 after Kimura et al. published the definitive histologic description.[2] Head and neck regions, specifically the salivary gland and regional lymph node are frequently involved.[3] Young adult Asian males in their second to fourth decade of life are predominantly affected, with male to female ratio ranging from 3.5:1 to 6.7:1.[3,4] Sporadic cases have been reported in Europe and America and showed a lower incidence of salivary gland involvement in non-Asian.[4]

The parotid gland is the most common salivary gland affected, while the submandibular gland is rarely reported and the reason for this predilection is still unknown.[3,4] It is paramount important to examine the patient systematically as KD can be systemic and may involve multiple organs, especially the kidney.[3] The marked variable and non-specific presentation of KD that may mimic other inflammatory and neoplastic conditions contribute to the challenges in the diagnosis. In addition, the diagnosis of KD is based on clinicopathological features, but unfortunately, there is no pathognomonic feature histologically.[3]

CASE REPORT

A 68-year-old male, with no underlying medical illness, presented with a history of painless right neck swelling for 10 years which rapidly increased in size over the past 3 months. There were no upper aerodigestive tract obstructive symptoms and no constitutional symptoms.

Upon examination, there was a 6 cm x 5 cm swelling at the right submandibular region. It was smooth surface with no overlying skin changes, firm in consistency, non-tender, immobile and not fixed to overlying skin (**Figure 1**). The lesion was ballotable on bimanual palpation, but the floor of mouth was not raised. There was no palpable swelling at the other level or contralateral side of the neck. Other ears, nose and throat examinations were unremarkable. He was subjected for fine-needle aspiration cytology (FNAC) twice but unfortunately, the samples were unsatisfactory. Subsequently a tru-cut biopsy was performed but again the result was inconclusive. A computed tomography (CT) scan of the neck was done which revealed an enlarged and heterogeneous enhancement of the right submandibular gland, measuring 3.3 cm x 4.5 cm x 5.4 cm (**Figure 2**). In addition, there was presence of multiple lymph node enlargements at the right level I to level IV.

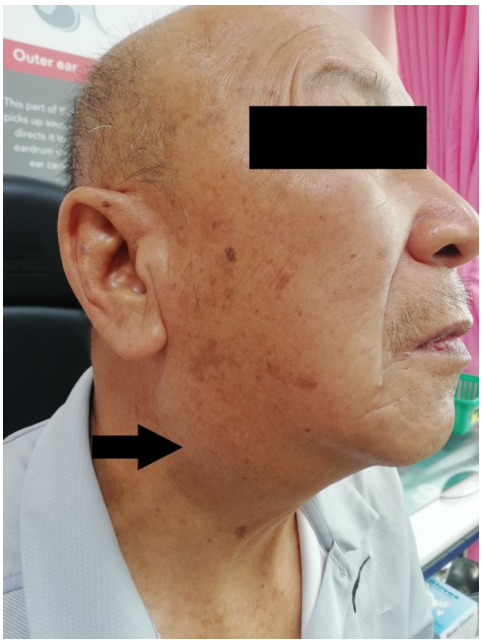

Figure 1 *A 6 cm x 5 cm swelling at the right submandibular region, smooth surface with no overlying skin changes*

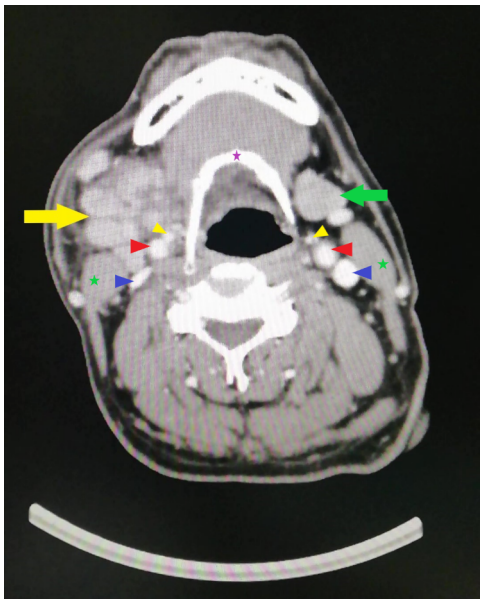

Figure 2 *CT neck shows right submandibular gland enlargement, measuring 3.3 cm x 4.5 cm x 5.4 cm, with heterogeneous enhancement (yellow arrow). Left submandibular gland - green arrow; external carotid artery – yellow arrowhead; internal carotid artery – red arrowhead; internal jugular vein – blue arrowhead; sternocleidomastoid muscle – green star; hyoid bone – purple star.*

In view of suspected malignancy with inconclusive pre-operative cytology and histopathology results, he was counselled for right submandibulectomy with intra-operative frozen section. A modified radical neck dissection will be performed if frozen shows features of malignancy. Intra-operatively the well-

encapsulated tumour measuring 10 cm x 8 cm was confined to the right submandibular gland (Figure 3). Part of the tumour was sent for a frozen section and the immediate result showed the features of chronic sialadenitis; salivary gland tissue infiltrated by lymphocytes and dense eosinophils, without malignant cells seen (Figure 4). Thus neck dissection was deferred. Histopathology examination (HPE) of the specimen showed features favouring KD; salivary gland tissue was infiltrated with lymphocytes, plasma cells and mast cells with dense eosinophilic infiltrates forming an eosinophilic abscess (Figure 5). Subsequently the patient was referred to rheumatologist for medical therapy and was started on oral corticosteroid. He was started on oral prednisolone tapering dose every 2 weeks for 2 months' duration (started with 30 mg, then 25 mg, 20 mg and 15 mg, once-daily dose) and maintenance with 10 mg once daily. The wound was completely healed and no neck swelling after 3 months of follow-up.

DISCUSSION

KD is a benign inflammatory disorder with no evidence or reported case of malignant transformation to date.[5] Although it is benign, the main problem of KD is that its characteristic commonly resembles other inflammatory or haematological malignancies in which the pre-operative cytology examination usually provides an unsatisfactory or inconclusive result. Angiolymphoid hyperplasia with eosinophilia, Hodgkin lymphoma, angioimmunoblastic T cell lymphoma, allergic granuloma, Langerhans cell histiocytosis, Castleman disease, and immunoglobulin G4-related disease are among diseases that have features mimic KD.[3]

Although the major salivary gland is among the common site for KD, however submandibular gland involvement is relatively very rare (5.5% to 6.5%), compared to the parotid gland (33.3% to 37%).[1,3] The diagnosis of submandibular gland KD may be more challenging due to its rarity and more difficult to differentiate from the cervical lymph node.

Our patient underwent FNAC twice but both samples were unsatisfactory for examination. The accuracy of FNAC is variable for salivary gland lesions, depending on the experience of FNAC operator and cytopathologist, use of rapid on-site evaluation, sample preparation, reporting terminology and characteristics of the salivary gland tumours.[6] Therefore the clinical usefulness of preoperative FNAC should be evaluated carefully, based case by case and depending on the local diagnostic performance.

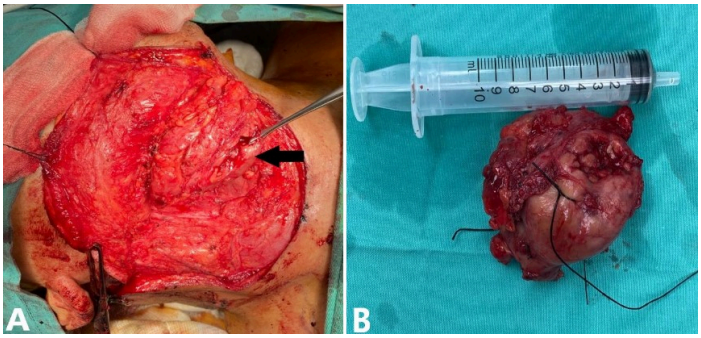

Figure 3 *Intra-operative view shows well-encapsulated tumour confined to right submandibular gland (A). Removed tumour measuring 10 cm x 8 cm, tag with string and sent for histopathological examination (B)*

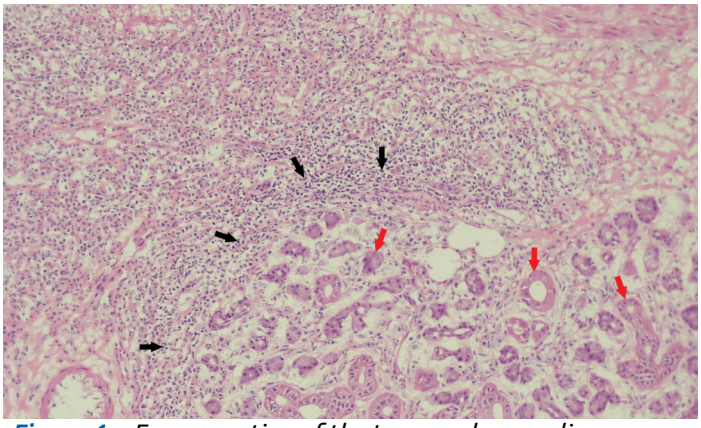

Figure 4 *Frozen section of the tumour shows salivary gland tissue densely infiltrated by lymphocytes (black arrow) x100. Salivary gland acini and ducts – red arrow.*

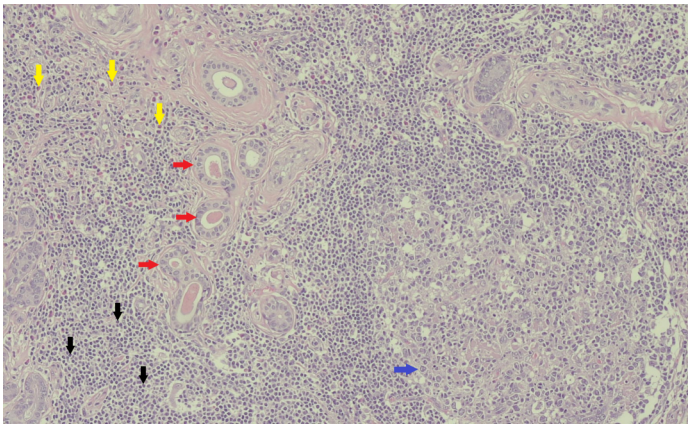

Figure 5 *The tumour shows salivary gland tissue infiltrated with lymphocytes (black arrow) and plasma cells with dense eosinophilic (yellow arrow) infiltrates forming eosinophilic abscess, H&E x100. Salivary gland acini and ducts – red arrow; hyperplastic follicle with germinal centre (blue arrow).*

Specifically the role of FNAC in KD is usually disappointed and the majority of cases required an open biopsy.[7] As increasing number of KD cases reported recently, few studies had highlighted certain cytologic characteristic features favouring the disease, which include presence significant

amount of eosinophils, polymorphous lymphoid population, fragments of collagenous tissue and Warthin-Finkeldey polykaryocytes. Due to the non-diagnostic FNAC result, we performed a tru-cut biopsy as it showed higher accuracy with a lower inadequacy rate.[8] The risk of tumour seeding in FNAC and tru-cut biopsy are very low, 0.00012% and 0.0011% respectively.[9] Unfortunately the tru-cut biopsy also failed to provide a definitive preoperative diagnosis.

The next investigation in line is incision biopsy but we decided against it because it may provide a route for tumour seedling to skin and automatically upstage the tumour as well as cause a bad painful experience to the patient. Furthermore taking into consideration of another pre-operative biopsy may produce a similar indefinite result, we counselled the patient for submandibulectomy for diagnostic and therapeutic in the same setting. Intra-operative frozen section was very helpful procedure in our case as it determines the extent of surgery and reduces the morbidity related to more extensive surgery without conferring an extra benefit or disease control. A meta-analysis study showed frozen section accuracy is clinically acceptable in salivary gland tumours.[10]

Imaging studies either ultrasound, CT scan or magnetic resonance imaging (MRI) also showed non-specific findings for KD.[5] KD should be suspected if present of multiple ill-defined enhancing masses within and around the parotid gland with associated regional lymphadenopathy seen in CT scan or MRI.[11] CT scan of our patient showed heterogeneous submandibular gland enlargement with presence of multiple cervical lymph nodes, thus more common diagnosis like salivary gland malignancy or lymphoma were initially suspected.

The definitive diagnosis of KD is based on the HPE of the excised lesion, but again there is no specific features.[5] Many studies described the common findings were reactive follicular hyperplasia, large number of eosinophils, lymphocytes and mast cells infiltrate, eosinophilic microabscess formation, presence of polykaryocytes and varying degree of fibrosis and vascular proliferation.[4,5,7] These characteristics are consistent with our HPE findings.

Several treatment modalities have been proposed however the definitive treatment is still unclear, with variable response and high recurrence rate up to 80%.[5] Generally the treatments that have been reported are surgical excision, systemic corticosteroids, radiotherapy, cytotoxic agents, cyclosporin, pentoxifylline, leflunomide, mycophenolate mofetil and imatinib.[11] A combination of at least two therapies produces a better result in term recurrence rate.[11] The treatment of submandibular gland KD specifically was not well described in the literature due to the rarity of the involved organ. We believed the treatment principle is similar to other benign submandibular gland tumours with submandibulectomy usually the treatment of choice. Submandibulectomy is generally a safe procedure due to its relatively superficial location of the submandibular gland and less complexity of the surrounding structures. Our patient underwent submandibulectomy and was subsequently followed by oral corticosteroid as adjunct medical therapy. There was no residual tumour at the operated site and no new lesion after 3 months of follow-up. We think this regime is a good combination as surgery help to reduce the tumour bulk and subsequently reduces the dosage and duration of corticosteroid required. Long-term use of corticosteroids especially in the elderly may result in multiple systemic complications.

CONCLUSION

KD is a rare benign chronic inflammatory disorder of unknown aetiology that substantially causes challenges to the managing team from diagnosis to treatment and effort to reduce the recurrence. It has variable presentations, but the involvement of the submandibular gland is very rarely reported. Its characteristic resembles other inflammatory or malignancy conditions and the rarity of the involved region contributes to the difficulties in managing the present case. Due to this non-specific presentation, the investigation of choice should be case-to-case basis, and every effort should be taken to get a preoperative diagnosis without delaying the treatment.

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CASE REPORT

A recalcitrant case of erosive Oral Lichen Planus

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Lichen Planus is an inflammatory condition of the skin and mucous membrane that can also affect oral mucosa in a variety of forms. The mucosal form has six types and at least two of them carry a risk for malignant transformation and thus warrant a follow-up. The cutaneous form is pruritic and sometimes can be self-limiting but oral lichen planus (OLP), is a chronic inflammatory disease with relapses and remissions. A case of erosive lichen planus, treated with topical clobetasol propionate 0.05% and systemic corticosteroids is reported. The lesion healed after 3 weeks of treatment, following which the patient was referred for needful restorative treatment. The patient had a recurrence during the follow-up and the second course of treatment was administered. There is no well-defined treatment for OLP yet steroids have a vital role in symptomatic relief. Although topical steroids are the mainstay, recurrent, multiple, and large lesions are supplemented with systemic corticosteroids.

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Lichen planus is a mucocutaneous disease of inflammatory origin affecting around 1-2% of the general population. It can occur in single or multiple cutaneous and non-cutaneous (mucosal) areas within the body. Consequently the disease can affect either skin alone, the oral cavity alone, or occur in both the areas simultaneously; it may also affect other sites namely nails, scalp, oesophagus, and the genital areas.[1,2]Although the aetiology is yet elusive, the various factors attributed include genetics, immunologic factors, medications, and hepatitis C infection. The literature shows six distinct types of OLP, namely reticular, atrophic, erosive, plaque-type, popular, and bullous type;[3]one or more forms can coexist in a single patient. The atrophic and erosive types are reported to carry an increased risk for malignant transformation. OLP is usually found in a bilateral fashion but need not be symmetrical. The common sites for OLP are buccal mucosa, dorsal surface of the tongue, and gingiva, at times occurring on other rare sites as well.[4] The reticular OLP is the most common form which is asymptomatic and is usually diagnosed on routine oral examination. The erosive OLP is the most noteworthy of all the types having characteristic symptoms and consisting of the lesions in the form of a network formed by radiating keratinized striations;[5] the other types with symptoms and difficult to treat include the atrophic and the bullous types. The erosive OLP becomes multifocal with time and patients complain of varying amounts of pain and interference with the normal mastication process. Topical or systemic corticosteroids remain the mainstay of treatment for OLP; however, it is advised to use further adjuvants to enhance the process of healing and assist in modulation of the immune process in the OLP microenvironment. We report a case of erosive OLP effectively treated with topical clobetasol propionate and systemic prednisone.

CASE REPORT

A 60-year-old male patient with no underlying systemic anamnesis approached our department of oral medicine, for a therapeutic opinion for a painful ulcer of 6 months duration on the left buccal mucosa. The patient had no history of smoking or tobacco chewing. The ulcer on the left buccal mucosa had increased in size in the last 6 months. In addition, the patient complained of pain and tenderness during phonetics and while having food. The patient was using Tess buccal paste (Triamcinolone acetonide 0.1%); advised by a local Dentist he had visited around 15 days back, but without any significant relief. On examination patient had an irregular shallow ulcer around 3cm x 2cm on the posterior

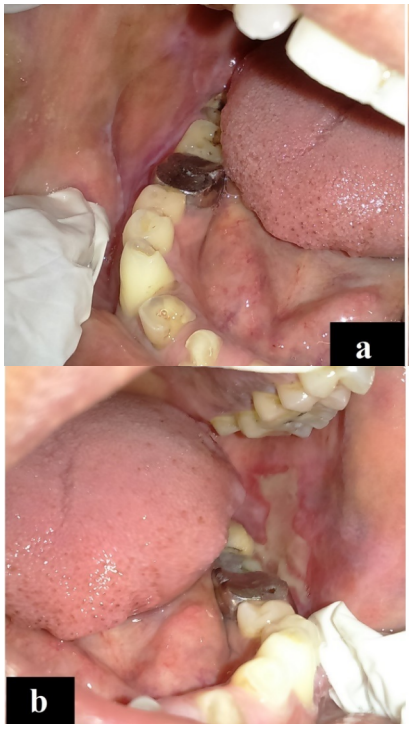

Figure 1 *A) Reticular lichen planus on the right buccal mucosa. B) Erosive lichen planus on the left*

region of the left buccal mucosa; the right buccal mucosa had white striations which the patient was not aware, possibly due to lack of any symptoms. (Figure 1a & 1b) The hard tissue examination revealed metal crowns on teeth numbers 36 and 46, and amalgam restoration with respect to tooth number 37. The approximation of amalgam restorations and the metal crowns prompted us for a provisional diagnosis of oral lichenoid reaction (OLL), and a differential diagnosis of OLP Incisional biopsy of the lesion on the left buccal mucosa was carried out and showed features of erosive lichen planus without any dysplastic features. Stratified squamous parakeratinised epithelium was noticed with saw tooth rete ridges in a few areas. (Figure 2a) Areas of ulceration surrounded by hyalinization and a thick band of inflammatory infiltrate can be appreciated below the dense mixed inflammatory infiltrate; chiefly neutrophils. (Figure 2b) Most of the areas

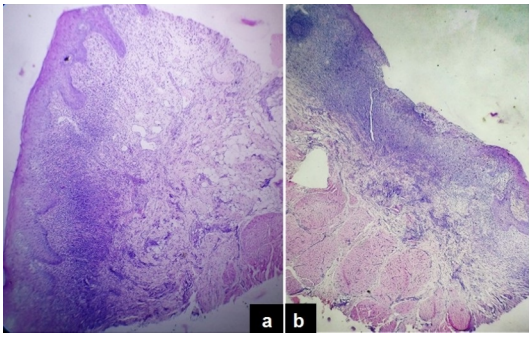

Figure 2 *A) Stratifed squamous parakeratised epithelium with saw tooth rete ridges and dense subepithelial lymphocytic infiltration. B)Ulceration surrounded by hyalinization and thick band of inflammatory infiltrateposterior buccal mucosa.*

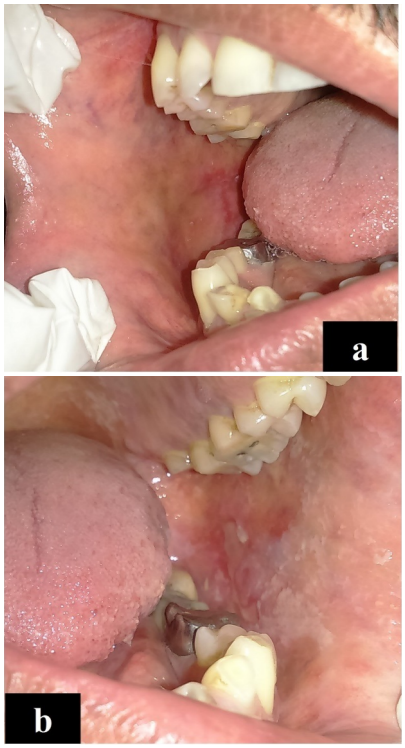

Figure 3 *A) Resolution of lesion on the right buccal mucosa at 7 days of treatment B) Marked improvement on the left buccal mucosa after 7 days of treatment*

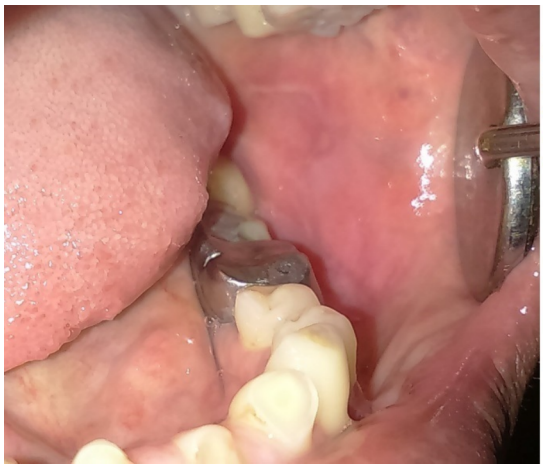

Figure 4 *Complete resolution of erosive lichen planus after initial course of corticosteroids, on the left buccal mucosa after 3 weeks of treatment.*

have subepithelial epithelium and the deep connective tissue has muscle fibers, adipose tissue, and extravasated RBCs. The patient was advised topical clobetasol propionate 0.05% and systemic prednisone in the form of 20 mg/day oral tablets for 1week. The patient was evaluated after 1 week with marked improvement noticed on both the right and the more severe left side. (**Figure 3a & 3b**) The patient was advised to continue topical clobetasol propionate 0.05% and systemic prednisone was tapered for another week. The patient showed remission in lesions bilaterally in 3rd week of treatment, and the erosive lesion on the left buccal mucosa was completely resolved. (**Figure 4**) The amalgam restorations and the metal crowns were replaced with ceramic restorations and the patient was kept on follow-up. The patient reported back with relapse even after the replacement of the restorations, (**Figures 5a & 5b**) supporting our clinicopathological diagnosis of OLP The patient was retreated with local and systemic corticosteroids and showed signs of healing during the second course of treatment. (**Figure 5 c & 5d**) The patient did not report for further evaluation.

DISCUSSION

The etiology of lichen planus is still not clear. Much of the data yielded through years of research, attributes immunologic mechanisms as the mainstay for the pathogenesis of the lichen planus.[6] The role of Langerhans cells, the mast cells, and their interactivity with the abundant T-cells assembled in the underlying connective tissue has been primarily focused on in the literature. The evidence gathered over the years suggests lichen planus is an autoimmune disorder mediated by T-cells in which apoptosis of basal keratinocytes occurs as a result of cluster of differentiation (CD8) + T cells. OLP is a non-infectious chronic inflammatory disorder of stratified squamous epithelium of oral mucosa and the underlying lamina propria with or without its

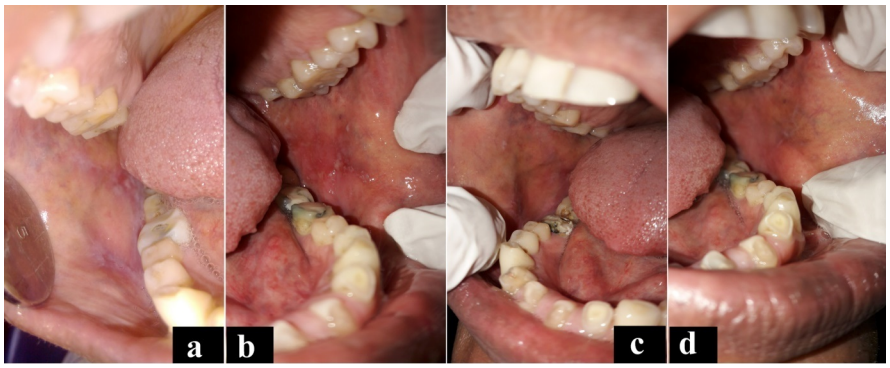

Figure 5 *A,B) Recurrence after replacement of metallic restorations. C,D) Improvement during second course of treatment.*

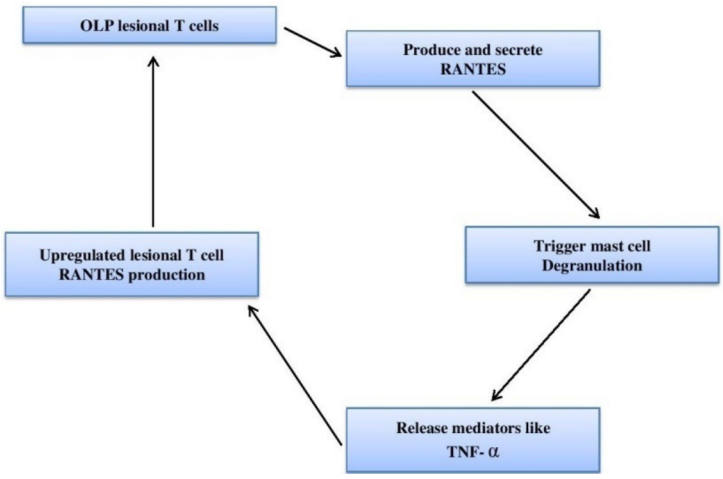

Figure 6 *The disease chronicity of oral lichen planus promoted by cyclic mechanism*

cutaneous form. It is estimated that 30% to 50% of cases with OLP have cutaneous manifestations, and such skin lesions can aid in the diagnosis of this disorder. Lichen planus occurs on cutaneous sites only, in 35% of cases, and 25% of cases have only a mucosal presentation. OLP usually occurs in the middle-aged and elderly with a female to male ratio of 1.5: 1. OLP has significantly higher chronicity than cutaneous lichen planus. Although this inconsistency in chronicity between OLP and its cutaneous counterpart is not clear, the role of T-cell RANTES (regulated upon activation, normal T-cell expressed and secreted) and mast cell degranulation, that releases tumor necrosis factor α and a cyclical process, where interleukin 4 and interferon may forecast the chronic nature of the disease in certain cases. (Figure 6)[1]

Clinical characteristics of OLP are dictated by the severity of the disease and present in the range of clinical appearances. The four types of OLP lesions most often described and discussed are reticular, erosive, plaque-like, and bullous. (Table 1) Topical and systemic `corticosteroids are the most widely used agents for OLP with the aim to modulate a patient's immune response. Topical corticosteroids constitute the mainstay and depending upon the degree of severity, the agents commonly used in increasing order of their potency are triamcinolone acetonide, fluocinonide, or fluocinolone acetonide (fluorinated steroids), betamethasone phosphate, and halogenated clobetasol propionate.[7] Topical corticosteroid resistant and recalcitrant OLP can alternatively be managed by other topical agents, like tacrolimus or cyclosporine, both calcineurin inhibitors, and sometimes by retinoids.[8] Systemic corticosteroids have a decent role in recalcitrant, erosive, or when topical agents are ineffective. A number of studies have established systemic corticosteroids as the most effective modality of treatment for OLP[9] As corticosteroids dosage has a wide range, and further due to variable patient responses to systemic corticosteroids, a number of dosing options exist. The oral dose of prednisone ranges from 10–20 mg/day for moderate OLP to as high as 35 mg/day for extreme cases.[7] It is challenging to treat and diagnose symptomatic OLP in a definite manner due to the lack of a uniform method and also due to variable individual factors.[10]

Figure 6 *The disease chronicity of oral lichen planus promoted by cyclic mechanism*

OLP type	Clinical features and favoured location
Reticular	Asymptomatic and most common type and hence diagnosed often during routine examination; lacy whitish streaks, surrounded by an erythematous border. Reticular OLP may change into one of the severe subtypes, like erosive form. Most commonly occurs on buccal mucosa bilaterally.
Erosive	The most advanced subtype, can present clinically as atrophic or erythematous ulcerations and erosions of the mucosa with faint radiating white striae. Occasionally the ulcers are covered by a pseudomembrane. The atrophic and ulcerative form confined to gingiva is giving rise to a pattern, desquamative gingivitis. This pattern may also represent pemphigus vulgaris or mucous membrane pemphigoid and thus warrants histopathological examination. It causes mild discomfort to severe episodes of pain and might cause dysgeusia on dorsum of the tongue.
Plaquelike	Large homogenous white patches are typical of plaque-like OLP. As most focal leukoplakia lesions have similar clinical picture, therefore leukoplakia should be ruled out. Most commonly seen in tobacco smokers, it occurs commonly on tongue.
Bullous	Rarely OLP may show bullous lesions, with bullae size ranging up to 2 cm. The bullae rupture in the oral cavity similar to other vesiculobullous lesions, leaving ulcerations on an inflamed mucosa. Bullous type most commonly involves posterior aspect of buccal mucosa.

CONCLUSION

The present case with a history of 6 months duration and ineffective results with topical triamcinolone acetonide was managed with a combination of a super potent topical agent (clobetasol propionate) and a systemic (oral) corticosteroid. The patient had a relapse during the course of the treatment. There is a need for large group studies of clinical trials to unravel potential medications for the effective treatment of OLP

Declaration Of Patient Consent

Duly signed informed consent was taken from the patient for publication purposes. It was conveyed to the patient that his name and initials shall be concealed, and all efforts would be taken to hide his identity although anonymity cannot be guaranteed.

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CASE REPORT

Interstitial lung disease secondary to oxaliplatin-raltitrexed based chemotherapy

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FOLFOX is a widely used regimen in the management of gastrointestinal malignancies and is a combination of 5-fluorouracil (5-FU), folinic acid, and oxaliplatin. Raltitrexed is an antifolate thymidylate synthase inhibitor which is used as an alternative when 5-FU is not tolerated. Here we present a case of interstitial lung disease as a rare side-effect of oxaliplatin and raltitrexed. Not much is known about the pathophysiology of the condition and most information available in the literature is taken from published case reports.

FOLFOX is a chemotherapeutic regimen consisting of the fluoropyrimidine 5-fluorouracil (5-FU), folinic acid, and the third-generation platinum compound oxaliplatin. Its main use is in colorectal cancer, however, it is also indicated for use in locally advanced (inoperable) or metastatic oesophageal or gastric cancer[1]. Those patients who develop coronary vasospasm and cardiotoxicity with 5-FU based regimens are switched to raltitrexed.[2] Recent studies have shown that gastric cancer with a high expression of thymidylate synthase (TS) mRNA levels can be efficiently managed with raltitrexed.[3] Phase 2 clinical trials are currently underway to assess the response rate, overall survival, and progression-free survival of raltitrexed in inoperable gastric cancer.[4]

In general, chemotherapy is associated with several side effects including myelosuppression, allergic reactions, mucositis, gastrointestinal disturbance, infertility, and others. Oxaliplatin may cause neurotoxicity (cold-associated dysaesthesia and peripheral sensory neuropathy) whereas fluoropyrimidines may cause coronary artery spasm, cardiotoxicity, and palmar/plantar erythema.[1] Raltitrexed may be associated with liver impairment.[5] There are very few documented cases of lung toxicity attributed to these regimens. Increasing awareness helps clinicians maintain a high index of suspicion and initiate effective treatment promptly to reduce morbidity and mortality.

CASE REPORT

A 72-year-old Maltese gentleman presented with dyspepsia and melaena in June 2021. A gastroscopy was performed, and a lesion in the body of the stomach was visualized and biopsied. Staging CT showed extensive carcinoma of the stomach with peritoneal metastasis and spread to the regional, abdominal, and retroperitoneal lymph nodes. Histology was reported as moderately differentiated intestinal-type adenocarcinoma of the stomach body. Thus a diagnosis of stage IV gastric cancer was made. He was planned for 12 cycles of 2 weekly FOLFOX chemotherapy at 80% of the full dose, with palliative intent.

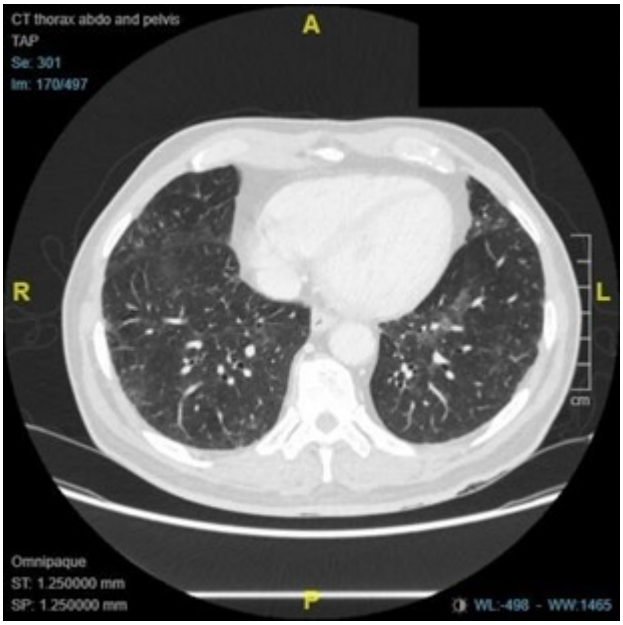


Figure 1 *Baseline CT Thorax pre-treatment*

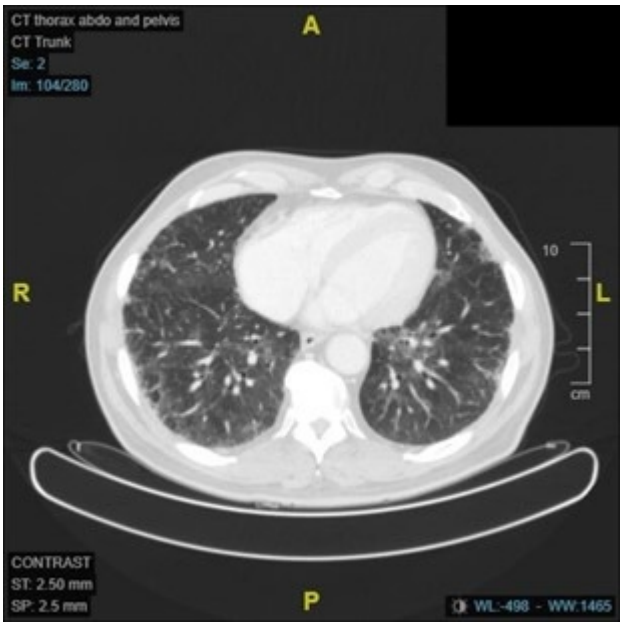


Figure 2 *Re-staging CT Thorax after cycle 8*

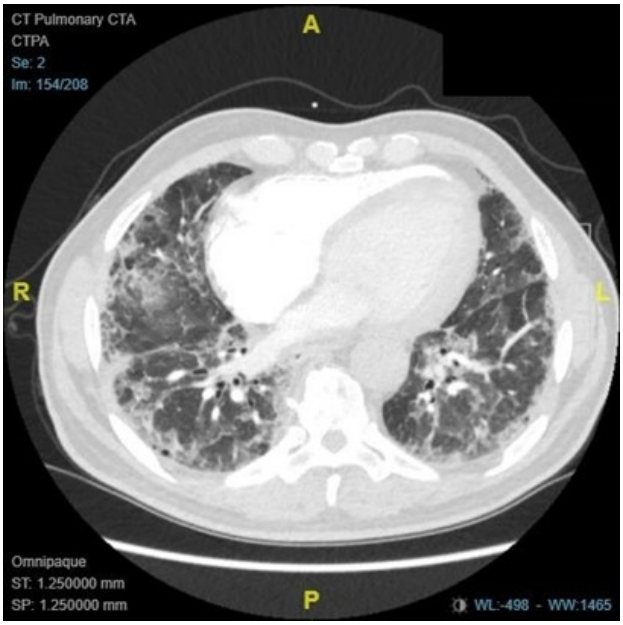


Figure 3 *CT Pulmonary Angiography after clinical deterioration*

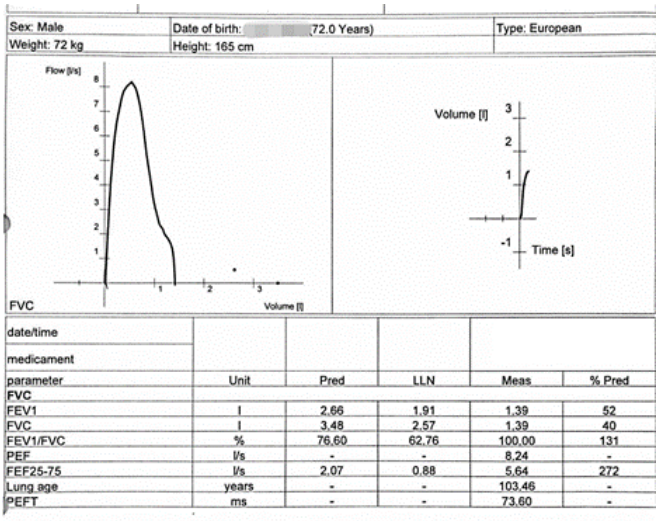
The patient did not have any underlying respiratory conditions. His medical history included gout, hypertension, glaucoma, and pancreatitis. There were no known drug allergies. He had no previous exposure to asbestos or other occupational hazards. He was an ex-smoker with a 30-pack-year history. His baseline Eastern Cooperation Oncology Group/World Health Organization (ECOG/WHO) performance status was 1 - fully independent and ambulatory, with limitations only in physically strenuous activities.

Baseline thoracic imaging at diagnosis showed tiny bilateral bullae and non-specific mosaic attenuation in the lower lung lobes (Figure 1). He underwent 4 cycles of FOLFOX chemotherapy from July 2021 to September 2021, with very minimal side effects and a good tolerability profile. For the 5th cycle of chemotherapy, 5-FU was omitted due to central compressive chest pain experienced during 5-FU infusion. The latter was switched to raltitrexed and was subsequently given together with oxaliplatin every 3 weeks at a reduced dose of 75% due to low creatinine clearance.

A re-staging CT (Figure 2) after cycle 8 revealed early ground glass and emphysematous changes as well as intra-lobar septal thickening. Due to good oncological response on imaging and down-trending tumour markers, no changes were done to the treatment, and another cycle was given.

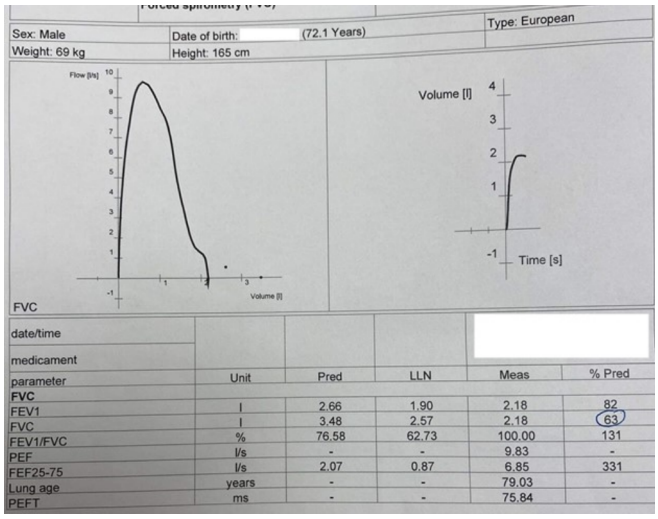
The patient presented acutely before his 10th cycle, with severely reduced exercise tolerance, exertional shortness of breath, and dry cough. These symptoms had started a few days after cycle 9 and were limiting most of his activities of daily living. His ECOG/WHO performance status was now measured at 3 - semi-dependent with limited self-care and severely restricted mobility. He denied any other symptoms. Clinically his oxygen saturation at rest was 95% on room air with a significant desaturation after a 6-minute walk test. He had fine bi-basal inspiratory crepitations up to mid-zones on chest examination. His blood results were within normal limits and were not indicative of an active infective process.

Repeat imaging of the thorax excluded pulmonary thrombosis, however, revealed extensive ground glass and emphysematous changes in the lower lobes with intralobular septal thickening in the lung bases (Figure 3). A preliminary diagnosis of chemotherapy-induced interstitial pneumonia was made. Spirometry (Figure 4) showed a severe restrictive abnormality, with an FEV1 of 1.39L (52%) and an FVC of 1.39L (40%).



date/time					
medicament					
parameter	Unit	Pred	LLN	Meas	% Pred
FVC					
FEV1	l	2.66	1.91	1.39	52
FVC	l	3.48	2.57	1.39	40
FEV1/FVC	%	76.60	62.76	100.00	131
PEF	l/s	-	-	8.24	-
FEF25-75	l/s	2.07	0.88	5.64	272
Lung age	years	-	-	103.46	-
PEFT	ms	-	-	73.60	-

Figure 4 *Baseline spirometry before steroid treatment*



date/time					
medicament					
parameter	Unit	Pred	LLN	Meas	% Pred
FVC					
FEV1	l	2.66	1.90	2.18	82
FVC	l	3.48	2.57	2.18	63
FEV1/FVC	%	76.58	62.73	100.00	131
PEF	l/s	-	-	9.83	-
FEF25-75	l/s	2.07	0.87	6.85	331
Lung age	years	-	-	79.03	-
PEFT	ms	-	-	75.84	-

Figure 5 *Repeat spirometry after steroid treatment*

The case was discussed within a multidisciplinary team and concluded the discontinuation of all chemotherapeutic agents, including oxaliplatin and raltitrexed, due to chemotherapy-induced interstitial pneumonia. Chemotherapy was stopped and 4mg dexamethasone was given daily. After 5 weeks of treatment, some improvement in exercise tolerance was reported and a repeat spirometry (**Figure 5**) showed an increase in FEV1 and FVC by 30% and 23%, respectively. The spirometry technique was poor on both occasions as the patient could only exhale for one second. In fact, the FVC is equal to FEV1 in both cases.

The dose of dexamethasone was tailed down slowly by 1mg every 4 weeks. Follow up imaging (**Figure 6**) performed 3 months after diagnosis showed near-complete resolution of changes of organising pneumonia with post-interstitial pneumonitis scarring, moderate basal predominant lung fibrosis, and traction bronchiectasis. He was later started on long-term oxygen therapy due to persistent dyspnoea.

His general condition deteriorated over the following weeks with worsening dyspnoea and saturations below 50% on room air. Unfortunately he passed away due to respiratory failure and progression of malignant disease.

DISCUSSION

The summary of product characteristics lists interstitial lung disease and pulmonary fibrosis as rare side-effects of oxaliplatin with a frequency of ≥1/10000 and <1/1000.[6] Homma et al report an incidence of 0.2% (11/5008 cases) in Japan in 2007.[7] Trials involving oxaliplatin reported an incidence of pulmonary fibrosis and grade IV pulmonary toxicity in less than 1%.[11] Several other reports note that the actual incidence might be higher, because many cases remain under-diagnosed or missed due to the relatively mild symptomatology of most patients. Unfortunately more than half of the reported cases were fatal.[8,11]

Both oxaliplatin and raltitrexed can cause pulmonary toxicity in the form of diffuse alveolar damage, subacute interstitial pneumonia and fibrosis.[12] Howlett et al report a case of an acute exacerbation of interstitial lung disease from raltitrexed therapy.[13]

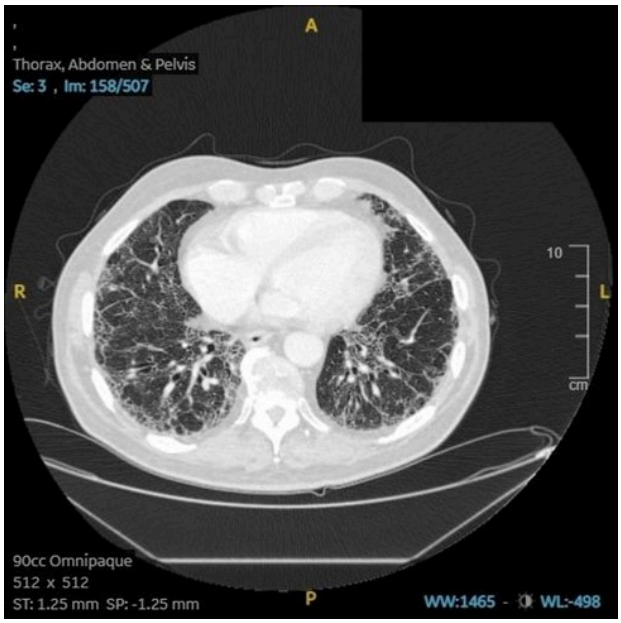


Figure 6 *Repeat CT Thorax 3 months after treatment*

Although the exact pathogenesis of drug-induced lung injury is unknown, several mechanisms have been proposed, including cytotoxic and immunological reactions.[7,8] Cytotoxic reactions are the dose-dependent effects exerted directly on the cells of the lung by the chemotherapy or its metabolites. Immunological reactions consist of type I (anaphylactic) and type IV (delayed) hypersensitivity reactions, with the incidence increasing after each cumulative dose.[7] Another school of thought is that oxaliplatin reduces the glutathione stores, making organs susceptible to oxidative damage.[7,8,11] One particular case describes a dramatic improvement of symptoms upon initiation of N-acetylcysteine which is used to replenish glutathione.[9] Pavlović et. al mention the use of imatinib for its lung fibroblast inhibition in the management of interstitial lung disease.[8]

Currently there are no randomised controlled trials on the most effective management of drug-induced interstitial lung disease. Most documented cases have been managed with prompt cessation of the culprit drug followed by corticosteroid therapy. Before commencing corticosteroids on a patient with suspected drug-induced lung injury, it is essential to exclude underlying infection. Homma et al mention the role of bronchoalveolar lavage fluid which plays a pivotal role in the diagnosis of drug-induced lung injury (presence of lymphocytes ± eosinophils) and in the exclusion of infection. However it might be difficult to obtain in patients who are unfit for a bronchoscopy due to respiratory failure. In such cases, an induced-sputum sample may prove useful.[7] This is not performed locally.

A temporal relationship between the initiation of a drug and the onset of signs and/or symptoms may be the only indicator of a suspected drug-induced reaction. Since chemotherapy is usually administered as a combination, it may be difficult to identify which is the main causative agent. Any one of the agents may contribute towards the toxicity, to a greater or lesser extent. Some papers mention the use of drug lymphocyte stimulation testing (DLST), but a positive result does not always mean the drug is the cause.[7] Diffuse alveolar damage is thought to be the main histopathological finding in over 50% of post-mortem studies.[10]

SUMMARY BOX

- Interstitial lung disease following FOLFOX or FOLFIRI is an uncommon but life-threatening complication.
- Pulmonary toxicity is an important complication associated with many of the antineoplastic agents in use. It should be considered in any patient undergoing chemotherapy who presents with dyspnoea and hypoxia in order to try and reduce the associated morbidity and mortality.
- Care must be taken regarding the onset of interstitial lung disease and a multidisciplinary approach is essential for the management of such complications.

A recent literature review has included 28 cases of oxaliplatin-induced lung toxicity, 16 of which resulted in a fatal outcome.[8] Age (>60 years), male gender, history of smoking, arterial hypertension, pre-existing lung conditions, and chronic kidney disease are thought to increase the risk of drug-induced lung injury.[7-9,11]

Homma et al suggest careful monitoring with frequent blood tests and chest radiographs in patients on oxaliplatin-containing regimens. Those patients who develop new-onset respiratory symptoms (dry cough, dyspnoea) or signs (crackles, new infiltrates on imaging) should be discussed with the Respiratory specialists. The causative agents should be stopped and the necessary investigations performed. Corticosteroids should be started without delay if interstitial lung disease is suspected.[6]

CONCLUSIONS

Pulmonary toxicity is a rare (sometimes fatal) side-effect of oxaliplatin and raltitrexed therapy with only a few documented cases worldwide. There is a lack of awareness about the condition which should be addressed. All chemotherapeutic protocols with these chemotherapeutic agents should alert the prescriber regarding the possibility of lung damage as a possible side-effect of therapy.

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