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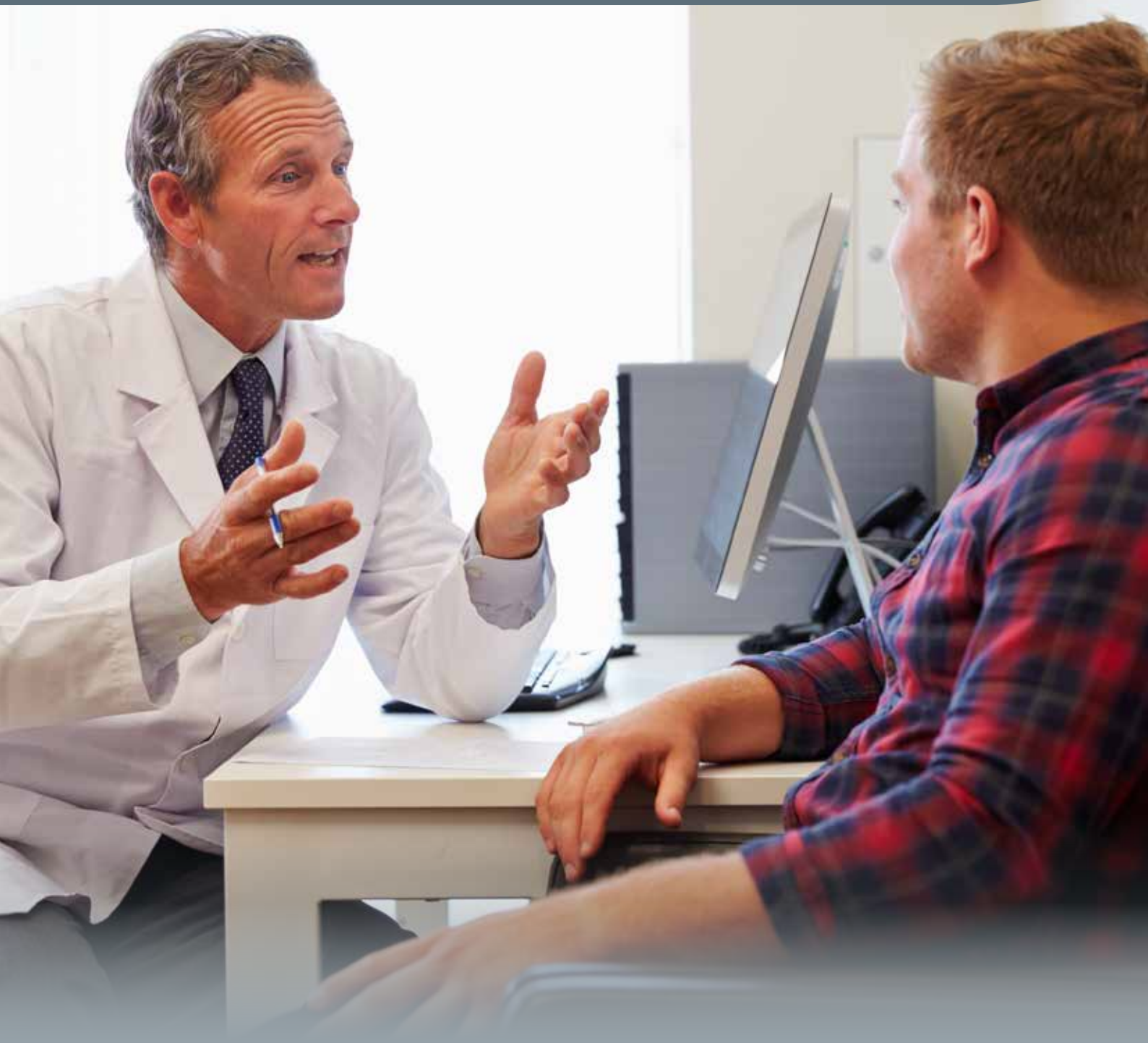

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The mission of the Journal of the Malta College of Family Doctors (JMCFD) is to deliver accurate, relevant and inspiring research, continued medical education and debate in family medicine with the aim of encouraging improved patient care through academic development of the discipline. As the main official publication of the Malta College of Family Doctors, the JMCFD strives to achieve its role to disseminate information on the objectives and activities of the College.

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Handling of third party information in the context of blood donation

Dr Monique ABELA, Dr George GALEA, Prof. Pierre MALLIA

The entire relationship between blood donors and the blood collection service is based on trust. Donors understand that the blood service has to be very careful in its selection procedures. Approximately 20,000 blood donors are seen annually in Malta and the vast majority of donors are committed, altruistic and correctly answer the screening questions designed to eliminate donors with risks to themselves or to the potential recipients.

However it is known that sometimes very few donors are not completely open and occasionally information is received by a third party about a donor which, if given by the donor, would have precluded donation. How this information is handled is critically important, since the blood service would not wish to compromise the trust which has been built with the vast majority of donors over the years. It becomes a difficult balancing act to ensure the rights of the donor and those of the third party are all respected.

The National Blood Transfusion Service (NBTS) is committed to providing safe blood components to all patients. As part of the donation process, all donors provide informed consent, undergo a detailed medical screening via a questionnaire and a medical check up. They are also offered advice on any queries that arise throughout the process. The pre-donation interview is always carried out in a private place, so that donors can be sure of not being overheard or seen while discussing personal information with the medical officer.

Third party information can be received verbally, by letter or via the telephone. It may also come from postings on the internet, social media or press articles, or through anonymous tips. Clearly some sources of information are perceived to be more reliable than others. The blood service has attempted to assess this by ranking the sources in order of reliability: identified informants, relatives of the donor, healthcare professionals, police, teachers or social workers. On occasion third party information may be obtained about the partner/husband/wife of a blood donor, shedding doubt as to the donation eligibility of the latter.

The following are broad principles that guide what is done.

If the third party information is received during a session it will not normally be discussed with the donor during the session and the donor may be bled, as long as the donor questionnaire has been completed and the answers would (but for the third party information) allow the donation to proceed. However the donation will be discarded if the evaluation is such that it would be considered potentially hazardous to transfuse that unit of blood.

In all other circumstances where the third party information is such that (if confirmed) it would affect the donor's future as a blood donor, or the safety of the donation collected, the donor in question is contacted (by telephone and if unreachable by registered mail) and asked to come to the donation centre for clarification. Precautions are taken to ensure that this communication is done directly with the donor involved and with nobody else. The donor is met by a named medical doctor of the blood service and a confidential discussion takes place to try and assess the veracity or otherwise of the third party statements. The substance of information is made clear to the donor whilst great effort is made to introduce the information gently and in a non confrontational way. It is important to be non critical and give the donor a safe environment to say whatever he or she wishes.

The follow up action is very specific to the information gathered from all sources but, as a general guideline, where it is deemed that the source of the information is not a reliable informant, denial by the donor may be accepted and the donor allowed to continue donating in future. If on the other hand, the source of the information is a reliable informant, the donor's denial is

not necessarily to be taken as being conclusive and it may be necessary to go back to the source for further comment before reaching a final decision. Sometimes donors do not respond to the invitation to comment on the information received, or there are instances where after all avenues have been explored doubt still persists on the accuracy of the information to hand. On these occasions such donors are permanently excluded from the donor panel in the interests of safety of the blood supply.

Donors who are excluded from the panel are always told of this outcome and receive a clear explanation of the reason either when they turn up for counselling or through a detailed letter if they don't. However in all circumstances the source of information is not disclosed (even though their identity can become obvious to the donor in at least some instances).

These are very sensitive situations and any action taken will be discussed and evaluated with senior managers at the blood centre and sometimes senior colleagues and other sources, e.g. lawyers, may be consulted for counsel. This is always done in an anonymous fashion.

Detailed records are kept of all communications in connection with such situations, be they verbal or written. If third party information is communicated in writing, the letter or other documents (including a fax or e-mail) containing it will be retained for 30 years in a secure place to comply with laboratory regulations to ensure traceability. Whilst the third party is informed at the earliest opportunity that the NBTS will not normally disclose their identity to the donor unless overruled by law, donors also have the statutory right of access to their records and the right to demand that any inaccuracies are corrected. Therefore the requirements under the Data Protection Act (2002) are followed and such information is classified as "sensitive personal data".

There is not much published work in this area; however the small number of studies that exist do indicate that there is a substantial likelihood that third party information may indeed be true (Paley, 2005). These studies have shown that, in many instances, donors who were ineligible to donate continued to give blood. This is worrying. Moreover these studies have also shown that a significant number of donors will not respond to requests from donation centre staff to discuss any third party information. This would indicate that the donor had a circumstance which he did not wish to discuss.

The scope of all pre-donation assessments is to establish a safe donor pool. Donor literature and questionnaires are made widely available to enable donors to self-exclude; however, donors might not always do so. This confirms that it is worth investigating third party information and having a robust system to handle it.

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Assessing the use of the Ottawa ankle rules when investigating traumatic pathology of the foot and ankle in a Maltese primary care setting

Dr Maria Christina AXIAQ, Dr Anton BUGEJA

ABSTRACT

Background

The judicious use of ankle and foot radiography should balance a correct diagnosis in all cases of traumatic distal lower limb fractures with the avoidance of unnecessary radiation exposure for the patient. For this objective the Ottawa ankle and foot rules (OAR) have long been established as valuable and proven tools for such assessments. The doctor's requests should provide all the necessary information to allow correct interpretation of the x-rays as well as for research purposes.

Objective

A prospective study was carried out to evaluate use of the criteria in the OAR over a four week period to assess the need for foot and ankle x-rays in a Maltese public health centre. It also sought to assess whether the related documentation is appropriate.

Method

All the requests for ankle and foot x-rays made during August 2016 in a Maltese primary health centre were analysed. The data were obtained from the Radiology Information System, the programme used for electronic referral, and from patients' health centre files. The demographic and clinical information obtained was analysed for use of the criteria in the OAR.

Results

In total, 75 patients had an ankle and/or foot x-ray taken, with fractures detected in 15 patients. There was evidence for use of the OAR in only 36 cases (48%). Minor differences were noted in the information recorded in the patients' files and in the electronic referrals.

Conclusions

Use of radiological services in primary care is useful in diagnosing ankle and foot traumatic pathology, but knowledge and use of the OAR is recommended to decrease the number of x-rays taken.

Keywords

Ankle injuries, foot injuries, primary healthcare, documentation, radiography.

INTRODUCTION

Acute ankle sprains are a common reason for primary care and emergency department visits, especially among adolescents (Tiemstra, 2012) and athletes (Yeung, 1994). In a cross-sectional study by Menz, et al. (2010), ankle and foot problems constituted 8 % of all musculoskeletal consultations but these were mostly of non-traumatic nature. This reflects the Maltese situation where consultations for the relevant trauma were not among the twenty most common reasons for GP consultations (Soler and Marnoch, 2008).

The Ottawa ankle and foot rules (OAR) are well-validated clinical decision aids that were developed in 1992 to avoid unnecessary radiography in cases of foot and ankle trauma. They have a sensitivity of 98%-100%, modest specificity and the potential to reduce unnecessary radiographs by 30-40% (Bachmann, et al.,

2003). A systematic review has confirmed the value of OAR for managing ankle sprains in primary care but has also pointed out the need for additional tests to exclude other injuries (Polzer, et al., 2012).

The OAR recommend that an ankle x-ray series is only required if there is malleolar pain and any of these findings:

(a) Bone tenderness at the posterior 6cm or tip of the lateral malleolus, or
(b) Bone tenderness at the posterior 6cm or tip of the medial malleolus, or
(c) Inability to weight bear or limping immediately after injury or in the clinic.

Furthermore, a foot x-ray series is only required if there is malleolar pain and any of these findings:

(a) Bone tenderness at the base of the most lateral metatarsal, or
(b) Bone tenderness at the navicular bone, or
(c) Inability to weight bear or limping immediately after injury or in the clinic (adapted from Stiell, 1996).

Assessment for the use and documentation of the OAR was made at Paola Health Centre which is the major public primary health care centre for the south of Malta. It has a direct catchment area for eleven localities with a subsidiary centre at Cospicua serving mainly the Cottonera area on the eastern shores of the Grand Harbour. Radiology services for all these localities, but also for other localities on the islands as needed, are provided at the Paola Centre from Monday to Saturday from 8am till 7pm (Government of Malta, 2016).

Referrals for x-rays are ordered electronically and the relevant handwritten medical records are kept in files. The possibilities provided by such referral are for foot x-ray, ankle x-ray, or foot and ankle x-ray. The doctor chooses the x-ray required, and is expected to input the relevant history and what information is expected for clinical decision making on the online request. Doctors working in private practice have access to the relevant radiology services through a purposely-designed form, from which the radiographer transcribes the above data. After patients' visits, the files are either archived at Paola Health Centre or sent to another clinic according to the patient's locality of residence.

METHOD

After the necessary permissions from the Primary Health Care and Medical Imaging departments were secured, all requests for ankle and foot radiographs taken at Paola Health Centre during August 2016 were obtained from the Radiology Information System (RIS). The patients' demographic details (namely gender, age, and locality of patient) were recorded. The clinical details present in the request were reviewed and the following additional information was tabulated:-

(a) Ankle x-ray requested? (Yes=1, No=0)
(b) Foot x-ray requested? (Yes=1, No=0)
(c) Online request (exact text recorded)
(d) Was a fracture reported by the radiologist? (Yes=1, No=0)
(e) If a fracture was reported, the exact text was recorded.

From the latter information (i.e. online request, (c) in the above list) the following information was extracted

(f) Was trauma recorded? (Yes=1, No=0)
(g) Was there tenderness in the malleoli, navicular or 5th metatarsal head or was the patient unable to weight bear or limped immediately after injury or in the clinic? (Yes=1, No=0).

From this information, use of the OAR was considered as present in cases where (f) and (g) were present. A search was also made in the relevant patients' files, recording whether:

- the file was found;
- an entry was present;
- the information listed in (f) and (g) above was present.

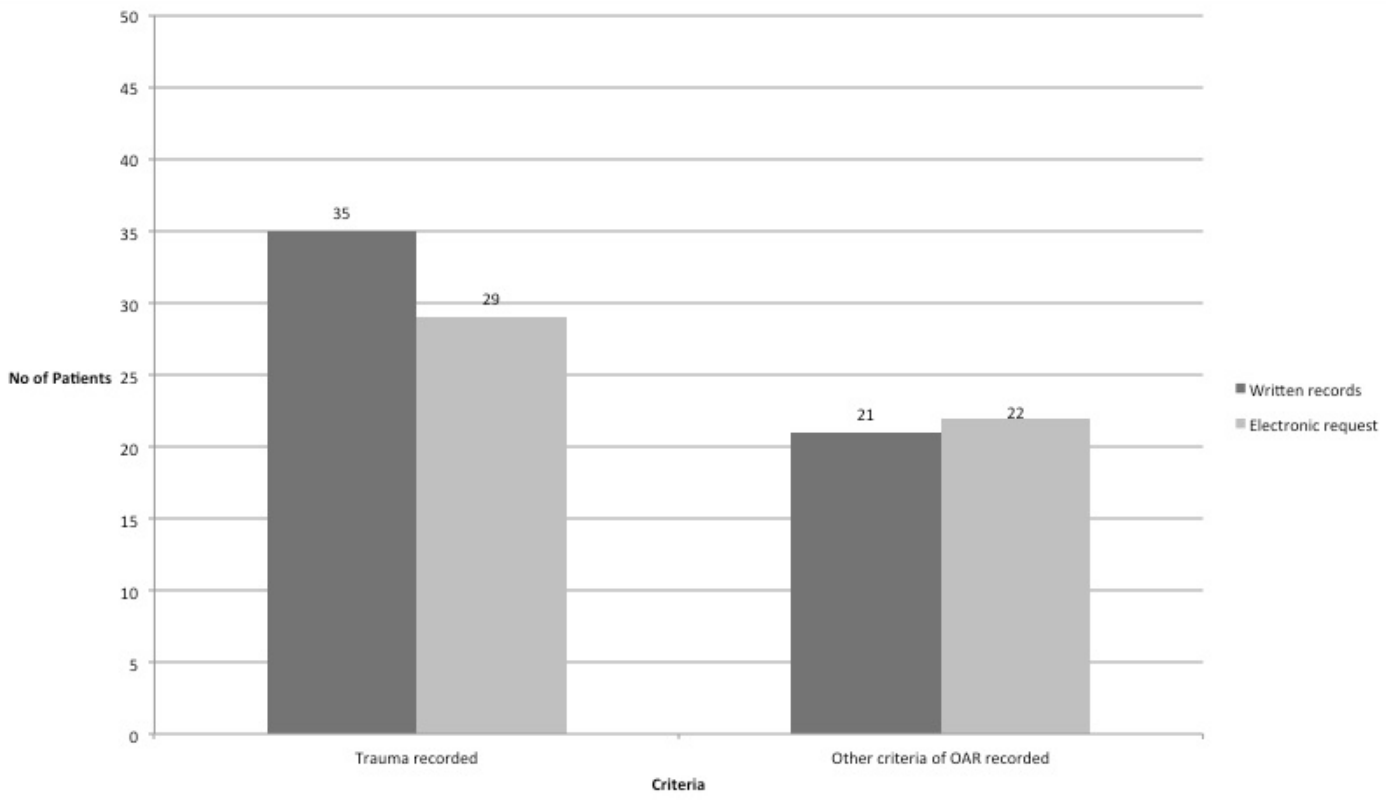
Use of the OAR through information present in the file was analysed as above. The physician's use of the OAR was considered as present if there was evidence of its use from the electronic request or from the information in the patient's file.

RESULTS

Out of the 793 people using the radiological services at Paola Health Centre in August 2016, 9.5% (n=75) had a radiograph of the foot and ankle. These were mostly female patients (M=32, F=43). The patients involved had a wide age range (8 to 103 years, mean=40 years, median=36 years). The radiographs taken were mainly ankle x-rays (with a total of 60 x-rays, 32 involving the ankle only) while 43 foot x-rays were taken (in 15 only a foot x-ray was taken). Twenty eight patients had both an ankle and foot x-ray series taken.

Fifty four patients (72%) came from the direct catchment area of Paola Health Centre, 11 (14.6%)

Figure 1: Recording of OAR criteria in the 50 patients with both electronic and written records.



patients came from the villages of the subsidiary clinic - Cospicua - while 10 (13.4%) lived at an address in other parts of the country. In 22 cases, 15 from the direct catchment area and 7 of other clinics, the handwritten documentation could not be readily accessed. In 3 cases, no entry was registered in the available written records.

When considering all the 75 patients, trauma was recorded either in the written documentation or in the electronic referral in 61 patients but reference to the OAR was only made in 36 cases (59%). Out of the 50 cases with both electronic and handwritten information, 35 had trauma recorded in the written documentation whilst 29 were recorded on the electronic request. Entries for other parameters of the OAR were almost equal, with criteria recorded in 22 cases and 21 recorded in the electronic request and files respectively (Figure 1).

Fifteen patients (20%) were diagnosed with at least one fracture. From all the x-rays under study, six ankle fractures were reported by the radiologists. Four involved the malleoli while two involved the tibial element of the ankle joint. Ten foot fractures were also reported; in four cases the fifth (i.e. most lateral metatarsal) was fractured and in another four, other metatarsals were fractured, including two cases where more than one metatarsal was fractured. A fractured phalanx and a navicular bone fracture were also reported. Of these, one had both a fracture of one of the ankle malleoli and the 4th metatarsal bone while in another a linear fracture of the shaft of the right tibia was recorded.

DISCUSSION

The number of cases where radiography was used could indicate investigations of non-traumatic complaints concerning the ankle and foot, although the need and value for such intervention needs to be studied separately. Nonetheless, it is evident that there is the need to implement and fully document use of the OAR, a recommendation that also emerged from an audit carried out in the local main Emergency and Admitting department in 2006 (Borg and Cachia, 2008). The reasons for such practice remain to be identified. Medicolegal implications of missed fractures and ease of ordering radiographs could be two reasons but a more direct assessment of the doctor's knowledge and use of the OAR on the lines studied in Ireland by Doherty and Quin (2008) may contribute towards more effective use of radiological services in cases of ankle or foot trauma. The use of templates which prompt the use of the OAR for electronic ordering of ankle and foot

x-rays in cases with trauma may also be of help, even though the effect of this has been shown to be limited by Salazar et al. (2011).

In view of the findings noted above, an audit of the documentation kept should also be carried out to implement an appropriate action plan to ensure that the relevant files are readily accessible to clinical practice and research. This should be done by particular assessment of the transferring of files and the adoption of common archiving practices within the different health centres. Until then, differences in the level of documentation between the handwritten and electronic records should be noted, studied further and actively considered when carrying out audits or research projects in Maltese health centres. In a setting whereby electronic and written documents or requests are used together to manage patients, an investigation into the discrepancies between information recorded in the two media should also be looked into.

LIMITATIONS

In the absence of a database recording traumatic and ankle foot pathology at the health centres, the above assessment used the electronic referral to the radiography department as the primary source to identify the cases for study. In doing so, it is acknowledged that cases where the use of the OAR with the consequent decision taken not to investigate by x-rays are not represented above. With the methodology used, both traumatic and non-traumatic x-rays were taken into account and this could have had an effect on the results, as the OAR apply only for traumatic cases. Furthermore, adoption of a larger sample for study would have allowed further analysis of the data gathered.

CONCLUSIONS

Through the results above, it emerges that there is a need to further adopt and document the use of OAR in the assessment of ankle and foot trauma in a public health centre in Malta. Assessment of the transferring of files and the adoption of common archiving practices within the different health centres should also be implemented.

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A study of general practitioners' awareness of the National Institute for Health and Care Excellence guidelines regarding the use of non-steroidal anti-inflammatory drugs

Dr Nadine Anne DE BATTISTA

ABSTRACT

Background

Non-steroidal anti-inflammatory drugs (NSAIDs) are widely prescribed for their analgesic, anti-pyretic and anti-inflammatory effects. There is no doubt regarding their benefits; however the importance of their side effects including gastrointestinal complications cannot be emphasized enough especially in high risk groups.

Objectives

This study assessed the awareness of general practitioners (GPs) working within Maltese health centres of the National Institute for Health and Care Excellence (NICE) guidelines on the proper prescription of NSAIDs, especially the co-prescription of gastroprotective agents in high risk groups.

Method

An online questionnaire based on the NICE guidelines on NSAID Prescribing Issues revised in July 2015 was distributed to doctors working within health centres across Malta.

Results

Trauma was the most popular reason for NSAID prescription (75%), with the commonest patient age group being that below 45 years of age. Diclofenac was the most popular NSAID choice (55.4%) with COX-2 inhibitors being the preferred choice for 23.2%. Most doctors were aware of factors that need to be considered when initiating NSAIDs, being least aware of liver comorbidities and fertility issues. The majority use licensed gastroprotective agents both in drug choice and in dose. More awareness is required on high risk patient groups especially patients with arthritis and patients on selective serotonin reuptake inhibitors (SSRIs).

Conclusion

There is room for improvement in awareness on proper NSAID use and gastroprotection especially in identifying high risk groups, drug interactions and choice of gastroprotective agents. The importance of gastroprotection, side effect monitoring, prevention of unnecessary chronic NSAID use and promotion of coxib use over standard NSAIDs needs to be emphasized further especially in high risk groups.

Keywords

General practitioners; awareness; protective agents; anti-inflammatory agents; proton pump inhibitors

BACKGROUND

Non-steroidal anti-inflammatory drugs (NSAIDs) are among the most widely prescribed medications within general practice in the community for a multitude of medical conditions. They are mostly prescribed in view of their analgesic, anti-pyretic and in higher doses, their anti-inflammatory effects. NSAIDs demonstrate variable inhibition of both cyclooxygenase-1 and cyclooxygenase-2 isoenzymes, both involved in the formation of prostaglandins which play an active role in inflammatory processes (Neal, 2012).

Table 1: Table showing the main recommendations highlighted in the NICE guidelines NSAID Prescribing Issues last revised in July 2015

NICE GUIDELINES NSAID PRESCRIBING ISSUES JULY 2015

Factors to consider when initiating NSAIDs
Contraindications
Alternative treatment
Patient already on NSAID?
Lowest dose & shortest duration for effective treatment
Gastroprotection especially in high risk groups
Side effect monitoring especially in high risk groups
Drug interactions

Absolute and Relative Contraindications
Hypersensitivity
Low eGFR
Skin reactions and angioedema
Asthma
Heart Failure
Liver fibrosis and cirrhosis
Acute liver failure and severe hepatic impairment (North Lewis, 2008)
History of/current treatment for GI problems
IBD
IHD, CVD, PAD
Dehydration especially in diabetics
HT
Women trying to conceive
Hepatitis and cholestasis

Monitoring in high risk patient groups
Blood pressure - especially within 1-2 weeks of starting/increasing dose
Renal function - especially within 1-2 weeks of starting/increasing dose
Features of heart failure including body weight
Enquire about GI bleeding and fluid retention in people with hepatic impairment

Licensed PPIs and their doses for gastroprotection
Lansoprazole 15-30mg daily.
Omeprazole 20mg daily
Esomperazole 20mg daily
Pantoprazole 20mg daily

High risk patient groups - to consider PPI
Patients on maximum recommended dose
65 years +
History of GI bleeding/perforation
Concomitant aspirin use
Concomitant steroid use
Concomitant SSRI use
Cardiovascular, hepatic, renal impairment
Diabetics
Hypertensives
Osteoarthritis & Rheumatoid arthritis
Chronic low back pain
Heavy smoking or alcohol use
H.pylori infection

Drug interactions in primary care
Low dose aspirin
ACE inhibitors
Ciclosporin
ARBs
Thiazide type, potassium and loop diuretics
Lithium
Methotrexate
Probenecid
Quinolones
Antidepressants
Anticoagulants

NSAIDs can be classified as standard (such as diclofenac, ibuprofen and naproxen) or COX-2 inhibitors such as celecoxib and etoricoxib (NICE Guidelines NSAID Prescribing Issues, 2015). Whilst there is no doubt about the various benefits that can be derived from NSAID use, research done throughout the years on these drugs has highlighted the importance of being aware of possible adverse effects, such as the development of cardiovascular and gastrointestinal complications, the latter through mucosal injury and COX-1 derived prostaglandin inhibition. This should be taken into consideration in all patients but especially in high risk patient groups, most notably individuals with a past history of peptic ulcer disease, the elderly and concomitant aspirin use (Sostres et al., 2010). Guidelines have therefore been devised in order to emphasise the importance of both risk factor modification when possible and more importantly, in considering alternatives to NSAID therapy and ensuring the proper prescription of gastroprotective agents when such therapy is required.

The guidelines used in this study as a standard on which questions and results were based were the National Institute for Health and Care Excellence (NICE) guidelines on NSAID Prescribing Issues last revised in July 2015 (NICE Guidelines NSAID Prescribing Issues, 2015).

The NICE guidelines currently recommend addition of a proton pump inhibitor (PPI) with all NSAIDs including COX-2 inhibitors based on two papers reporting three randomised controlled trials (RCTs) by Scheiman et al. (2006) and Chan et al. (2007). Table 1 highlights the main recommendations in the NICE guidelines which this study aimed to explore.

OBJECTIVES

This study was designed to assess awareness of NICE guidelines on NSAID Prescribing Issues among general practitioners on proper NSAID prescription. In light of these guidelines it specifically intended to address the following objectives:

- Assessment of the factors and medical issues considered by community doctors before initiating NSAIDs including knowledge of contraindications and drug interactions;
- To explore medical scenarios for which NSAIDs are used and patient age groups for which such medication is prescribed;
- To explore NSAID choices amongst general practitioners when NSAIDs are used;
- Assessment of NSAID side-effect monitoring within the community;
- Assessment of awareness amongst general practitioners (GPs) of which patients qualify as high risk;
- Assessment of co-prescription of gastroprotective agents by community doctors for high risk patient groups.

METHODOLOGY

Permission to carry out this study was obtained from the administration of the Primary Health Care Department prior to distributing an online questionnaire in September 2016 to 139 doctors working in health centres across all regions in Malta. The data collected was then analysed in light of the NICE guidelines on NSAID prescribing issues last revised in July 2015.

Questions were aimed to assess awareness and practices amongst doctors working in the community and designed to address the objectives mentioned above.

RESULTS

The questionnaire was distributed to a total of 139 doctors. Fifty-six doctors participated in the study – four foundation trainees, eleven GP trainees and forty-one general practitioners giving a response rate of 40.3%.

The most common reasons for which NSAIDs are usually prescribed in general practice resulted to be trauma (75%), followed by chronic back pain (12.5%) and osteoarthritis (10.7%). When questioned about patient age groups for which NSAIDs are usually prescribed, 76.8% (43 doctors) answered that they prescribe NSAIDs to patients less than 45 years of age whilst 23.2% (13 doctors) answered that they mostly prescribe NSAIDs to patients between 45 and 64 years of age. There were no doctors who chose the 65 years + patient age group as their most common patient group to which they prescribe NSAIDs.

The doctors were also asked what factors they usually consider when initiating a patient on NSAIDs in their practice. Contraindications and drug interactions were the two most common factors considered, with dose and side effect monitoring resulting to be the least popular responses. Figure 1 further demonstrates the results.

Figure 1: Factors considered by GPs when initiating a patient on NSAIDs

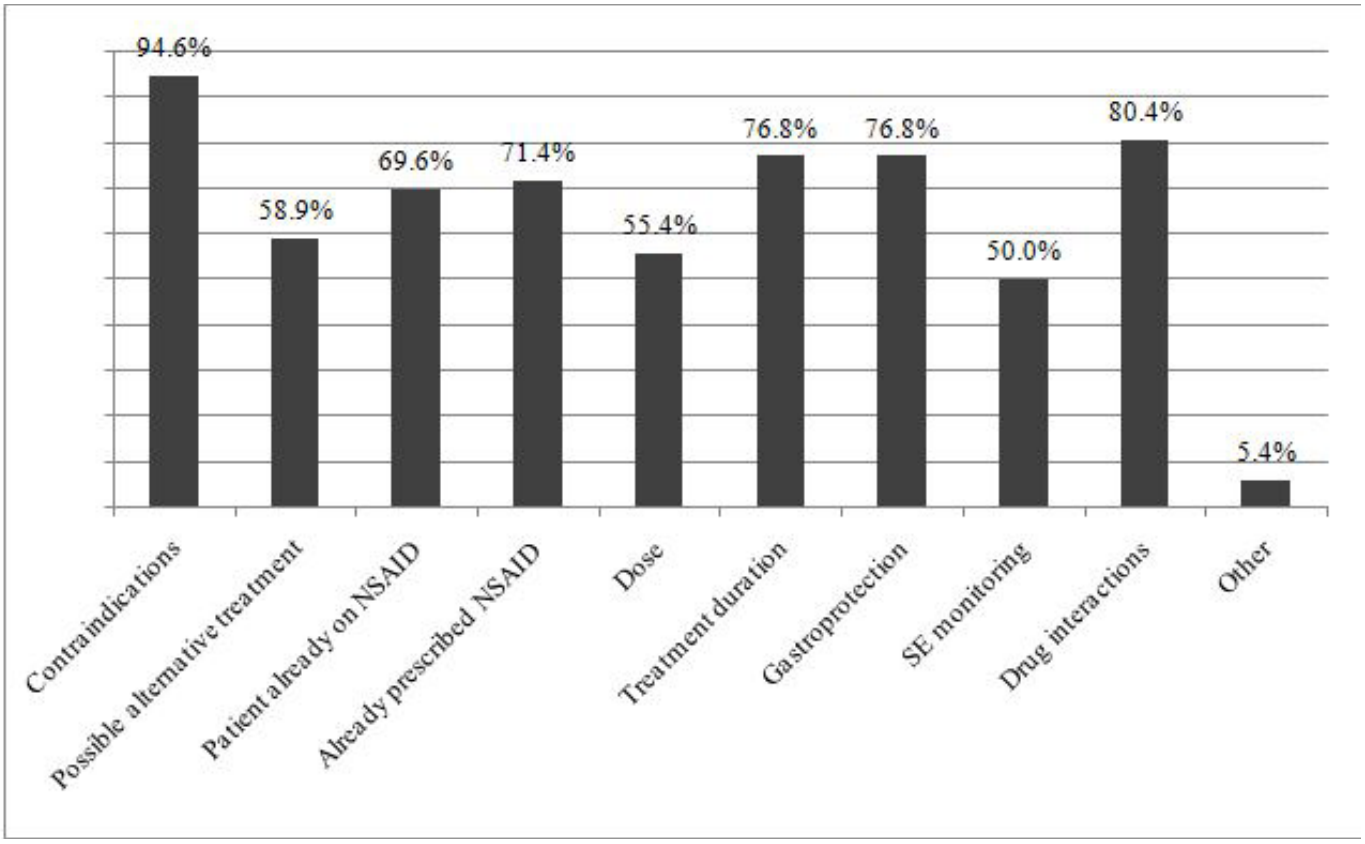
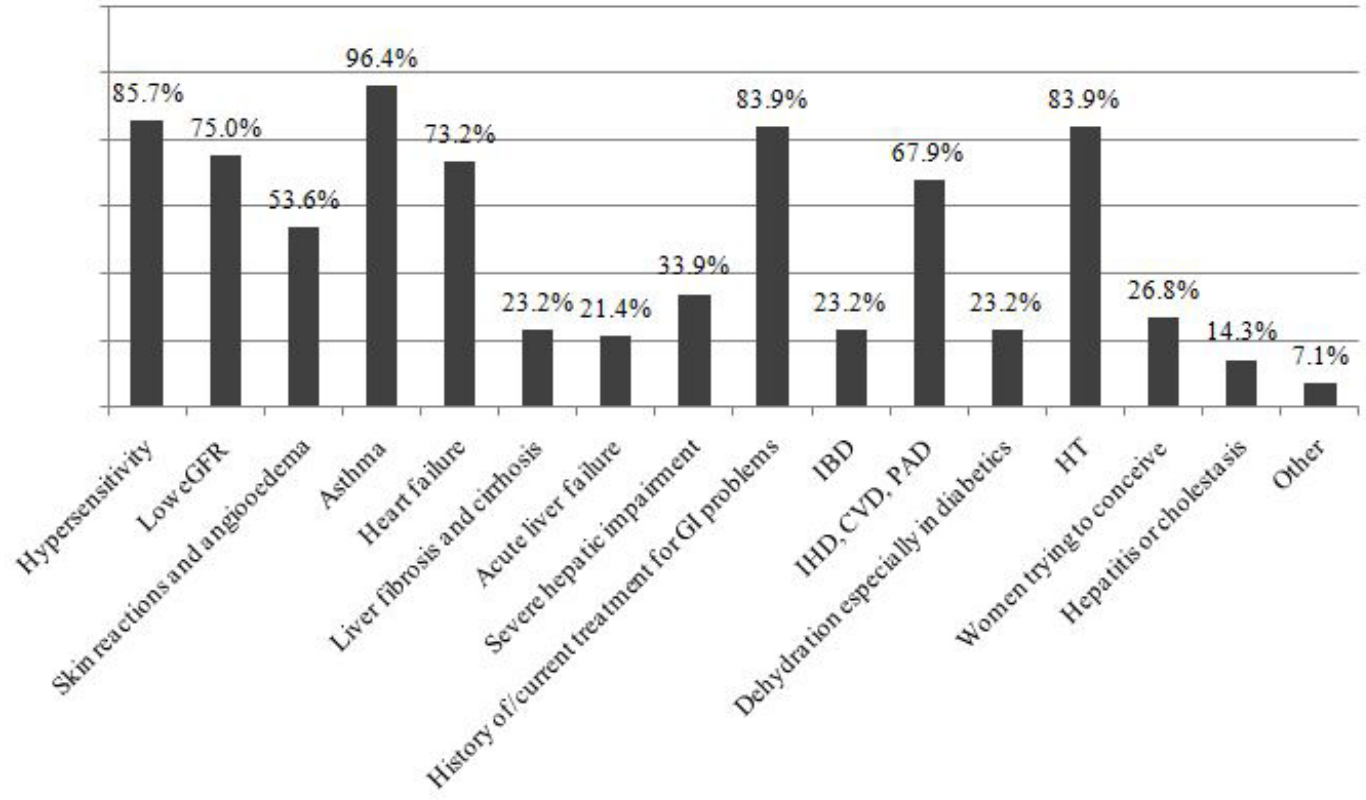


Figure 2: Patient medical issues looked out for by GPs when considering NSAID use



The most popular type of NSAID used resulted to be diclofenac (55.4%) followed by COX-2 inhibitors (23.2%), ibuprofen (14.3%) and naproxen (7.1%). This shows that standard NSAIDs are still the most popular choice at 76.8% versus COX-2 inhibitors at 23.2%.

Doctors were also asked whether they usually bring patients started on NSAIDs back for review of progress and to assess for continued need of NSAID use. 69.6% (39 doctors) replied that they review patients only in cases of no improvement or in cases of patients experiencing adverse events. 19.6% (11 doctors) responded that they do not review patients after NSAID initiation whilst 10.7% (6 doctors) replied that they always review patients started on such treatment.

Figure 2 demonstrates patient medical issues usually looked out for by general practitioners when considering NSAIDs. Hypersensitivity, asthma and history of GI problems were the three commonest medical issues looked out for by community doctors when considering NSAID use with liver problems, fertility and dehydration amongst the least popular responses.

GPs were also questioned on awareness regarding drugs commonly encountered in primary care and their interactions with NSAIDs. Anticoagulants were by far the most popular choice at 87.5%, unlike drugs such as diuretics, ciclosporin and probenecid that were amongst the least popular choices. Figure 3 further demonstrates these results.

87.5% of respondents perform blood pressure monitoring within their practice when monitoring for NSAID adverse effects. This was closely followed by monitoring for heart failure features at 82.1%. Interesting to note was that only 5.4% include body weight assessment as part of their monitoring. Results are shown in Figure 4.

Figure 5 demonstrates data for scenarios in which doctors co-prescribe a gastroprotective agent when prescribing NSAIDs:

When asked regarding co-prescription of PPIs in high risk patients, 60.7% replied that they only co-prescribe a PPI when they use potent NSAIDs such as diclofenac. 28.6% always prescribe a PPI irrespective of NSAID choice. 7.1% replied that they usually co-prescribe a PPI when they use ibuprofen whilst 3.6% advise a PPI when prescribing COX-2 inhibitors.

Study participants were also asked about regimes they use in their practice for gastroprotection when prescribing NSAIDs and results of their responses are demonstrated in Figure 6.

Figure 3: Awareness amongst GPs on NSAID interactions with medications frequently used in the community

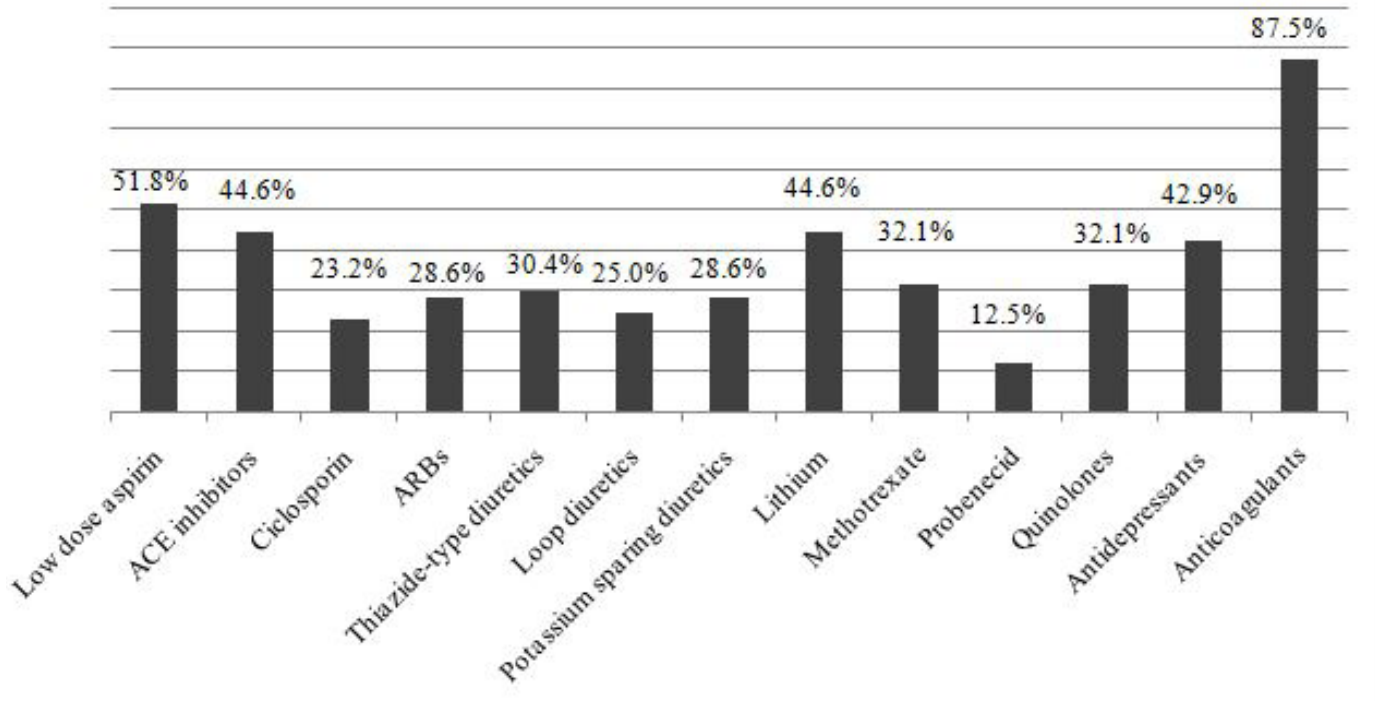


Figure 4: Parameters, investigations and examination findings used by GPs to assess for NSAID adverse events

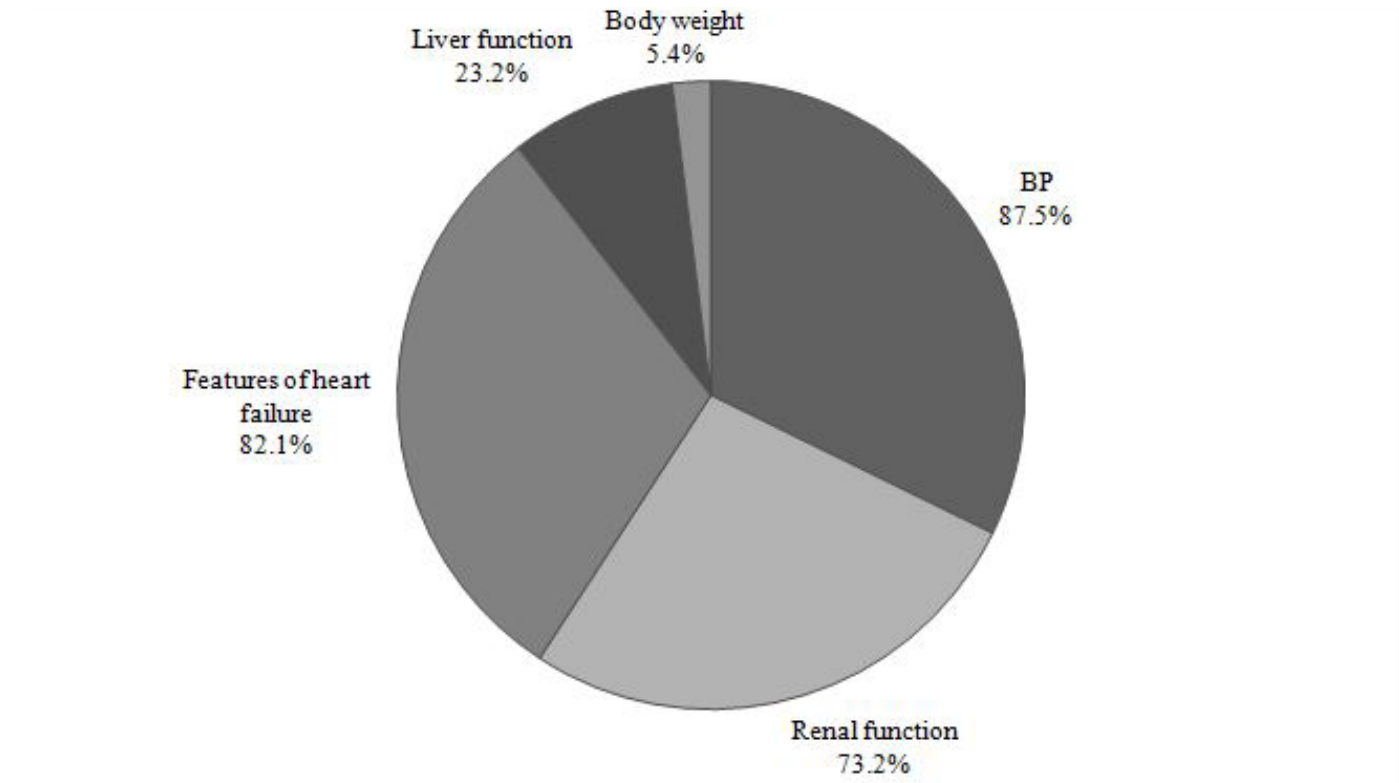


Figure 5: Scenarios in which doctors co-prescribe a gastroprotective agent with NSAIDs

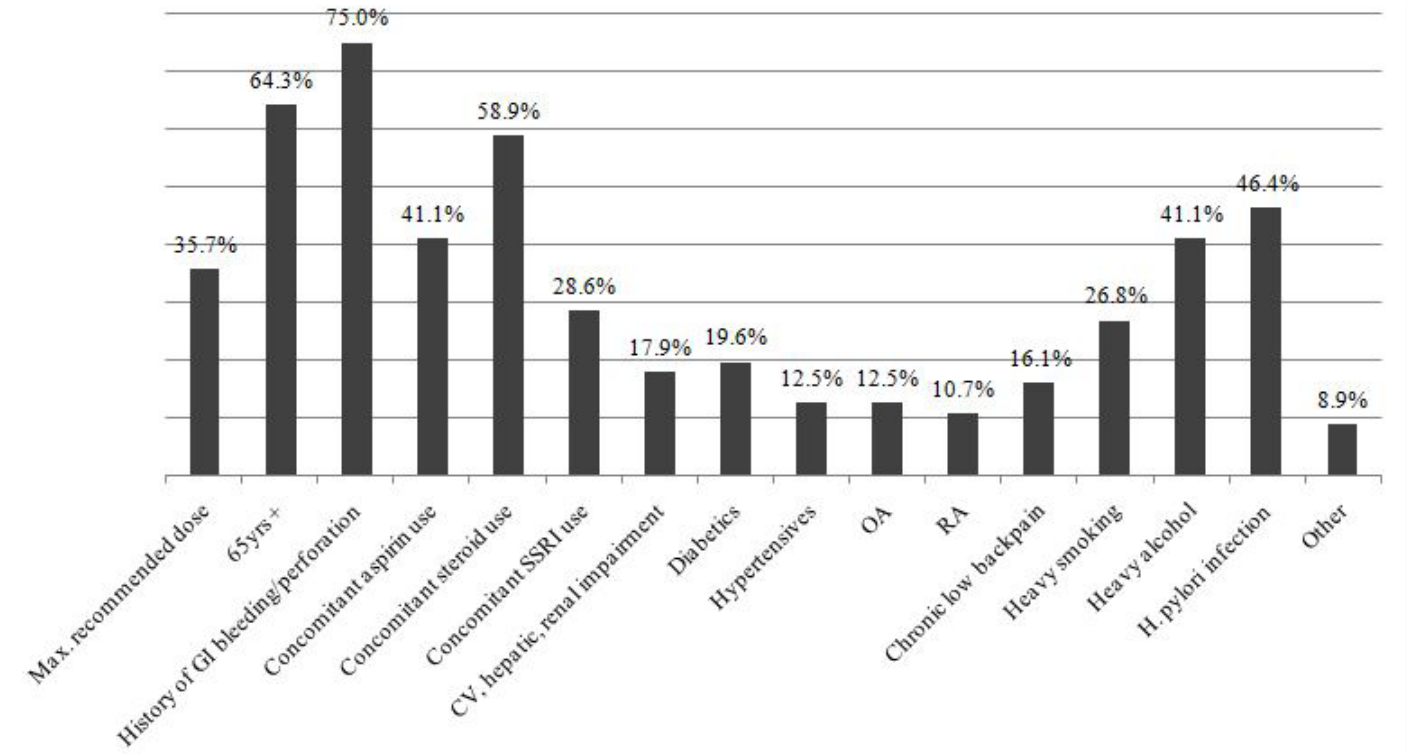
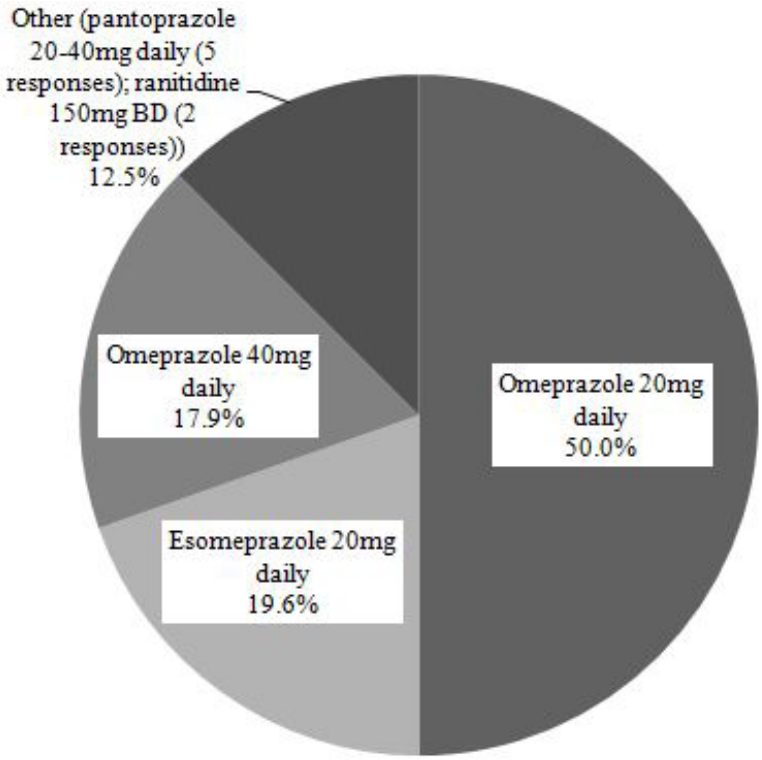


Figure 6: Regimes used by GPs for gastroprotection when prescribing NSAIDs



DISCUSSION

The popularity of NSAID use within the community is undisputable as demonstrated by various studies performed throughout the years such as that by Bradbury in 2004 performed in Ireland, showing diclofenac, nimesulide and ibuprofen to make up 80% of total prescription issued by GPs (Bradbury, 2004). Similar to the current study, an Italian study by Motola et al. in 2004 showed that the main reasons for NSAID use within the community were osteoarticular pain (19%), unspecified pain (15%) and osteoarthrosis (9%). Given the usual chronicity of such scenarios, this further emphasises the importance of correct NSAID prescription including the identification of high risk groups to avoid potential adverse effects. It is also of note that in this study, diclofenac resulted to be the most popular choice (55.4%) despite its various documented side effects, with COX-2 inhibitors being the preferred choice for only 23.2% of the GPs. This is in contrast to what seems to be the current situation within the UK as outlined by a clinical audit on NSAID safety performed across the UK in 2014 demonstrating the most frequently prescribed agents to be naproxen (59%), ibuprofen (19%) and diclofenac at 9% (NHS Specialist Pharmacy Services, 2014). Possible reasons for such a choice are many, including the fact that standard NSAIDs have been on the market for years and therefore clinicians might feel more comfortable with their use. It might also result from the fact that from past clinical experience, community doctors have found diclofenac to result in the highest patient satisfaction.

The NICE guidelines recommend using NSAIDs with caution in the elderly in view of an increased risk of serious adverse effects such as gastrointestinal bleeding and perforation which may be fatal. In this study, patient age groups for which NSAIDs are preferably prescribed resulted to be 76.8% for patients less than 45 years of age and 23.2% for patients between 45 and 64 years of age. There were rightly no responses for patients older than 65 years of age, reflecting the fact that patients older than 65 years are the patient group most likely to have multiple co-morbidities and therefore increased likelihood of contraindications, drug interactions and side effects.

The majority of GPs were aware of most of the factors that should be considered when initiating NSAID treatment as outlined in the NICE guidelines, with contraindications to NSAID use being the most popular factor (94.6%). Of note is that only 76.8% currently consider the use of gastroprotection especially in high risk patients. Moreover, whilst 76.8% of doctors stated that they take into consideration treatment duration, only 55.4% of doctors highlighted the need to consider the actual dose

used to address the medical problem in question. Possible reasons for this include that it might come as second nature to most GPs to start at the lowest possible dose when initiating treatment. It might also be due to the fact that community doctors might have their own preferred standard dose prescription which they have found most effective based on their past clinical experience.

It was also interesting to note that the least factor considered was side-effect monitoring, with only 50% of doctors highlighting the need to look out for possible medical reasons requiring closer monitoring for adverse effects. This fact was also brought out in other parts of the study namely when doctors were also asked whether they usually bring high risk patients started on NSAIDs back for review of progress and to assess for continued need of NSAID use. Whilst the majority of doctors (69.6%) replied that they usually review patients in cases of no improvement or in cases of patients experiencing adverse events, 19.6% responded that they do not review patients at all after NSAID initiation. This might reflect the fact that this study was distributed to community doctors working within government health centres which provides a walk-in service with duty allocation and thus makes such monitoring, patient review and follow up a challenge. This can encourage chronic NSAID use with a resulting increase in adverse side effects.

The majority of the GPs were able to mention most of the contraindications listed in the guidelines namely hypersensitivity (85.7%), asthma (96.4%), severe heart failure (73.2%), vascular disease including ischaemic heart disease, peripheral vascular disease, cerebrovascular disease at 67.9% and current treatment for gastrointestinal issues at 83.9%. However, a significant number of doctors failed to look out for severe skin reactions and angioedema (53.6%) which are listed as absolute contraindications within the guidelines, whilst the majority of GPs overlooked liver fibrosis and cirrhosis (23.2%), acute liver failure (21.4%) and severe hepatic impairment (33.9%). This might be due to the fact that, despite links between NSAID use and exacerbation of liver impairment being established, research is still ongoing on the subject, while acute symptomatic liver disease secondary to NSAID use is not a frequently encountered clinical problem when compared to respiratory and cardiovascular complications and therefore more awareness is required on the subject.

Although the level of risk of NSAIDs on conception is not yet known, the NICE guidelines recommend avoiding NSAID use based on advice from the Committee on Safety of Medicines (2006). In this study, only 26.8% of doctors mentioned using caution in women trying to conceive and giving due consideration of possible impairment of female fertility. This might be due to the fact that whilst adverse renal, cardiovascular and gastrointestinal complications are well known, potential for NSAIDs to adversely affect ovulation has received much less attention overall, even though this potential complication has been described in the medical literature for multiple decades. Moreover the actual level of risk on conception is still unknown, as no large-scale, prospective controlled trials have yet proven a link between female infertility and NSAID or COX-2 inhibitor use.

The online questionnaire distributed also aimed to explore further knowledge amongst GPs with regards to key drug interactions with NSAIDs mentioned within the guidelines, in primary care. The majority of GPs (87.5%) rightfully mentioned concomitant anticoagulant use such as warfarin as being a key interaction. However, only 51.8% of GPs considered low-dose aspirin to be a key interaction. Of note is also the fact that the majority failed to mention looking out for possible interactions with anti-hypertensives (responses ranging between 44.6% for ACE inhibitors to 25% for loop diuretics) that might require dose adjustments of the anti-hypertensives or avoidance of concurrent use in certain cases (e.g. in cases of potassium-sparing diuretics). It also became evident that awareness on important interactions with drugs such as antidepressants, ciclosporin, methotrexate, quinolones and probenecid is also currently lacking. This emphasizes the importance of continued medical education and can be addressed in the form of evening medical updates outlining recently revised guidelines.

Whilst the majority of GPs successfully identified patients over 65 years of age and those with history of gastrointestinal (GI) problems as being patients at high risk of GI side effects thus requiring PPI prescription; the majority failed to identify hypertensives, people with chronic low back pain who are 45 years or older, patients with osteoarthritis or rheumatoid arthritis at any age and those with concomitant use of selective serotonin reuptake inhibitors (SSRIs). A study performed within GP practice in the UK by Hutchinson (2014) showed similar results. Moreover, awareness was also low for patients with cardiovascular, hepatic and renal impairment (17.9%), diabetics (19.6%), patients with concomitant aspirin and steroid use (41.1% and 58.9% respectively), patients with a history of heavy smoking or heavy alcohol use (26.8% and 41.1% respectively) and those with Helicobacter pylori infection (46.4%).

Doctors were also asked on the need for co-prescription of PPIs when prescribing different types of NSAIDs. The majority of GPs stated that they usually consider gastroprotection as an issue only when prescribing potent NSAIDs such as diclofenac (60.7%). Only 28.6% of GPs reported using gastroprotection with all kinds of NSAIDs used long term.

The NICE guidelines on NSAID prescription also describe specific licensed doses of proton pump inhibitors that should be used for gastroprotection for people who require continued NSAID treatment. Licensed PPIs and their doses mentioned in the guidelines include lansoprazole 15-30mg daily, omeprazole 20mg daily (the choice of 46.4% of GPs in this study), esomeprazole 20mg daily (used by 19.6% of GPs) and pantoprazole 20mg daily (used by 5.4% of GPs, though 3.6% reported also using a dose of 40mg of pantoprazole at occasions). Other responses in the study included use of omeprazole 40mg daily (19.6%) and of note was the fact that 3.6% of GPs chose ranitidine 150mg twice daily as their choice of gastroprotective agent, which is not licensed for gastroprotection during chronic NSAID use.

LIMITATIONS

One limitation was the low response rate by GPs, the reasons for which could be various including lack of motivation and interest, the perception that participation may be time consuming and fear of lack of anonymity in the study with possible repercussions.

Results in this study were based on a questionnaire distributed amongst doctors working within the community and therefore only awareness of guidelines could be assessed. Data on actual implementation of such guidelines by GPs can only be gathered by assessing the actual practice records found within the various health centres for NSAID prescriptions. However, further addressing the objectives of this study by doing this was not possible in view of the high number and unpredictability of visits to the clinics, a lack of updated treatment records and furthermore, the lack of non-readily available lists of patient comorbidities within patient files. As a result, gathering information on treatment interactions and adverse effect monitoring was difficult. Participants' recall bias could have also occurred.

CONCLUSION

This study showed that there is room for improvement in overall awareness on proper NSAID use and gastroprotection, identification of high risk patient groups, drug interactions and choice and dose of gastroprotective agents. It is evident that there is need for further awareness on the importance of gastroprotection, need for more frequent monitoring of patients to prevent unnecessary chronic NSAID use and promoting coxib use over standard NSAIDs especially in high risk patients groups.

ACKNOWLEDGMENT

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Repetitive transcranial magnetic stimulation in Malta – a revolutionary therapy for psychiatric and neurological disorders

Dr Mark XUEREB

ABSTRACT

Severe depression is one of the most common psychological disabilities, with a global point prevalence of 4.7%. The World Health Organisation predicts it to be the leading cause of disease burden by 2030. With 350 million depressed people, depression is a debilitating condition where only a third of treated patients achieve remission after the first antidepressant treatment. Up to 34% of the patients are treatment resistant, whereas another 15% respond partially, following standard doses of antidepressants for 6 weeks or more. Failure to respond to two consecutive antidepressants leads to greater reductions in remission rates.

Recurrence rates, despite specialised care, are 60% and 85% after 5 and 15 years post-recovery respectively. Inadequate efficacy, adverse effects, and sensitivity to current treatments call for more effective and tolerable treatment options. With over 20 years of research, repetitive transcranial magnetic stimulation (rTMS) is a non-invasive treatment that alters brain activity and cortical excitability permanently, making it an effective antidepressant treatment beyond the conventional ones, including electroconvulsive therapy (ECT) in some studies.

Furthermore, rTMS is safe, natural, painless, fast acting and approved by the Food and Drug Administration (FDA) and the National Institute for Health and Care Excellence (NICE). It has virtually no side effects and only one absolute contraindication (epilepsy). Experience of its use in Malta has shown improvement in diminishing the key symptoms of depression, decreased suicidal ideation and a decrease in other psychiatric and neurological symptoms within hours of the first sessions. Besides providing immediate relief and hope for patients and relatives, this improvement has many clinical and future management implications. Research is now underway to apply this novel technology and its variants to other physical and psychological disorders.

KEYWORDS

Treatment resistant depression; repetitive transcranial magnetic stimulation; intermittent theta burst stimulation; transcranial direct current stimulation

BASIC PRINCIPLES AND HISTORY

Repetitive transcranial magnetic stimulation (rTMS) is a safe, painless, effective, natural, evidence-based treatment for patients suffering from severe unipolar affective disorder/depression who are treatment resistant and/or treatment intolerant, i.e. they are generally labelled as suffering from treatment-resistant severe/major depression (TRD) (Carpenter et al., 2012; Connolly et al., 2012). Others find rTMS appealing as they may be sceptical of conventional treatment.

Revolutionary in its approach to treating TRD, rTMS is the brainchild of Baker and his colleagues who have been experimenting with single pulse TMS in Sheffield, UK since the 1980s (Hotlzheimer and Mc Donald, 2014). The UK team pioneered stimulating the human brain's cortex after being inspired by Galvani and Aldini's eighteenth century experiments on electrically stimulating the peripheral muscles of dead animals and humans respectively. Their objective at the time was to map the cortex and elicit a corresponding short-lived motor stimulation of peripheral muscles (Baker, Jalinous and Freeston, 1985). Technological developments subsequently produced repetitive pulse TMS which was shown to have long lasting effects on the cortex that

persisted beyond the stimulus delivery (Pascual-Leone et al., 1996; Maeda et al., 2000).

This non-invasive and novel treatment is based on the discoveries of British nineteenth century physicist Michael Farady, whose Law of Electromagnetic Induction predicts how a changing magnetic field will interact with an electric circuit to produce an electromotive force - a phenomenon called electromagnetic induction. In essence, exposing a conductor to a rapidly changing magnetic field will induce a current in the conductor. rTMS works by inducing a rapidly changing magnetic field in a "depression sensitive" brain/cortical area, which is populated by neurons and is located just under the skull. This rapidly changing field induces a current in the neurons (the conductor). Hence, the area is stimulated to be more electrically active.

To achieve this, TMS devices consist of a large capacitor, a control mechanism that enables the capacitor to be rapidly discharged, and a conductive coil through which the current travels to generate a powerful and fluctuating magnetic field (Barker, 1999). Through the process of electromagnetic induction described above, this rapid pulse of electric current induces a rapidly fluctuating magnetic field, which in turn induces an electric current in the underlying brain neurons (Wagner, Valero-Cabre and Pascual-Leone, 2007). How much brain tissue is stimulated is dependent on the shape of the coil as well as the intensity of the stimulation i.e. amount of current discharged by the machine (Pascual-Leone et al., 2002).

In biophysiological terms, several studies concerning depression show that the left dorso-lateral pre-frontal cortex (LDLPFC), along with deeper cortical structures such as the limbic system, are associated with mood regulation. Hence the LDLPFC is a lynchpin in the pathogeneses of an affective illness. Overall, a depressed patient's brain is less active than a healthy brain, as evidenced by several neuroimaging studies. One study in particular demonstrates that depressed patients have fewer brain receptors, less circulating neurotransmitters (e.g. serotonin) and fewer healthy synaptic connections between neurons (Psych Central, 2008).

rTMS addresses this neuronal "apathy" (or hypoactivity) by progressively re-stimulating a current in the LDLPFC neurons (i.e. a wave of depolarisation down the neuron membranes), so as to eventually restore the balance of neurotransmitters and healthy nerve contacts with each other. The postulated principle which keeps neurons healthy, active and interconnected is based on the principle of Hebbian neuroplasticity (i.e. the development of new specialised neural networks, which allows for sustained improvement over time). Hebbian neuroplasticity resembles the long term potentiation (LTP) or long term depression (LTD) of neurons. LTP implies an increase in the development of synaptic transmission of neurotransmitters, which induces a wave of depolarisation along the neuronal membrane. This depolarisation is thus the generated current running down the neuron. The opposite of LTP is LTD, which produces a long lasting decrease in synaptic activity.

The positive behavioural effects of this technology persist after a course of rTMS treatment through neuroplasticity (Christyakov et al., 2010). Bickford and his colleagues first extended the domain of TMS research into neuropsychiatry in 1987. Transient mood elevation in healthy subjects receiving single-pulse stimulations to the motor cortex was described (Bickford et al., 1987). This triggered the scientific investigation of the effects of depolarising magnetic fields in a variety of neuropsychiatric disorders. The clinical utility breakthrough came in 2008 to treat patients suffering from severe depression, who had not responded to at least one antidepressant in their current episode (i.e. they were deemed to be treatment-resistant or intolerant according to FDA criteria) (Herwig et al., 2007; O'Reardon et al., 2007; George et al., 2010). The LDLPFC was targeted with very positive outcomes.

EXPERIMENTAL AND THERAPEUTIC FUNCTIONS - THE E/I RATIO

rTMS is used both experimentally and therapeutically. In the experimental domain TMS can be applied in single pulses to depolarize a small population of neurons in a targeted brain region. Cortical motor outputs can thus be mapped, central motor conduction times can be assessed and the cortical silent period can be measured (a measure of intracortical inhibition). These parameters may be affected by pathologies of the central nervous system such as autism (Kobayashi and Pascual-Leone, 2003). Therapeutically, trains of rTMS pulses can be applied at various stimulation frequencies and patterns to modulate local cortical excitability beyond the duration of the stimulation itself. Depending on the parameters of stimulation, the excitability can be either facilitated or suppressed (Pascual-Leone et al., 1994). The after-effects of rTMS are thought to be related to changes in efficacy (in either the positive or negative direction) of synaptic connections of the neurons being stimulated

(Hoogendam, Ramakers and Di Lazzaro, 2010). These after-effects have thus been used to study cortical plasticity mechanisms in a number of populations (Pascual-Leone et al., 2011).

rTMS has the potential to detect and define the Excitatory/Inhibitory (E/I) ratio for a particular disorder. E/I ratios are a measure of the activity-dependent neural feedback systems that tightly control network excitability. Thought to be crucial for proper brain development, the relative degree of excitatory and inhibitory drive in a neural circuit reflects a form of homeostatic plasticity that helps to maintain neuronal activity within a narrow, safe range. Processing of neural information is thought to occur by integration of excitatory and inhibitory synaptic inputs. As such, precise control mechanisms must exist to maintain an appropriate balance between each synapse type. Altered E/I ratios are noted in neuropsychiatric disorders including depression, Obsessive Compulsive Disorder (OCD), schizophrenia, epilepsy and autism.

As E/I ratios are specific for a disorder, they may thus provide a screening/confirmatory test for physical and psychological conditions which are difficult to detect clinically. rTMS can then be used therapeutically for these disorders as it alters the relative excitability and inhibition (E/I ratio) in targeted circuits to restore these networks to a healthy baseline.

Table 1: Some neurological and psychiatric disorders where rTMS is being applied

Anorexia nervosa
Autism
Bipolar affective disorder
Cocaine dependence
Depersonalisation Disorder
Fibromyalgia
Migraine
Neuropathic pain
Obsessive Compulsive Disorder (OCD)
Parkinson's disease
Post Traumatic Stress Disorder (PTSD)
Stroke
Suicidal ideation (rapidly reduced with rTMS)
Tinnitus

Clinically, there is much research for various neurological and psychiatric conditions. The list continues to grow as researchers alter the neurostimulator settings, type of magnetic field, and the cortical area to be stimulated (see Table1).

EFFICACY

While antidepressants, psychotherapies and electroconvulsive therapy (ECT) are effective in treating depression, a substantial proportion of patients fail to respond to these treatment regimens and hence are known as treatment-resistant depression (TRD) patients. TRD is estimated to occur in around 50 to 60% of all patients (i.e. 5 out of 100 people in the general healthy population) (Fava and Davidson, 1996). Despite providing relief to a proportion of patients, other interventions bear weak or inconsistent evidence for routine clinical recommendation.

Table 2 summarises the various characteristics of the routine, evidence-based available treatments for TRD compared to rTMS. The evidence base for psychological and other therapies is variable or incomplete. This is due to many factors including the heterogeneous therapies available, lack of standardised data and sample populations, study design, and funding. This does not mean, however, that such therapies do not have an important role to play in the management of depression. The most widely researched therapies to date are CBT and mindfulness-based therapies.

rTMS does not require hospital admission or anaesthesia, unlike another more commonly used form of brain stimulation namely electroconvulsive therapy (ECT) (Cusin and Dougherty, 2012). Apart from the potential anaesthetic complications (e.g. nausea and heart problems), ECT is known to cause deficiencies with respect to remembering facts and with learning new material, as well as inducing post ictal confusion and muscle aches, among others. Many researchers argue that rTMS is poised to dethrone ECT as the 'gold standard' treatment for TRD.

TREATMENT RESISTANT DEPRESSION PROTOCOL, FDA AND NICE APPROVAL

A specific protocol defining the dose and frequency of the magnetic pulses delivered by rTMS has been widely studied for TRD. This protocol has been used in several countries after approval was granted by the American FDA (FDA Approval K061053) (Horvath et al., 2010).

Table 2: Characteristics of routine, evidence-based available treatments for TRD compared to rTMS

	Antidepressants	ECT	Psychological / other therapies	rTMS
Effectiveness	28 - 59% (Geddes et al., 2003; Sinyor, Schaffer & Levitt, 2010)	60 - 80% (Geddes et al., 2003)	Comparable to medication?	Comparable to ECT or better (O'Connor et al., 2003; Schulze-Rauschenbach, 2005; Rosa et al., 2006)
Beginning of therapeutic effect	4 - 6 weeks	1 week	Weeks	<1 week
Common side effects	Headache; Dry mouth; Dizziness; Constipation; Nausea; Blurred vision; Urinary retention; Sexual issues	Loss of memory; Muscular pain; Nausea; Headache	Stress which may cause symptom exacerbation: Emotional turmoil; Higher expressed emotions in families	Self limiting mild headache or resolves with a single dose of paracetamol
Incidence of side effects	Up to 86% will experience at least one significant adverse event (Hu et al., 2004); Up to 34% will experience secondary sexual dysfunction due to medication (Hu et al., 2004)	29 - 55% (Rose et al., 2003)	Unknown	Up to 20% (Carpenter, 2005)

rTMS was also approved by other countries, including by NICE in the U.K. in 2015 (IPG542) (NICE, 2015). Moreover, it has been suggested that the clinical effectiveness could be improved by developing further novel protocols and identifying local brain regions using neuro-navigation to improve the targeted pulse delivery (Fitzgerald et al., 2009; Fox et al., 2012). Hybrid protocols are also being devised to reduce the duration of the session, while maximising the efficacy of treatment. These protocols also include adding standard treatments to achieve remission faster.

ADMINISTERING rTMS

After an initial assessment and after obtaining consent, rTMS treatment is administered by sitting in a comfortable, reclining airline-like chair (Figure 1). The treatment coil is placed on the scalp over the LDLPFC, as shown in Figure 2. The patient then receives a sequence of several short "trains" (or pulses) of stimulation for up to 40 minutes. Throughout the entire procedure, the patient remains awake and alert. He can read a magazine, watch TV or even undergo psychological therapy during the session. No extra medication is administered. Clinical experience has shown that patients often need less regular medication as they improve with rTMS, as endorsed by NICE in 2015.

ADVANTAGES, SAFETY AND SIDE-EFFECTS OF rTMS

rTMS has a number of advantages over other treatments as listed below:

- Natural, evidence-based, non-invasive, localised, and harmless treatment.
- No debilitating side effects related to pills or psychotherapy.
- No anaesthesia required (i.e. it is non-systemic).
- rTMS is an outpatient treatment, with no restriction of daily activities.

- The patient remains awake (can talk, listen to music, etc).
- Rapid improvement in the patient's symptoms (3 – 7 days for depression).
- No adverse side effects in the vast majority of patients.
- Reduce need for regular medication.
- Can be used concurrently with medication/ psychological therapies.

rTMS is now widely used and has been approved by major centres worldwide (including Mayo Clinic, Johns Hopkins, Yale, Nottinghamshire NHS Trust, New South Wales University, and Sydney University). Butler Hospital in Providence, Rhode Island, USA is one such centre of excellence and a pioneer in the field. Headed by world expert Professor Linda Carpenter, Butler Hospital has conducted more than 10,000 active treatments to date without adverse outcomes or severe side effects (Carpenter, 2015).

The most frequently experienced side effect of rTMS is a mild headache that responds to a low dose of paracetamol. This is reported in only about 1 in 10 patients. Headaches tend to diminish over the course of treatment, although adjustments can be made immediately in coil positioning and stimulation settings to remove the discomfort. To date, no single serious side effect has been encountered in the local cohort, ever since the start of rTMS treatments in 2016.

Seizures are a theoretical possibility and hence the only absolute contraindication for TMS is a history of active epilepsy. However, less than 20 cases of TMS induced seizures have been reported out of more than 10, 000 subjects in the past 25 years. To put this in perspective, the risk of a seizure is much more likely to occur by ingesting co-amoxyclav. In other words, this minute risk is considered to be less than 0.01% (Rossi et al., 2009).

In summary, the established benefits of treatment by far outweigh the probability of side effects.

rTMS IN PREGNANCY AND IN CHILDREN

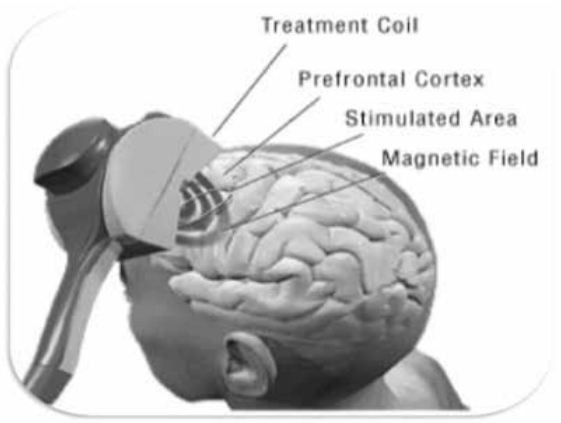
So far, there is no long term safety data available on pregnancy, nursing women or children. A recent study has demonstrated that rTMS can be used effectively in pregnant patients (Kim et al., 2015). Studies are ongoing on the use of rTMS in children. More research is however needed to address the safety and efficacy of rTMS in these special populations.

PROMISING FUTURE STIMULATION THERAPIES

Other treatments like direct current stimulation, vagal nerve stimulation, and deep brain stimulation are also being actively investigated and researched. Deep brain stimulation in particular, which uses an H-shaped coil as opposed to a standard figure of eight coil, is emerging as a promising "close second" to rTMS. This was indicated in a recent multi-centre randomised control study, which concluded that the effects appear "durable", and a "clinically significant improvement" was seen in patients resistant to multiple antidepressants (Levkovitz et al., 2015). A further recent analysis corroborated these findings (Hardy et al., 2016).

Figure 1: An image showing the set up of an rTMS Clinic in Malta

Figure 2: The position of the rTMS treatment coil on the scalp



INTERMITTENT THETA BURST STIMULATION

A recent protocol has been devised as a variant of rTMS for TRD. This protocol, now available locally, delivers theta waves in 'bursts' to the brain, hence the term 'intermittent theta burst stimulation' (iTBS). Theta waves are naturally present over the cortex and hippocampus and are readily detectable by electroencephalography (EEG). In the right concentration and location, these waves are associated with healthy cognitive function, levels of alertness, and mood (Lega, Jacobs & Kahana, 2012).

The principle of electromagnetic induction also applies here in order to revive the depressed person's brain (Chung, Hoy & Fitzgerald, 2014). Being similar to classic rTMS in terms of administration and preparation, preliminary data shows that iTBS has a similar efficacy and side effect profile. The huge advantage of iTBS over rTMS is that the treatment session only lasts 3 minutes.

TRANSCRANIAL DIRECT CURRENT STIMULATION

This technology is easy to use and can be used at home or at work. Transcranial direct current stimulation (tDCS) is a non-invasive method of electrical stimulation of the brain using a weak direct current applied to the scalp through electrodes to treat TRD (Loo et al., 2012). The aim is to modify cortical excitability and activity in the brain areas under the scalp electrodes. It is thought to work through the depolarisation and hyperpolarisation of cortical neurons. The patient, who remains awake and alert during the procedure, is usually seated, while a portable battery-operated stimulator delivers a constant low-strength direct current to two saline-soaked sponge electrodes placed on the scalp. Data on this technology is still inconsistent in terms of efficacy, and scalp burns have been reported. Another concern is that self-medication without professional supervision is a strong possibility. The advantage of tDCS is that it can be used in the privacy of one's own home.

rTMS – THE EXPERIENCE IN MALTA

Crisis Resolution Malta was the first to offer rTMS in Malta to the public since early 2016, having conducted over 1000 sessions so far. Patients have different expectations and fears, hence the need for accurate, evidence-based and patient explanation of the technology. A lot of these fears stem from the novelty and from inaccurate or outdated information on the web. The majority of patients (approximately 70%) improve within a few hours of a single treatment. They may feel somewhat 'lighter' in mood and/or experience better quality sleep. They also tend to feel more refreshed in the morning.

Importantly, suicidal ideation is also markedly reduced after a single session, making the difference between immediate hospitalisation versus supervised discharge home. The implications of the latter cases are significant in many ways from a social, clinical and economic standpoint, among others. On the latter point, there is also potential in rTMS being routinely used by crisis teams. The burden of symptoms in disorders such as post-traumatic stress disorder, obsessive–compulsive disorder (OCD), cocaine dependence and autism are also being reduced. Furthermore, patients have not yet experienced significant side effects.

iTBS has also been carefully introduced with somewhat promising results for other disorders including OCD, eating disorders, cocaine abuse and neuropathic pain. tDCS is now also available under supervision.

CONCLUSION

rTMS and its variants are safe, effective, evidence-based and natural electromagnetic stimulation treatments which have growing applications in physical and psychological health. They provide an appealing alternative to those who are treatment resistant, treatment intolerant or treatment sceptical to conventional therapy for whatever reason. The technology also works fast and synergistically with other established treatments or therapies. This is important in potentially life threatening scenarios. Finally, the side effect profile is very good indeed and there are very few contraindications. Although still in their infancy, other future therapies look promising.

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Applying leadership styles to the healthcare sector

Dr Marthese GALEA

ABSTRACT

Introduction

Leadership can have a different meaning to different individuals. The way a person defines a leader depends on many aspects, such as cultural background, beliefs and experiences. Leaders are not in short supply but leaders that truly make a positive difference are not easy to come by.

Leadership styles

There are many leadership styles that are mentioned in the literature. In this review, four models are discussed which the author thinks best apply to the healthcare sector. The leadership styles that will be described are the Situational Leadership Model, the Exemplary Leadership Model, the Authentic Leadership Model and Goleman's Leadership Styles. Examples of how these styles can best be adapted to the healthcare system will be discussed.

Conclusion

A leader can only be successful if there is a proper communication system in place. Leaders of a healthcare system have to capitalize on the fact that the healthcare system is a learning organisation. This will ease the implementation of the strategies since the employees will be more willing to learn new things related to these strategies.

Keywords

Leadership, healthcare, leadership styles

INTRODUCTION

Leadership can have a different meaning to different individuals. The way a person defines a leader depends on many aspects, such as cultural background, beliefs and experiences. Admiring an inspirational leader can also influence the way one sees other leaders as one would have the tendency to compare the leadership style of every leader to him or her. This can be a reason why there are many ways of defining leadership in the literature.

Although according to Winston and Patterson (2006) an expanded search with the word "leadership" returned more than 26,000 reviews, most of these articles were not developed in a healthcare organization as confirmed by Al Sawai (2013). According to Al Sawai (2013), published data offers modest information of how leadership styles can be linked to improve patients' wellbeing and advancement in the care given to patients. Most of the definitions discussed in the literature relate to business organizations.

The author believes that a leader should be someone who is influencing the people around him so they do what the leader wants while at the same time recognizing the potential of his or her team members so as to help them improve their potential. A great leader is someone who believes in inspiring others to reach a common goal for the common good in an organization, hospital, etc. A leader has to embrace change and encourage an environment of expressing an opinion while at the same time listening to the ideas of others. Everyone has the potential to be a leader, if placed in the right situation and with the right team. A leader needs to know how to implement his or her ideas and how to communicate them to the team.

Leaders are not in short supply but leaders that truly make a positive difference are not easy to come by. According to Schyve (2009) an excellent leader is essential for an organization to triumph; however having an excellent leader in a healthcare department is not just essential, it is vital.

METHOD

As there are many leadership styles mentioned in the literature, in this review four models are described which the author thinks best apply to the healthcare sector. These leadership styles are the Situational Leadership Model, the Exemplary Leadership Model, the Authentic Leadership Model and Goleman's Leadership Styles. Examples of how these styles can best be adapted to the healthcare system will be also discussed.

THE SITUATIONAL LEADERSHIP MODEL

According to Hersey, Blanchard and Johnson (1996) leadership is not a straightforward science; a leader needs to be able to change their leadership style according to the task in hand and depending on the person or persons they need to lead. Being a leader in the healthcare sector comes with many responsibilities especially if one has also to retain his clinical responsibilities. There is definitely no shortage of different situations and challenges that need different leadership skills. Although the model has rigid guidelines, in practice this model is not always applicable. Research on this model has not been conclusive, therefore more studies are needed.

As described by Kramer and Nayark (2013) a nonprofit leader, such as a leader in the healthcare sector, is aware that the day is not long enough to give the same attention to every situation that arises. Prioritizing and delegating are crucial, with both being mentioned in the leadership style explained by Hersey, Blanchard and Johnson (1996).

In the healthcare sector every step and decision taken needs to be planned and thought through well in advance. This planning is needed so to have a more organized and structured healthcare system, with a more efficient decision making process and a better learning structure, all benefits mentioned by Bryson (2011).

The majority of the persons that a leader in the healthcare sector has to deal with are all health care professionals, most of them being highly specialized. Therefore one assumes that the level of experience and intellectual ability of these persons should be at a high level. A leader has to be aware that, although his subordinates can show high abilities, they might not be necessarily willing to do the task at hand. This can make the delegation of tasks difficult. One way how to overcome this is by using the Theory of Human Motivation, as explained by Maslow (1943). According to Maslow (1943) people are motivated only to achieve their needs. Therefore, to get the best out of a person, one needs to identify what makes that person motivated and try, where possible, to adapt the task to that person and not the other way round.

Although delegation is important especially when you have highly educated and mature individuals, one has to be careful regarding the level of delegation that is done. A leader cannot follow the Situational Leader Model to the letter. As described by Graeff (1983) this model might encourage a leader not to become involved in certain situations, keep things as they are, not take an action and even avoid conflict. Graeff (1983) has stated that a leader also needs to keep in mind that a decrease in motivation is not the only reason why subordinates reduce their input at work.

THE EXEMPLARY LEADERSHIP MODEL

As Kouzes and Posner (2003) wrote, for a person to become a leader there must be a relationship between those who want to lead and those individuals who decide to follow the leader. Relationship is imperative to have a successful leader. Regarding this model the author found no evidence during the literature search that this model actually works. This model is mainly based on experience and theories.

The model described by Kouzes and Posner (2003) lists 5 main points:

- Model the way.
- Inspire a shared vision.
- Challenge the process.
- Enable others to act.
- Encourage the heart.

For a leader to be respected s/he must lead the way. A clinical leader needs to have the required qualifications and experience. He or she needs to be available for his or her subordinates and needs to be always ready to listen and, where possible, help. At the same time one cannot shy away from taking tough decisions if they are for the common good of the department.

According to Riordan (2014), a leader should listen with empathy to others. A leader must understand and be aware of his subordinates' ambitions and try to use them for the good of the organisation.

A good leader does not sit down and let everything run on its own. A leader needs to be able to implement change. The more radical the change is, the more it shows what a strong and inspirational leader he or she is as normally, according to Fine (1986), it is inevitable that people oppose change. According to Baker (1989), resistance to change can occur if managers do not convince their employees that there is a need to change the things as they are. Communication is crucial to manage change with as little opposition as possible. Meetings and discussions need to be a priority where everyone listens to each other's opinion and where the leader can show and explain his or her vision until everyone is on board. Discussions and open communications are crucial in the health care sector. As mentioned by Bennis (1999), top to bottom leadership is not the solution especially in complex situations such as the ones experienced in a hospital department. Bennis (1999) also stated that to be an exemplary leader one needs to have an exemplary group.

Working with professional people, a leader can feel challenged if he or she is not confident. This can result in a leader discouraging initiative and motivation. A leader needs to show, wherever possible, that he or she wants his staff to be

able to give their full potential. Encouraging initiatives can lead to a more active, more motivated and dynamic department.

According to Riordan (2014) caring about what your employees are saying earns a leader respect. Respect is something that every leader wants to achieve but it is very difficult to realize. Praise of staff, showing appreciation and encouraging them when they need encouragement are also important factors that help a leader earn respect.

THE AUTHENTIC LEADERSHIP MODEL

An authentic leader does not need to make an effort to be a good leader. According to Kruse (2013) many leaders try to act differently at work, making an effort not to show their true personality. Kruse continues by saying that employees are human beings and, if not immediately, after a certain time they can realize that someone is not being honest. This can lead to distrust among employees as they do not feel connected with their leader, and this results in a lack of respect and honesty thus creating a negative working environment.

Authenticity has been explored throughout history, from Greek philosophers to the work of Shakespeare ("To thy own self be true" – Polonius, *Hamlet*). Authentic leadership has been explored sporadically as part of modern management science, but found its highest levels of acceptance by George (2004). According to May et al. (2003) being authentic is knowing yourself and being yourself which are important attributes if one wishes to be an authentic leader.

Avolio et al. (2004) have similar definitions to May et al. (2003). According to Aviolo and Gardner (2005) an authentic leader is deeply aware of how he or she thinks and behaves and others see him as knowing and understanding their own values and the values of others. Aviolo and Gardner (2005) stated that an authentic leader is aware of the environment where he/she works. This model depends on how people perceive their leader; however, during the literature search, the author did not come across any research papers where the influence that an authentic leader might have on his subordinates has been proven to work. It would be ideal if a number of leaders and their subordinates are studied to assess the psychological impact that a leader might have on his employees and how the organization might be affected.

A leader that is authentic can also be a transformational or charismatic leader. There is nothing wrong if good attributes from other models are amalgamated in one leadership model. Bass (1998) stated that a leader that is transformational can also be described as being optimistic, hopeful, focused on development and of a strong moral character, all ideal attributes that a leader should have and similar to those of an authentic leader.

An authentic leader does not necessarily have all the necessary qualities needed. As Aviolo and Gardner (2005) stated, an authentic leader might not have the intention of changing his/her employees into leaders but an authentic leader can model their leading by example and have a positive impact on their employees. As stated by George (2003) it is important to have a company that is mission driven and not financially driven. An authentic leader is in a position to do just that.

Authentic leadership is what the healthcare sector needs, especially if the department in question is the only department in the country. While looking after finances is important, the primary aim in the healthcare sector is to save lives and to improve the lives of others. A leader needs to be seen by his employees as having a strong character with high morals. A good leader does not try to hide his or her character and definitely does not need to act: a leader needs to be a true authentic leader. As also explained by Avolio and Gardner (2015) a leader in the healthcare sector paid by the government might not be interested in changing followers into leaders, as working for a state run hospital one does not chose his followers and definitely does not chose the leaders. However what a leader needs to do is lead by example.

Hersey and Blanchard created the Hersey-Blanchard Situational Leadership Theory which states that it is important to have a leader that is flexible (Leadership-central.com, 2016). Every situation is different; therefore, according to Hersey and Blanchard, there is no ideal leadership style that one can use. This fits perfectly well when dealing with human beings; every situation is different and would require a unique leadership style. This theory according to the author might be perfect if the leader has the authority needed but would not work with leaders that do not have the final say. If time is an issue this theory might also not be the best option.

GOLEMAN'S LEADERSHIP STYLES

Golemen (2000) lists six styles of leadership and has concluded that leaders switch from one style to the other depending on the situation. The ability to choose the right style depends on how emotional the leader is. A leader needs to be aware of his surroundings and of the person in front of him. According to Golemen (2000) he or she needs to be aware of the emotions at that time and adapt the leadership style accordingly. But which style is best for which situation? This is an answer that a good leader needs to know and incorporate in his character. Reading through the 6 models presented by Golemen (2000), the author realizes that they all fit well with a leader that needs to work in the healthcare sector.

A leader in the healthcare sector needs to be a coercive leader in certain situations, as they would still need to deal with very sick and weak persons, where sometimes fast decisive actions need to be taken. This is when a leader in the healthcare sector shows that he or she is a coercive leader where he or she leads and directs his team to be able to save a life. There is no room for discussions in situations like this: just pure leadership showing decisiveness, responsibility, maturity, a high level of education and aware of his/her surroundings. In moments like this, although being a coercive leader, he or she gains the most respect from his peers.

Sometimes a leader needs to be an authoritative leader. Medicine and clinical guidelines are all the time being updated .A leader in the healthcare sector needs to change, sometimes also radically, the structures in his or her department to offer a more up to date and better service to the patients. This is not easy to do as change is very difficult to implement, especially a radical one. Opening new specialties also involves inspiring people to specialize is a specific area and convincing the department of health about the importance of such a specialty so that the funds and necessary approvals are found.

Being an affiliative leader in the healthcare sector is not easy. Normally a department consists of more than 50 people, each with different specialities, ambitions and personal conflicts. When working with so many people having different characters, conflicts are always ready to erupt. A good leader does not shy away from conflicts and tries to get to the bottom of the situation and solve it. The sooner the conflict is resolved, the sooner one can go back to team building and strengthening. Team building exercises should also be embraced by a good leader.

Being a democratic leader in the healthcare sector is very important especially since you are all the time dealing with highly intelligent employees with great ambitions. A healthcare leader needs to have regular meetings with his consultants, senior registrars, and other ancillary staff so to encourage dialogue and to share opinions. This results in the staff being more motivated and encouraged to share their opinion as they know that they are being listened to and, when needed, their opinion is acted upon.

Being a pace-setting leader is crucial in the healthcare sector as the majority of the staff is self motivated and highly skilled; therefore a leader needs to be able to keep them focused and motivated. According to Nanus (1992) a vision needs to inspire and be able to motivate the persons that carry out the implementation. If a leader has a clear vision and is able to inspire others a number of successful projects can be concluded. However before implementing a new project, a leader, as also stated by Thompson et al. (2005), needs to have the project well defined, well studied, well financed, and once it is ready and the green light is given for the project to start, the project needs to be executed in a timely manner and monitored throughout.

Working in the healthcare sector, a leader needs to be a coaching leader. One needs to organize routine meetings for continuing education, with tutorials also needing to be organized so that experienced doctors can teach those less experienced. Obviously the success of a teaching programme can only be possible if a leader has the ability to delegate and coordinate such a programme. This would not be possible if a leader does not have a coaching attitude.

For a leader to be able to use Goleman's Leadership Styles, the author believes that the leader in question needs to be mature and to know the subject, the people and the department that he or she is working in, as otherwise it would be difficult to adapt and use different styles.

CONCLUSION

Hourston (2013) stated that everyone is affected by leadership, and everyone can relate to a good or bad leader as we meet them on a regular basis. Leadership is very common but very few actually give it the importance needed. Hourston (2013) also concluded that the majority of leaders use the leadership technique that they feel comfortable to use. In a few cases this can be of advantage but, just like any other skill, you need to work on leadership to maximize your potential.

Style and Substance

The substance of what one does is the result of what one delivers and this is fundamental in today's economy. But working on the *way* that one does it is what will launch a leader into a different sphere of success altogether—even if s/he already counts her or himself as being quite successful. The style that one chooses should not be a natural one but a good leader takes a conscious decision.

Goffee (2008) stated that to be a good leader one has to work hard with a lot of personal sacrifices. This is also a continuous process which never stops. As stated by the University Alliance (2016), apart from choosing the best leadership style a good leader need to have excellent communication skills, be able to motivate his team and be able to build a team. A good leader should not be scared to take risks and should have a vision with clear goal settings.

A disciplined and skilled leader is essential to keep the organisation focused on implementing these strategies.

However being a good leader is not enough. A leader has to possess communication and delegation skills. The senior managers of an organisation have to make sure that the strategies are properly implemented in the desired timeframe and that all those involved in implementing each strategy have a full understanding of it, as concluded by Kaplan and Norton (2001). "The ability to execute strategy is more important than the quality of the strategy itself," (Thompson et al. 2005). A transformational leader as described by Bennis (1999) would be the ideal candidate to create visions that inspire the employees to adopt the strategies and the changes involved with them. A charismatic leader as suggested by Weber (1947) would appeal to the employees' hearts and minds to create the needed commitment for the strategies.

The leader has to paint a convincing and inspiring picture of the new strategy. This is essential so the employees can commit themselves to make the strategy a reality. When implementing the strategy the management have to make sure that all the resources needed are available such as enough and well trained employees, budgets that steer resources into the activities critical to strategic success, continuous improvement and changes for the strategy to be successful, motivation of the employees to work on the strategy, and the setting of objectives to be able to convert the strategy vision into specific performance targets that can be measured to track the company's progress and performance. The achievement of these objectives can be linked to a performance bonus for the employees involved. One has to keep in mind that long term vague goals are difficult to excite the employees. Therefore short term gains ideally should be celebrated along the way. This has a strong behavioural boost (Anon. 2002).

All this can only be successful if there is a proper communication system in place. Leaders of this organisation have to capitalize on the fact that this organisation is a learning organisation. This will ease the implementation of the strategies since the employees will be more willing to learn new things related to these strategies.

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Giovanni Francesco Buonamico (1639-1680)

Dr Jason J BONNICI

The Environment and Resources Authority has set up the Buonamico Award on the occasion of the World Wildlife Day in recognition of contribution by enthusiasts to our knowledge on the environment. The first Buonamico Award winners were Mr Hubert Spiteri and Mr Michael Briffa. The award-giving ceremony was on 9th March 2017 under the auspices of Her Excellency President Marie-Louise Coleiro Preca. This award is inspired by Giovanni Francesco Buonamico, also known as Ġan Franġisk Bonamico.

Buonamico was a 17th century Maltese traveller, poet, writer, doctor and naturalist, who also wrote the first Flora of the Maltese Islands. As an intellectual he is best renowned as the author of the second oldest poem in Maltese, "*Mejju ġie bil-ward u ż-żahar*", but has also written various accounts of his travel experiences.

His varied intellectual interests resulted in the writing of at least four important manuscripts on natural history, which included the first flora of the Maltese Islands, the so-called "Brevis Notitia" manuscripts - two manuscripts written in 1670, and another two manuscripts on the Malta Fungus: "Dissertatio De Fuco Spicato Coccineo Melitensis". These are undated, but the general consensus is that these go back to a date either earlier than or contemporary with the "Brevis Notitia".

The manuscript on the Malta Fungus essentially describes this species for the first time, and the "Brevis Notitia" includes notes on the flora and agriculture in Malta, with information on cultivated and ornamental plants at the time. The latter also included a detailed list of species of wild flora observed by Buonamico comprising 244 entries – a major feat considering that no earlier studies of the sort seem to have been carried out.

Unfortunately, Buonamico's naturalistic works were never published and survive only as manuscripts in the National Library of Malta in Valletta. Due to this, such pioneering works remained mostly unassessed, despite their considerable importance, and were thus underestimated until studied recently by Darrin T Stevens and Edwin Lanfranco.

Buonamico is therefore considered as a good metaphor to show the importance of undervalued people, who still give valuable input to the academia and authorities in the environment field.

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Symposium "Societal Impact of Pain" (SIP) 2017

STRUCTURED CO-OPERATION TO TACKLE THE SOCIETAL IMPACT OF PAIN

The **Symposium "Societal Impact of Pain" (SIP) 2017** will build on the successes of previous years and continue to set the agenda for better pain policy in Europe. It offers a unique opportunity to connect with the pain community thereby facilitating consensus building and policy recommendations.

The SIP symposium is the paramount event on the European pain policy calendar and isn't to be missed. As evidenced by this, SIP 2017 will take place under the auspices of the **2017 Maltese Presidency of the Council of the EU.**

WHAT WILL BE DISCUSSED?

1. European and national platforms addressing the societal impact of pain
2. Pain and employment
3. Pain as a quality indicator for health systems
4. Challenges, models and best practices in pain policy
5. Evolving concepts in the definition of chronic pain: a dynamic process

WHO WILL PARTICIPATE?

The meeting is relevant for anyone involved in pain policy e.g. health care professionals, politicians, representatives of pain advocacy groups, health insurance companies, health authorities, regulators and budget holders.

WHEN?

June 7 – pre-symposia meetings
June 8 – working groups & European Civic Prize on Chronic Pain
June 9 – Plenary sessions

WHERE?

Grand Hotel Excelsior, Great Siege Road, Valletta, Island of Malta FRN 1810, Malta

REGISTRATION

Due to the limited space available at the conference, participation at SIP 2017 will be confirmed by the organisers on a first-come, first-served basis. Priority will be given to active participants (e.g. speakers, working group members). Early Bird Fee Registration for SIP 2017 is 25 Euros if registered before the 1st of May, 2017. Registration fee is 50 Euros if registered after the 1st of May 2017. The deadline for registration is the 1st of June 2017. For participation at the event dinner on the 8th of June the fee is 25 Euros. The registration fees will be donated for the support of activities addressing the Societal Impact of Pain on Malta by the Malta Health Network and the No Pain Foundation.

Register for SIP 2017 here:
www.sip-platform.eu/SIPRegistration

ACCOMMODATION

Participants will need to cover their own travel and accommodation costs. For participants of SIP 2017 a special hotel rate has been negotiated. More information you will receive on registration.

The scientific framework of the SIP platform is under the responsibility of the European Pain Federation EFIC®. Cooperation partners for SIP 2017 are Pain Alliance Europe and Active Citizenship Network. The SIP 2017 symposium is co-hosted by the Malta Health Network and the No Pain Foundation. The preliminary program has been pre-approved as being in line with the code of conduct of the Pharmaceutical Research Based Industry Malta Association (PRIMA). The pharmaceutical company Grünenthal GmbH is responsible for funding and non-financial support. SIP 2017 is made possible with the financial support of the Ministry for Finance in Malta.

For further event information please visit
www.sip-platform.eu
or contact us by e-mail: **sip-platform@grunenthal.com**

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