Management of metastatic prostate cancer

Endodontic consideration in medically compromised patients

Adherence to ATLS Protocols

Duration of hearing aid use in elderly
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Changing trends in the Management of metastatic prostate cancer

Abhishek Laddha*, Ginil Kumar Pooleri*, Ravi Chandran k’, Sanjay Mohan**, Appu Thomas*

ABSTRACT
Presentation of high grade and high stage prostate cancer is common in Indian population. In this comprehensive systemic review we have presented a detailed review of changes in management of metastatic prostate cancer. There is a drastic change in the management of prostate cancer from just Orchidectomy to a current basket of medications. We have a new approach to management of hormone-sensitive prostate cancer with addition of Docetaxel, Abiraterone, and Enzalutamide to primary ADT as first-line treatment. Addition of radiation to the prostate in patients with less than five metastasis has shown improved survival as well, it may change the way we look at metastatic prostate cancer in the future. Newer drugs and new indications for current drugs will hopefully further improve survival and quality of life in metastatic prostate cancer.

Key words: Prostate cancer, PSA.

ABSTRACT

INTRODUCTION
There is a famous saying in medicine “fifty percent of what we learn today may be wrong tomorrow, we learn anyway” .Prostate cancer is common cancer affecting men all around the globe. Incidence of advanced disease varies substantially by race and geography. Presentation of high grade and high stage prostate cancer is common in Indian population. In some studies upto 70 % patient presented during primary evaluation has distant metastatic disease. Progression of metastatic disease from hormone sensitive to castrate resistant is inevitable. Therapy which might delay the progression to castrate resistant may improve overall survival as well. Being a spectrum of disease, metastatic prostate cancer has varied presentation and response to treatment.1,2

METHODS
A comprehensive literature search focusing on the management of metastatic prostate cancer was done. All articles in PUBMED, Medline, EMBASE and the Cochrane Libraries were reviewed. Final selection of articles was limited to studies representing high levels of evidence such as prospective comparative studies, randomised controlled trials, systemic reviews and metanalysis.

Evaluation and follow up of metastatic prostate cancer
Evaluation of health status and life expectancy is important in clinical decision-making on screening, diagnosis, and treatment of Prostate cancer. Once a diagnosis of prostate cancer is confirmed, the primary aim is of management is an accurate determination of disease extent and risk for management decisions and prognostication. PSA, Digital rectal examination , findings on TRUS biopsy (Gleason score, grade, number of cores, the percentage of each core involved), bone scan, SPECT CT or PSMA scan help in the evaluation of the locoregional extent of disease and/or to rule out metastases.

Imaging
Radionuclide bone scan (bone scintigraphy) is the most commonly employed imaging used for the detection of skeletal metastases. During primary evaluation, bone scan is recommended for carcinoma of prostate with PSA level greater than 20 ng/mL, Gleason score of 8 to 10, clinical stage T3 or T4, or with clinical symptoms suggestive of metastasis.

Changing trends in Imaging for skeletal metastases
Evaluation of skeletal metastases has progressed from plain x-ray which was the only evaluation available once, to dedicated nuclear scans and hybrid scans now. Skeletal evaluation can be done with bone scan ( most commonly used and widely available ), 18F-sodium fluoride (18F-NaF) PET/CT ,(similar specificity and superior sensitivity to bone scan)3,4, F-18 fluciclovine PET/CT or PET/MRI , choline PET/CT, (detect LN metastases as well), Diffusion-weighted whole-body and axial MRI ( more sensitive than bone scan )5,6 and PSMA PET CT /MRI hybrid scan (one-stop-shop for prostate cancer for local , systemic , visceral and bone metastasis ).

In a direct comparison, PSMA PET outperformed planer bone scan for detection of affected bone regions as well as overall bone disease volume3,6. PSMA PET has significantly higher sensitivity and accuracy than bone scan for detection of bone metastasis. (90.5% vs. 73.68%, and 97.0% vs. 86%).17.6 % lesion in bone were exclusively recognized only by PSMA PET in comparison only 1.2 % lesion were exclusively detected by the bone scan3. Overall PSMA PET CT /MRI may replace all other investigations for the local and systemic staging of prostate cancer.

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Prognostic factors

Metastatic prostate cancer is a heterogeneous population with a median survival of 42 months\textsuperscript{10}. Prognostic factors for survival include number and location of bone metastases, visceral metastases, Gleason score of a primary tumor, performance status and initial PSA\textsuperscript{11}, alkalinephosphatase\textsuperscript{12}, but only a few have been validated\textsuperscript{13}. Most important factor that has been used in most trials is number and location of bone metastases with presence and absence of visceral metastases\textsuperscript{14}. Prognostic factors specific to Docetaxel include visceral metastases, pain, anemia (Hb< 13 g/dL), bone scan progression, and prior estramustine. Absence of the above factors predicts a good response to Docetaxel\textsuperscript{16}. Visceral metastases, more than five bone metastases on bone scan, appendicular locations, and International Society of Urological Pathology (ISUP) groups ≥ 3 are all independently associated with a decreased survival. Based on a large SWOG 9346 cohort, the PSA level after seven months of ADT was used to create three prognostic groups. Median survival was 75 months, 44 months and 13 months for PSA values of less than 0.2, 0.2 to 4 and more than 4 respectively.

Management options

Management options for metastatic prostate cancer can be discussed in two headings; that for (a) hormone sensitive and (b) for Castration-resistant prostate cancer.

Hormone sensitive metastatic prostate cancer

First-line hormonal treatment

The recommendation of castration for the initial treatment of hormone-sensitive metastatic prostate cancer has remained almost unchanged for seven decades\textsuperscript{15} till the emergence of medical castration with LHRH agonists and antagonists. There is no level 1 evidence in favor of a specific type of ADT, neither for orchidectomy nor for an LHRH analogue or antagonist. In patients with impending spinal cord compression, either a bilateral orchidectomy or LHRH antagonists are the preferred options in view of the quick response.

Complete androgen blockade using a non-steroidal anti-androgen appears to provide a small survival advantage (<5%) vs. monotherapy (surgical castration or LHRH agonists)\textsuperscript{16,17} beyond five years of survival\textsuperscript{18} but this minimal advantage in a small subset of patients must be balanced against the increased side-effects associated with long-term use of non-steroidal anti-androgens. Non-steroidal anti-androgen monotherapy\textsuperscript{19} is less effective and should not be offered as primary therapy.

Intermittent androgen deprivation therapy is well addressed in metastatic setting in SWOG 9346\textsuperscript{20}. Less than 50 % of patients (N=3040) were candidates for Intermittent androgen deprivation with best PSA response. Continuous androgen deprivation therapy seems to have better overall and progression-free survival. Till we have further evidence continuous ADT in metastatic patients should be considered standard of care.

ADT with Abiraterone acetate or chemotherapy

Role of Abiraterone acetate in addition of ADT is well studied in two large randomized control studies ((STAMPEDE, LATITUDE)\textsuperscript{21,22}). Both trials showed a significant overall survival benefit of 38% at three years\textsuperscript{23}. All secondary objectives such as progression-free survival, time to radiographic progression, time to pain, or time to chemotherapy were positive and in favor of the combination. The main complication was discontinuation of therapy due to side effects (20% in STAMPEDE and 12% in LATITUDE). Enzalutamide is under evaluation for a similar indication in hormone-sensitive prostate cancer.

Role of chemotherapy has been evaluated in three large randomized controlled studies (GETUG 15, CHAARTED and STAMPEDE)\textsuperscript{24,25,26}. All three trails reported improved overall survival with around 10% incidence of hematologic complications mainly febrile neutropenia.

Both Abiraterone acetate and docetaxel with ADT appear to improve overall survival in men presenting with metastases at first presentation. The choice between two will be driven by patient preference, side effects specific to each drug (febrile neutropenia with docetaxel and cardiovascular events with Abiraterone acetate), and availability of drugs and cost of long-term treatment\textsuperscript{27}. Further, we need predictive biomarkers to select patients between two, until then ADT plus docetaxel may be given to patients who have more than 4 metastases with good performance status, desire shorter total treatment time or have financial concerns with the cost of long-term therapy with Abiraterone. People who have less than four sites of metastases or who are not fit or not willing for the potential side of chemotherapy may be better candidates for ADT plus Abiraterone.

Management of primary tumor in newly diagnosed metastatic disease

Randomized comparison of more than 2000 patients newly diagnosed metastatic prostate cancer ((STAMPEDE)\textsuperscript{28}) has shown improved survival in selected patients with low metastatic burden with local radiotherapy (around 40% of study population). Overall local RT to prostate did not improve survival in unselected study population emphasizing the need for proper patient selection with a low burden of metastatic disease.

The value of prostate radiotherapy in men receiving abiraterone is being tested in the PEACE1 trial (NCT01957436),\textsuperscript{29} and the prospectively planned STOP-CAP M1 meta-analysis of these trials will explore this further\textsuperscript{30}. The feasibility of prostate surgery in this setting is being tested in the theg-RAMMP trial (NCT02454543) and the TROMBONE feasibility study\textsuperscript{31}. 

Changing trends in the management of metastatic prostate cancer
Metastatic castration-resistant Prostate cancer (mCRPC)
Progression from hormone sensitive to castrate state is inevitable, till we have good prospective data it is advisable to continue ADT during further management of such patients\(^{32,33}\).

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Table 1: Management options for metastatic prostate cancer

**Treatment options for metastatic castration-resistant Prostate cancer**

**Abiraterone**
Patients without visceral metastases with good performance status and minimal symptoms were randomized to Abiraterone and placebo in phase III trial COU-AA-302. This study showed a significant survival advantage in Abiraterone arm over placebo arm (34.7 vs. 30.3 months \(p = 0.0033\))\(^{34,35}\).

Abiraterone is well tolerated with minimal toxicity due to mineralocorticoid excess and liver function abnormalities and is well tolerated even in the elderly subset of patients\(^{36}\). Abiraterone acetate has shown a survival advantage in patients with prior docetaxel in a large phase III trial (COU-AA-301) with a median survival of 15.8 vs 11.2 against the placebo arm\(^{37,38}\).

**Enzalutamide**
Enzalutamide has shown survival advantage in non metastatic CRPC. Recently FDA approved its use in the scenario.

Similar to COU-AA-302 trial for Abiraterone patients were randomized to receive enzalutamide and placebo in PREVAIL trail\(^{39}\). This trial included a small number of patients with visceral metastases. All patients except with liver metastasis showed significant benefit in progression-free and overall survival\(^{40-42}\). Drug is well tolerated. Fatigue and hypertension were the main side effects. 0.6 to 1% incidence of seizures was noted with Enzalutamide.

Like Abiraterone acetate, Enzalutamide too has shown a survival advantage in patients with prior Docetaxel. Combined with prednisolone, Docetaxel given on every-3-weekly schedule has shown survival advantage of 2-2.9 months over mitoxantrone\(^{44,45}\). The duration of treatment with docetaxel should be based on its benefit and toxicities. Even though six cycles of docetaxel is the most common treatment schedule, up to 10 cycles were used in the pivot trials.

**Docetaxel**
The role of docetaxel in CRPC is well established.

**Sipuleucel-T**
Survival benefit with sipuleucel-T was shown in a phase III trial. Sipuleucel-T has good tolerance with a survival advantage over placebo (25.8 vs 21.7 months, \(p = 0.03\))\(^{47}\). High cost and lack of data on symptomatic disease are constraints.

**Cabazitaxel**
Cabazitaxel is generally considered as second-line chemotherapy in patients who have failed or progressed after prior Docetaxel (docetaxel-resistant cancers). The response rate with Cabazitaxel is inferior to docetaxel and is associated with more toxicity preventing its use as the first-line drug in CRPC\(^{48-50}\).

**Targeted Therapies for the Treatment of Bone Metastases**

**Radium-223**
Radium-223 has shown an overall survival advantage in phase III ALSYMPCA trial of 3.6 months. Secondary endpoints related to the bone like time to a first skeletal event, improvement in pain scores and improvement in QoL also showed benefit in radium 223 arms. It is safe in patients with or without a history of prior docetaxel\(^{51-52}\).

\(β\)-emitting radionuclides containing radiopharmaceutical drugs such as 153 samarium–ethylene diamine te-
triamethylene phosphonate and 89 strontium are used to bony pain in cancer patients with osteoblastic lesions\textsuperscript{53,54}. Bone marrow toxicity of these drugs is a major concern\textsuperscript{53}.

**Lutetium 177 PSMA radionuclide therapy**

Low energy $\beta$-particle emitter chemically bound to monoclonal PSMA antibody with a half-life of around 6.7 days is used as Lutetium 177 PSMA radionuclide therapy for prostate cancer. It has lower killing power emissions and longer destructive range\textsuperscript{55}.

Around 30 to 70 % men archive more than 50 % reduction in PSA levels which is comparable to results obtained by chemotherapy agents used in mCRPC. Around 10 to 32 % of patients progress with response to 177Lu PSMA therapy. As most of the data at present are retrospective survival advantage with 177Lu PSMA therapy is not known at present. Platelet level and the need for pain relief are the most significant predictor of poor response to 177Lu PSMA in a small study population, likely reflecting the burden of metastatic bone disease\textsuperscript{58}.

**PSMA-Actinium-225 (Ac-225) radiolgand therapy**

Alpha-emitting radioisotope Actinium-225 (Ac-225) may be more efficacious than beta-emitting Lutetium-177, due to higher rates of double-strand DNA breaks in prostate cancer cells, with less tissue penetration and minimal bystander effects in PSMA-negative cells. PSMA-Actinium-225 (Ac-225) has shown a remarkable response in small subsets of patients. Larger studies are required to study the effect on overall survival\textsuperscript{58}.

**Thorium 227**

Similarly to actinium-225, thorium-227 belongs to the actinide series of elements and results in an $\alpha$-emitting radionuclide. Trails are underway for clinical use in prostate cancer.

**Palliative Radiotherapy for bone metastasis**

Palliative Radiotherapy should be offered for patients with painful bone metastases even as single fraction external beam radiotherapy\textsuperscript{59}.

**Impending Spinal cord compression**

Impending Spinal cord compression is a medical emergency, early recognition and prompt action is important. High dose corticosteroid is administered and neurosurgical consultation should be sought. Surgical decompression and /or radiation may be offered once the patient is stabilized\textsuperscript{60}.

**Preventing skeletal-related events**

Bisphosphonates and RANK ligand inhibitors

Zoledronic acid 4 mg in metastatic CRPC is associated with few skeletal-related events and pathological fractures. It also delayed time to first skeletal-related event with no overall survival advantage. Denosumab (fully human monoclonal antibody directed against RANKL) is another option for patients with metastatic CRPC with some advantage and slightly superior results than Zoledronic acid. Dental examination before starting these drugs is recommended and potential toxicity like osteonecrosis of the jaw should be kept in mind\textsuperscript{60-62}. None of the studies have shown benefit in hormone-sensitive prostate cancer and these drugs should not be given in such patients.

**Monitoring of treatment**

Patients should be followed every 3 months with blood investigations (CBC, RFT, PSA, ALP, LFT) with bone scan and CT scan every 6 months even in absence of clinical indications as patients may progress to have visceral metastases even without rising PSA\textsuperscript{63,64}.

**Upcoming modalities**

**Pembrolizumab**, an anti-PD1 antibody was approved by FDA in 2017 for treatment of tumours with microsatellite instability high (MSI-H) and mismatch repair (MMR) deficient solid tumours including that of prostate who are depleted of other treatment options. Recently registered trial, PERSEUS1 trial will give an idea about its effectiveness in metastatic prostate cancer\textsuperscript{65,67}. Genetic analysis of prostate cancer showing somatic homologous recombination deficiency (HRD) has shown high rates of response to Poly(ADP-ribose) polymerase(PARP) inhibitors(Olaparib). Patients who were positive for these mutations (demonstrated homoygous deletions or deleterious mutations in DNA-repair genes) showed 88 % response rate to in patients who were previously treated with both docetaxel and at least one novel hormonalagent\textsuperscript{65}. Novel combinations in hormone-sensitive cancers with a combination of ADT and androgen axis inhibitors like apalutamide, darolutamide, and orteronel are in phase III clinical trials.

**CONCLUSION**

There is a drastic change in the management of prostate cancer from just orchiectomy to a current basket of medications. We have a new approach to management of hormone-sensitive prostate cancer with addition of Docetaxel, Abiraterone, and Enzalutamide to primary ADT as first-line treatment. Addition of radiation to the prostate in patients with less than five metastasis has shown improved survival as well, it may change the way we look at metastatic prostate cancer in the future. All our current treatment approach in hormone-sensitive prostate cancer aims to improve overall survival with prevention and delay of complications and emergence of castrate resistant state. Emergence of CRPC status is inevitable. CRPC patients are usually offered the second line of hormone treatment in form of Abiraterone, Enzalutamide or first-line chemotherapy in from of Docetaxel. Treatment after the failure of a primary line of treatment is more controversial and must be tailored to individual patients with a discussion about the pros and cons of each available therapy. Second-line chemo-
therapy (cabazitaxel). Lutetium 177 PSMA radionuclide therapy, Radium-223, PSMA-Actinium-225 (Ac-225) radioligand therapy are usual options available.

Newer drugs and new indications for current drugs will hopefully further improve survival and quality of life in metastatic prostate cancer.

REFERENCES


28. Christopher C Parker, Nicholas D James, Christopher D Brawley, Noel W Clarke, Alex P Hoyle*, on behalf of the Systemic Therapy for Advanced or Metastatic Prostate cancer: Evaluation of Drug Efficacy (STAMPEDE) investigator team. Radiotherapy to the primary tumour for newly diagnosed, metastatic prostate cancer (STAMPEDE): a randomised controlled phase 3 trial. https://doi.org/10.1016/S0140-6736 (18)32486-3


48. de Bono, J.S., et al. Phase III non-inferiority study of cabazitaxel (C) 20 mg/m2 (C20) versus 25 mg/m2 (C25) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) previously treated with docetaxel (D). J Clin Oncol 2016; 34: abstr 5008.


Endodontic considerations in medically compromised patients - A Review


ABSTRACT
Oral diseases are linked to several medical conditions. Dental management in medically compromised patients requires special attention. Thorough knowledge about the pathophysiology of diseases, pharmacological action and their interactions with dental procedures is mandatory. This review focuses on a number of medical problems that dental professionals might encounter, which necessitate care to prevent potential complications.

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INTRODUCTION
Systemic medical condition affects the routine dental procedures. A good number of the adult and geriatric patients may invariably be medically compromised, the incidence might be slightly lesser among young patients.

Medical conditions which may be hidden and without symptoms are detected only on elaborate investigations. Such conditions may adversely affect the patients and is a concern for dental practitioners causing unexpected problems. Therefore, a thorough evaluation of the medical conditions of the patient is the first priority in the management of medically complex cases. This review focuses on a number of medical problems that dental professionals might encounter, which necessitate care to prevent potential complications. These include hypertension, ischemic heart disease, cardiac arrythmia, liver disease, allergy, acquired immuno deficiency syndrome, organ transplantation and diabetes mellitus.

Hypertension
Hypertension is an abnormal elevation in arterial pressure that can be fatal if sustained and untreated. People with hypertension may not display clinical signs or symptoms for many years but eventually can experience symptomatic damage to several target organs including kidneys, heart, brain and eyes.1

Endodontic Management
Medical consultation and management is needed in patients with Systolic Blood Pressure greater than 180 and/or Diastolic Blood Pressure greater than 110 prior to dental treatment and only emergency management of pain or acute infection should be considered. The use of local anesthetics with vasoconstrictors may precipitate significant elevation in blood pressure. However, the use of one to two cartridges of 2% lidocaine with 1:100,000 epinephrine (0.018 to 0.036 mg) is of little significance in most patients with hypertension.

Elective dental care should be avoided in the following situations
1. Patients with blood pressure greater than or equal to 180/110 (Stage III hypertension).
2. Patients having hypertensive symptoms which include occipital headache, failing vision, ringing in the ears, dizziness, weakness and tingling of the hands and feet. In patients with blood pressure of 160-179 / 100-109 (Stage II hypertension), epinephrine should be limited to three cartridges (0.054 mg).
3. The use of retraction cord with epinephrine and intra-ligamentary and infra-bony injections should be avoided. (Stage 2 and 3) 2.

Ischemic Heart Disease
When coronary atherosclerotic heart disease becomes sufficiently advanced to produce symptoms, it is referred to as ischemic heart disease. Atherosclerosis is the thickening of the intimal layer of the arterial wall caused by the accumulation of lipid plaques. The atherosclerotic process results in a narrowed arterial lumen with diminished blood flow and oxygen supply. Ischemic symptoms are the result of oxygen deprivation secondary to reduced blood flow to a portion of the myocardium.1

Chest pain secondary to ischemic heart disease results when the oxygen demand of the myocardium exceeds the oxygen supply. Transient pain is referred to as angina pectoris and is often described as an aching, squeezing sensation or tightness in the middle of the chest. Angina is often precipitated by physical activity or stress and may radiate to the arm or jaw and may present as facial or dental pain.

Fear and anxiety associated with dental treatment may be a precipitating factor for angina in some patients. Sublingual or other forms of nitrates are the standard treatment for angina and should result in rapid reversal of symptoms. If symptoms are not relieved with oral nitrates and suspension of stress-inducing activity, then...
Myocardial infarction should be suspected and immediate emergency treatment should be initiated.

**Endodontic Considerations**

Treatment modification considerations for patients with ischemic heart disease should include morning appointments, short appointments, oral premedication with an anxiolytic drug or nitrous oxide or oxygen sedation, limited use of vasoconstrictors. If a vasoconstrictor is necessary, patients with intermediate clinical risk factors and those taking nonselective beta blockers can safely be given up to 0.036 mg epinephrine (two cartridges containing 1:100,000 epinephrine) at one appointment. However, intravascular injections are to be avoided. Adequate pain management during and after the dental appointment is mandatory along with possible cardiac monitoring.

**Cardiac Arrhythmias**

Cardiac arrhythmia refers to variation in the normal heart beat, includes disturbances in rhythm, rate or the conduction pattern of the heart. Anxiety associated with dental treatment may induce arrhythmias in susceptible patients. In addition, patients with cardiovascular disease are more prone to arrhythmias during oral surgery procedures with local anesthesia. Patients taking digoxin for atrial fibrillation or congestive heart failure are especially at risk for arrhythmias during oral surgery procedures.

**Endodontic Considerations**

The use of vasoconstrictors in local anesthetics poses potential problems for patients with arrhythmias because of the possibility of precipitating cardiac tachycardia or another episode of arrhythmia. A local anesthetic without vasoconstrictor may be used as needed. Vasoconstrictors should be avoided in patients taking digoxin because of the potential for inducing arrhythmias. For patients at major risk for arrhythmias, the use of vasoconstrictors should be avoided, but if their use is considered essential, it should be discussed with the physician.

**Liver Disease**

**Hepatitis**

Hepatitis is inflammation of the liver that may result from infectious or other causes. Noninfectious hepatitis can result from excessive or prolonged use of toxic substances such as drugs (i.e., acetaminophen, alcohol, halothane, ketoconazole, methyldopa and methotrexate) or, more commonly, alcohol.

**Endodontic Considerations in Specific Patient Groups**

The recommendations for infection control practice in dentistry published by the Centers for Disease Control and Prevention (CDC) and the American Dental Association have become the standard of care to prevent cross-infection in dental practice.

**Patients with Active Hepatitis**

No dental treatment other than urgent care should be rendered for a patient with active hepatitis unless the patient has attained clinical and biochemical recovery.

**Patients with a History of Hepatitis**

Most carriers of HBV, HCV and HDV are unaware that they have had hepatitis. An explanation is that many cases of hepatitis B and hepatitis C apparently are mild, subclinical and icteric. Such cases may be essentially asymptomatic or resemble a mild viral disease and therefore go undetected.

Patients with cirrhosis have an increased susceptibility to infection. Odontogenic infections should be treated aggressively with appropriate antibiotic treatment. Antibiotic prophylaxis prior to dental procedures is recommended only if the patient has a history of spontaneous bacterial peritonitis or ascites. When antibiotic prophylaxis is indicated in the patient with end-stage liver disease, recommended antibiotic regimen should be followed. (Table 1)

Alteration of medication dosage based upon hepatic compromise and additional medications may require consultation with the patient’s physician.

**Allergy**

One of the most common medical emergencies that occurs in the dental office is an acute allergic reaction. It is a requirement for every dental practitioner to have a basic understanding of the pathophysiology of these reactions, as well as risk factors and clinical manifestations. Allergy is defined as an abnormal or hypersensitive response of the immune system to a substance introduced into the body.

**Endodontic consideration**

1. **Local Anesthetics**

The reaction to local anesthetics results from inadvertent intravenous injection of the anesthetic solution. Excessive amounts of an anesthetic also can cause a toxic reaction or a reaction to the vasoconstrictor. Signs and symptoms associated with toxic reactions to a local anesthetic include tachycardia, dizziness, nausea, depression, euphoria, excitement and convulsion. Whereas to a vasoconstrictor reaction include talkativeness, slurred speech, dizziness, nausea, depression, euphoria, excitement and convulsion. Whereas to a vasoconstrictor reaction include tachycardia, apprehension, sweating and hyperactivity.

History supporting an interpretation of loss of consciousness and not a toxic or allergic reaction, the clinician’s primary task is to work with the patient to reduce anxiety during dental visits. If the history supports a true allergic reaction to a local anesthetic, the dentist should try to identify the type of local anesthetic that was used. Once this has been ascertained, a new anesthetic with a different basic chemical structure should be used. The two groups of local anesthetics in dentistry consist of the following:

1. Para-aminobenzoic acid (PABA) esters (procaine and
tetracaine)

2. Amides (articaine, bupivacaine, lidocaine, mepivacaine and prilocaine)

Procaine is the local anesthetic associated with the highest incidence of allergic reactions. If patients are allergic to local anesthesia the two additional options available are:

- An antihistamine (e.g., diphenhydramine, chlorpheniramine maleate) can be used as the local anesthetic.
- The patient may be referred to an allergist for provocative dose testing.

The use of diphenhydramine often is the more practical option.

A 1% solution of diphenhydramine that contains 1:100,000 epinephrine can be compounded, but it must be confirmed that methylparaben is not used as a preservative. This solution induces anesthesia of about 30 minutes average duration and can be used for infiltration or block injection. When it is used for a mandibular block, 1 to 4 ml of solution is needed. Some patients have reported a burning sensation, swelling or erythema after a mandibular block with 1% diphenhydramine, but these effects were not serious and cleared within 1 or 2 days. Not more than 50 mg of diphenhydramine should be given during a single appointment. Diphenhydramine also can be used in patients who report a previous allergic reaction to either an ester or amide local anesthetic.

<table>
<thead>
<tr>
<th>Situation</th>
<th>Agent</th>
<th>Adults</th>
<th>Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>Amoxicillin</td>
<td>2 g (500 mg)</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Unable to take oral medication</td>
<td>Ampicillin OR Cefazolin or Ceftriaxone</td>
<td>2 g IM* or IV+ 1 g IM or IV</td>
<td>50 mg/kg IM or IV 50 mg/kg IM or IV</td>
</tr>
<tr>
<td>Allergic to penicillins or Ampicillin - Oral</td>
<td>Cephalexin &amp; OR Clindamycin OR Azithromycin or Clarithromycin</td>
<td>2 g 600 mg 500 mg</td>
<td>50 mg/kg 20 mg/kg 15 mg/kg</td>
</tr>
<tr>
<td>Allergic to Penicillins or Ampicillin and unable to take Oral medication</td>
<td>Cefazolin or Ceftriaxone  OR Clindamycin</td>
<td>1 g IM or IV 600 mg IM or IV</td>
<td>50 mg/kg IM or IV 20 mg/kg IM or IV</td>
</tr>
</tbody>
</table>

*IM: Intramuscular
+IV: Intravenous
& or other first- or second-generation oral Cephalosporin in equivalent adult or pediatric dosage.

Table 1 – ADA recommended antibiotic regime

2. Rubber Products

Reports have shown that certain health care workers and patients are at risk for hypersensitivity reactions to latex or agents used in the production of rubber gloves or related materials such as rubber dam. Latex from surgical gloves has been known to cause cardiovascular collapse in surgical patients, anaphylaxis in physicians, hypersensitivity reactions in health care workers and anaphylaxis in some patients.

Most cases in health providers are type IV reactions, caused by agents used in the production of rubber products, serious type I hypersensitivity reactions may occur in physicians, dentists, other health care workers and patients as the result of contact with latex products such as gloves or rubber dam.

Anaphylaxis may occur in sensitized person after prior contact has been made with rubber gloves, rubber dam material or any other product containing latex. Studies
have shown that latex-allergic persons have IgE antibodies for specific latex proteins. Latex skin tests are a satisfactory means of identifying individuals who may be sensitized to latex. Nitrile gloves should be considered for use to minimize these adverse reactions to latex proteins\textsuperscript{7,8}.

**Treatment option**

In case of immediate reaction administration of corticosteroids or antihistamine is essential. If rashes are present topical application of lotion gives a symptomatic relief.

3. **Dental Materials and Products**

Type I, type III and type IV hypersensitivity reactions have been reported to result from various dental materials and products. Mouth rinses and toothpastes containing phenolic compounds, antiseptics, astringents or flavoring agents have been known to cause type I, and type IV hypersensitivity reactions involving the oral mucosa or lips. Hand soaps used by dental care workers also have been reported as a cause of type IV reactions. Some of the dental agents that can lead to type IV hypersensitivity (contact stomatitis) include dental amalgam, acrylic, composite resin, nickel, palladium, chromium, cobalt, eugenol, rubber products, mouthwashes and toothpastes\textsuperscript{7,8}.

4. **Irrigating Solutions**

Sodium hypochlorite in concentrations varying from 0.5\% to 6\% is currently the most commonly used canal disinfectant and irrigating solution in endodontics. It not only possesses excellent tissue solvent and antimicrobial properties but also demonstrates concentration-related tissue toxicity. It has been suggested that some patients may be sensitized by exposure to household bleaching products. Alternatives to sodium hypochlorite include sterile saline or water, (CHX) chlorhexidine (0.2\% to 2\%), iodine potassium iodide (2\% to 5\%), hydrogen peroxide (3\%), (EDTA) ethylenediamine tetra acetic acid (10\% to 17\%), citric acid (10\%) and other agents such as MTAD.

Allergic responses to CHX are rare and there are very few reports of reactions following root canal irrigation with CHX. However, some allergic reactions such as anaphylaxis, contact dermatitis and urticaria have been reported following direct contact to mucosal tissue\textsuperscript{9}.

**Acquired immuno deficiency syndrome and related conditions**

Acquired immuno deficiency syndrome (AIDS) is an infectious disease caused by Human immunodeficiency virus (HIV) that is transmitted predominantly through intimate sexual contact and by parenteral means. In view of the nature of this blood borne pathogen, HIV (a non-transforming retrovirus of lenti virus family) infection and AIDS have important implications for dental practitioners. Several conditions may be seen in patients suffering from AIDS viz. bacterial (multiple and recurrent) infections, fungal infections (predominantly candidiasis) and viral infections (e.g. cytomegalovirus)\textsuperscript{10}.

**Endodontic Considerations**

An assessment of CD4+ counts as well as baseline kidney and liver function would be desirable prior to the initiation of any dental procedure. No modification of irreversible procedures or surgical treatment is recommended unless patients have reduced platelet count (<50,000 cells per milliliter) or neutrophil counts (<1,000 cells per milliliter) and the patient may require antibiotic prophylaxis. Routine antibiotic use is contraindicated\textsuperscript{1}.

Dental clinicians should be aware of potential drug interactions in HIV-positive patients. Many of the medications commonly administered may interfere with the metabolism of the antiretroviral medications. Statistically, the chances of treating a HIV-positive patient in a dental practice have increased because of a steady state of rise of new HIV infections annually and increasing longevity from highly active antiretroviral therapy. The prognosis for successful healing of necrotic teeth with chronic apical periodontitis following root canal treatment is essentially the same for HIV-positive patients as for non-infected patients\textsuperscript{1}.

A small subgroup of patients with advanced HIV disease may require customized modification, such as antibiotic prophylaxis or transfusion of blood products for their care. However, no data currently exists supporting the need for routine antibiotic coverage to prevent bacteraemia or septicemia arising from a dental procedure.

**Organ Transplantation**

Patients who have undergone organ transplantation have a risk of contracting an infection as they would be on immunosuppressants. Pre-transplant patients should undergo eradication of dental disease, including endodontic procedures as warranted to remove any potential sources of infection and deferral of any elective treatments\textsuperscript{1,2,3}.

**Endodontic Considerations**

The endodontist should take into account the underlying condition for which the transplant is required. In the immediate post-transplant period, emergency dental procedures may be necessary. At this stage, patients are highly immunosuppressed to prevent organ rejection, so the American Heart Association (AHA) regimen of antibiotic prophylaxis with possible postoperative antibiotics may be recommended for invasive procedures. Further, patients may have indwelling catheters that may lead to a recommendation for antibiotic prophylaxis. After the post-transplant patient has stabilized, indicated dental procedures may be performed after consultation with the patient’s transplant team. Post-operative guidelines regarding prophylactic antibiotics have not been established but, if recommended, AHA...
Diabetes mellitus

Diabetes mellitus (DM) is a group of metabolic diseases characterized by high blood glucose level (hyperglycemia) and the inability to produce and/or use insulin. It results from several pathogenic processes ranging from autoimmune destruction of pancreatic beta cells in type 1 diabetes to abnormalities that cause insulin resistance as in type 2 diabetes mellitus. DM is diagnosed by assessing HbA1c (glycated hemoglobin A1c) level. Higher levels of HbA1c indicate poor control of blood glucose level.

Endodontic Considerations

It has been well established that hyposalivation, gingivitis, periodontitis and dental caries are associated with DM, when poorly controlled. Defects in immune status, altered bacterial flora and microvascular disease are the postulated pathogenesis of diabetic periodontal disease. In uncontrolled diabetes, there are chances of infection and poor wound healing. However it is imperative to ascertain how well controlled the diabetic status is, prior to the beginning of dental procedures. Restorative and endodontic appointment should be scheduled taking into account the patient’s diet and type of anti-diabetic medicament administered, in order to avoid the risk of hypoglycemia. For most patients with diabetes, routine use of local anesthetic with 1:100,000 epinephrine is well tolerated. When endodontic surgery is indicated in poorly controlled diabetics, antibiotic prophylaxis should be considered due to the altered function of neutrophils in diabetics.

CONCLUSION

Dental clinicians should be aware of the systemic conditions of the patient before they start with the routine dental procedure. Dental clinician and physician can work together to provide a holistic approach to improve patients care. They should identify and diagnose the conditions in order to take interceptive measures.

REFERENCES

1. Little and Falace’s Dental Management of the Medically Compromised Patient - 9th Edition
2. Ingle JI, Bakland LK, Baumgartner JC, Ingle JI. Ingle’s Endodontics 6th. Hamilton, ON; Maidenhead: BC Decker; McGraw-Hill Educa-
Role of Oral Physician in Improving Quality Of Life in Post Cancer Treated Patients


ABSTRACT

Aim: The awareness of patients regarding the importance of oral hygiene and dental checkup is still minimal. Even the dental professionals are not aware of the significant role they can play in the post therapy period and quality of life of the patient. This is a brief paper, which emphasizes the importance and role of oral physician in post cancer therapy. A treatment is never complete until all sources of disease are removed physically and mentally from the patient. Oral health and systemic health are mutually related.

Background: To achieve the complete well-being of the patient, structured protocols and methodologies are necessary right from referring the patient to the oncologist to final treatment and post treatment management. Society, relatives and internet resources affect the patients’ attitude and psychological set up towards the treatment and they need someone to listen to and understand. People who have received treatment for cancer are at risk of developing short term and long term oral side effects which may affect eating habits and quality of life. An oral physician may be the first person to see the patient and diagnose the oral disease and refer him/her for further treatment. So this may create a positive influence on the patient which could be used to work towards a better outcome. In the present era improved and advanced treatment options increase the patient’s survival rate. This calls for superior protocols to enhance post treatment quality of life of the patient where an oral physician also has a definite role.

Case scenarios: Four different case scenarios are presented with different backgrounds and strategies.

Conclusion: The oral physician, having close association with the patient, can create a positive influence on the patient which could be used to work towards a better outcome. In the present era, better and advanced treatment options increase the patients’ survival rate. This calls for better protocols to improve post treatment quality of life of the patient where an oral physician also has a definite role.

Key words: oral physician, post cancer therapy, quality of life,

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INTRODUCTION

Cure sometimes; Treat often; Comfort always:– Hippocrates (c. 460 - 400 BC)

Much has been discussed about pre, peri, and post cancer treatment needs and also about the role of an oral physician in the reinstatement and improvement of the quality of life of the post cancer treatment patient. But still there is paucity in connecting dental personnel to the team treating the cancer patient. This article discusses the problems faced by and the role of an oral physician in managing the post cancer treatment patient with examples from real life situations.

Common problems associated with post cancer treatment

1. Fear of not getting completely cured
2. Fear of recurrence
3. Morbidity associated with the disease as well as treatment
4. Fear of the expenses incurred and being a financial burden to others
5. Fear of not being socially accepted
6. Radiation, chemotherapy and surgery all can affect the food habits secondary to treatment especially in oral cancer.

Complications/after effects of various treatments

When surgical management is undertaken, functional deficits caused by initial alterations to facial structures affect patient’s ability to eat during and post treatment, which may pose a threat for patient’s nutritional needs and affect the speed of healing and recovery. Neurological concerns may arise due to cranial nerve involvement which may also lead to considerable disfigurement and reduction in self-esteem and social adjustment.2

Pain and other neurological problems after cancer therapy

Pain is a major problem even after therapy. Phantom metallic tastes are important new pieces of evidence about neural damage which need to be routinely assessed. Evaluation of taste sensation can frequently predict post treatment pain.3

Impaired speech

Communication and psychosocial functioning of patient are affected. International studies have reported that communication difficulties are a major source of psychological distress for patients with head and neck cancer. Chemoradiotherapy can affect functions like swallowing, speech etc. and may necessitate the early initiation of suitable exercises.4,5

Psychological affect

Various phases in the treatment of cancer and the as-
sociated complications will affect the patient’s mental status to a great extent. Other factors like cost of treatment, quality of life during and after therapy etc., will make the cancer patient isolated from society. A study by Neeraj K. Arora et al demonstrated that the patients felt that the doctor was not fully aware of the post treatment quality of life. Another study revealed that depression rather than pain is the major problem that is prevalent in post treatment patients.

An investigation among US patients revealed that psychological issues are not properly conveyed to and discussed with care providers.

**Post treatment care**

**Referral to the Dental surgeon**

Most diseases and treatment modalities for systemic diseases have an effect on the oral cavity. Certain interrogatives like how, when and what arise when referring a patient to the dental surgeon. Which need to be addressed. There should be a standardized protocol for referring a patient to a dental surgeon. For example patient should be educated and informed to carry all medical records which he needs to show the dental surgeon. A few personal experiences are cited here.

**Patient education**

**Case 1:** A male patient of age 60 years came to our OPD (Outpatient department) for dental consultation. He had undergone treatment for multiple myeloma and was referred to the dental professional for dental evaluation. Patient was not carrying any records of previous treatment which made us difficult to decide a proper treatment plan. When patient was educated and informed the necessity of carrying the previous records, he said that he, being a poor and uneducated daily worker, was not aware of the significance of revealing his medical problems and showing relevant records to the dental clinician and agreed to do so in future. Currently people are educated and well informed and most of the patients know the relevance of their medical status while undergoing dental treatment. But there is a stratum of society who needs to be intimated about such matters.

**Note:** Most of the time patient will be given proper guidance before being referred for the dental consultation and management. But in few cases this may not happen, thus posing problems and delay in treatment.

**Mental status of the patient**

**Case 2:** A 72 year old male patient came to OPD after treatment of oral cancer of the palate. There was an extensive Oro-antral communication in the hard palate extending to soft palate. An obturator was given for the patient, which helped him talk and have food normally. When the patient came to us, he was having mucositis, masticatory myalgia and carious tooth in the lower jaw. Patient was worried about undergoing any dental treatment for fear of getting recurrent cancer or even a new oral cancer. We had to educate and enlighten the patient before carrying out treatment. The obturator was removed and mucositis and myalgia were duly treated. To convince the patient for undergoing treatment and to remove his phobia of dental treatment a psychologist’s help was taken.

**Note:** Post cancer treatment patient needs a proper mental support. Many a time the dental treatment or consultation with the dental surgeon may reveal the lesion. Cancerophobia, negative attitude of society, and relatives may pose a challenge for patient. Depression

### Table 1 Challenges patient faces in everyday activities after different modes of treatment

<table>
<thead>
<tr>
<th>Treatment modality</th>
<th>Treatment specific outcome</th>
<th>Common problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical therapy</td>
<td>Facial appearance, Functional deficits, Surgical scar</td>
<td>Inability to speak, Loss of self esteem</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>Functional deficits, Fibrosis and Trismus, Salivary gland hypofunction and xerostomia, Oral fungal infection, Osteoradionecrosis, Altered taste.</td>
<td>Change in dietary habits, Decrease in relations, Isolation from society, Loss of job &amp; working atmosphere</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>Mucositis, hair loss, immune compromised state, Oral fungal infection</td>
<td></td>
</tr>
<tr>
<td>Bisphosphonate therapy if done</td>
<td>Bone necrosis at a later date</td>
<td></td>
</tr>
</tbody>
</table>
happens to be part of the disease as suggested by A D Davies, C Davies and M C Delpo. Careful management, educating the patient and relatives, counseling the patient and informing the do's and don'ts to the patient all will lead to a good outcome. Development of a positive attitude towards the cancer and its treatment helps in fast recovery and better prognosis.

Case 3: Another patient after surgical therapy of oral cancer used to come to us with the fear of recurrence of his cancer. Surgical scar in the area always reminded him of the previous cancer which made him visit us every month to confirm that no recurrence was present. Early death of his brother due to oral cancer had contributed and added up to his fear.

Note: Many patients will be apprehensive after the diagnosis of a malignancy even if it is in some other known person. So a lot of reassurance and counselling may be needed. Since the Oral Physician will be the first to see the patient, he/she may be more comfortable with him in revealing his fears and apprehensions.

Case 4: A male patient of age 55 came to us with drug induced osteonecrosis with bone exposure in maxilla and mandible and pain in the jaws. Patient gave a history of multiple myeloma 10 years back which was treated and cured. Retreatment following recurrence for the same was done 3 years back. Patient was on bisphosphonate therapy, initially parenteral and later oral which was the cause for osteonecrosis. Patient was having a strong positive attitude and was ready to face any kind of treatment. He was treated with plasma rich protein and other dental treatments were carried out duly. After dental treatment there was fast improvement in patient's condition. One of the reasons behind his fast recovery was his positive attitude and mental strength.

Note: The reaction to disease is an individual matter. When the patient has a positive attitude it is one's duty to boost and strengthen this. The outcome in this case is highly positive.

Considering the varied attitudes and diversity in psychological makeup of patients and their attitude towards cancer and its treatment we need a special training to handle the post cancer treated patients. It is prudent for the oral physician to have training in counselling also.

Why wellness of orofacial region is important in systemic diseases and in cancer therapy?

Research has shown that dental and occlusal harmony is directly linked to the normalization of many chronic symptoms in varied disease states. The neural crest cell derivatives are found throughout the body. The neural crest cells produce the balance of the nervous system, part of hormonal system, and part of dental system. These three systems are intimately related in origin, and are associated throughout life in all bodily functions, in health and in disease. According to Penfield and Rasmussen, about 50% of sensory and motor attributes of brain correspond to stomatognathic system. So, this system plays a major role in the neuronal control of the body. This again puts the stomatognathic system in a controlling position and the integrity of the dental occlusion also may be crucial in the health of other parts of the body in more ways than we have understood. This understanding of the close relationship dental health and systemic health and need for maintaining both underlines the significance and the role of oral physician in maintaining general health.

What is the role of dental clinician in the management of post malignancy treatment?

Currently the survival rate of cancer patients including oral cancer has increased. This has created a special category of patients with different needs and care protocol. Since many of them are associated with oral and peri-oral areas it is only prudential that the oral physician be the one to carry out the same. So special training needs also arise for the oral physician as well.

Effective communication between the patient and doctor can enable the patient to harmonize his/her emotions. It also helps patient understand the essentials of the medical aspects and the doctor understand patient's perspectives.

Management strategies

1. Manage side effects of cancer therapy
2. Full mouth periodontal examination
3. Review plaque control and motivation
4. Scaling and root debridement
5. Review home fluoride use
6. Administer topical application of fluoride
7. Review xerostomia
8. Assess dietary practices
9. Additional hygiene appointments

Children

Monitoring of Growth and development

Dental review at least every six months

For patients with xerostomia, trismus, severe graft-versus-host disease or severe mucositis a three month review is recommended. The patho-biologic outcomes of oral tissues after various modalities of cancer treatment, especially after head and neck cancer therapy, is exigent for both the oncologists and the dental professional. So quality of life of patient can be improved if we plan the treatment anticipating this.

Efforts to incorporate earlier and more effective end-of-life care must address honestly and unambiguously patients' unrealistic expectations about the outcomes of chemotherapy. Patients should be educated truthfully and clearly beforehand about the complications and outcomes so as to restore the faith without imparting either unrealistic expectations or hopelessness.
all food can be a driving force in life and so is smile and communication. It is the mouth that facilitates all these and the oral physician definitely can contribute much in this area.

**Take home messages**

1. Cancer is one disease that is still not understood completely by the clinician and feared by the patient.
2. Anybody who has come across the anguishs, complications, hitches and torments related to cancer and its therapy directly or indirectly are frightened, petrified and scared stiff of the condition.
3. Any attempt to pacify and palliate the patient will have positive effect.
4. Oral physicians have a definite role to play as they are the care takers of the oral cavity and mouth is an important part of the body for a comfortable life.

**CONCLUSION**

The oral complications are not restricted to head and neck cancer patients. Almost every systemic disease or medication patient is using will have one or other oral manifestation, which has to be diagnosed and managed by the oral physician. Most of the patients may not correlate oral manifestation as a part of cancer treatment. At the same time some patients may relate everything to the cancer and its treatment. So the onus to convince both groups and to manage them according to the need is vested on the oral physician.

**Cure May Be Limited; But Not Care**

**REFERENCES**

Adherence to ATLS protocols for primary survey


ABSTRACT

Background and methods: Advanced Trauma Life Support Program has been developed by the American College of Surgeons Committee on Trauma providing comprehensive and easily adaptable knowledge and techniques for the systematic, concise approach to the early care-rapid and accurate assessment, resuscitation and stabilization, transfer and management-of multiply injured patients. The golden hour for the trauma patients starts from the time of injury. The primary survey is to quickly identify, assess, stabilize and manage life-threatening conditions, if exist, adhering to the sequence of ABCDE (vide under Introduction). This prospective observational study was performed on trauma patients presenting to the Emergency Department, Amrita Institute of Medical Sciences, Kochi, Kerala, India-a tertiary care hospital.

Objective: To evaluate the adherence to the ATLS protocols for the Primary Survey by the medical professionals in trauma care for the Continuous Quality Improvement.

Results: In this study, which was conducted over a period of six months, in the first month we had 42 patients, second month 28 patients, third, fourth, fifth and sixth months- 24, 27, 25 and 29 patients respectively. In the first month ABC were secured in more than 80% of patients. In second and third month it was more than 80% to 85%. In the fourth and fifth month the adherence improved and became between 85% to 100%. Last month showed significant improvement in the adherence and ABC were secured in more than 95% to 100% of patients.

Conclusion: In conclusion, we found that adherence to ATLS protocols for primary survey in the management of trauma patients had shown quality improvement from first month to the last month. Immediate intervention by the team leader ensured appropriate patient care in instances of non-adherence to the Protocols by attending medical persons. Followed by regular monitoring of the care givers’ adherence to the Protocols, frequent training at the interval of at least three months, improved the adherenc rate. Whenever there is a decline in adherence rate, immediate interventions were made by reinforcing with retraining. Educating EMTs, paramedics and other medical professionals on ATLS Protocols for primary and secondary survey resulted insignificant improvement in the adherence rate.

We recommend frequent training, on the spot monitoring and evaluation of adherence to protocols, immediate corrective measures and frequent retraining at periodic intervals to achieve improved patient care with increased rate of adherence to the protocols.

Keywords: Advanced Trauma Life support, life-threatening injuries, airway, primary survey.

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INTRODUCTION

Advanced Trauma Life Support guidelines and protocols have been developed to standardize the rapid and accurate assessment and management of trauma patients with a systematic, concise approach keeping in mind the golden hour which starts from the time of trauma. The primary survey is to quickly identify, assess, stabilize and manage any life-threatening condition(s) if exist adhering to the sequence of ABCDE: A-Airway maintenance with cervical spine protection. B- Breathing with ventilation. C-Circulation with hemorrhage control. D- Disability: Neurologic status. E- Exposure/Environmental control:

In single responder settings, these may be addressed in a linear or sequential fashion; however, when a team is assembled, these elements may be addressed simultaneously. Though the term ‘survey’ implies only the assessment, it also encompasses simultaneous assessment and management of the life threats identified.

Quality Control involves systematic, formal approach to the analysis and evaluation of existing practice performances and measures to further improve the same. Continuous Quality Improvement is an essential scientific management tool for the improvement of quality in patient care which will be reflected by better patient outcomes.

METHODOLOGY

Inclusion criteria

All trauma patients presenting to our Emergency Department.

Exclusion criteria

• Patients brought dead.
• Patients with open brain injury
• Pregnant patients

Structure, material and location

This is a prospective observational study conducted.
from July 2017 to December 2017 at Amrita Institute of Medical Sciences (AIMS), Kochi. A trauma team is developed to provide a safe and efficient evaluation and care to the trauma patients. These members are available immediately or within minutes of trauma team activation. The team has the following members who have preassigned roles:

1. Team leader-EDPhysician
2. Anesthesiologist
3. Trauma surgeon
4. Emergency medical technicians (EMT)
5. ED nurses
6. ED interns
7. Radiographers

Other in house consultants available on call include:
1. Neurosurgeon
2. Cardiothoracic surgeon
3. Plastic surgeon
4. Radiologist

All patient care activities were monitored by an ATLS trained person. Both actions and documentations were monitored. Steps were monitored by the team leader without affecting the patient care. The patient assessment and management sequences are as follows:

1. -- Airway with cervical spine precautions or protection.
4. Placing airway adjuncts- oropharyngeal or nasopharyngeal airway.
5. Definitive airway- endotracheal intubation.
6. Surgical airways-

**Breathing and ventilation.**

Respiratory rate
1. Oxygen saturation
2. Supplementation of oxygen.
3. Assessment of cyanosis
4. Assessment of air entry

Physical examination – inspection, palpation, percussion and auscultation.

**Circulation with hemorrhage control.**

1. Heart rate
2. Character of pulse, pulse volume,
3. Blood pressure
4. Capillary refilling time.
5. External hemorrhage.

6. 2 large bore IV cannulas.

**Disability (assessing neurologic status)**
1. GCS
2. Pupillary reaction, size
3. Other neurological deficit

**Exposure and environmental control.**
1. Temperature
2. Random blood sugar.

**RESULTS**

The six month period study included a total of 175 patients. Their month wise distribution is as follows:

1. 1st month- 42 patients
2. 2nd month-28 patients
3. 3rd month- 24 patients
4. 4th month- 27 patients
5. 5th month- 25 patients and
6. 6th month-29 patients

The results of the adherence to ATLS Primary Survey Protocols by medical professionals are all self explanatory from Figures 1 to 6.
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Fig 2: Graph showing adherence to primary survey in second month.

Fig 3: Graph showing adherence to primary survey in third month.

Fig 4: Graph showing adherence to primary survey in fourth month.

Fig 5: Graph showing adherence to primary survey in fifth month.
**DISCUSSION**

This is a prospective observational study conducted on trauma patients presenting to our Emergency Department over a period of 6 months. First month we had 42 patients and the number of patients presented in the second, third, fourth, fifth and sixth month were 28, 24, 27, 25 and 29 respectively.

The adherence to the ATLS Primary Survey Protocols is as follows:

Regarding the Airway with Cervical spine protection it was 81% (34 patients) in the first month which steadily improved to 96% in the last two months.

With regard to Breathing, the adherence started at 86% in the first month to reach a target of 100% in the last month through 96% in the preceding month five.

As for as the Circulation (except 2 large bore cannula insertion) was concerned, the adherence rate was 96% from the beginning itself to reach and maintain at 100% from third month onwards with a slight dip to 90% in month two.

In the Circulation, adherence to 2 large bore cannula insertion initially in the first three months were 48%, 50% and 59% respectively which raised to 70% in the fourth month and ultimately to 100% in the last two months, of course with multiple reinforcements with repeated training.

Adherence to GCS assessment was 93% in the first month. There was a dip to 75% in the second month which raised to 96% and 100% in the subsequent months again to go to 96% in the last two months.

Pupillary assessment adherence was only 91% in the first three months which touched 100% in the fourth month to fall back to 92% and 93% in month five and six respectively.

When comparing the first month with the last month there is a marked improvement in approach to patient and adherence to the protocol. Appropriate training, and monitoring of the adherence to the protocol, on the scene reinforcement measures for non adherence and frequent retraining at regular intervals all fetched this improvement. Proper training and frequent retraining at regular intervals of 3 or 6 months made EMTs and other medical personnel to adhere more and more to ATLS Protocols.

At an average of three monthly interval there arrives a new health care personnel to the Emergency Department needing training if not already trained in the needed areas.

**CONCLUSION**

From our study we found that there had been a steady increase in the adherence rate to ATLS protocols in primary survey in the management of trauma patients from the first month to the last month which reflected the continuous quality improvement in the patient care. Any non adherence to the protocol by any one is immediately intervened by the team leader to ensure appropriate patient care. Apart from frequent retraining at regular intervals, on the scene monitoring of adherence and reinforcement if any non adherence found enabled the improvement in the adherence rate and quality care. There is a need for frequent assessment and retraining at least at the interval of three months. During our study period, the EMTs and other medical personnel were appropriately trained with different case scenarios and simulations which resulted in improved adherence to the protocols.

**REFERENCES**


Factors influencing duration of hearing aid use in elderly population

Aparna Prasanna*, Praveena Davis**, Sreebha Sreedhar**

ABSTRACT

Literature describes that percentage of successful hearing aid users in elderly are comparatively less. Hence the purpose of this study was to explore the influencing factors for increasing hearing aid use among elderly.

Objectives: To develop a questionnaire capable of identifying the influence of known factors on hearing aid use. To explore the percentage of known factors that may contribute to hearing aid use. To find out the relation between age, gender, speech discrimination score (SDS), and known factors, on duration of hearing aid use per day.

Methods: Participants included 35 elderly individuals fitted with hearing aid for the first time since a month, having SDS > 60%, within the age range 60-80 years. Based on the identified variables from literatures, a questionnaire (Hearing aid Use checking Profile [HUP]) was developed and administered in the participants.

Results and Conclusions: 34 participants were hearing aids users of which 30 were daily users with varied duration per day from 2 to 16 hours. The factors attitude, localisation difficulty, hearing aid performance in noisy environment, telephonic conversation, and booming quality of sound from hearing aid were found to have the greatest negative influence. There is no statistically significant correlation between age, gender, SDS and the duration of hearing aid use per day. Six among 35 statements in the questionnaire highly correlate with duration of hearing aid use per day. The study could find out certain factors which need to be addressed and emphasized in rehabilitation to increase the hearing aid use among elderly.

Key words: Hearing aid, Use, Factors, Elderly, Hearing loss

INTRODUCTION

Hearing impairment is the most common disability, affecting more than 250 million people in the world1. In accordance to World Health Organisation 2012, “Disabling hearing loss”, is defined as hearing loss greater than 40 dB in the better hearing ear in adults (15 years or older) and greater than 30 dB in the better hearing ear in children (0 to 14 years)2. The prevalence of hearing loss in Southeast Asia ranges from 4.6% to 8.8%3. In India, 63 million people, which counts to 6.3% of total population, suffers from significant hearing loss or hearing impairment, which is a result of structural or functional deficit in the auditory system. This can be divided into congenital and acquired hearing loss. WHO global estimates 2018 reveals that 93% of hearing impaired population are adults and 7% are children and also suggest that one-third of elderly persons are affected by disabling hearing loss.

Taking note of birth-death rate, the elderly population is projected to grow from 8 percent to 16 percent of the world population from 2010 to 2050 based on WHO, 20113. In India, this growth is very steady, and is expected to rise up to 12.7 percent by 2026. According to 2001 census, the proportion of elderly in total population vary from around 4% in small states like Dadra & Nagar Haveli, Nagaland, Arunachal Pradesh, Meghalaya to more than 8% in Maharashtra, Tamil Nadu, Punjab, Himachal Pradesh and 10.5% in Kerala (Ministry of Statistics & Programme Implementation, Government of India)4. This statistical growth indicates the requisite for interventions to ensure life and dignity for the elderly population in the country.

The primary clinical management for people with hearing loss is hearing aids which primarily focus on amplification of sounds. It is recommended to help the individual in the day to day communication situation and to avoid social isolation or impairment. Recent studies on hearing aid use in elderly population, describes that percentage of successful hearing aid users are comparatively less5. The estimated proportion of hearing aids that have been either discarded or seldom used varies from 5%6 to 30%7. The reason for this down ratio in statistics for less hearing aid usage can be poor benefit,
lack of comfort, or personal issues.
Several factors may affect the frequency of hearing aid use and its success, like audiological factors, personal factors, hearing aid performance\(^8\) and care and maintenance of hearing aid.

Audiological factors include type and degree of hearing loss, configuration of hearing loss, experience and skill of audiologist and speech discrimination scores as having an influence on hearing aid use. Speech discrimination score (SDS) predicts the benefit from hearing aid fitting. For individuals who have a SDS of greater than 60 percent are expected to benefit from hearing aid fitting.

Numerous studies have examined on the influence of different personal factors on hearing aid use. The reason for non use and factors affecting included cosmetic appeal, discomfort and motivation\(^9\), family support, attitudinal beliefs\(^3,10\,12\), self perception of hearing loss\(^13\,15\) awareness\(^16\), motivation\(^14\), need for hearing aid, impact of hearing loss, and expectations from hearing aid\(^15\).

Greater hearing-related activity limitations and participation restrictions predicts hearing aid (HA) uptake and use\(^17,18\).

Even though several advancement in hearing aid technologies has been evolved for better listening comfort, the hearing aid usage ratio is less among elderly, which is of significant concern. Hearing aid performance related factors such as ‘hearing aid does not help or provides poor benefit’\(^6,8,19\,21\) and difficulty in noisy situations/background noise as a reason for deduced hearing aid use\(^6,8,20,21\), poor sound quality\(^8,22\,24\) and ‘difficulty in putting hearing aid in and out’\(^6,20,21,25\), uncomfortable\(^6,8,12,20-25\), hearing aid not working properly/broken\(^11,21,25\), feedback and whistling\(^6,19,21\), disappointment with the hearing aid\(^12\), ‘hearing aid needs servicing’\(^25\), battery life is too short ‘and’ ‘poor directivity’ as an influence on hearing aid use.

Literatures suggest that factors in relation with care and maintenance of hearing aid such as handling problems/manual dexterity\(^8,11,19,22,24\), need help changing the batteries\(^6,20,25\), problems with ‘volume control adjustment’\(^20\) and rashes and itching\(^6,19\) do influence hearing aid use among elderly population. The identification of these factors of hearing aid use is necessary for moulding an appropriate rehabilitation approach for the elderly\(^15\), which can be obtained through a questionnaire.

There are several standardised questionnaires which aim to measure hearing handicap and hearing aid benefit in English. But in Malayalam, the questionnaires are limited, and the only questionnaire which is available is for obtaining hearing aid benefit and that is Abbreviated Profile of Hearing Aid Benefit (APHAB) in Malayalam version. The questionnaires focus on measuring hearing aid benefit and satisfaction in specific situations, which is either given in the questionnaire or suggested by the hearing aid user. The use of hearing aid is depended on the benefit from hearing aid, even though, hearing aid benefit questionnaires does not help to study the factors associated with hearing aid use. And there are no standardised questionnaires which are available for finding out the factors affecting hearing aid use.

Hence the present study aims to explore the variables that may contribute to hearing aid use in elderly through a developed questionnaire and to suggest future modifications needed in rehabilitation. The objectives were 1) To develop a questionnaire capable of identifying the influence of known factors on hearing aid use 2) To explore the percentage of known factors that may contribute to hearing aid use 3) To find out the relation between age, gender, SDS, and factors affecting hearing aid use on duration of hearing aid use per day.

**MATERIALS AND METHODS**

**Participants**

Our study was conducted on 35 participants within the age range of 60-80 years, (Mean=69.3years). Out of the participants, 15 were females and 20 were males. All the participants selected were Malayalam speaking elderly individuals with acquired hearing loss having speech discrimination scores greater than 60% and fitted with hearing aids for the first time, since one month from National Institute of Speech and Hearing (NISH), Trivandrum from July 2015 to December 2015. Elderly individuals with any kind of associated conditions such as intellectual disabilities, motor, visual or any other neurological conditions and congenital hearing loss were excluded.

**Procedure**

The study was completed in two stages. Stage 1 included questionnaire development. The questionnaire was developed in 2 steps. Initial step of the development dealt with the item generation based on review of literature, book reference, clinical experience and expertise opinion. Statements were developed based on the known factors, in Malayalam language, which are capable of exploring the factors influencing hearing aid use in elderly individuals. These statements were designed as to rate on a five point likert rating scale, ranging from strongly agree to strongly disagree (strongly agree, agree, neutral, disagree, strongly disagree). In the second step for item reduction and to obtain the content validity, the statements were rated by eight experts in the field of audiological rehabilitation, based on relevance, language appropriateness, grammatical structure and comprehension in a 5 point likert scale. The statements scored greater than 60% by six of the experts were considered for the study and other statements were avoided. The developed questionnaire named ‘Hearing Aid Use Checking Profile’ (HUP), consisted of 35 statements. These statements in the questionnaire were grouped under four domains such as personal factors,
audiological factors, hearing aid related factors and care and maintenance of hearing aid, for the ease of analysis and understanding. Known factors under each domain are tabulated in Table I.

<table>
<thead>
<tr>
<th>Personal factors (17 statements)</th>
<th>Audiological factors (2 statements)</th>
<th>Hearing aid related factors (10 statements)</th>
<th>Care and maintenance of hearing aid (5 statements)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attitude</td>
<td>Audiological service</td>
<td>Satisfaction from aid</td>
<td>Hearing aid complaints</td>
</tr>
<tr>
<td>Awareness</td>
<td>Service from dispenser</td>
<td>Localisation ability</td>
<td>Service availability</td>
</tr>
<tr>
<td>Motivation</td>
<td></td>
<td>Quality of sound from hearing aid</td>
<td>Troubleshooting capability</td>
</tr>
<tr>
<td>Acceptance</td>
<td></td>
<td>Listening in different situation</td>
<td>Ear mould discomfort and maintenance</td>
</tr>
<tr>
<td>Expectation</td>
<td></td>
<td>Feedback problem</td>
<td>Battery life</td>
</tr>
<tr>
<td>Satisfaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dexterity</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table I: Known factors under each domains based on which statements in the questionnaire were formulated.

Each HUP items are rated on a 5 point Likert scale ranging from strongly agree to strongly disagree (strongly agree, agree, neutral, disagree, strongly disagree). Higher scores indicates more positive influence of the factor. The second stage of the study includes data collection and data analysis. The data was collected from 35 participants from National Institute of Speech and Hearing (NISH), when patients reported to NISH for their first reprogramming of hearing aid after 1 month of hearing aid fitting. Prior to the participation in the study, the researcher explained about the aim of the study and took consent from each participant. A case history which included details about demographic data, results of audiological evaluation, hearing aid prescribed and its duration of use was obtained from the selected participants. Then Hearing aid use checking profile (HUP) was administered on each of the participants. For the analysis, the options in the questionnaire were scored on a 5 point rating scale, based on its effect on hearing aid use. In the rating scale, 4 indicates greater than 90% positive effect of the factor, 3 indicates greater than 75% positive effect of the factor, 2 indicates neither positive nor negative effect of the factor, 1 indicates greater than 75% negative effect of the factor and 0 indicates greater than 90% negative effect of the factor. The data obtained from each participant were documented and percentages of the influenced factors in the participants were obtained using SPSS software (version 22.0). The relation between age, SDS, and statements in the questionnaire on duration of hearing aid use were analysed using spearman rank correlation and relation between gender and duration of hearing use tested using independent $t$ test.

**RESULTS**

**Demographics and hearing aid use**

The age of the participants varied from 60-80 years (mean=69.34 years) in which 20 were males and 15 were females. The SDS scores varied from 60 % to 100 % with a mean score of 80.71% with a standard deviation (SD) of 13.73. Based on the audiogram, all participants were fitted with digital hearing aids, and only one participant was using hearing aids binaurally. Of the 35 participants, 30 participants (85.7%) had used the hearing aids daily (all thirty days), though the duration of use per day varied. Among the five who had not used hearing aids daily, one had discontinued hearing aid use after 2 days of aid fitting, one used hearing aid only during working hours (15 days), and other three used for 10, 12 and 20 days respectively. The duration of hearing aid use among participants in a day varied from 2 hours to 16 hours with a median of 4.5 hours per day. Of the 35 participants, $n=19$. 54.3% where found to be using hearing aid more than the obtained median of 4.5 hours per day (Figure 1).

![Graphical representation hearing aid use per day obtained from 35 Participants](image)

**Note:** Median 4.5 hours is indicated by a straight line
Factors influencing duration of hearing aid use in elderly population

**Known factors affecting hearing aid use in elderly**

Response scoring in the questionnaire was collated for the purpose of analysis. In the likert scale, scores 0 and 1 were considered as a factor having a negative influence on hearing aid use and scores 3 and 4 were considered as a factor having a positive influence on hearing aid use.

Out of the 17 statements focused on personal factors, greater percentage of negative influence was observed in statement 11, which focused on attitude about hearing aid use, and second greater negative influence in statement 6, which focused on expectation from hearing aid, and third greater influence on statement 2 about attitude. Percentage of negative influence indicated by 35 participants in each statement related to personal factors is depicted in figure 2.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percentage of Negative influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>35%</td>
</tr>
<tr>
<td>6</td>
<td>30%</td>
</tr>
<tr>
<td>2</td>
<td>28%</td>
</tr>
</tbody>
</table>

The three main statements which showed the greater negative influence on hearing aid use out of the 10 statements in hearing aid performance related factors were the responses from statement 19, 22 and 26 which focused on localisation difficulty, telephonic conversation and listening through noisy situation respectively. Percentage of negative influence indicated by 35 participants in each statement related to hearing aid related factors is depicted in figure 3.

<table>
<thead>
<tr>
<th>Statement number</th>
<th>Percentage of negative influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>31%</td>
</tr>
<tr>
<td>22</td>
<td>28%</td>
</tr>
<tr>
<td>26</td>
<td>25%</td>
</tr>
</tbody>
</table>

In the audiological factors, Statement 28, pinpointing satisfaction from audiological services, was positively opined by 63% of the participants, whereas 37.1% were not satisfied with the services provided. In statement 29, regarding the hearing aid servicing, 91.4% of the participants were unsure and 8.6% of the participants indicated good hearing aid servicing availability.

In factors related to care and maintenance of hearing aid, Statement 30 and 31, which focused on damage of hearing aid and hearing aid repair and service availability, majority of the participants were unsure, with percentage of 88.6% and 94.3% respectively. In statement 32, 60% of the participants indicated lack of knowledge about troubleshooting and volume adjustment whereas 31.4% were unsure. In statement 33, which is concerned with discomfort with the use of ear mould, 42.8% of the participants indicated discomfort, 54.3% indicated comfortable wearing and 31.4% were unsure. In statement 34, difficulty in maintenance of hearing aid from ear wax and sweat is focussed, 60% indicated positive influence, and 31.4% suggested having maintenance difficulty due to sweat and wax. In statement 35, which focused on the battery drain, 48.5% indicated difficulty whereas 45.8% indicated positive influence showing no difficulty and 5.7% of the participants were unsure.

In total, out of the 35 statements, the statement 11 (At-
titude as, to use hearing aid only when needed), 19 (Localisation difficulty), 22 (telephonic conversation difficulty with hearing aid), 26 (hearing aid performance in noisy environment), 20 (booming quality of sound from hearing aid) had the greatest percentage of negative influence (Figure 4).

![Percentage of negative influence](image)

Figure 4: The graphical representation of negative influence obtained statement 11, 19, 22, 26, 20.

**Relation of age, gender, SDS and factors affecting hearing aid use to duration of hearing aid use per day**

**Age and duration of hearing aid use**

The relation between age and the duration of hearing aid was calculated using spearman rank correlation. Results revealed no statistically significant correlation between hearing aid use and age with a p value of 0.874.

**Gender and duration of hearing aid use**

The mean duration of hearing aid use among males is 5.72 hours and for females it is 7.23 hours. Even though there is differences between the mean values of hearing aid duration among males and females, there is no statistically significant difference between duration of hearing aid use across gender in the current study, when tested using Independent sample t test, (p</=0.05).

**SDS and hearing aid use**

The relation between SDS and the duration of hearing aid was calculated using spearman rank correlation and found that there is no statistically significant correlation between hearing aid use and SDS.

**Questionnaire analysis and duration of hearing aid use.**

The correlation between each statements and duration of hearing aid use had been calculated using Spearman rank correlation and found that the statement 10 (Attitude), 12 (Attitude), 14 (Accessibility), 18 (Satisfaction), 25 (Hearing aid performance in TV listening) and 28 (Audiological service) is found to have highly correlated with the duration of hearing aid use per day, (p</=0.05) (Table II).

<table>
<thead>
<tr>
<th>Statement No</th>
<th>Statements</th>
<th>P-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>S:10</td>
<td>It’s better to adjust with hearing loss than to be fitted with hearing aid.</td>
<td>.001</td>
</tr>
<tr>
<td>S:12</td>
<td>I feel the decision made to procure and use hearing aid is good.</td>
<td>.039</td>
</tr>
<tr>
<td>S:14</td>
<td>I am able to approach the audiologist for hearing evaluation and aid pro-</td>
<td>.017</td>
</tr>
<tr>
<td></td>
<td>gramming when needed.</td>
<td></td>
</tr>
<tr>
<td>S:18</td>
<td>I am satisfied with my hearing aid performance.</td>
<td>.001</td>
</tr>
<tr>
<td>S:25</td>
<td>My hearing aid helps me in TV listening.</td>
<td>.047</td>
</tr>
<tr>
<td>S:28</td>
<td>I am not satisfied with the audiological service provided to select the</td>
<td>.023</td>
</tr>
<tr>
<td></td>
<td>hearing aid.</td>
<td></td>
</tr>
</tbody>
</table>

Table II. Statements with their correlation p values with duration of hearing aid use.
DISCUSSION

As the above results points out, of the 35 participants except one, all 34 were receiving benefit from using a hearing aid, even though the duration of use varies. Only one participant (2.9% of the total participants) was a non-user, who rejected hearing aid after 2 days of fitting. Twenty five percent of the participants used the hearing aids more than 8 hours per day, while 34% used it 4-8 hours per day and 40% used it 2-4 hours per day. The data clearly indicates an increased proportion of hearing aid use among elderly in the participants studied, when compared to findings from other literatures. When compared to studies showing a hearing aid rejection rate of 5% to 30%, our study showed a rejection rate less than 3%. Lup-sakko et al 11 reported 55% “full-time hearing aid users”, 20% “part-time users” and 35% “non-users” based on the user’s perception in informants older than 75 years, Whereas Stark and Hickson26, reported only 14% using more than 8 hour and 28% using 4-8 hours, 31.2% using for 1-4 hours and 26.9% using less than 1 hour per day. This discrepancy in results obtained in this study compared to the literatures, could be either due to reduced sample size and strict criteria of speech discrimination score used in this study or due to differences in geographical, regional and service delivery approaches across areas where researches are conducted.

Greater negative influence obtained in statement 2, indicate that majority avoids conversation and this can have an influence on hearing aid use which is in agreement with the results suggested by Helvik et al 17 that the social stigma or attitude to hide the disability might influence the hearing aid use. Out of the participants, majority had higher expectation as indicated by the results from statement 6; this indicates the need for detailed counselling during the rehabilitation procedure. Attitude as, to use hearing aid only when needed has been agreed by majority of the population suggesting that this could be an important factor which would have limited the duration of hearing aid use per day. Several literatures reported a difficulty in multi-listening environments such as telephonic conversation, noisy environment, group discussions, listening in quite environment and TV listening (Kochkin, 2000). As per the current study majority of the participants had telephonic conversation difficulty, difficulty listening in noisy environment, group conversation difficulty and minority of the participants had difficulty in listening in quite environment and TV listening. 85% to 89% of participants were satisfied with hearing aid performance for watching television and conversing in quiet than in noisy situation.

Several other studies have also shown a higher percentage of participants report satisfaction in quiet than in noise. Studies suggested that difficulty coping with signals in noise and inappropriate hearing aid fitting as a reason for non use of hearing aids. Poor help and benefit from hearing aid is another main reason for reduced hearing aid use among elderly. Telephonic conversation difficulty leads to lesser satisfaction from hearing aid thereby affecting hearing aid use. Greater satisfaction with hearing aid can be attributed to clarity of sound; comfort with loud sounds and its performance in multi listening situations specifically group conversations. The results obtained from statement 28 suggest that majority of the participants were satisfied with the audiological service provided. And the pointed dissatisfaction by other participants can be suggested as a cause for reduced hearing aid usage among elderly in literatures, even though contradictory conclusion has been obtained in other studies. In statement 29, regarding the hearing aid servicing, 91.4% of the participants were unsure and 8.6% of the participants indicated good hearing aid servicing availability. The results obtained indicated that majority of the participants had no complaints on hearing aid working condition as it is a newly procured hearing aid and hence no need for hearing aid servicing. The results from statement 30 and 31 also suggest that majority of the participants had no compliant of hearing aid and there was no need for hearing aid servicing within a month. Results from statement 33 indicate that near to half of the participants had difficulty with ear mould. The results from statement 34 indicate majority did not have the maintenance problem due to sweat and wax. The results from statement 35 indicated that nearly half of the participants had difficulty with battery drain. Factors like ‘changing the batteries’, problems with ‘volume control adjustment’ and rashes and itching do influence hearing aid fitting in elderly population and is well documented by researchers. The participant who had rejected hearing aid after 2 days of fitting, due to distortion and increased background noise was unsure of most of the statements.

CONCLUSION

Out of the 35 factors assessed using questionnaire, the statement 11 (Attitude as, to use hearing aid only when needed), 19 (Localisation difficulty), 22 (telephonic conversation difficulty with hearing aid), 26 (hearing aid performance in noisy environment), 20 (booming quality of sound from hearing aid) had the greatest percentage of negative influence. There is no statistically significant correlation between age, gender, SDS and the duration of hearing aid use per day. Six among 35 statements in the questionnaire highly correlate with duration of hearing aid use per day suggesting that these factors are important and needs to be emphasized in rehabilitation. Although the results obtained from this study indicates that majority of the participants are daily hearing aid users, the duration of hearing aid use is varying. Even then when comparing with available literature, user’s...
ratio is greater with 34 participants using the hearing and only one person rejecting it. The increased user rate and increased satisfaction may be the result of better hearing aid selection and fitting criteria. The user rate could have been influenced by the factor that the study was conducted in participants who came for routine reprogramming after their first hearing aid fit. In spite of this, 97% of the participants were using their hearing aids pointing better selection criteria. As inclusion criteria was stringent with elderly participants having SDS greater than 60%, and questionnaires was administered after one month of first hearing aid use, the number of participants obtained were less within the stipulated time frame. This might also have reflected in the user non user ratio. The minority who are nonusers or users with difficulties also pose an important concern for an audiologist. Hence there is a need to solve problems like negative attitude, satisfaction, telephonic conversation difficulty etc through modifications, needed from the part of audiologist, client, family or care giver, and hearing aid manufacturers.

Although this study provides much insight into the known factors affecting hearing aid use in elderly population, there were some limitations. Current study of one month might not give a clear depiction of the factors, a duration of 6 month or 1 year could have been more informative and factors such as number of channels of hearing aid could have influenced the results. The small sample size that was obtained for this study is also a limitation which is to be considered in future research. The current study failed to compare the influence of factors between hearing aid users and non-users, due to non-availability of enough non users with the inclusion criteria constraints. The types of hearing aid used by the participants vary in the current study.

ACKNOWLEDGEMENT

The present study is not funded by any authority and there is no conflict of interest.

REFERENCES
23. Hickson, L., C. Meyer, K. Lovelock, M. Lampert et al. “Factors Associated with Success with Hearing Aids in Older Adults.” Interna-


ABSTRACT

In today’s setting, one of the great challenges is to fulfill the proper execution of measurements and compliance of various laboratory investigations, with the internal and external quality control specifications. Our aim was to compare the values of the highly critical parameter haemoglobin (Hb) determined with Point of Care Testing (POCT) devices and central laboratory analyzers (ZL) in a highly vulnerable setting of an emergency department in a tertiary care hospital and to assess the quality of POC devices performance. Haemoglobin measurements using POCT devices (POC-Hb) were compared with Hb measurements performed at the central laboratory (Hb-ZL) in 490 patients and analysed. Overall, the correlation between POC-Hb and Hb-ZL was a highly significant positive correlation (r = 0.823, p<0.001) & the results were showing excellent agreement between POC-Hb & HB-ZL (ICC=0.902, 95%confidence interval = (0.88,0.92)). Additionally, sub collective groups, WHO anaemia classification, patients with Hb <8 g/dl and geriatric patients (age > 85 yrs.) were analysed. In the former group, and in clinically significant Hb < 8 g/dl showed good similarity between POC-Hb and Hb-ZL, while in geriatric patients, the study showed highly significant positive correlation (r=0.974, p value< 0.001).

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INTRODUCTION

Implementation and utilization of point-of-care testing (POCT) has steadily increased over recent years in Emergency departments all over India. Using POC devices allows for rapid diagnosis right at the patient’s bedside, allowing for prompt forward management, which integrates treatment processes, with immediate therapeutic and diagnostic advantages. The benefits of POC devices over routine laboratory investigations include low sample volumes, less invasive sample collection, and the absence of long transport periods and sample preparation procedures, especially in the emergency setting where time is of at most essence. Potentially, the main disadvantage which stands out is the relatively higher cost of procedure when weighed against typical routine blood investigations. Moreover, accuracy of POCT measurement results when compared with the results from other confirmed methods are not always warranted, though inconsistencies are generally rare. In an emergency setting, a parameter like haemoglobin is of high critical value especially in diagnosing anaemia, malignancies, trauma, internal and external blood loss, blood transfusion and its response, and to make various other therapeutic decisions. Therefore, the efficiency & reliability of POC devices is critical.

AIM OF THE STUDY

The aim of this study is to compare the results of haemoglobin values determined with POCT Device with ZL, and review the quality of POCT testing in an emergency setup. For the study design, the Department of emergency medicine was deliberately chosen as a highly vulnerable area with a large caseload and high stress level. Economic observations, such as a cost benefit analysis, were not the focus of the present study.

METHODOLOGY

Inclusion criteria: Patients of any age group whose blood samples are simultaneously checked in both point of care testing device & central laboratory diagnostics.

Exclusion criteria: Patients not willing to participate in this study, blood samples collected from 2 different sites /time

Structure, material and location

This was a prospective observational study which was conducted from June 2018 to February 2019 at Amrita Institute of Medical Science (AIMS), Kochi. The department of emergency medicine in AMRITA is visited by more than 25,000 patients per year. With today beds of 36, triage area of 18 beds, adult resuscitation area of 6 beds, neonatal resuscitation area 1, decontamination area 1, procedure room 2, emergency critical care unit 8. Each of these areas is equipped with hydraulic beds, compact and portable monitors, defibrillators, AEDs, infusion pumps, ventilators etc. Our 24x7 in- hospital services include emergency dialysis facility, cardiac pacing and endoscopy, dedicated ultra-sonographic machine for aiding diagnosis and also for assisting emergency surgeries. Point of care devices for haemoglobin, electrolytes (sodium, magnesium, potassium, calcium), creatinine, bilirubin, ABG, CBC, CRP &high sensitive TROP - I for aiding quick diagnosis are available.

Data Collection

Over the course of 24 hours, 24 nurses work on weekdays and 27 nurses on the weekend, in a mix of specialist nurses, employees with additional qualifications and paramedics. All medical staff members and all nursing staff were trained in POCT diagnosis. The details of patients who satisfy inclusion criteria were collected along with their POC haemoglobin values, all
sample measurements carried out by the 24 care employees were included in the analysis. During the evaluation period, there was no change in observational conditions, e.g. number of staff or workflow; POCT training also remained unchanged. At the central laboratory, specialists in laboratory medicine, residents and laboratory technicians are in attendance 24 hours/day. During the evaluation period, haemoglobin values from the central lab. was collected and tabulated.

Central laboratory measurements

The reference method results for the Hb value at the central laboratory (Hb-ZL) were established with Sysmex XN2000 and MINDRAY BC6800. Hb concentration is photo metrically measured with the SLS haemoglobin method (SLS = Sodium-Lauryl-Sulphate) and calorimetric method respectively. Examination material for the central laboratory analysis consisted of venous EDTA whole blood. In all samples, analyses were performed within 15 minutes of arrival at the central laboratory.

POCT measurements

In Amrita Institute of Medical Science, POCT-Hb diagnosis is done with System Radiometer ABL800. For blood gas analysis, arterial, venous, capillary and mixed venous heparinized whole blood samples can be used. Co-oximetry allows measurement of blood oxygenation as well as total Hb concentration. Examination material for the blood gas analysis was heparinized venous whole blood. In line with hospital quality control measures, this analyser is subject to internal and external quality control check under the responsibility of the medical director of the central laboratory at regular interval.

Accordingly, the stipulated external quality control requires participation in ring trials where results from haemoglobin measurements must not exceed a particular reference method value (cyanohaemoglobin method) (Hb: maximum 6% deviation from target value). These conditions have been met regularly for Hb-ZL and POCT-Hb. In fact, for POCT-Hb as well as Hb-ZL, all results were significantly below the maximum 6% deviation from the target value as stipulated by the guidelines.

Statistical analysis

Data were statistically analysed (Microsoft Excel, Version 2010; IBM SPSS Statistics, Version 20.0). Continuous variables are expressed using mean and standard deviation. Categorical variables are presented using frequency and percentage. To test the statistical significance of the correlation between Hb-ZL & POCT-Hb, Pearson correlation method is used. To find the agreement between two measurements, intraclass correlation coefficient is calculated. To test the statistical significance of the diagnosis of anemia using POCT-Hb compared to Hb-ZL, McNemar’s Chi-square test is used. Diagnostic measures such as sensitivity, specificity and accuracy were calculated. P <0.05 was considered statistically significant.

RESULTS

Average age of the 490 analysed patients was 48.35 +/- 26.09 years (range 1–99 years); data of two emergency patients were excluded due to inconclusive identity. The Male-to-female ratio was 274/216 (55.9% male, 44.1% female) and the mean value of Hb-ZL was 11.324g/dl (SD 2.7910), while the mean value of POCT-Hb was 11.363 g/dl (SD 2.97). The correlation between both the parameters (POC-Hb & Hb-ZL) was highly significant (r = 0.823, p<0.001) (Fig 1) (Table 2) and the results were showing excellent agreement between POC-Hb & HB-ZL(ICC=0.902,95% confidence interval = (0.88,0.92)).

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>216</td>
<td>44.1</td>
</tr>
<tr>
<td>Male</td>
<td>274</td>
<td>55.9</td>
</tr>
<tr>
<td>Total</td>
<td>490</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 1: Gender frequency and percent

![Gender frequency and percent](image1)

![Hb Correlation](image2)
WHO anaemia

Table 3 shows the cross tables in anemia patients according to WHO classification (male <13g/dl, female <12g/dl, children above 6yrs<12gm/dl, children below 6 years < 11gm/dl) in the whole collective and separated by gender. The McNemar test revealed good agreement in diagnosis of anemia among male (♂ p value=0.076), female (♀ p value=0.678,) and in paediatric (<6 years p value = 0.375 & >6 years p value = 1.00) when comparing POC-Hb vs Hb-ZL.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Category</th>
<th>LAB</th>
<th>p value</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>ABG</td>
<td>Yes (187)</td>
<td>179(95.7)</td>
<td>8(4.3)</td>
<td>.076c</td>
<td>90.86%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No (86)</td>
<td>18(20.9)</td>
<td>68(79.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>ABG</td>
<td>Yes (109)</td>
<td>109(89.3)</td>
<td>13(10.7)</td>
<td>.678c</td>
<td>91.60%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No (10)</td>
<td>10(10.6)</td>
<td>84(89.4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Paediatrics

<table>
<thead>
<tr>
<th>Age</th>
<th>Category</th>
<th>LAB</th>
<th>p value</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6 Years</td>
<td>ABG</td>
<td>Yes (24)</td>
<td>20(83.3)</td>
<td>4(16.7)</td>
<td>0.375</td>
<td>95.24%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No (28)</td>
<td>1(3.6)</td>
<td>27(96.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;=6 years</td>
<td>ABG</td>
<td>Yes (30)</td>
<td>212(87.2)</td>
<td>31(12.8)</td>
<td>1.000</td>
<td>87.60%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No (15)</td>
<td>30(15.4)</td>
<td>165(84.6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Comparison of WHO anemia between two measurements

Anemia < 8g/dl

Table 4 displays the cross table with a clinically relevant Hb value of <8g/dl. Here, in 34/490 samples with Hb <8g/dl, the McNemar’s chi-square test yielded no significant difference between Hb-ZL and POCT-Hb (p = 0.383).

<table>
<thead>
<tr>
<th>ABG</th>
<th>LAB</th>
<th>p value</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes (34)</td>
<td>yes</td>
<td>21(61.8)</td>
<td>13(38.2)</td>
<td>0.383</td>
<td>72.4%</td>
</tr>
<tr>
<td></td>
<td>no</td>
<td>8(3)</td>
<td>258(97)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sub collective geriatric patients

Table 5 The correlation between both parameters (POCT-Hb, Hb-ZL) was highly significant perfect positive correlation (r = 0.974, p<0.001)

<table>
<thead>
<tr>
<th>Variable</th>
<th>LAB Hb</th>
<th>p value</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABG Hb</td>
<td>.974**</td>
<td>&lt;0.001</td>
<td>11</td>
</tr>
</tbody>
</table>
DISCUSSION

In Amrita Institute of Medical Sciences, multiple point of care devices were developed and established and are in use effectively and with good compliance. In the current study, it was evaluated whether the POC implementation did in fact result in the expected quality and efficiency and for the first time, the success of a POC concept was verified in a highly vulnerable setting of emergency medicine department, using a surrogate parameter haemoglobin. Main finding of this study is that the analytical accuracy of the point of care devices at the Emergency Medicine Department, meets diagnostic quality and thus complies with the therapeutic demands. Moreover, the benefits of POC over routine laboratory investigations include low sample volumes, less invasive sample collection, and the absence of long transport periods and sample preparation procedures, especially in the emergency setting where time is of the essence.

In this study, 490 samples were considered and haemoglobin measured using point of care device and central lab devices were analysed, correlation between both the parameters (POC-Hb & Hb-ZL) was highly significant ($r = 0.823$, $p<0.001$) & The results were showing excellent agreement between POC-Hb & Hb-ZL (ICC=0.902, 95% confidence interval = (0.88,0.92)). However, some significant measurement deviations did occur. When examining these deviations more closely, it was found that only in 19 patients (i.e. 4% of the data) the difference exceeded >1g/dl. These findings demonstrate a good conformity between both measurement methods, which proves the validity of the implemented POC concept. However, when looking at clinically relevant subgroups, Hb level of <8g/dl cut-off level was considered. Here, in 34/490 samples with Hb <8g/dl, the McNemar’s chi-square test yielded no significant difference between Hb-ZL and POC-Hb. Critical decisions like arrangement of blood and transfusions were decided upon this. Similarly, for diagnosis of anemia in males, females & in paediatric age group the study revealed good agreement between point of care haemoglobin value and lab value. The results were more or less same for the subgroup geriatric patients with age >85, highly significant perfect positive correlation ($r = 0.974$, $p<0.001$) between point of care haemoglobin and lab haemoglobin.

In some cases, we identified various interfering substances. However, in extreme situations, the enormous time pressure at the emergency centre may lead to pre-analytical errors, which are mainly due to comorbidities, difficulties with vein access and exsiccosis. The haematology analyser at the central laboratory analyses samples by overhead mixing to ensure sufficient and standardized mixing of the sample, whereas the POC analysis requires sufficient manual mixing of the ABG vial. Clearly, this is not always done correctly and long enough. For example, in some cases, clot formation or air bubbles in the vials resulted in incorrect measurement values. Despite the fact that the ABG device had flagged the Hb value, the error report was ignored by the users and the incorrect value were applied. Therefore, proper training of POC users is crucial to ensure that flagged values are recognized and incorrect measurement results are dismissed. As a consequence of the outlier evaluation, the areas of responsibilities of the POC coordinators now include follow-up training and on-site troubleshooting, which are now provided individually and when problems arise.

With increasing costs through diagnosis, a scientific confirmation of the benefits of POC in the decision making process in patient care has to be examined. Therefore, studies on the comparability of POC vs. laboratory results with an existing and lawful POC concept are particularly important.

In Amrita Institute of Medical Science, POC-Hb measurement is a standard procedure in patients with any bleeding manifestation and parallel intake of anticoagulants immediately upon admission. The Hb value is used in the categorization of the priority level and can influence the next steps in the emergency treatment. Additionally, POC devices also aids in the clinical assessment of a patient, during primary survey in the trauma room. In trauma rapid accessibility to results is a decisive advantage of POC, every second can be important for the patient outcome. The validity of the obtained measurement values has to be guaranteed. During implementation as well as continuous quality control of POC diagnosis in patient care, risks and benefits must be identified and minimized or maximized accordingly. In Amrita, all POC quality control measures are the responsibility of the medical director of the central laboratory and thus
by law equivalent to the quality control measures at the central laboratory. If a POC device fails to pass the internal quality control, it is automatically disabled for the failed parameter and will only be released after successfully passing a follow-up control.

**CONCLUSION**

Our comparison of POC devices with central laboratory haemoglobin determination in emergency patients at a tertiary care hospital showed a highly significant correlation between the two analysed haemoglobin concentration measurement methods, using POC devices and the SLS haemoglobin method. This is an example of the successful implementation of point of care device in a highly vulnerable area like emergency medicine and critical care in Amrita Institute of Medical Sciences. Also, not only is continuous quality control of utmost importance both internally and externally, but also, a clear-cut area of well-defined training for the users. The study also holds good correlation between point of care haemoglobin and central lab haemoglobin in subcollective groups like geriatric age group and clinically relevant haemoglobin value of <8 mg/dl and in diagnosis of anaemia according to WHO.

**REFERENCES**


Substance misuse among medical students: What can be done?
Sanju George*, Valsraj Menon**

ABSTRACT

Although there are no studies of substance misuse among medical students in India, anecdotal reports suggest that it is a significant problem. Despite this, like medical practitioners, medical students too are reluctant help-seekers when it comes to their own substance misuse and related problems. In this paper, we discuss prevention strategies to address the issue of substance misuse among medical students in India.

A recent newspaper feature described a private medical college’s (in Kerala) move to mandatorily drug screen its medical students1. That is where we got the idea for this paper.

There are no studies that have looked at substance misuse among medical students in India. However research, albeit limited, has looked at stress, depression and anxiety among medical students in India. Studies in Indian medical colleges found high stress levels in nearly three-quarters of medical students2 and in 91% of interns3. Similar findings were also reported in other studies of Indian medical students when assessed for depression (51.3%), anxiety (66.9%) and stress (53%)4,5,6. It is well known that these (stress, anxiety and depression) are all potential risk factors for substance misuse. Despite the glaring lack of research evidence, any practising psychiatrist would attest to having seen medical students with substance misuse-related problems in his/her clinic. Anecdotal evidence also strongly suggests that most if not all of these medical students preferred accessing psychiatric help outside their own medical college. So it is clear that medical students do use and misuse psychoactive substances such as alcohol, tobacco and other addictive substances. While we wait for research evidence to emerge, there is an urgent need to debate the issue of what can be done pragmatically to deal with this problem.

In this paper, we will discuss some prevention strategies to deal with substance misuse among medical students. Before getting into that discussion we will briefly look at why is that the medical profession is ‘risky’ in terms of its potential for its practitioners to get addicted to substances and will then also highlight why medical professionals are very reluctant help-seekers, especially when it comes to their own psychological/psychiatric issues.

Some of the proposed explanations for medical professionals being more at risk to getting addicted to psychoactive substances include: psychological theories (such as ‘helping profession syndrome’7 and ‘compulsive care giving theory’, individual vulnerability8, socio-environmental factors specific to medical training (such as over competitiveness, easy access to drugs and a ‘macho’ culture) and clinical medical practice (such as more knowledge of and easy access to drugs, peer attitudes and socialisation opportunities), and stress at work. However, in reality the causation is more likely to be multi-factorial with work-related stress and individual vulnerability being two crucial interplaying factors. A study of addicted doctors in London highlighted the following as the most common reasons for doctors developing an addiction: personality difficulties (53%), anxiety or depression (32%), non-specific drift and family stress (26%), work stress (23%) and bereavement (10%)10.

It has to be noted that despite the above-noted risk factors, even when medical students or medical practitioners develop problems related to substance misuse, they seldom seek help early. Often-cited barriers to timely help-seeking include feelings of guilt, stigma and shame, poor insight and denial of the problem, anxieties about potential impact on career, fears about negative response from colleagues and employer, and mistrust of the relevant regulatory institution/organisation. A study from a South Indian medical college that explored barriers to psychiatric help-seeking among its medical students found that stigma, confidentiality issues, lack of awareness, and fear of unwanted intervention to be the most important factors11. Such barriers to help-seeking are a shame, and are a missed opportunity, because early and appropriate treatment interventions can be effective. Today’s medical students are tomorrow’s doctors. Further the negative consequences of untreated substance misuse in this group can impact not only on the doctor’s own health and well-being but also on the safety of patients they care for.

Having said all the above, we will now discuss some substance misuse prevention measures as relevant to medical students. We also hope to raise awareness of this issue among medical college administrators and policy makers with a view to stimulating further discussion. It is also hoped this will result in more help becoming avail-

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able to help substance misusing medical students.

Prevention strategies

“The late dramatic intervention might not be called for if minor, sensible, and friendly interventions were more often practised at an earlier stage.” (Griffith Edwards in ‘The alcoholic doctor: a case of neglect.’)

Although this was stated in 1975, it remains relevant today—even more so in the case of medical students. A prevention model often used to conceptualise the prevention of addictive disorders is the three-tiered model—consisting of prevention at primary, secondary and tertiary levels. But given the age of medical students, in the large majority, one is often faced with those misusing substances rather than those who are addicted. It naturally follows that the interventions that need to be offered are also mostly at the primary or secondary levels, rather than at the tertiary care level, which is for those heavily dependent patients who need intensive inpatient treatment and other complex interventions.

Primary prevention means preventing the onset of addiction; secondary prevention implies early diagnosis and treatment of addictive disorders; and tertiary prevention includes offering treatments/interventions to prevent chronic negative consequences of addiction.

Primary prevention strategies should target medical students. Perhaps most importantly, much more work needs to be done to raise awareness of addictions (and risk factors) among medical students. Second, co-ordinated and comprehensive health checks need to be on offer and measures could be put in place to ensure take up and engagement, as they can help identify ‘at risk’/hazardous substance using medical students and doctors. Third, better support structures and systems in medical colleges to ensure a healthier work-life balance for medical students. There are a host of risk factors for the development of addictive disorders among medical students such as the competitiveness of medical training, examinations, stress of postgraduate training and specialisation and so on. Hence specific support should be on offer to medical students during intensely stressful times such as examinations, job interviews, job changes and personal (non-work) stressors such as separation, bereavement, health problems, etc. Medical students need to be offered to enhance their own coping skills and stress management strategies.

From a secondary prevention perspective, it is crucial to facilitate early help-seeking and subsequent early intervention. There should be no stigma (or very little) attached to disclosure and or treatment of substance misuse disorders among the medical students. To minimize stigma and to encourage easy and early help-seeking, there also needs to be easily accessible and confidential services for psychological and psychiatric treatments. We are not making the case for specialist psychiatric treatment services for medical students but instead are calling for confidential and specialized treatment services, and this is best offered outside the host institution. Some work also needs to be done in having clear guidance and support for all medical students in what they can/ought to do if they suspect their fellow students to be using substances. Finally, a more contentious secondary prevention strategy applicable to early detection of substance misuse is random drug tests in medical colleges. In our view, if this is made part of the college policy from the point of entry into the medical college, it will be met with less resistance. Such workplace policies are already running in many private sector organisations and in our view, are definitely worth considering in medical colleges.

CONCLUSION

In conclusion, substance misuse among medical students is not uncommon. But, more often than not, most of them go unrecognised and untreated, at considerable cost to the individual, his/her family and his patients and future employers. Very little is being done in Indian medical colleges to address this problem. We discuss some strategies to prevent the onset of and/or minimise the harm caused by substance misuse in this group. We hope our paper stimulates interest in this field so more help becomes available to substance misusing medical students. Lastly, given the limited evidence base available in this field, we call for further research.

REFERENCES

cle26063706.ece.
2. Supe AN. A study of stress in medical students at Seth G.S. Medi
tertiary care hospital in central India. Sch J Appl Med Sci 2016;
4:3128-3131.
4. Chakraborti A, Ray P, Sanyal D, Thakurta RG, Bhattacharayya AK,
Mallick AK, et al. Assessing perceived stress in medical personnel:
In search of an appropriate scale for the Bengali population. Indi-
5. Iqbal S, Gupta S, Venkatarao E. Stress, anxiety and depression
among medical undergraduate students and their socio-demo-
of stress among resident doctors working in Medical Colleges of
7. Malan D. 1979. Individual psychotherapy and the science of psy-
8. Tillett R. 2003. The patient within – psychopathology in the help-
ing professions. Advances in psychiatric treatment, 9: 272-279.
and personality: their relationships over time. Hospital Medi-
hazard: 144 doctors with drug and alcohol problems. Br J Addict

Utility of Published Medical Research – A soul searching exercise waiting to happen.

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Medical research publication has become an integral part of the existence of medical and paramedical professionals. This thought holds true for those who are actively involved in providing clinical care as well as in teaching roles. The amount of medical research currently published is mind blowing. The volume of published clinical research documents currently available both in print and via the internet runs to billions of documents. A rather worrisome thought relating to the actual usefulness of published clinical research precipitates from this rapid turnover cycle in medical research. One physician researcher who has shed light into the actual quality of published research and in turn its real utility is Dr. John Ioannidis. Dr. Ioannidis’s work primarily focuses on the accuracy and usefulness of medical research. He published a landmark paper in PLOS Medicine (2002) titled “Why most published research findings are false”. The paper revolutionized the way current researchers view the quality and integrity of medical research publications.

In 2016, Dr. Ioannidis penned his thoughts on another domain related to medical research-the usefulness of published medical research. In this article, he encourages the reader who indulges in a decent dose of medical research to question every research output/proposal from a multidimensional point of view. The questions, though framed from the multitude of research that happens predominantly in the resource rich countries, has more relevance when applied to low resource settings. Medical research in these settings are an everyday struggle where hurdles one after the other present before the rather novice researcher who is forced to work his/her way out on their own wit and gut. Unfortunately, a significant portion of these forced adventurers fall deep into the dark crevices of medical research error and leave the arena all stained in blood and guilt. A sad part of this phenomenon is that the waste of resources and time is not restricted to the researcher but is shared by the millions of readers when sub optimal studies find their way into publication and from there to the clinical perspective of the treating physician.

Dr. Ioannidis segregates the dissection of every research work into several critical domains that are rather precisely worded into independent, intriguing and justifiable queries. There are eight such questions he inspires us to ask ourselves before we embark on the journey to imbibe newly published research. The same holds true when we pen down our new research proposals. The eight domains can be broadly worded as follows—the problem base, the context, information gained, pragmatic element, patient centeredness, value for money, feasibility and transparency.

The two papers by Dr. Ioannidis are eye openers to every medical researcher and is a must read if you believe in quality and utility of published medical research. Our work will only be relevant to our patients and their caretakers if the quality and utility of the same is visible and validated. Only such research will end up saving lives and improving the quality of life of the patient population we wish to serve.

REFERENCES

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A rare case of Myxedema Coma
Sonal Singh*, Anuj Singhal*

INTRODUCTION
Myxedema coma is a rare life threatening complication of decompensated uncontrolled Hypothyroidism and has a high mortality rate of 25-60% even with best possible treatment1-3. Therefore, a high index of clinical suspicion and early treatment is the key to the management of these patients. Although named as Myxedema coma, patients rarely present in comatose condition and are frequently obtunded or disoriented. Therefore, Myxedema crisis is a more apt term. The incidence of Myxedema coma is reported to be 0.22 million per year4 in western literature and there is scarcity of case reports and case series in the Indian literature5-7. Moreover only 5% of cases are known to be due to secondary Hypothyroidism8.

Here we present a rare case of Myxedema coma secondary to Central Hypothyroidism.

Case
70 year old female was brought to the emergency by relatives with history of lethargy and altered sensorium in the form of easy forgetfulness, not participating in family matters and decreased verbal output of 01 month duration with recent worsening in the past 02 days. Her relatives also gave history of weight gain, facial puffiness, swelling of feet, constipation, decreased appetite, dry skin and hoarseness of voice. She was diagnosed as Hypothyroidism 05 years back and had defaulted on her medication for the past 6 months. She was a post menopausal lady and her obstetric history was uneventful. On examination, she was drowsy but arousable and her vitals were as follows- axillary temperature-96.8°F, pulse-48/minute regular, blood pressure- 90/50 mm Hg, respiratory rate- 12/minute regular, SpO2-92%at room air. On general systemic examination she was found to have coarse expression less facies, dry skin, facial puffiness, pallor, bilateral pedal non pitting pedal edema, enlarged tongue and supraciliary madarosis.

Systemic examination revealed a GCS of 15/15 with delayed relaxation of ankle jerks. Her cardiovascular, respiratory and abdominal examination was essentially normal. Investigations revealed normocytic normochromic anemia (Hb-9.9gm%, MCV-102fl), transaminitis (AST/ALT-110/96 IU/L), deranged creatinine (Serum urea/creatinine-28/1.8 mg/dl), ECG- low voltage complexes, Chest X-ray- cardiomegaly, 2D ECHO- Ejection fraction of 45% with minimal pericardial effusion. Thyroid profile was suggestive of secondary Hypothyroidism T3 – 0.8 pg/ml (1.7-4.2), T4- 0.11 mcg/dl (0.7-1.8), TSH- 0.72 IU/ml (0.3-5.5). Further evaluation revealed low serum Cortisol- 16.08 nmol/L (263-724), low FSH- 0.65 IU/ml (1.3 to 11.5) and Low LH- 0.6 IU/ml (0.5-10.0) and low Serum Prolactin- 0.96 m IU/L.

MRI Brain-normal study

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She was diagnosed as a case of Panhypopituitarism with Myxedema Coma. Patient was managed with supportive care in the form of passive rewarming, IV fluids and Inotropes. She was started on injectable steroids followed by oral thyroid hormone replacement, patient responded well to treatment and was discharged on oral steroids and tab Thyroxine.

**CONCLUSION**

The pathophysiology of Myxedema crisis is due to low intracellular T3 which leads to depressed mental status, Hypotension, bradycardia, hypothermia, hypoventilation, hyponatremia and hypoglycemia. The two most important precipitating events are discontinuation of thyroid medication and infections. Whereas, hypothermia is a rare precipitating event in tropical countries. The diagnosis of Myxedema crisis should be made on clinical basis and treatment should be started immediately while awaiting lab reports. Underlying precipitating factor should be aggressively sought and treated. With low TSH values a diagnosis of secondary hypothyroidism and sick euthyroid syndrome should be entertained. Secondary Hypothyroidism is usually associated with other pituitary hormone deficiencies as seen in this case. Treatment of Myxedema crisis is multidimensional and the importance of supportive measures cannot be overemphasized. Patients should be managed in ICU and may require mechanical ventilation, fluid replacement and correction of hyponatremia, hypoglycemia and hypothermia. External rewarming should be avoided as it leads to vasodilatation and can worsen the hypotension. Both primary and secondary Hypothyroidism can be associated with underlying adrenal insufficiency and therefore steroids should be administered first before starting thyroid hormone replacement therapy as it can precipitate adrenal crisis. Thyroid hormone replacement forms the backbone of management of Myxedema crisis. Both oral replacement via Ryle’s tube and intravenous preparations can be used and are found to be equally effective. However, oral replacement has a drawback of poor absorption due to gastric atony and risk of aspiration. In severe illness there is decreased peripheral conversion of T4 to T3. T3 is the active hormone, has got rapid onset of action and has shown beneficial effects on neuropsychiatric symptoms. However, T3 is not easily available. T4 has slow and steady onset of action, is easily available and its values are easy to interpret. A combination of T3 and T4 can also be used. Treatment should be started with a high loading dose followed by maintenance dose.

Baseline and day 3 SOFA score of more than 6 and high APACHE II score are predictors of high mortality. Other factors associated with high mortality include advanced age and cardiovascular disease.

**REFERENCES**


A Rare Cause of Acute Kidney Injury

T Murari*, Arun Valsan†, Rohit Tewari**; Nimitha Mohan***; Vikas Kumar, Rabindra Raymajhi

ABSTRACT

IgG4 related renal disease is a relatively new entity being recognised and diagnosed only lately. The disease can affect multiple organ systems and rarely isolated involvement may be seen. The pathognomonic feature is the presence of a plasmacytic infiltrate with IgG4 positivity leading to fibrosis affecting a large number of organ systems. It may present commonly as acute or sub acute kidney dysfunction in middle to elderly males. Recognition of this disease entity requires strong clinical suspicion and specific tests to identify IgG4 and often remains under diagnosed. The results of treatment with corticosteroids are gratifying if recognised and treated early in the course of the disease.

Keywords: Acute kidney injury; Renal biopsy; IgG4 related disease

INTRODUCTION

IgG4 related renal disease is a relatively new entity being recognized and diagnosed only lately. The pathognomonic feature is the presence of a plasmacytic infiltrate with IgG4 positivity leading to fibrosis affecting a large number of organ systems. It may present commonly as acute or sub acute kidney dysfunction in middle to elderly males. Recognition of this disease entity requires strong clinical suspicion and specific tests to identify IgG4 and often remains under diagnosed. The results of treatment with corticosteroids are gratifying if recognized and treated early in the course of the disease. We present here a case of renal limited IgG4 disease in a patient who presented with acute kidney injury to our hospital.

Case presentation

A 35 year old lady, who was a known case of persistent Gestational trophoblastic disease who had undergone bilateral hysterectomy and salpingo-oophorectomy presented to our clinic with history of loss of appetite, nausea and vomiting of 15 days duration. She also complained of unquantified weight loss (≈5 kg) in the past one month. On examination, she had pallor and was found to be hypertensive (BP-150/102 mm of Hg) and rest of the clinical examination was unremarkable. She had no jaundice, fever, abdominal pain, loose stools or urinary symptoms. Initial evaluation revealed anemia (Hb-7.7 g/dL, TLC-9300/ cu mm, polymorph 63%, platelet 3.03 lac/ cu mm, peripheral smear was suggestive of microcytic hypo chromic red cells), raised ESR (62 mm / 1st hour), deranged renal tests function (Urea-18.8 / creatinine-3.82 to 6.2 mg/dL), normal serum electrolytes and liver function except for reversed albumin globulin ratio (Protein/Albumin/globulin-9.1/3.2/5.9 mg/dL). Urine microscopy, urine protein creatinine ratio- 288.57 mg/gm; C3, C4 normal; ANA, ds DNA was negative. USG abdomen revealed normal sized kidneys with raised renal cortical echotexture with well preserved cortico-medullary differentiation. Serum electrophoresis was negative for M spike, free light chain assay was normal. Bone marrow examination was unremarkable. She was subjected a renal biopsy which revealed acute on chronic tubulointerstitial nephritis with moderate degree of lymphoplasmacytic inflammatory infiltrate with few foci of tubular atrophy in approximately 25% of biopsy area and presence of casts in a few tubules associated with granulocytes. The histopathology slides are illustrated in Figure 1. Her serum IgG4 levels measured by nephelometry was found to be raised (4.51g/L, normal values 0.03-2.01g/L). PET CT revealed increased uptake in both the kidneys with no focal FDG avid lesions. She was managed with dialysis and subsequently started on oral steroids, calcium channel blockers and supportive treatment. She had symptomatic improvement as well as a declining trend in creatinine values. Presently, her creatinine is 1.5 mg/dL and is on tapering of her steroid doses. She is being monitored on outpatient basis.

Fig 1 (a) Section through kidney biopsy shows interstitial fibrosis with tubular atrophy. Marked interstitial inflammation is also present. Plasma cells appear increased (vertical arrow), (H&E, X 40) (b) Increased interstitial fibrosis (Masson Trichrome, X 40) (c) Features of interstitial fibrosis are highlighted with complete sparing of the glomerulus (PAS, X 40) (d) Immunohistochemistry for IgG4 shows IgG4 positive plasma cells in aggregates of more than 10 cells in a high power field (horizontal arrow) (IHC for IgG4, X 40)
DISCUSSION

IgG4 related disease is a recently reported entity with a number of new cases being diagnosed of late mostly from Asian countries1,2. The initial description was in a case of chronic pancreatitis which showed lymphoplasmacytic infiltration and autoimmune mechanism underlying its pathology with an elevated IgG43,4. Investigators from Japan proposed to unify the diagnosis of all such diseases for better understanding of the pathogenesis and elucidate effective therapy5. However, true prevalence and incidence estimates are not known. In the hope of deriving the same, a diagnostic criteria for IgG4 related disease was proposed by workers from Japan6. This led to awareness regarding the entity and more cases started appearing in medical literature.

Kidneys are frequently involved in the disease with a wide spectrum of abnormalities. Patients usually present with unexplained renal dysfunction or characteristic radiologic findings. It mostly affects men in their sixth decade or later. Renal parenchymal lesions, tumoral7,8 growths and interstitial disease occur most frequently. Less commonly, membranous glomerulonephritis, IgA nephropathy, membranoproliferative glomerulonephritis5, and mesangiproliferative immune complex glomerulonephritis may also be found. Rare cases of renal arteritis have also been reported. Imaging modalities like CT and MRI has helped further our diagnostic armamentarium10. CT usually reveals evidence of low density lesions that occur singly or groups. MRI may show characteristic hypointensity lesions in the kidneys. FDG PET has been used recently to gauge the extent of systemic involvement. Kawano et al11, had proposed as diagnostic criteria and classified renal IgG4 disease into 3 stages of definite, probable and possible according to the combinations of the above conditions. Steroids form the backbone of treatment and a non response to the same is often used to clinically rule out the disease. It is usually given in a dose of 0.6mg/kg body weight for up to 4 weeks followed by gradual taper12. Refractory cases may warrant treatment with second line agents like rituximab13.

CONCLUSION

Our case is unique in that it has occurred in a relatively younger female and also on the background of a persistent gestational trophoblastic disease. To the best of our knowledge this is the first case of such simultaneous occurrence. The patient had shown good response to steroids and is on regular follow up.

REFERENCES

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