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Editorial

Hazards of Ventilators in Treating Covid-19 Patients

Mohammad Iqbal Adil
Member Editorial Board / Consultant Surgeon, NHS, UK

Serious doubts have been raised about the effectiveness of ventilators.

In New York 85% patients on ventilators died. In China early in 2020, 95% people on ventilators died.

Ventilator was considered to be a treatment for the deadly lung infection pneumonia as used in China and then in Europe, Britain and USA.

Dr Cameron Kyle Sidell, New York A/E doctor had broken ranks with the medical establishment and warned it was wrong to use ventilators in such patients.

Now experts are thinking about saving patients by saturating their bloods with oxygen delivered through a mask (non invasive) technique without using ventilators as an invasive technique which has high mortality rate.

This is approach used for Boris Johnson when he was admitted in St. Thomas hospital London.

Mat Hancock said Uk need 1500 ventilators. With the number to 30,000.

Donald Trump, said we need more ventilators etc.

Death rate for those treated on ventilators is devastating.

In one British study of 98 Covid patients who were treated with ventilators the mortality was 80%.

Reported by Intensive care National Audit and Research Centre.

In New York. Which has been hit particularly hard by the virus, 80% of ventilated patients failed to recover.

Loss in other countries are also terrifying.

Dr David Farcy, the president of the American Academy of Emergency Medicine warns against the use of ventilators indiscriminately.

In Covid-19 patient struggle for O2 but they are not like pneumonia.

Dr Kyle Sidell said “it is some sort of viral disease resembling high altitude sickness“. He said “patients I am seeing as fallen off from high altitude to 30,000 feet or decelerations from the Mount Everest . They don’t look like dying from pneumonia “.

Muscles of the Covid -19 are fine compare to the pneumonia patient.

Dr. Luciano Gattinoni of Germany’s medical University of Gittingen supported him. In a letter to the American Journal of Respiratory and Critical Care Medicine, Dr Gattinoni warned that conventional use of ventilators may injure the lungs of Covid -19 victims.

In one of the European Hospital where virus patients were ventilated in this way, 80 % of them died.

Into the fray Professor Sharif Sultan , the Ireland based president of vascular surgery said Covid 19 patient doesn’t resemble pneumonia or similar respiratory ailment. We need to stop treating patients with ventilators for the wrong disease.

He summarises his analysis in Medical research into virus.

He added Covid19 attacks both lungs at the same time which is different than pneumonia.

Nick name of this disease is happy hypoxia!

One of the distinctive feature of Covid-19 is the way a yellow mucous gunk clogs the millions of tiny air sacs lining the lungs.

This means however hard the ventilator push oxygen into the lungs, that oxygen cannot get through the mucous barrier and into body. Thus makes patient starved of O2.

Ventilators causes barrow trauma and pneumothorax .

Older patients who survive are at the risk of permanent brain damage because of heavy sedation for long time.

Thus all explains why death rate is quite high in patient on the Ventilators .

In China and USA the death rate in patients on Ventilators is 90%.

One of the tragically high fatality rate is Dr Muriak Gillick, a geriatric and palliative Care unit, Harvard university school Massachusetts, USA.

Patients with bacterial pneumonia may be on a ventilator for no more than a day or two . But it’s common in Corona patients to be on ventilators for 7, 10 and 15 days and they are passing away said, New York Governor Andrew Cuomo when asked in a News Break.

CONCLUSION

Non invasive technique with O2 cannula or CEPAP is better for such atypical pneumonia of Unknown cause.

Use of Ventilators are catastrophic due to barrow trauma to the lungs. However, only 3-4 % patients with critical condition would require ventilators but their chance of survival is remote.
Objective: To determine Sero-prevalence of Hepatitis B and C virus among blood donors in local population of Sahiwal, Punjab, Pakistan.

Study Design: Descriptive, retrospective, cross-sectional Study

Place and Duration of Study: This study was conducted at the Blood Bank of DHQ Teaching Hospital, Sahiwal from August 2019 to November 2019.

Materials and Methods: Data from August 2014 to July 2019 was included. Blood grouping was done and serum extracted from blood donors was screened by the use of Immuno-Chromatographic Diagnostic Kits (ICT) for Hepatitis B (HBsAg) and Hepatitis C (Anti-HCV).

Results: A total number of 39114 subjects were investigated for Hepatitis B and C viral infections. Out of these 1775 (4.54%) were found to be Anti-HCV positive, 467 (1.19%) were HBsAg positive and 30 (0.08%) were positive for both. Hepatitis B infection was found more prevalent (33.83%) in blood group B and the highest prevalence of Hepatitis C was found in blood group O.

Conclusion: Prevalence of Hepatitis C is found high among blood donors visiting DHQ Teaching Hospital Sahiwal, which warrants mandatory regular screening for all blood donations to prevent transfusion related transmission of infections. There is dire need of implementation of community based preventive measures and improved strategies to decrease Sero-prevalence across the region.

Key Words: Anti-HCV, Hepatitis B, Hepatitis C, HBsA, Immuno-Chromatographic Diagnostic Kits (ICT), Sero-prevalence


INTRODUCTION

Hepatitis B and Hepatitis C are considered to be a worldwide health issue especially in developing countries like Pakistan. Most of infectious diseases are spread through blood transfusion. In Pakistan, the social norms, cultural diversity, poor health delivery system, lack of proper health facilities and unsafe blood transfusion ways are responsible for high prevalence of Hepatitis B and C from blood donors to the recipients. The other major modes of transmission of these infectious diseases in Pakistan are also use of adulterated needles, razors in barber shops, tattoo created with unsterilized needle, unsterilized equipment in medical practice and sharing things of personal use with infected persons. It can be transmitted vertically from an infected mother to her infant as well as during breast feeding.

In Pakistan annually round about 1.5 million units of blood or blood products are transfused as reported by WHO. Of this 15% are from professional donations, 75% are from replacement donations and 10% are from voluntary unpaid donations. Epidemiological individualities and risk factors for transmission of infection are different from region to region across the country. It has been reported that the occurrence of Hepatitis B and C viruses varies according to locality in different parts of country. According to various studies directed at various times the prevalence of HBV and HCV infections is 1.1%–6.2% and 2.06%–7.69% respectively in Pakistan. A gradual decrease in prevalence of HBV is noted, which may be the result of introduction of immunization program against HBV infections from birth and at different stages of life. Conversely, an increase in prevalence of HCV is noted that is because ineffective and improper vaccine against it. In 2003, The Federal Ministry of Health, Pakistan made a National Blood Policy to ensure inappropriate
screening of blood before labeling it safe for transfusion. In Pakistani population, the risk of spread of Hepatitis B and C viruses through blood transfusion has been observed to be high which is certainly because of deficiency of proper screening of blood before transfusion and awareness in past. The other reason of so much high spread rate of HBV may be the late introduction of vaccination. However, the continuous spread of Hepatitis B and C viruses in the community may increase to develop high risk of morbidity and mortality among infected persons due to its chronic carrier state, which ultimately end up with Acute-on-Chronic Hepatitis, Fulminant Hepatic Failure, Liver Cirrhosis and Hepatocellular Carcinoma (HCC). The main objective to conduct this study was to assess the prevalence rate and minimize the potential of spread of Hepatitis B and Hepatitis C viruses amid the healthy blood donors at Sahiwal, Pakistan.

MATERIALS AND METHODS

A descriptive, retrospective, cross sectional study was conducted in DHQ Teaching Hospital, Sahiwal from August 2014 to July 2019 after getting the data of blood donors over period of five (5) years from Blood Bank. The current study is based on official records of Blood Bank of DHQ Teaching Hospital, Sahiwal. During the described period, a total number of 39114 blood donors visited Blood Bank of this institute, and all of the donors were screened for Anti-HCV and HbsAg. Physically healthy donors, some of them with history of pre-donation screening test for HBsAg and Anti-HCV, within the age range of 16-60 years of both genders, were included in this study. Those donors who had history of pervious exposure to HBV, HCV and HIV infection were excluded. 3ml blood sample was collected from each donor and samples were sent to Laboratory of DHQ Teaching Hospital for screening of HBsAg and Anti-HCV by using rapid Immuno-Chromatographic Test (ICT).

RESULTS

In our study data of total number of 39114 blood donors were analysed from August 2014 to July 2019 with an average of 6512 donations per year. Of these donors 99.9% were male. These were mixed donors (volunteers, replacement or direct donors). Average age of the blood donors was 23 years (range 16-60 years). This comparison shows that HBsAg positive donors are younger than Anti-HCV positive donors. Blood grouping was also done for all the HBsAg positive donors and Anti-HCV antibody positive donors. The prevalence of HBV and HCV were almost same among all the blood groups but the blood group B+ve showed maximum prevalence for HBV and blood group AB-ve showed minimum prevalence for HBV. For HCV blood group O+ve showed maximum prevalence and blood group AB-ve showed minimum prevalence.

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of Donations</th>
<th>HBsAg positive</th>
<th>Anti-HCV positive</th>
<th>HBV+HCV positive</th>
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<tr>
<td>2014</td>
<td>2236</td>
<td>22</td>
<td>131</td>
<td>0</td>
</tr>
<tr>
<td>2015</td>
<td>9936</td>
<td>130</td>
<td>439</td>
<td>9</td>
</tr>
<tr>
<td>2016</td>
<td>6085</td>
<td>67</td>
<td>269</td>
<td>6</td>
</tr>
<tr>
<td>2017</td>
<td>6937</td>
<td>92</td>
<td>278</td>
<td>6</td>
</tr>
<tr>
<td>2018</td>
<td>11190</td>
<td>114</td>
<td>457</td>
<td>7</td>
</tr>
<tr>
<td>2019</td>
<td>2730</td>
<td>42</td>
<td>201</td>
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practice of using

Table No.2: Comparison of Prevalence of Hepatitis B and Hepatitis C in Consecutive Years

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<th>Years</th>
<th>HBsAg</th>
<th>Anti-HCV</th>
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<td>2014 vs 2015</td>
<td>0.99% vs 1.31%</td>
<td>5.85% vs 4.42%</td>
</tr>
<tr>
<td>2015 vs 2016</td>
<td>1.31% vs 1.10%</td>
<td>4.42% vs 4.42%</td>
</tr>
<tr>
<td>2016 vs 2017</td>
<td>1.10% vs 1.32%</td>
<td>4.42% vs 4.00%</td>
</tr>
<tr>
<td>2017 vs 2018</td>
<td>1.32% vs 1.02%</td>
<td>4.00% vs 4.08%</td>
</tr>
<tr>
<td>2018 vs 2019</td>
<td>1.02% vs 1.54%</td>
<td>4.08% vs 7.36%</td>
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The prevalence data for HBsAg and Anti-HCV antibody for each year was compared with each successive year. There was irregular increasing and decreasing trend of prevalence.

A total of 2242 blood donors were found to be infected with Hepatitis B and C. Out of these 2242 cases 79% were anti-HCV antibody positive, 20% were HBsAg positive and 1% were positive for both anti-HCV antibody and HBsAg.

DISCUSSION

In the current study an effort has been made to estimate the sero-prevalence of Hepatitis B and C viruses after analysis of healthy donor’s population from Sahiwal region, Punjab, Pakistan. Age distribution is shown in Figure 1 and 2. The earlier peak of Hepatitis B could be due to vertical transmission of HBV in our population. In this study, donors less than 16 years of age were not considered so it was not possible to assess the minimum age of acquisition of HBsAg. Cross sectional sero survey of population less than 16 years may show the age of highest prevalence of HBV in our population.

WHO’s Criteria for endemicity of Hepatitis B virus in different countries by dividing into low endemic, intermediate endemic and high endemic region. In countries, where carrier rate is less than 3% fall in the low endemic region, those with carrier rate is between 3-5% come in intermediate endemic region and those are more than 5% in high endemic region. There is high possibility to cause a major disease burden in our country due to low EPI coverage of Hepatitis B vaccination in some of districts. To improve the vaccination status in countries having endemicity of hepatitis B virus, supportable strategies have to be laid down. About 3% of world population is suffering from HCV infection and on the other hand in Pakistan the prevalence of HCV infection is about 5%. Both Hepatitis B and C viruses are present in the population of Pakistan, though the data available about their prevalence varies in different studies. Globally, HCV is considered to be the fatal, which has more hazardous than HBV because there are often no clinical signs and symptoms until HCV is diagnosed, huge damages have already been done to the patients. According to some research studies, there are about 9 million HBV carriers in Pakistan and over 14 million HCV carriers. These figures could not be biased due to limited resources and the population sample selected is limited to a specific area or part or high-risk group. Since our male population starts their occupation and become socially and sexually active in the earlier half of their third decade of life. The late positivity of HCV may be due to this late exposure to the risk factors for HCV. Detailed epidemiological studies are required to correlate these observations with prevalence of Hepatitis C.

Overall prevalence of Hepatitis B during these 5 years was 1.21% which is comparable to the previous studies conducted in different districts of Pakistan. The study shows irregular downward and upward trends during this period. There is no obvious explanation for this irregular trend. The average sero-prevalence of Hepatitis C was 5.03% which was 3.82% higher than Hepatitis B prevalence. These results were also comparable to the previous studies conducted in different districts of Pakistan. The higher prevalence of Hepatitis C maybe due to non-availability of vaccine, non-availability of wider screening methods and absence of screening of donors for HCV in many centers. It may be due to a common practice of using used syringes while giving injections and an unknown mode of transmission other than parenteral route. The maximum sero-prevalence of both Hepatitis B & C among the positive blood group donors may be owing to the reason that positive groups are more common.

CONCLUSION

In conclusion, our retrospective cross sectional study of healthy donors visiting DHQ Teaching Hospital, Sahiwal, reveals that both Hepatitis B and C viruses affect younger age groups which ultimately leads to Liver related diseases (e.g Liver Cirrhosis, Fulminant Liver Failure & HCC) thus putting extra burden on Healthcare Delivery System. Furthermore, to decrease the prevalence of both viruses, auxiliary information about risk of transmission of Hepatitis B and Hepatitis C from donors must be included in the donation form. It is important to take adequate steps to strengthen the vaccination program for Hepatitis B virus and stop the modes of transmission of Hepatitis C virus.

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Leucocytosis in Acute Ischemic Stroke and its Effect on Short Term Morbidity

Sohail Khan1, Fawad Jan4, Muhammad Shahid Iqbal1, Muhammad Fozan Khan2, Wajeeha Qayyum3 and Muhammad Waqas5

ABSTRACT

Objective: To find out the frequency of leucocytosis in acute ischemic stroke and its effect on short term morbidity.

Study Design: Descriptive Cross-Sectional study.

Place and Duration of Study: This study was conducted at the Department of Neurology, PGMI Lady Reading Hospital Peshawar for six months January, 2012 to July, 2012.

Materials and Methods: Data was collected by non-probability consecutive sampling technique. 126 adult patients with ischemic stroke were included in the study. Full blood count was obtained for all patients on admission and possibility of infection ruled out with history and relevant clinical examination. Presence of disability was assessed using Modified Rankin Scale (mRS).

Results: A total number of 126 patients having ischemic stroke were included in this study. The mean age was 61.9 years. 114 (64.4%) were males. Leukocytosis was seen in 61 (76.25%) of the patients with significant morbidity, whereas 19 (23.75%) of patients with morbidity had no leukocytosis. In patients without any significant morbidity leukocytosis was seen in only 12 (26.09%) of the patients.

Conclusion: It is concluded from this study that early leukocytosis in ischemic stroke patients is associated with increase morbidity and can therefore be considered as a prognostic factor.

Key Words: Leukocytosis, Ischemic Stroke, Morbidity.


INTRODUCTION

Stroke is a major health problem worldwide because of its high risks of morbidity and mortality.1 Approximately 15 million people worldwide suffer from stroke annually of which 5.5 million die while the remaining are left with permanent disability and over 50% of cases occur in Asians.2,4 Ischemic Stroke accounts for over 50% of all types of stroke.5 Inflammation and inflammation-related atherosclerosis play a crucial role in Ischemic stroke progress and prognosis.5

Exact data about the incidence and prevalence of stroke in Pakistan is lacking but the burden is assumed to be high because of the high prevalence of major risk factors for stroke in our population.6

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An episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction attributable to ischemia, based on pathological, imaging, or other objective evidence of cerebral, spinal cord, or retinal focal ischemic injury in a defined vascular distribution; or clinical evidence of cerebral, spinal cord, or retinal focal ischemic injury based on symptoms persisting ≥24 hours or until death, and other etiologies excluded.5 The burden of ischemic stroke is increasing worldwide because of the rise in the major risk factor for ischemic stroke i.e. hypertension, diabetes, obesity, smoking and dyslipidemia.6

Leukocytosis is an elevation of the concentration of leukocytes or white blood cells in blood, and is generally considered to be present when the white cell count (WCC) exceeds 11 × 10^9/l.7 Widely considered to be an indicator of infection or inflammation, leukocytosis can also occur in a variety of other clinical situations, such as trauma, exercise, therapy with drugs such as steroids or lithium, malignancy, poisoning, psychosis and diabetic ketoacidosis.8,9,10 Leukocytosis may represent an ‘acute phase marker’ analogous to C-reactive protein (CRP) or the erythrocyte sedimentation rate (ESR). Interestingly, raised circulating catecholamines can cause leukocytosis, perhaps as part of a generalized stress response.9,10 A large study showed that higher admission leukocyte count was associated with several fold increase risk of...
dependency and death among acute cerebral infarction patients. The same study showed that short term morbidity was 29.6% using modified Rankin scale (mRS)>2.11

A large prospective observational study showed that an elevated leukocyte count in the acute phase is a significant independent predictor of poor initial stroke severity, poor outcome at 72 hours and discharge disability.12

One of the study evaluating role of leukocytosis and high ESR in acute ischemic strokes showed that raised WBC was associated with increased undesirable results while releasing from hospital as well as in hospital mortality.13

Recruitment of neutrophils can be detected as early as 5 hours after stroke onset and peaks at 24 hours.14 Work over the past few decades indicates that aspects of inflammatory response may in fact be detrimental to final stroke outcome. In the acute setting inflammation appears to have a detrimental effect, and anti-inflammatory treatments have been studied as a potential therapeutic target.15

The rationale of the study was to investigate the frequency of leukocytosis obtained at admission in first ever acute ischemic stroke patients and its effect on early outcome in terms of morbidity using a Modified Rankin scale (mRS) at discharge. Varying conclusions have been drawn on the relationship of leukocytosis and stroke, a greater understanding of leukocytes contribution in acute ischemic stroke and its effect on morbidity and mortality is still required. Although international studies on this topic have been done, local data on this aspect of stroke is lacking. Better understanding of the effect of leukocyte count in the acute phase of stroke might have profound implications for the acute management of stroke, and it might improve clinical outcome.

MATERIALS AND METHODS

This cross sectional study was carried out in Department of Neurology, PGMI, Lady Reading Hospital, Peshawar for 6 months from January, 2012 to July, 2012 after approval from hospital ethical committee. Patients with both gender and above 18 years of age with ischemic stroke were included. An episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction attributable to ischemia, based on pathological, imaging, or other objective evidence of cerebral, spinal cord, or retinal focal ischemic injury in a defined vascular distribution; or clinical evidence of cerebral, spinal cord, or retinal focal ischemic injury based on symptoms persisting ≥24 hours or until death, and other etiologies excluded.1 Leukocytosis was defined as WBC count ≥11,000 cells/cm³.9 Short term morbidity was defined as moderate or severe disability on discharge using Modified Rankin Scale (mRS)>2.16 Patients with focal neurological deficit due to transient ischemic attacks, haemorrhagic stroke and with other causes of stroke, i.e. hereditary, metabolic, acquired coagulopathies, drugs, and all other causes of stroke were excluded from study. Similarly, all patients with other causes of leukocytosis e.g.: Infections, blood disorders, drugs (e.g. steroids) were excluded from study.

All patients who presented with acute ischemic stroke were selected by consecutive non probability sampling and were admitted to Neurology ward. Detailed history and clinical examination was performed for all patients. Early CT scan head was performed for all patients to rule out haemorrhage. Relevant neuroimaging was performed to rule out other causes of stroke like MRI for space occupying lesions, CTA (CT angiography) for carotid or vertebral artery dissection where ever indicated.

CBC was collected at admission. All other causes of leukocytosis were ruled out with detailed history and clinical examination, and relevant investigations like urine RE, chest X-ray, Ultrasound abdomen. Temperature monitoring was carried out through out admission. All the data was stored and analysed on SPSS version 16. Descriptive statistics were used to calculate Mean ± SD for numerical variables like age. Frequencies and percentages were calculated for categorical variables like gender, leukocytosis and morbidity. Leukocytosis was stratified among age and gender to see effect modifiers. All results were presented in the form of tables. Chi square test was applied to see the effect of leukocytosis on morbidity.

RESULTS

There were 126 patients in our study. Mean age was 61.9 years ± 14.49 with age range from 20 years to 99 years. Most of the patients presented in 6th decade of life followed by 7th and 5th decade. There were114 (64.4%) male and 63 (35.6%) female patients with male to female ratio of 1.8:1. Out of the 126 patients presenting with ischemic stroke 66.7% were hypertensive, 23.7% were diabetics and 14.3% had heart disease. (Table 2)

Out of the 126 patient’s leukocytosis was seen in 73 (57.9%), whereas normal counts in 53 (42.1%). Out of 66 males 38 (57.57%) and 60 females 35 (58.3%) had leukocytosis. The mean leukocyte count was 11800 with range from 4400 to 27000. Leukocytosis was seen in 61(76.25%) of the patients with significant morbidity as defined by mRS scale (>2), whereas 19(23.75%) of patients with morbidity had no leukocytosis. In patients without any significant morbidity leukocytosis was seen in only 12(26.09%) of the patients. (P value <0.05).

Table No.1: Age and gender distribution

| Mean Age | 61.9 ± 14.49 |
| Gender | Male | 114 (64.4%) |
DISCUSSION

Most of our study participants presented in 6th decade of their life with male predominance. This is well supported by the fact that age and gender is one of the non modifiable risk factor of stroke. HTN followed by DM and then Heart diseases were present as risk factors of stroke. They are well studied risk factors for stroke. Leucocytosis was found in 57% of ischemic stroke patients in our study. This observation is supported by a study by Nikanfar et al, which stated 46.7% of the patients had leucocytosis in his study. The slightly higher count could be because we relied on clinical examination and only basic investigations were carried out to rule out infection, rather than obtaining cultures. In our study leucocytosis was seen in 76.25% of patients with significant morbidity. Similar results were obtained in a study done in Poland to determine the predictive value of leucocyte count at admission. It was concluded in this study that an increase in the WCC within the first 12 hours of stroke was an independent and strong predictive factor for adverse outcome. A study by Nardi et al which included 811 patients yielded similar results. They found out that higher leucocyte counts predicted a worst clinical presentation and poor functional outcome in terms of morbidity. A study by Peng et al was carried out in china which yielded similar results. It was concluded in this study that higher leucocyte counts at admission were associated with several fold increased risk of dependency (morbidity).

In our study morbidity was observed in 63% of the patients. These counts were comparable to a study conducted in Canada by Buck et al where morbidity was seen in 54.7%. The slightly higher percentage of morbidity in our study could be the limited resources translated into lack of intensive care facilities, limited number of nurses and rehabilitation team to most of our stroke patients. This study has some limitations. This is a cross-sectional study, and the cause and effect relationship between total leukocyte count and long term morbidity or outcome cannot be determined. Secondly we did not carry out complete workup to explore other causes of leucocytosis in detail.

CONCLUSION

It is concluded from this study that leucocytosis in the early phase of ischemic stroke is more frequently observed in patients with significant morbidity and therefore can be considered as an important prognostic factor. Determining whether suppressing the early leucocyte response can help reduce the propagation of ischemic damage should continue to be an important goal of future investigations.

REFERENCES


Table No.2: Morbidity in patients with Leukocytosis.

<table>
<thead>
<tr>
<th>Leukocytosis</th>
<th>mRS</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>&gt;2</td>
<td>61(83.6%)</td>
</tr>
<tr>
<td></td>
<td>&lt;2</td>
<td>12(16.4%)</td>
</tr>
<tr>
<td>No</td>
<td>&gt;2</td>
<td>19(35.8%)</td>
</tr>
<tr>
<td></td>
<td>&lt;2</td>
<td>34(74.2%)</td>
</tr>
<tr>
<td>Total</td>
<td>&gt;2</td>
<td>53(42.1%)</td>
</tr>
<tr>
<td></td>
<td>&lt;2</td>
<td>53(42.1%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>126(100%)</td>
</tr>
</tbody>
</table>


INTRODUCTION

Post-operative nausea and vomiting (PONV) is most common complication encountered after laparoscopic cholecystectomy under general anaesthesia.\(^1\)

It often causes pulmonary aspiration electrolyte imbalance, dehydration and esophageal rupture.\(^2\) The incidence of PONV is as high as 60-70% and is influenced by various patient related factors, anaesthesia technique, type of surgery, drugs used and post-operative factors such as pain, dizziness, ambulation etc.\(^3,4\)

We have modified our anaesthetic techniques to secure more rapid and smooth recovery as a result of improved pre-operative and post-operative medication, refinement of operative techniques and identification of patient’s predictive factors.\(^5,6\) The management of nausea and vomiting has been improved in last couple of years with the introduction of 5 Hydroxytryptamine (5-HT3) receptor antagonists. Ondansetron is a prototype of 5-HT3 receptor antagonist and commonly used drug. Ondansetron is considered as a gold standard drug for treatment of PONV.\(^7\) Dexamethasone is very potent and highly selective long lasting glucocorticoid. It causes prostaglandin antagonism serotonin inhibition in Gut and release of endorphins that elevates mood and
stimulates appetite.\textsuperscript{8} It augments efficacy of other primary antiemetic drugs like ondansetron.\textsuperscript{8} A number of pharmacological agents have been tried for prevention and management of PONV but no agent is found to be 100% successful. It has been proved that combination pharmacological modality is better than monotherapy in this regard.\textsuperscript{10-12} The present study was conducted to examine the efficacy of ondansetron only and compare with combined dexamethasone and ondansetron for preventing postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy.

\section*{MATERIALS AND METHODS}

This randomized controlled trial was conducted at Department of Surgery DHQ Teaching Hospital Mirpur AJK from 15\textsuperscript{th} December 2018 to 20\textsuperscript{th} December 2019. A total of 140 patients of both genders with ages 20 to 65 years undergoing laparoscopic cholecystectomy were enrolled. Patients detailed demographic including age, sex, body mass index (BMI) and physical examination (ASA class I and II) were recorded. Patients who received antiemetics within 48 h before surgery, patients with cardiovascular diseases, pregnant women, and Patients with a history of recurrent vomiting in the postoperative period were excluded. All the patients were equally divided into two groups I and II. Group II consist of 70 patients and received ondansetron 4mg and group I contains 70 patients received combined dose of ondansetron 4mg and dexamethasone 8mg. The study medications were prepared and presented to anesthetist as identical 2ml filled syringes, who administered drugs at the time of induction of anesthesia. Effectiveness of medication was examined at 24 hours after surgery and compares the frequency of nausea and vomiting between both groups. All the data was analyzed by SPSS 24. Chi-square test was applied to compare the effectiveness of medication with p-value <0.05 was taken as significant.

\section*{RESULTS}

In group I, 50 (71.42\%) patients were females and 20 (28.57\%) were males with mean age 40.52±9.48 years while in group II, 48 (68.57\%) patients were females and 22 (31.43\%) were males with mean age 41.06±10.14 years. No significant difference was observed regarding BMI between both groups I and II 25.4±2.57 kg/m\textsuperscript{2} and 25.8±3.06 kg/m\textsuperscript{2} (p-value >0.05). 60 (85.71\%) and 10 (14.29\%) patients in group I had ASA class I and II. In group II 58 (82.86\%) and 12 (17.14\%) patients had ASA class I and II with no significant difference between both groups (p-value >0.05) (Table 1).

In group I, 5 (7.14\%) patients had nausea/vomiting while in group II, 25 (35.71\%) patients had nausea/vomiting. A significant difference was observed between both groups I and II regarding effectiveness of doses with p-value 0.001 (Table 2). According to the comparison of effectiveness between both groups we found that Dexamethasone+Ondansetron had efficacy 92.86\% while Ondansetron only had efficacy 64.29\% for the prevention of postoperative nausea and vomiting (Fig. 1).

\begin{table}[h]
\centering
\caption{Demographics of all the patients}
\begin{tabular}{|c|c|c|}
\hline
\textbf{Variable} & \textbf{Group I} & \textbf{Group II} \\
\hline
\textbf{Age (years)} & 40.52±9.48 & 41.06±10.14 \\
\hline
\textbf{Gender} & & \\
\hline
\textbf{Male} & 20 (28.57) & 22 (31.43) \\
\hline
\textbf{Female} & 50 (71.42) & 48 (68.57) \\
\hline
\textbf{BMI} & 25.4±2.57 & 25.8±3.06 \\
\hline
\textbf{ASA Class} & & \\
\hline
\textbf{I} & 60 (85.71) & 58 (82.86) \\
\hline
\textbf{II} & 10 (14.29) & 12 (17.14) \\
\hline
\end{tabular}
\end{table}

\begin{table}[h]
\centering
\caption{Comparison of efficacy of medication between both groups (nausea/vomiting)}
\begin{tabular}{|c|c|c|}
\hline
\textbf{Nausea/vomiting} & \textbf{Group I} & \textbf{Group II} \\
\hline
\textbf{Yes} & 5 (7.14) & 25 (35.71) \\
\hline
\textbf{No} & 65 (92.86) & 35 (64.29) \\
\hline
\end{tabular}
\end{table}

\section*{DISCUSSION}

Laparoscopic cholecystectomy is one of the commonly performed surgical intervention in all over the world. Postoperative nausea and vomiting are most common complications associated with surgical procedures.\textsuperscript{13} Many of many of medications have been used for the prevention of post-operative nausea and vomiting, in which Ondansetron is considered as a drug for choice in prevention of postoperative nausea and vomiting.\textsuperscript{14} We conducted this study with aimed to compare the efficacy of Ondansetron alone versus Ondansetron and Dexamethasone combination for the prevention of postoperative nausea and vomiting in patients underwent laparoscopic cholecystectomy. In the present study, majority of patients 70\% were females while male patients population was 30\% and the mean age was 40.86±11.8 years. These results showed similarity to many of previous studies conducted regarding...
laparoscopic cholecystectomy in which female patients population was high as compared to males and accounted 65% to 78%. Studies demonstrated that majority of patients were ages above 40 years. This study showed that no significant difference regarding body mass index and ASA class I and II between both groups with p-value >0.05. A study conducted by Hammad et al. reported that Ondansetron and dexamethasone combination was effective in 90% patients where as Ondansetron alone was effective in 68% patients which was statistically significant with P-value=0.0001. Hammad et al. reported that at postoperative 6 hours patients in Ondansetron group had high rate of nausea and vomiting 27.5% as compared to combine dose group 7.5% with p-value 0.019. However at 24 hours 100% patients in both groups had no complications of nausea and vomiting. Meitra et al. reported that incidence of postoperative nausea at 4–6 h is significantly lower when dexamethasone was used instead of ondansetron (; OR 0.49, 95% CI 0.24–0.98, M-H fixed). Incidence of nausea is similar at 24 hours (p<0.08). Azim et al. reported that Ondansetron and dexamethasone combination group had significantly lower rate of nausea and vomiting as compared to ondansetrone alone group with p-value <0.001. We found that the effectiveness of ondansetron and dexamethasone combination was 92.86% and significantly higher than the ondansetron alone group with p-value <0.001. These results were comparable to study by Halimi et al. and Azim et al. A study by Besra et al. regarding prevention of postoperative nausea and vomiting, in which they used palonosetron 0.05 mg in group I and other group received intravenous ondansetron and dexamethasone combination. They demonstrated that no significant difference was observed between both groups in term of postoperative nausea and vomiting with p-value >0.05.

CONCLUSION

Postoperative complications such as nausea and vomiting can create the severe complications and highly contributed in increasing length of hospital stay and cost. We concluded that dexamethasone and ondansetron combination is very effective for preventing postoperative nausea and vomiting in patients with laparoscopic cholecystectomy.

Author’s Contribution:
Concept & Design of Study: Mohammad Arif Mahmood
Drafting: Zardad Khan, Amjad Mahmood Khan
Data Analysis: Sajid Razzq, Nisar Ahmed, Mohammad Nadeem Khan
Revisiting Critically: Mohammad Arif Mahmood, Zardad Khan
Final Approval of version: Mohammad Arif Mahmood

Conflict of Interest: The study has no conflict of interest to declare by any author.

REFERENCES

Treatment Outcomes of Non-Adenocarcinoma Prostate in a Developing Country

Siddique Adnan, Muhammad Arshad Irshad Khalil, Shaukat Fiaz, Azfar Ali, Zubair Ahmad Cheema and Khurram Mir

ABSTRACT

Objective: To assess the oncological outcomes of non-adenocarcinoma prostate cancers in a specialized cancer hospital in a developing country.

Study Design: Retrospective study.

Place and Duration of Study: This study was conducted at the Shaukat Khanum Memorial Cancer Hospital and Research Centre, Lahore from January 2002 to July 2017.

Materials and Methods: All the patients with prostate cancer were studied retrospectively. The patients with ages more than 18 years and having histologically proven non-adenocarcinoma prostate cancers were selected for this study.

Results: A total of 7 patients of non-adeno prostate cancer were identified. The most common presenting complaint was acute urinary retention (57.1%) followed by hematuria (14.3%). As per TNM staging, most of the patients belonged to T4 (57.1%), N1 (57.1%) and M1 (57.1%). Radical chemotherapy and radiotherapy were given to 4 (71.4%) patients. Local recurrence was found in 1 (14.3%) and metastasis were reported in 4 of the patients and the mortality rate was 71.4%.

Conclusion: Chemotherapy, radiotherapy and surgery were the main treatment modalities. Low recurrence and high mortality rates were observed.

Key Words: Prostate cancer, Ewing sarcoma, Chemotherapy, Radiotherapy, Adenocarcinoma

INTRODUCTION

Prostate cancer is identified as one of the main reasons for morbidity and mortality among men. Its prevalence is increasing worldwide due to an increase in life expectancy, especially in developing countries. Prostate cancer is considered as the fourth commonest cancer of the male gender. According to GLOBOCAN, in 2012 approximately 1.1 million cases of prostate cancer were reported globally and nearly 307,000 died due to this disease. Ferly et al. predicted that with increasing life expectancy worldwide, the incidence of prostate cancer will be increased to 1.7 million patients and mortality up to 499,000 in 2030.

Delay in prostate cancer diagnosis leads to disease metastasis resulting in higher mortality. Adenocarcinoma accounts for 90% of the prostate tumors. Other less common histological diagnoses include small cell cancer, urothelial cancer, Ewing sarcoma, Carcinosarcoma, and adenoid cystic cancer. The rarity of these histological diagnoses leads to the term non-adenocarcinoma of prostate cancers and constitute to about 10% of all cases.

Prostatic Small Cell Carcinoma (SCC) constitutes 0.5–2% of prostate cancers. However, autopsy studies of patients with castrate resistant cancers revealed SCC histology in up to 10–20% of patients. Morphology of SCC of prostate was found to be similar to SCC involving other organs. However, some differences have been reported including slightly more chromatin and minor nucleoli in about 30–40% of cases. Prostatic urothelial cancer is a rare solid tumour of prostate that arise from transitional epithelium of intraprostatic peri urethral ducts. Patient mostly present with obstructive voiding and hematuria. It should be differentiated from urothelial cancer of bladder with urethral or secondary prostate involvement. Radical surgery (prostatectomy and cyst prostatectomy) provides optimum results in localized disease and external beam radiotherapy has promising results for short term local control. However, combination
chemotherapy provides good results in metastatic disease.
Ewing sarcoma (ES) is frequently mentioned as part of ES family tumors (ESFT). Based on molecular studies Ewing’s sarcoma (ES) and primitive neuroectodermal tumor (PNET) are considered as a single entity. These are the rare prostatic cancers. Carcinosarcoma is another rare type of prostate cancer, comprising of a combination of an epithelial component (carcinoma) and mesenchymal or mesenchymal-like (Sarcomatoid) component. Due to its local growth in the urinary bladder it may present with lower urinary tract symptoms. Carcinosarcoma has a poor prognosis and around 25% of patients have metastasis upon presentation. Rodrigues et al. reported 3 patients of Sarcomatoid carcinoma having a TMPRSS2-ERG gene, which is associated with adenocarcinoma, therefore suggesting that carcinosarcomas may arise from epithelial cells. Adenoidcystic cancer (ACC) constitutes 0.01% of prostate malignancies. ACC of prostate arises from basal cells and acini of the prostate.

MATERIALS AND METHODS
This retrospective study was conducted at Shaukat Khanum Memorial Cancer Hospital and Research Centre, Lahore, Pakistan. All the patients with prostate cancer presenting to the department of Uro-oncology, from January 2002 to July 2017 were included in the study. Patients above 18 years of age and those having histologically proven non-adenomatous prostate cancers were selected for this study. The clinical information of patients including demographics, medical comorbidities, presenting complaints, pre-operative and post-operative tumor characteristics and treatment in the form of surgery, radiotherapy or chemotherapy were extracted from the hospital information system. Records of included patients were followed for a minimum period of six months and a maximum of one year. Those patients who were unable to complete the proposed follow up were excluded from the study. IBM SPSS Version 20.0 was used for Statistical analysis. Continuous variables were stated as mean ± standard deviation and categorical variables were computed as frequencies and percentages. Ethical approval was taken from the Institutional Review Board (IRB) of Shaukat Khanum Memorial Cancer Hospital and Research Centre, Lahore before starting data collection.

RESULTS
A total of 7 patients of non-adenomatous prostate cancer were included in our study. Mean age of the patients was 64 ± 10 years. Most common (57 %) comorbidity was hypertension, while 28.6% had no comorbid conditions. The main presenting complaint was acute urinary retention (57.1%). Currently 2 patients are alive and on follow up. The main cause of death was disease progression with development of metastasis. Patient characteristics are shown in (Table 1).

Table No.1: Baseline patient’s characteristics
<table>
<thead>
<tr>
<th>Variables</th>
<th>Categories</th>
<th>Total = N* (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Mean ± standard</td>
<td>64 ± 10.36</td>
</tr>
<tr>
<td>Comorbidity</td>
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<td>2 (28.6%)</td>
</tr>
<tr>
<td></td>
<td>Hypertension</td>
<td>4 (57.1%)</td>
</tr>
<tr>
<td></td>
<td>Multiple</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td>Present complaints</td>
<td>Hemanuria</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td></td>
<td>LUTS*</td>
<td>2 (28.6%)</td>
</tr>
<tr>
<td></td>
<td>AUR**</td>
<td>4 (57.1%)</td>
</tr>
<tr>
<td>Present status</td>
<td>On follow up</td>
<td>2 (28.6%)</td>
</tr>
<tr>
<td></td>
<td>Death</td>
<td>5 (71.4%)</td>
</tr>
<tr>
<td>Cause of death</td>
<td>Alive</td>
<td>2 (28.6%)</td>
</tr>
<tr>
<td></td>
<td>Tumor progression</td>
<td>5 (71.4%)</td>
</tr>
</tbody>
</table>

Table No.2: Clinicopathological tumor characteristics
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</thead>
<tbody>
<tr>
<td>cT</td>
<td>T3</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td></td>
<td>T4</td>
<td>4 (57.1%)</td>
</tr>
<tr>
<td>cN</td>
<td>N0</td>
<td>2 (28.6%)</td>
</tr>
<tr>
<td></td>
<td>N1</td>
<td>4 (57.1%)</td>
</tr>
<tr>
<td></td>
<td>N2</td>
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</tr>
<tr>
<td>cM</td>
<td>M0</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td></td>
<td>M1</td>
<td>4 (57.1%)</td>
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<tr>
<td>Histology</td>
<td>Small cell carcinoma</td>
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</tr>
<tr>
<td></td>
<td>Urothelial carcinoma</td>
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</tr>
<tr>
<td></td>
<td>Ewing sarcoma</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td></td>
<td>Carcinosarcoma</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td></td>
<td>Adenoid cystic carcinoma</td>
<td>1 (14.3%)</td>
</tr>
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</table>

Table 3: Disease management and treatment
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<td>Recurrence</td>
<td>No</td>
<td>6 (85.7%)</td>
</tr>
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<td></td>
<td>Yes</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td>Metastasis</td>
<td>No</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>4 (57.1%)</td>
</tr>
<tr>
<td>Site of metastasis</td>
<td>None</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td></td>
<td>Bone</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td></td>
<td>Multiple</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td>Treatment of Metastasis</td>
<td>None</td>
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</tr>
<tr>
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</tr>
<tr>
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<td>Radiotherapy</td>
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</tr>
<tr>
<td></td>
<td>Chemotherapy+ Radiotherapy</td>
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<tr>
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</tr>
<tr>
<td></td>
<td>Radical</td>
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</tr>
<tr>
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<td>None</td>
<td>2 (28.6%)</td>
</tr>
<tr>
<td></td>
<td>Palliative</td>
<td>3 (42.9%)</td>
</tr>
<tr>
<td></td>
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<td>2 (28.6%)</td>
</tr>
<tr>
<td></td>
<td>Palliative</td>
<td>3 (42.9%)</td>
</tr>
</tbody>
</table>
According to TNM staging, most of the patients belonged to T4 (57.1%), N1 (57.1%) and M1 (57.1%) stage. Most common histological diagnosis was SCC and was reported in 3 patients followed by one each patient in Ewing sarcoma, Urothelial, Adenoid cystic and Carcinosarcoma as shown in Table 2. Patients were managed with chemotherapy, given with curative intent in 2 patients and with palliative intent in 3 patients. Radical and palliative radiotherapy was given to 3 patients respectively.

**DISCUSSION**

Prostate cancer is a common tumor of male gender. It constitutes 29% of all Male tumors and accounts for 9% of all male cancer deaths.\(^1\) The most common histology of prostate cancer is adenocarcinoma. In literature, other rare histologies area categorized as non-adenocarcinoma of prostate.\(^1\) Palmgren et al. reviewed 107 studies of small cell carcinoma of prostate from 1983-2005, it was observed that most typical age of diagnosis is 61 to 70 years, with range from 24 to 90 years, and prevalent complain was voiding urinary symptoms in 72 patients. Hematuria and hematochezia were found only in 9 patients.\(^2\) Chemotherapy regimens specific for small cell carcinoma have been employed with a reported response rate of (60%) and median survival of 9 to 10 months. However, one large retrospective univariate analysis showed primary surgery to be the only independent prognostic factor for prolonged survival.\(^3\) The prognosis of small cell carcinoma of the prostate is poor. The median survival is measured in months and long-term survivors are rare. Improved survival appears to be achieved with concurrent external beam radiation therapy and chemotherapy. In patients with resectable localized disease, radical prostatectomy with adjuvant chemotherapy and possibly radiation therapy may result in improved survival.\(^4\) Metastatic disease is treated with primary chemotherapy. The role of radiation should be palliative.\(^5\)

Furthermore, three patients of small cell carcinoma of prostate were included in this study. First patient of 66 years diagnosed as metastatic small cell cancer of prostate (T4N1M1b). He received palliative chemotherapy, and after follow up of 16 months developed brain metastasis for which he received palliative radiotherapy. He died due to progression of disease with a total follow up of 18 months from the day of presentation. Second patient of 70 years presented with metastatic small cell cancer of prostate (Lungs and liver). He underwent palliative chemotherapy and after 8 months of follow up he was diagnosed with brain metastasis for which he received radiotherapy. Patient succumbed due to tumor progression after a total follow up of 18 months. Third patient of 73 years of age was presented with small cell prostate cancer at stage T3N1M0. Chemo radiotherapy was given to the patient as a primary treatment and patient is on regular follow for last 39 months.

Primary urothelial carcinoma of prostate is an extremely rare tumour accounts for 1 to 5 % of all prostate cancers.\(^6\) Patients presented with mean age of 54yrs which is about 10 years younger than adenocarcinoma of prostate.\(^7\) Zhou et al. presented the case history of a 55-year-old man with primary prostate urothelial carcinoma with presenting complaints of Lower urinary tract symptoms. Treated with radical cyst prostatectomy and adjuvant chemotherapy. After 6 months of follow-up local recurrence or metastatic was not found.\(^8\) It is biologically aggressive in nature with high tendency of recurrence and progression resulting in poor survival. Most patients die within 2 years of diagnosis.\(^9\) In the current study an elderly patient of age 75 years with a history of LUTS was diagnosed as metastatic prostatic urothelial cancer of prostate (T4N1M1b). Patient survived for 36 months with palliative treatment.

Ewing’s sarcoma is a rare entity arising from mesenchymal component of prostate stroma with incidence of less than (0.1%) of primary prostate cancers.\(^10\) A study of 7 patients with Ewing sarcoma of prostate revealed a median age of 27 years on diagnosis. Main presenting complaints were dysuria and pelvic pain. Majority of patients were treated with chemotherapy.\(^11\) Four patients underwent radical surgery (cyst prostatectomy or radical prostatectomy). External radiotherapy was administered in 3 cases. Local as well as distant metastasis is reported on presentation, with common involvement of urinary bladder and seminal vesicle. Chemotherapy, radiotherapy, and surgery are the main treatment modalities. Multiple treatment strategies lead to improvement in survival of localized disease with a 5-year relapse free survival of (55%) while patients with metastatic disease have poor relapse free survival of <25%.\(^12\) In current study, one patient with Ewing’s Sarcoma of prostate presented with hematuria at the age of 45 year with no co morbidity with clinical stage of T4N1Mo. He received radical radiotherapy and chemotherapy. After follow up of 40 months he developed recto vesical fistula due to local recurrence, for which he underwent urinary and fecal diversion. He died of tumour progression after 48 months from the date of presentation.

Prostatic Carcinosarcoma (PCS) that was first described in 1967 by Hamlin and Lund,\(^13\) with mean age at diagnosis is around 66, it is very rare entity and has a poor outcome with the survival of around seven months.\(^14\) The origin is still controversial with some believing that both carcinoma and sarcoma developed simultaneously with in the prostate while others suggest that adenocarcinoma transforms in to sarcoma.\(^15\) Niwa et al. presented the case study of a 77 old man with the complaint of hematuria; TNM staging revealed
T3aN0Mo disease. Due to rapid growth of tumour, patient underwent pelvic exenteration with bilateral ureterostomies and colostomy. Local recurrence was again detected and the patient died within 12 months of first visit. Treatment strategies for prostatic urethelial carcinoma are multimodal, including surgery, adjuvant chemotherapy, and radiotherapy. The most common site of metastasis of PCss was the lung (43%). Despite the multiple therapies used to treat PCS, the reported 5-year survival is (41%) and 7-year survival of (14%). Our study include 59 year old patient presented with metastatic Carcinosarcoma of prostate (metastasis to pelvic lymph nodes and bones). He received palliative radiotherapy for bone pains and died after 11 months of diagnosis due to tumour progression. Adenoid cystic/basal cell carcinoma of the prostate (ACBCC), was described in 1974. It has been reported in patients between 28-72 years of age. Iczkowski studied 19 cases with a having mean age of 66 years, the main presenting symptom was of urinary retention (15 patients). Radical prostatectomy was performed in 5 patients, 2 underwent pelvic exenteration, while one patient was treated with radiotherapy. The remaining patients had no further treatment after trans urethral resection of prostate. Metastases advanced in 4 (21%) patients: liver in two, lung in two, and bowel in one, and corpus cavernous involvement in one patient. In fifteen patients during follow-up (3months–11.8 years), only 2 deaths were reported. We have one patient of adenoid cystic carcinoma of prostate in our study. He was diagnosed at the age of 60 year following TURP for urinary retention. He received radical radiotherapy for stage T3NoMo. Currently remains well on follow up for the last 60 months.

CONCLUSION

Non-adenocarcinoma prostate cancers are rare and generally aggressive tumours with a poor prognosis. They present at a relatively younger age and require aggressive therapy in the form of chemotherapy, radiotherapy and surgery.

Author’s Contribution:

Concept & Design of Study: Siddique Adnan

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Muhammad Arshad
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Final Approval of version: Siddique Adnan

Conflict of Interest: The study has no conflict of interest to declare by any author.

REFERENCES


Original Article

Examine the Efficacy of Rifaximin for Hepatic Encephalopathy Patients with Chronic Liver Disease

Muhammad Uthman¹, Syed Waseem Ahmad Mujtaba² and Abdul Matin Qaisar³

ABSTRACT

Objective: To evaluate the effects and outcomes of rifaximin for the treatment of hepatic encephalopathy with chronic liver disease patients.

Study Design: Prospective/Randomized controlled trial study.

Place and Duration of Study: This study was conducted at the Department of Medicine, Shaikh Zayed Hospital Lahore from 1st July 2019 to 31st December 2019.

Materials and Methods: Eighty four patients of both genders whom were diagnosed with hepatic encephalopathy with chronic liver disease were including in this study. All the patients were divided into two groups, Group A included 42 patients and received treatment rifaximin with lactulose, Group B (control group) included 42 patients receiving placebo with lactulose. Follow-up was taken at 15 days or at discharge. Hepatic encephalopathy index and Child-Turcotte-Pugh (CTP) score and model for end-stage liver disease (MELD) were recorded to examine the outcome of treatment.

Results: In group A 30 patients were males and 12 were females while in Group B, 32 patients were males and 10 patients were females. In Group A, 34 patients were ages <60 years while 8 patients had ages >60 years, In Group B, 33 patients were ages <60 years and 9 patients were ages >60 years. At start of treatment Child-Turcotte-Pugh score p-value 0.467 and model for end-stage liver disease index p-value 0.874 were not statistically significant difference between two groups. Toward the finish of treatment there was noteworthy distinction discovered identified with hepatic encephalopathy file p-esteem 0.039 and model for end-stage liver ailment file p-esteem <0.05 than fake treatment gathering. Youngster Turcotte-Pugh score 0.621 was additionally lower in rifaximin bunch than Group B.

Conclusion: The use of rifaximin with lactulose for the treatment of hepatic encephalopathy resulted better outcome than placebo with respect to model for end-stage liver disease index and hospital stay.

Key Word: Rifaximin, Chronic liver disease, Hepatic encephalopathy


INTRODUCTION

Hepatic encephalopathy (HE) is a reversible neuro-mental disorders related with ceaseless and intense liver brokenness. It is portrayed by subjective and engine shortfalls of fluctuating seriousness. Early manifestations incorporate inversion of rest design, lack of care, hypersomnia, peevishness and individual disregard. In later stages, daze and unconsciousness can emerge with neurologic signs including hyperreflexia, unbinding nature, myoclonus, and asterixis.¹

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The pathophysiology of HE is mind boggling and it shows with dynamic disintegration of the predominant neurological capacities. Hepatic encephalopathy happens within the sight of inadequate hepatic leeway of poisons ingested from the digestive tract bringing about neurochemical anomalies over the blood mind barrier.² Elevated serum smelling salts level is the best portray reason for HE and is identified in60%-80% of influenced patients.³,⁴ Current treatment systems are planned for diminishing the serum level of ammonia.⁵ This is finished by presenting operators that decrease or restrain creation of intestinal alkali or limit its assimilation from the gastrointestinal tract just as adjusting fastening components, for example, gastrointestinal discharge, electrolyte lopsided characteristics and blockage, contamination, prerenalazotemia, hypokalaemic alkalosis, stoppage, hypoxia, hypovolemia or the utilization of narcotics and tranquilizers.⁶ Various medications have been attempted either separately or in blend of at least two and in correlation with fake treatments too. These included lactulose, lactitol, anemas, dietary limitation of dietary...
protein and oral anti-infection agents as metronidazole, neomycin, vancomycin, rifaximin, probiotics, amino acids and different minerals have been attempted. They have indicated diverse level of viability. Anyway metronidazole, lactulose and douche are the most regularly utilized. Rifaximin is an oral anti-infection which isn't invested in the gut and has indicated great efficacies in adjusting gut flora. On the other hand, rifaximin is an ineffectively consumed expansive range anti-microbial with not many foundational symptoms and at okay of prompting bacterial resistance. These properties make rifaximin a perfect anti-infection for the treatment of patients with HE as a few investigations have demonstrated a noteworthy lessening in plasma smelling salts levels with negligible effect on the ordinary gastrointestinal flora. This study was conducted aimed to analyze the outcome of rifaxime in chronic liver disease patients, so that better treatment could be provided and to reduce the morbidity and mortality rate of chronic liver disease patients.

MATERIALS AND METHODS

This study was conducted at Department of Medicine, Shaikh Zayed Hospital Lahore from 1st July 2019 to 31st December 2019. A total of 84 patients of both genders whom were diagnosed with hepatic encephalopathy with chronic liver diseases were included. All the patients were divided into two groups, Group A included 42 patients and received treatment rifaximin with lactulose, Group B (control group) included 42 patients receiving placebo with lactulose. Patients with heart failure, alcohol users, neurological and patients with severe bad health were excluded. Rifaximin 550mg dosage for two time daily and Group B was put on placebo for 10days. Follow up was taken at 15 days or at discharge. Hepatic encephalopathy index and protosystemic encephalopathy index was recorded to examine the outcome of treatment. All the statistical data was analyzed by SPSS 20. P-value <0.05 was considered as significant.

RESULTS

In group A 30 (71.43%) patients were males and 12 (28.57%) were females while in group B, 32 (76.19%) patients were males and 10 (23.81%) patient were females. In group A, 34 (80.95%) patients were ages <60 years while 8 (19.05%) patients had ages >60 years, in group B, 33 (78.58%) patients were ages <60 years and 9 (21.43%) patients were ages >60 years (Table 1).

At start of treatment Child-Turcotte-Pugh score p-value 0.467 and model for end-stage liver disease index p-value 0.874 were not statistically significant difference between two groups. At the end of treatment there was significant difference found related to hepatic encephalopathy index p-value 0.039 and model for end-stage liver disease index p-value <0.05 than placebo group. Child-Turcotte-Pugh score 0.621 was also lower in rifaximin group than Group B. [Tables 2-3].

DISCUSSION

Liver cirrhosis particularly because of hepatitis B and C is an incredible wellbeing concern and their numbers on the ascent in creating nations where there are lesser wellbeing offices and poor mindfulness. This prompts movement of malady and afterward entanglements like hepatic encephalopathy have been seen which were not overseen forcefully can be lethal. Various pharmacological and non-pharmacological moves have been considered to maintain a strategic distance from this with various level of accomplishment. In this study we found that males patients population was high as compared to females 3:1 in both rifaximine group and placebo group. These results shows similarity to some other studies in which number of male patients population was high as compared to females 75 to 85%. We found that there is no significant difference in mean age in both groups. It showed similarity to the study conducted by Paik et al.
in which there was no significant difference according to mean age and gender in placebo and rifaximin group. In our investigation we found that at enlistment, there was no critical contrast of HE grade between two groups (p=0.87). Toward the finish of treatment, there was noteworthy distinction of mean HE grade between two groups (p=0.04). This outcome like two different examinations directed by Hussain et al11 and Massa et al17 where rifaximin treated patients more altogether improved HE grade than lactulose treated patients. In any case, this outcome contrast with other investigation led by Paik et al. indicated the mean HE grade was comparatively diminished inside the examination groups (p=<0.001).18 At development, there was no critical contrast of CTP score mean between two groups (p = 0.489 and 0.62 individually). Study directed with respect to utilization of rifaximin demonstrated no noteworthy distinction of CTP score mean between two groups (p = 0.404, 0.505 respectively).19 In our investigation, we found that there was huge distinction of methods for length of emergency clinic remain between two groups (p=0.008). This outcomes bolster two review audit considers, where rifaximin and lactulose decreased hazard and length of hospitalization.20

CONCLUSION

Hepatic encephalopathy in chronic liver disease is a common clinical disorder with high rate of morbidity. We concluded from this study that rifaximine with lactulose showed better efficacy than lactulose alone for reducing the morbidity associated with hepatic encephalopathy.

Author’s Contribution:

Concept & Design of Study: Muhammad Uthman
Drafting: Syed Waseem Ahmad Mujtaba
Data Analysis: Abdul Matin Qaisar
Revisiting Critically: Muhammad Uthman, Syed Waseem Ahmad Mujtaba
Final Approval of version: Muhammad Uthman

Conflict of Interest: The study has no conflict of interest to declare by any author.

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Risk Factors Associated with Gastro-Esophageal Reflux Disease

Shahid Karim, Syeda Nosheen Zehra, Hamid Ali Kalwar, Afsheen Faryal and Muhammad Tanweer Khalid

ABSTRACT

Objective: To study the risk factors associated with Gastroesophageal reflux disease (GERD), in a tertiary care Hospital of Karachi.

Study Design: Prospective, cross sectional study

Place and Duration of Study: This study was conducted at the Department Internal Medicine and Gastroenterology, Liaquat National Hospital, Karachi from February 2009 to March 2010.

Materials and Methods: Attendants of patients sitting in the waiting area with no comorbid, and who were non-smoker and non-alcoholic were recruited after taking informed consent. Data was entered in given performa. Logistic regression was applied with 95% confidence interval.

Results: Total 2191 participants were included in our study. 1130 patients (51.6%) were males and 1061 (48.4%) were females, with mean age of 33.92±12.36 years. GERD symptoms were present in 760 patients (34.7%). GERD symptoms were common in patients taking spicy meals (37.2%) and in urdu speaking ethnic group (52.5%). In those who had a high waist hip ratio, 0.9+-0.15 waist height ratio 0.52+-0.07 and waist circumference ratio 84.57+-10.92.

Conclusion: Gastroesophageal reflux disease is common in our population and there is significant inverse association of GERD with Waist hip ratio and waist height ratio.

Key Words: Gastroesophageal reflux disease, body mass index


INTRODUCTION

Gastroesophageal reflux disease (GERD) is one of the commonly known disorders in upper gastrointestinal tract. GERD has been observed in an increasing extent in Europe as well as United States of America. The symptoms of GERD are considered as the most common symptoms among the gastrointestinal symptoms in the regions as mentioned earlier with the occurrence of 10-25% as indicated by the different population based studies.

The occurrence of Gastro esophageal reflux disease <5% is reported for Asia. Literature from Iran indicates same rate of prevalence of GERD which have been reported for the western countries. GERD can be categorized on the basis of typical, atypical and esophageal symptoms. Typical symptoms include heart burn, regurgitation and dysphagia the atypical symptoms include cough and wheezing, hoarseness, sore throat, otitis media, non cardiac chest pain, enamel erosion or dental manifestations. The treatment is based on lifestyle modifications and control of gastric acid secretion through medical therapy with proton pump inhibitors and antacids or through corrective antireflux surgery.

Contributing factors of GERD have been examined in the population generally as reported by various studies but some of potential contributing factors have indicated different results. The data from the developing and under developed countries have been obtained in limited amount and only few population based studies have been conducted which present the determinants of GERD. This study is aimed to investigate the contributing factors of Gastro esophageal reflux disease (GERD). A potential unit of around 2290 volunteers was recruited in a tertiary care hospital of Karachi, Pakistan. Data was analyzed on the basis of frequency, perceived severity of symptoms and the time of first occurrence of GERD symptoms.

MATERIALS AND METHODS

Single center Prospective, cross sectional study was conducted from the duration of February 2018 to March 2019. Patients were recruited after taking informed consent and were above 18 years of age present in outpatient clinic of the various section of hospital having no history of comorbids such as;
diabetes, ischaemic heart disease, hypertension, stroke, and renal diseases and were non smokers and non addicts with no history of taking beta-blocker, aspirin or NSAIDS within the duration of last 6 months. This study was conducted by the team of trained doctors and medical students who explained everything to the respondents in the case of any confusion. Patients were inquired about GERD and screening questions were asked from them i.e. presence of retrosternal burning, burning of throat’s back, sour / bitter taste, symptoms of GERD after meal, simultaneously, they were asked about the symptoms of GERD two or more times in week. Two or more "Yes" for asked questions was interpreted as the presence of symptoms of GERD.

On the basis of presence or absence of gastroesophageal reflux symptoms (GERD) the respondents were divided into two groups. The variables i.e. age, gender, geographical background, education, eating habits, frequency of meals, GERD symptoms, BMI, hip waist circumference, hip waist ratio, height waist ratio were recorded by the researcher on already designed Performa/questionnaire. The questionnaire was already validated and as well as translated in local language for the study which was conducted at the department of gastroenterology (medicine) in 2005 at Agha Khan University Hospital (KUH). Exclusion criteria were strictly followed so that the confounding variables could be avoided.

Statistical analysis: The obtained data was analyzed by using the commonly used software i.e. statistical package for social sciences (SPSS) version 22. At the very first the descriptive statistics was used for the analysis. Frequency distribution i.e. counts and percentages were reported. The whole data was presented by using the mean ± standard deviation. The level of statistical significance of comparison of means was investigated by using chi square and t-test and Fisher’s exact formula. 5% statistical significance i.e. p—value = 0.05 was considered.

RESULTS

Total 2191 participants were included in our study. 1130 patients (51.6%) were male and 1061 (48.4%) were females, with mean age of 33.92±12.36 years.

In our study GERD symptoms were present in 760 patients (34.7%), as shown in Table-1

<table>
<thead>
<tr>
<th>Variables</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>1130</td>
<td>51.6%</td>
</tr>
<tr>
<td>Female</td>
<td>1061</td>
<td>48.4%</td>
</tr>
</tbody>
</table>

Table No. 1: Frequency distribution of total number of study participants and gender

<table>
<thead>
<tr>
<th>Total number of study participants</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gerd present</td>
<td>760</td>
<td>34.7%</td>
</tr>
<tr>
<td>Gerd not present</td>
<td>1431</td>
<td>65.3%</td>
</tr>
</tbody>
</table>

Table No. 2: Frequency distribution of age, bmi, waist hip ratio, waist height ratio and waist circumference

<table>
<thead>
<tr>
<th>Variables</th>
<th>Min.</th>
<th>Max.</th>
<th>Mean+sd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age years</td>
<td>18</td>
<td>87</td>
<td>33.92±12.36</td>
</tr>
<tr>
<td>Bmi</td>
<td>18</td>
<td>41.88</td>
<td>24.09±3.98</td>
</tr>
<tr>
<td>Waist hip ratio</td>
<td>0.67</td>
<td>3.95</td>
<td>0.90±0.15</td>
</tr>
<tr>
<td>Waist height ratio</td>
<td>0.36</td>
<td>0.92</td>
<td>0.52±0.07</td>
</tr>
<tr>
<td>Waist circumference</td>
<td>66</td>
<td>140</td>
<td>84.57±10.92</td>
</tr>
</tbody>
</table>

Table No. 3: Frequency distribution of ethnicity, education level and occupation

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Punjab</td>
<td>351</td>
<td>16%</td>
</tr>
<tr>
<td>Sindh</td>
<td>332</td>
<td>15.2%</td>
</tr>
<tr>
<td>Kpk</td>
<td>256</td>
<td>11.7%</td>
</tr>
<tr>
<td>Urdu speaking</td>
<td>1150</td>
<td>52.5%</td>
</tr>
<tr>
<td>Balochistan</td>
<td>111</td>
<td>4.8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education level</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graduate</td>
<td>1068</td>
<td>48.7%</td>
</tr>
<tr>
<td>Inter pass</td>
<td>320</td>
<td>14.6%</td>
</tr>
<tr>
<td>Middle pass + matriculation</td>
<td>415</td>
<td>18.9%</td>
</tr>
<tr>
<td>Illiterate</td>
<td>388</td>
<td>17.7%</td>
</tr>
</tbody>
</table>

Table No. 4: Frequency distribution of frequency of GERD symptoms

<table>
<thead>
<tr>
<th>Uncomfortable feeling behind the sternum</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>944</td>
<td>43.1%</td>
</tr>
<tr>
<td>No</td>
<td>1247</td>
<td>56.9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Burning back of throat</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>528</td>
<td>24.1%</td>
</tr>
<tr>
<td>No</td>
<td>1663</td>
<td>75.9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bitter taste of mouth</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>577</td>
<td>26.3%</td>
</tr>
<tr>
<td>No</td>
<td>1614</td>
<td>73.3%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptoms after meal</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>856</td>
<td>39.1%</td>
</tr>
<tr>
<td>No</td>
<td>1335</td>
<td>60.9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Two or more times gerd symptoms/week</th>
<th>Frequency (n)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>460</td>
<td>21%</td>
</tr>
<tr>
<td>No</td>
<td>1731</td>
<td>79%</td>
</tr>
</tbody>
</table>

Temporary relief with proton pump inhibitor and h2 receptor blocker

| Yes | 507  | 23.1% |
| No  | 1684 | 76.9% |

The majority of subjects 1150 (52.5%) included in our study were Urdu speaking people, 351 (16%) were Punjabi, 332 (15.2%) were Sindhi, 256 (11.7%) were pathan and 111 (4.8%) were Balochis as in table I.

Regarding education status in our study, majority of patient were 1068 (48.7%) were graduate, 388 (17.7%)
were illiterate, 320 (14.6%) were intermediate pass and 415 (18.9%) were middle pass / matriculation pass. The mean BMI was 24.09±3.98 kg/m², the mean Waist hip ratio was 0.90±0.15 cm, the mean Waist height ratio was 0.52±0.07 cm and the mean waist circumference ration was 84.57±10.92 cm as shown in table 2.

History of fixed meal was observed in 706 patients (32.2%), spicy meal 816 (37.2%), cold drink in 158 (7.2%) and history of chocolate was seen in 80 patients (3.7%), as shown in Table 5.

GERD symptoms e.g. uncomfortable feeling behind breast bone moving upward were observed in 944 (43.1%) patients, burning back of throat in 528 (24.1%), bitter taste in mouth in 577 (26.3%), symptoms after meal in 856 (39.1%), as shown in Table 4.

Two or more time GERD symptoms per week were observed in 460 patients (21%), temporary relief with medicine was observed in 507 (23.1%), as shown in Table 4.

GERD symptoms were more common in graduates and in Urdu speakers and patients taking spicy meals. GERD is significantly associated with increased Waist hip ratio and waist height ratio.

**Table No. 5: Frequency distribution of aggregating factors**

<table>
<thead>
<tr>
<th>Aggregating factors</th>
<th>Fixed meal</th>
<th>Spicy meal</th>
<th>Cold drink</th>
<th>Chocolate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency (n)</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Percentage (%)</td>
<td>67.8%</td>
<td>32.2%</td>
<td>62.8%</td>
<td>96.3%</td>
</tr>
</tbody>
</table>

**DISCUSSION**

GERD is an unremitting disease of multi-factorial etiology in which genetic and environmental factors play a pivotal role. It was shown in global studies that different anthropometric measurements were studied for GERD, that included Hip circumference grips, BMI, Waist circumference grips along with other factors like Age, Education level, Socioeconomic status. In most but not in all studies, positive relation between GERD and age have been kept under consideration. The relationship between GERD symptoms and gender are mixed in present evidences. But in most of the studies this association has not been shown. In our study GERD symptoms were more common in graduates and in Urdu speakers and patients taking spicy meals. GERD is significantly associated with increased Waist hip ratio and waist height ratio.

**Table No. 6: Frequency distribution of GERD**

<table>
<thead>
<tr>
<th>BMI</th>
<th>Confidence Interval (Ci)</th>
<th>P-value</th>
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<td>18-23</td>
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<td>23-25</td>
<td>1.25(0.99-1.56)</td>
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<td>1.11(0.88-1.4)</td>
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<td>1.70(1.38-2.09)</td>
<td>0.001</td>
<td>1.15(0.88-1.51)</td>
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<td>91-100 cm</td>
<td>1.24(0.97-1.60)</td>
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<td>0.74(0.55-1.01)</td>
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<td>&gt; 101</td>
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<td>0.91(0.58-1.42)</td>
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<td>≤0.90</td>
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<td>1</td>
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<tr>
<td>0.91-1.00</td>
<td>1.47(1.22-1.77)</td>
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<td>1.38(1.14-1.68)</td>
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<tr>
<td>&gt;1.01</td>
<td>2.35(1.71-3.80)</td>
<td>0.001</td>
<td>2.15(1.42-3.25)</td>
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<tr>
<td>Waist height ratio</td>
<td></td>
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<td></td>
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<td>≤0.50</td>
<td>1</td>
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<tr>
<td>0.51-0.6</td>
<td>1.67(1.38-2.02)</td>
<td>0.001</td>
<td>1.59(1.24-2.02)</td>
<td>0.001</td>
</tr>
<tr>
<td>&gt;0.61</td>
<td>2.16(1.63-2.87)</td>
<td>0.001</td>
<td>2.06(1.30-3.27)</td>
<td>0.002</td>
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</table>
level. This association can be explained by the fact that the greater the educational level of an individual more will be the level of perception of stress by these individuals, secondarily these people are more likely to be employed in sedentary desk jobs.

In our study GERD symptoms were seen more in males (20.5%) as compared to females (15.2%), the previous literature did not highlight any difference regarding the relationship of GERD and obesity in terms of gender [23]. In relation to age (17.6%) observed in age group of 31-50 years. This is the most active age group where an individual is exposed to more stress as well as the body starts losing the lith with tends to accumulate abdominal fat.

Higher prevalence of GERD symptoms i.e. 23% were documented in the respondents with body mass index (BMI) i.e. 23-27.4 kg/m2. Those Respondents having overweight and normal BMI, GERD was commonly found as compared to patients with BMI above 28, highlighting the fact that overall obesity is not as important a risk factor than central obesity this is in accordance with another study which showed that central obesity seemed a more important factor than overall obesity. However many previously conducted studies have indicated the relationship between GERD symptoms and higher level of BMI [6,17]. Increased inner abdominal pressure probably is the explanation of relationship of GERD with body mass index (BMI) and especially central obesity. Although, other mechanisms also seemed to be there which contribute in this relationship i.e. lower pressure of esophageal sphincter in fat individuals [20,21]. Exposure of esophageal acid has been positively correlated with body mass index (BMI) as well as waist circumference as the clear relationship of GERD and obesity has been indicated in the western countries [23]. But in this study the relationship between generalized obesity and GERD was not found. Inconsistent results have been concluded from the population based studies of China on the relationship between GERD and BMI. The association of GERD and abdominal fat was assessed in the study conducted by Chen et al; but no significant relationship between central obesity and reflux symptoms was found [25]. However our study is showing only association of central obesity with GERD rather than generalized obesity. This study found the significant inverse association between GERD symptoms with waist hip ratio and waist height ratio. More longitudinal studies on this issue are required to be conducted.

**CONCLUSION**

In conclusion GERD is common in our population and there is significant inverse association of GERD with Waist hip ratio and Waist height ratio. Thus abdominal obesity rather than generalized obesity was more prominent risk factor in our population.

**REFERENCES**

Prevalence/Trend of Bone Fractures in Road Traffic Accidents
Muhammad Asif Saeed¹, Imran Idrees Butt², Maqsood Ahmed Khan³, Kamran Hamid⁴, Salman Imran Butt⁴ and Muhammad Haris Muaaz⁴

ABSTRACT

Objective: To study Prevalence/Trend of bone fractures in road traffic accidents.
Study Design: Observational Study
Place and Duration of Study: This study was conducted at the Department of Surgery, Idris Teaching Hospital Sialkot Medical College Sialkot from Jan 2009 to Jan 2019.
Materials and Methods: This Study was conducted on 1366 victim of road traffic accidents. The age, gender and bone involved was noted down. The informed consent was taken from each patient of road traffic accident. The findings were noted on the design Perfora. The permission of ethical committee was also considered before start of the study and publishing in research journal.
Results: At the age of 5-15, there were 198(14.5%) were male and 19 (1.4%) female patients were found in road traffic accident in which different bones were found fractured. At the age of 16-25 there were 391 (28.6%) male and 74 (5.4%) were female. At the age of 26-35 there were 248 (18.1%) male and 59 (4.3%) were female. At the age of 36-45 there were 217 (15.9%) male and 47 (3.44%) female. At the age of 46-55 there were 66 (4.83%) and 16 (1.17%) were female. At the age of 56-65 there were 11 (0.80%) male and 03 (0.22%) female. At the age of 65-70 there were 08 (0.58%) male and 02 (0.14%) female. Above 70 there were 06 (0.44%) male and 01 (0.07%) female. There were total 1145 (83.8%) male and 221 (16.2%) female. There was femur fracture in male patients at proximal 81 (4.73%), shaft of femur 267 (15.61%) , distal part of femur 31 (1.81%) and in female patients proximal part 06 (0.35%), Shaft of femur 42 (2.46%), at distal part of femur 03 (0.18%). There was Tibia/fibula fracture in male at proximal part 85 (4.97%), shaft part 301 (17.60%), distal part 72 (4.21%) and in female patients proximal part 06 (0.35%), shaft part 56 (3.27%), distal part 05 (0.29%). There was humerus fracture in male patients at proximal part 18 (1.05%), shaft 107 (6.25%), distal part 14 (0.82%). In female patients, shaft part 21 (1.23%), distal part 03 (0.17%). There was fracture of radius/ulna 246 (14.38%) in male patients and 56 (3.27%) in female patients. There was pelvis fracture 27 (1.57%) in male patients and 12 (0.70%) in female patients. There was clavicle fracture in 63 (3.68%) male patients and 17 (0.99%) female patients. Hand/feet bone fracture 134 (7.83%) in male, 33 (1.92%) in female.
Conclusion: It was concluded from the study that there were multiple bony fracture take place during road traffic accidents.
Key Words: Prevalence/Trend, bone fractures, road traffic accidents


INTRODUCTION

Road traffic injuries (RTIs) are responsible for a substantial proportion of deaths and injuries and are responsible for more years of life lost than most human diseases. Human behavior factors, vehicle factors, and road factors contribute to the causation of road traffic crashes¹. Although the numbers of lives lost in road crashes in high-income countries indicate a downward trend in recent decades, for most of the world’s population, the burden of road-traffic injury in terms of societal and economic costs is rising substantially². The distribution of road traffic deaths by road user group varies dramatically across epidemiological WHO sub-regions and also varies across low-income, middle-income, and high-income countries. For example, 45% of road traffic fatalities in low-income countries are among pedestrians, whereas an estimated 29% in middle-income and 18% in high-income countries are among pedestrians³. Global efforts to reduce road traffic injuries may be facilitated. For example, motorcycle helmets were found to reduce the risk of head injury and from five well-conducted studies the risk reduction is estimated to be 72% (odds ratio (OR): 0.28, 95% confidence interval (CI): 0.23–0.35) although there was

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Email: doctorasifa@gmail.com

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Printed: April, 2020
some evidence that the effect of helmets on mortality is modified by speed\(^4\).

There is a dearth of information on injury patterns that could be used to prioritize injury prevention measures. For example, hospital discharge data from eight European countries, including 10,341 pedestrians sustaining 19,424 injuries, have been used and fractures (51.1\%, 95\% CI: 50.3–51.8) and internal injuries (21.3\%, 95\% CI: 20.7–21.9) are the most frequently found in the data\(^5\). From the viewpoint of preventive medicine, a comprehensive survey of nationwide traumatic epidemiology, especially related to traffic accidents, should be necessary for Taiwan's health authority to redistribute medical resources to the major injuries. The present study, based on the Taiwan's national admission data, is aimed to (1) investigate the occurrence of injuries associated with traffic accidents, (2) find the major distributions of injury patterns, and (3) evaluate the risk factors of the main injury. \(^6\)

**MATERIALS AND METHODS**

This study was conducted at the Department of Surgery, Idris Teaching Hospital Sialkot Medical College Sialkot from Jan 2009 to Jan 2019. This Study was conducted on 1366 victim of road traffic accidents. The age, gender and bone involved was noted down. The informed consent was taken from each patient of road traffic accident. The findings were noted on the design Performa. The permission of ethical committee was also considered before start of the study and publishing in research journal.

**RESULTS**

At the age of 5-15, there were 198(14.5\%) were male and 19 (1.4\%) female patients were found in road traffic accident in which different bones were found fractured. At the age of 16-25 there were 391 (28.6\%) male and 74(5.4\%) were female. At the age of 26-35 there were 248 (18.1\%) male and 59(4.3\%) were female. At the age of 36-45 there were 217(15.9\%) male and 47 (3.4\%) female. At the age of 46-55 there were 66 (4.8%) and 16(1.17\%) were female. At the age of 55-70 there were 11(0.80\%) male and 03(0.22\%) female. At the age of 65-70 there were 08 (0.58\%) male and 02 (0.14\%) female. Above 70 there were 06 (0.44\%) male and 01(0.07\%) female. There were total 1145(83.8\%) male and 221(16.2\%) female.

There was femur fracture in male patients at proximal part 81(4.73\%), shaft part 267(15.61\%), distal part 03(1.81\%) and in female patients proximal part 06(0.35\%), Shaft of femur 27(1.57\%), at distal part of femur 03(0.18\%). There was Tibia/fibula fracture in male at proximal part 85(4.97\%), shaft part 301(17.60\%), distal part 72 (4.21\%) and in female patients proximal part 06(0.35\%), shaft part 56(3.27\%), distal part 05 (0.29\%). There was humerus fracture in male patients at proximal part 18(1.05\%), shaft 107(6.25\%), distal part 14(0.82\%). In female patients 04(0.23\%), shaft part 21 (1.23\%), distal part 03(0.17\%). There was fracture of radius/ulna 246(14.38\%) in male patients and 56(3.27%) in female patients. There was pelvis fracture 27(1.57\%) in male patients and 12(0.70%) in female patients. There was clavicle fracture in 63(3.68%) male patients and 17(0.99%) female patients. Hand/feet bone fracture 134(7.83%) in male, 33(1.92\%) in female.

<table>
<thead>
<tr>
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<th>Female</th>
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<tr>
<td>1</td>
<td>Femur</td>
<td>5-15</td>
<td>198 (14.5%)</td>
<td>19 (1.4%)</td>
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<tr>
<td>2</td>
<td>Tibia/Fibula</td>
<td>16-25</td>
<td>391 (28.6%)</td>
<td>74 (5.4%)</td>
</tr>
<tr>
<td>3</td>
<td>Humerus</td>
<td>26-35</td>
<td>248 (18.1%)</td>
<td>59 (4.3%)</td>
</tr>
<tr>
<td>4</td>
<td>Radius/Ulna</td>
<td>36-45</td>
<td>217 (15.9%)</td>
<td>47 (3.4%)</td>
</tr>
<tr>
<td>5</td>
<td>Pelvis</td>
<td>46-55</td>
<td>66 (4.8%)</td>
<td>16 (1.17%)</td>
</tr>
<tr>
<td>6</td>
<td>Clavicle</td>
<td>56-65</td>
<td>00 (0.0%)</td>
<td>03 (0.22%)</td>
</tr>
<tr>
<td>7</td>
<td>Hand/Feet</td>
<td>65-70</td>
<td>08 (0.58%)</td>
<td>02 (0.14%)</td>
</tr>
<tr>
<td>8</td>
<td>Above 70</td>
<td>70</td>
<td>06 (0.44%)</td>
<td>01 (0.07%)</td>
</tr>
<tr>
<td>Total</td>
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<td>1145 (83.8%)</td>
<td>221 (16.2%)</td>
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<table>
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<th>Male</th>
<th>Female</th>
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</thead>
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<tr>
<td>1</td>
<td>Femur</td>
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<td>81(4.73%)</td>
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<td>Shaft</td>
<td>267(15.61%)</td>
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<td></td>
<td>Distal</td>
<td>31(1.81%)</td>
</tr>
<tr>
<td>2</td>
<td>Tibia/Fibula</td>
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<td>85(4.97%)</td>
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<td>Shaft</td>
<td>301(17.60%)</td>
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<td>Distal</td>
<td>72(4.21%)</td>
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<tr>
<td>3</td>
<td>Humerus</td>
<td>Proximal</td>
<td>18(1.05%)</td>
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<td></td>
<td>Shaft</td>
<td>107(6.25%)</td>
</tr>
<tr>
<td></td>
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<td>Distal</td>
<td>14(0.82%)</td>
</tr>
<tr>
<td>4</td>
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<td>246(14.38%)</td>
<td>56(3.27%)</td>
</tr>
<tr>
<td>5</td>
<td>Pelvis</td>
<td>27(1.57%)</td>
<td>12(0.70%)</td>
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<td>6</td>
<td>Clavicle</td>
<td>63(3.68%)</td>
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<td>Hand/Feet</td>
<td>134(7.83%)</td>
<td>33(1.92%)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1446(84.56%)</td>
<td>264 (15.43%)</td>
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**DISCUSSION**

An international evaluation of the Global Burden of Diseases, Injuries, and Risk Factors Study 2010 (GBD 2010), identifying all available data on causes of death for 187 countries from 1980 to 2010, showed that the fraction of global deaths due to injuries was marginally higher in 2010 (9.6\%) compared with two decades earlier (8.8\%). This was driven by a 46\% rise in worldwide deaths due to road traffic accidents and a
rise in deaths from falls. Because of this significant burden, the primary purpose of this study was to explore the incidences of injuries associated with traffic accidents and their modifiable risk factors to promote the advance of health and injury-prevention policies in Taiwan.

In this present study, annual road traffic injury incidences rate in recent ten years was from 9.17% to 11.54%; the highest was in 2011. These high incidences were similar to those reported in the Vorko-Jović (2006) study, which focused on urban road traffic accidents in Croatia. Another similar result was also found in an America study, which also reported the gender difference that males are much more likely to get injury in a road traffic crash than females, especially among adults and the elderly. Our study was consistent with previous studies. Table 1 demonstrates that males are much more likely to be killed in a road traffic injury than females.

Head and spine injuries were most common among front and rear vehicle occupants and drivers. Among motorcycle riders admitted to the hospital, the most common head injuries are concussions, followed by brain injuries or hemorrhage, facial fractures, and skull fractures. In Taiwan, 18% of the inpatients who suffered from head injuries were estimated in the present study. Around 7.6% to 75.1% of motorcycle riders got head injuries without helmets; oppositely, the incidence of head injuries in motorcycle riders who wear helmets is 3.4% to 40.6%. These highly differences of injury incidence between helmeted or nonhelmeted riders were similar to those reported in a meta-analysis study. Motorcycle helmets were estimated to reduce 72% risk of any kinds of head injury (odds ratio (OR): 0.28, 95% confidence interval (CI): 0.23–0.35). That is another issue worthy to be investigated in Taiwan.

Head injuries are the leading cause of death in motorcycle accidents, even in helmeted riders. For instance, in the US, 53% of motorcycle deaths were a result of head injuries. Incidence of head injuries caused by a rotational acceleration has been pointed out in the literature, but they underestimate the number of pedestrian fatal victims in eight European countries and in San Francisco study. A previous study in the United Arab Emirates reported that road traffic victims are predominantly male (89%), pedestrians (88%). In UAE study, the Trauma Registry of Al Ain city was collected over 3 years, and showed that there were 1070 patients, mainly from non-Arabic speaking expatriates, low-income countries. Overall mortality was 4%; pedestrians accounted for 61% of deaths. Head injury was the major factor affecting hospitalization and mortality.

In the USA, 5,838 admissions of an academic Level I trauma center registered over 10 years were reviewed and showed that there were 1,136 patients (19.4%) 14 years old or less, 3,741 (64.1%) who were 15 to 55 years old, 420 (7.2%) 56 to 65 years old, and 541 (9.3%) older than 65 years. Overall mortality was 7.7% and ranged from 3.2% in the age group of 14 years or less to 25.1% in patients over 65 years. In the USA, another National Trauma Databank study during a 5-year period including 12,429 admissions revealed that there were 4,095 patients (32.9%) ≤14 years, 3,806 (30.7%) 15 to 35 years old, 3,413 (27.5%) 36 to 55 years old, 688 (5.5%) 56 to 65 years old, and 427 (3.4%) >65 years old, The overall mortality was 3.7% and ranged from 2.4% in the age stratum of ≤14 years to 12.2% in the stratum of >65 years. In the present study, the traffic incidents-related mortality rate among those admitted populations was noted as a significant gender difference in Taiwan (in average, 0.18% for the female and 0.50% for the male).

A cross-sectional study in India showed that fractures were the commonest injury among the victims of nonfatal road traffic accidents, and majority of the victims were in the age group of 18–37 years. A road trauma analysis based on Data of the Trauma Registry in the United Arab Emirates showed that injuries of the extremities and head were frequent among pedestrians, motorcyclists, and bicyclists; the mean hospitalization was 9.7 days and overall mortality was 4%. In China, the data of 2213 in patients with traffic trauma showed that fracture of extremities (53.3%) occurred most often, craniofacial trauma (19.4%) next, then followed in turn by thoracoabdominal visceral injury (6.5%), spine fracture (5.3%), fracture of ribs (4.8%), and pelvic fracture (4.1%) in Africa, a retrospective analysis of nonfatal road traffic crash victims still showed that the commonest injuries were fractures (69.0%) with the tibia/fibula being the most fractured bones (30.3%). Age group of 15–44 years was the most affected (81.9%). In the present, fractures of upper limb, lower limb, and spine and trunk account for about 30% of the inpatients caused by traffic incidents in Taiwan.

The USA National Trauma Databank study of 12,429 admissions showed that bicycle-related injuries involving motor vehicles are associated with a high incidence of head injuries and extremity fractures. Age plays a critical role in the severity and anatomic distribution of injuries sustained, with a stepwise increase in mortality with increasing age. In Pakistan, of the 132,504 victims of road traffic crashes (RTCs), there were 67% males and 65% aged 16–35 years, and minor injuries (65%) and fractures (25%) were the most reported. Another hospital-based study of 450 cases admitted due to traffic accidents in India revealed that the commonest type of injury was fracture (49.33%) and the most common site of fracture was lower limb (48.2%), and several risk factors such as age, sex, type of vehicle, use of alcohol, absence of driving license, nonuse of helmets, and casual attitude are associated.
with increased occurrence of road traffic accidents\textsuperscript{20}. In the present study, gender, age, and socioeconomic level were significant risk factors of the most orthopedic fractures among traffic incidents-related inpatients in Taiwan. Otherwise, different hospital level receiving these orthopedic fractured cases was another cluster factor found in the present study. The study of national estimates of motor vehicle crash (MVC-) related hospitalization and associated use of health care resources among patients of 20 years old and younger in 3438 hospitals in 36 USA states revealed that mean (SD) hospital charges and lengths of stay (LOS) were $33,440 ($55,113) and 4.8 (7.7) days, respectively. Older age, being male, urban hospital location, mortality during hospitalization, higher injury severity, and longer LOS were significantly associated with higher total charges\textsuperscript{21}. Another study based on the Iranian National Trauma Registry Database (INTRD), including data from 14 general hospitals in eight major cities in Iran, enrolled 8,356 patients with road traffic injuries (RTIs) admitted to the hospitals and showed that the mean hospital charges for the patients were US$128 ± US$210 and the mean LOS for the patients was 6.8 ± 8.0 days. Older age, being a bicycle rider, higher injury severity, and longer LOS were associated with higher hospital charges\textsuperscript{22}. Compared to the two above studies, the direct medical cost and LOS for the traffic incidents-related hospitalization in Taiwan would be reasonable and accessible to the people. Furthermore, our study demonstrates that integrating all road users and pedestrian patients with hospital discharge data provides better estimates of the incidence of injury and more comprehensive information about injury type than other local hospital-based ED reports.

CONCLUSION

It was concluded from the study that there were multiple bony fracture take place during road traffic accidents.

Author’s Contribution:
Concept & Design of Study: Muhammad Asif Saeed
Drafting: Imran Idrees Butt, Maqsood Ahmed Khan
Data Analysis: Kamran Hamid, Salman Imran Butt, Muhammad Haris Muazaz
Revisiting Critically: Muhammad Asif Saeed, Imran Idrees Butt
Final Approval of version: Muhammad Asif Saeed

Conflict of Interest: The study has no conflict of interest to declare by any author.

REFERENCES

Incidence / Prevalence of Scabies in Sialkot
M Naeem¹, Abdul Rehman³, Shafiq ur Rehman Jamil⁴ and Anwar Khan²

ABSTRACT

Objective: To study the incidence/prevalence of Scabies in Sialkot.

Study Design: Retrospective study

Place and Duration of Study: This study was conducted at Idris Teaching Hospital Sialkot from Jan 2019 to December 2019.

Materials and Methods: There were 2520 patients of scabies were included in this study, Male 1297(51.46%) and female 1223 (48.51%), the history and family history were recorded. The examination was conducted on all the patients. The demographic bio data and incidence of patients of scabies from Jan-Dec 2019 were recorded. The written informed consent was taken before the study of patients. The permission of ethical committee was considered for collection of data and publishing it in medical journal. The data was analyzed on SPSS version 10 for results.

Results: The incidence of scabies was the highest at the age of 5-15 years 621 (24.64%) of total patients. The incidence of scabies was the lowest at age below 5 years 100(3.96%). The incidence of scabies was the highest in lower class 1263(49.72%) and the incidence of scabies were lowest in high class 400(15.74%). The incidence of scabies was highest in rural area 1581(62.73%) and in urban area it was lowest 939(37.26%). The incidence of scabies was the highest in month of MAY-June 501 (19.88%) patients and lowest in the month of Jan-Feb 310 (12.30%) patients.

Conclusion: It was concluded that the incidence of scabies was highest in the rural area and in the lower class at age of 5-15 years and highest in hot weather and lowest in cold weather.

Key Words: Scabies, Incidence, Prevalence, Sialkot, itching


INTRODUCTION

Scabies is a skin infestation caused by the burrowing action of a female parasite, Sarcoptes scabiei (Itch mite) resulting in irritation and vesicle or pustule formation¹. Human scabies has played a modest, but not nugatory role in the history of dermatology. Hebra, Beeson, Heilesen and Friedman have related the story of scabies in detail²⁵. Scabies infestation is ubiquitous and age, sex or skin colour plays no part in its aetiology⁶. Scabies affects all races and social classes worldwide⁷.

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². Department of DPT, Imam Idris Institute of rehabilitation Sciences.
³. Neuro Surgeon, Aziz Bhatti Hospital Gujrat.

Accurate figures of its incidence are difficult to obtain and most reports are based on hospital outpatient attendance records⁸. The incidence of scabies in developed countries shows cyclical fluctuations for which, there is, as yet, no satisfactory explanation⁹. The reported incidence of scabies for Karachi is 22.7%, which is more than other infections¹⁰. Medical staffs, especially General Medical Practitioners (GPs) are an integral part of any health care system. Treatment of scabies is domiciliary, so mostly patients are in contact with GPs. GPs are not only involved in the management of scabies but they are also responsible for providing health education to the patients about this disease. The patients’ queries about scabies, such as mode of spread, prevention and protection of family members, are often directed at the GPs, as they are more readily available than the skin specialists. Although national data for scabies is not available but reports based on hospital outpatient attendance records shows alarming prevalence indicating a lack of awareness about this common skin problem among GPs¹¹.

MATERIALS AND METHODS

There were 2520 patients of scabies were included in this study Male 1297(51.46%) and female 1223...
The incidence of scabies was recorded. The examination was conducted on all the patients. The demographic bio data and incidence of patients of scabies from Jan-Dec 2019 were recorded. The written informed consent was taken before the study of patients. The permission of ethical committee was considered for collection of data and publishing it in medical journal. The data was analyzed on SPSS version 10 for results.

RESULTS
At age below 5 years, male 40(3.08%) and female 60(4.90%) patients of scabies were observed. At the age of 5-15 years male patients 321(24.74%) and female 300(24.52%) were observed. At the age of 16-25 years male patients 215(16.57%) and female 207(16.92%), at the age of 27-37 years male patients 187(14.41%) and female 210(17.17), at the age of 38-48 years male patients 262(20.20%) and female patients 181(14.79%) of scabies, at the age of 49-60 years male patients 152(11.71%) and female patients 150(12.26%), at age above 60 male patients 120(9.25%) and female patients 115(9.40%) of scabies were observed. As shown in table 1. In high gentry the male patients 134(11.91%) and female 266(18.79%) of scabies were observed. In middle class male patients 370(32.88%) and female patients 507(35.83%) of scabies were observed. In lower class the male patients 621(55.20%) and female patients 642(45.37%) of scabies were found. As shown in table 2. It was seen that in urban area 402(35.57%) male patients and 537(38.63%) female patients of scabies were found, in rural areas the incidence of scabies in male patients 728(64.42%) and 853(61.36) female patients was found. As shown in table 3. In month of Jan-Feb the male patients 107(9.12%) and female patients of scabies 203(15.05%).In month March-April the male patients 176(15.01%) and female patients 221(16.39%), in month of May-June the male patients 246(20.98%) and female patients 255(18.91%), in July-August the male patients were 215(18.34%) and female patients 235(17.43%), in Sept-Oct the male patients 217(18.51%) and female patients 213(15.80%), in Nov-Dec male patients 211(18.00%) and female patients 221(16.39%) of scabies were found. As shown in table 4.

Table No 1: Age and Gender distribution in scabies at Sialkot

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Age (years)</th>
<th>Male</th>
<th>Gender</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Below 5yr</td>
<td>40(3.08%)</td>
<td>60(4.90%)</td>
<td>100(3.96%)</td>
</tr>
<tr>
<td>2</td>
<td>5-15</td>
<td>321(24.74%)</td>
<td>300(24.52%)</td>
<td>621(24.64%)</td>
</tr>
<tr>
<td>3</td>
<td>16-25</td>
<td>215(16.57%)</td>
<td>207(16.92%)</td>
<td>412(16.34%)</td>
</tr>
<tr>
<td>4</td>
<td>27-37</td>
<td>187(14.41%)</td>
<td>210(17.17%)</td>
<td>397(15.75%)</td>
</tr>
<tr>
<td>5</td>
<td>38-48</td>
<td>262(20.20%)</td>
<td>181(14.79%)</td>
<td>443(17.57%)</td>
</tr>
<tr>
<td>6</td>
<td>49-60</td>
<td>152(11.71%)</td>
<td>150(12.26%)</td>
<td>302(11.98%)</td>
</tr>
<tr>
<td>7</td>
<td>Above 60</td>
<td>120(9.25%)</td>
<td>115(9.40%)</td>
<td>235(9.32%)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1297(100%)</td>
<td>1223(100%)</td>
<td>2520(100%)</td>
</tr>
</tbody>
</table>

Table No 2: Socio economic Status distributions in scabies

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Social economic status</th>
<th>Male</th>
<th>Gender</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>High</td>
<td>134(11.91%)</td>
<td>266(18.79%)</td>
<td>380(15.07%)</td>
</tr>
<tr>
<td>2</td>
<td>Middle</td>
<td>370(32.88%)</td>
<td>507(35.83%)</td>
<td>877(34.52%)</td>
</tr>
<tr>
<td>3</td>
<td>Lower</td>
<td>621(55.20%)</td>
<td>642(45.37%)</td>
<td>1263(49.72%)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1125(100%)</td>
<td>1415(100%)</td>
<td>2520(100%)</td>
</tr>
</tbody>
</table>

Table No 3: Area distribution in scabies

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Area</th>
<th>Male</th>
<th>Gender</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Urban</td>
<td>402(35.57%)</td>
<td>537(38.63%)</td>
<td>939(37.26%)</td>
</tr>
<tr>
<td>2</td>
<td>Rural</td>
<td>728(64.42%)</td>
<td>853(61.36%)</td>
<td>1581(62.73%)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1130(100%)</td>
<td>1390(100%)</td>
<td>2520(100%)</td>
</tr>
</tbody>
</table>

Table No 4: Monthly distributions of patients of scabies

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Month</th>
<th>Male</th>
<th>Gender</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Jan-Feb</td>
<td>107(9.12%)</td>
<td>203(15.05%)</td>
<td>310(12.30%)</td>
</tr>
<tr>
<td>2</td>
<td>March-April</td>
<td>176(15.01%)</td>
<td>221(16.39%)</td>
<td>397(15.75%)</td>
</tr>
<tr>
<td>3</td>
<td>May-June</td>
<td>246(20.98%)</td>
<td>255(18.91%)</td>
<td>501(19.88%)</td>
</tr>
<tr>
<td>4</td>
<td>July-August</td>
<td>215(18.34%)</td>
<td>235(17.43%)</td>
<td>450(17.85%)</td>
</tr>
<tr>
<td>5</td>
<td>Sep-Oct</td>
<td>217(18.51%)</td>
<td>213(15.80%)</td>
<td>430(17.06%)</td>
</tr>
<tr>
<td>6</td>
<td>Nov-Dec</td>
<td>211(18.00%)</td>
<td>221(16.39%)</td>
<td>432(17.14%)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1172(100%)</td>
<td>1348(100%)</td>
<td>2520(100%)</td>
</tr>
</tbody>
</table>
DISCUSSION

“Very little epidemiological work has been done in dermatology, as this branch of medicine has been neglected in Pakistan due to lack of interest by medical professionals.” “To the best of our knowledge, this is the first study of its kind among GPs of Sialkot in Pakistan.” “So we are unable to compare the results of this study with other studies.” “Scabies is a condition that may involve the whole body and medical and paramedical staffs working in all disciplines of medicine are involved in its management.” “The present study showed that substantial numbers of GPs have inadequate knowledge regarding the causative parasite for scabies, the importance of scrapping the burrow and its examination in the diagnosis and health education for patients and family members”. “At the same time, however, there is reasonably good awareness about practical aspects such as mode of spread of the disease, clinical features and treatment of scabies.”

“Improper application of topical medications often occurs because the patient fails to fully understand the necessity and importance of application of topical preparations on whole body and treatment of whole family at the same time. Not only must patients be taught to take their medications, but they must also gain sufficient understanding of disease and its treatment, in order to become convinced that this is necessary.”

“This study evinced that GPs are not clear about health education to be imparted to scabies patients. Consequently, the responsibilities of GPs have been increased manifold.”

“Another important observation was that neither increasing age nor increasing years of experience of GPs improved the level of satisfactory awareness among the GPs. This reflects the total lack of refresher courses or continuous medical education programmes for the GPs”.13,14

“Some limitations of our study need to be acknowledged. First, the study is limited by cross-sectional design so temporal or cause-effect relationship cannot be established. Final and most important is small sample size with networking sampling strategy for selection of GPs”.

“In our study, the incidence of scabies was the highest at the age of 5-15 years 621 (24.64%) of total patients. The incidence of scabies was the lowest at age below 5 years 100(3.96%). The incidence of scabies was the highest in lower class 1263(49.72%) and the incidence of scabies were lowest in high class 400(15.74%). “The incidence of scabies was highest in rural area 1581(62.73%) and in urban area it was lowest 939(37.26%). The incidence of scabies was the highest in month of MAY-June 501 (19.88%) patients and lowest in the month of Jan-Feb 310 (12.30%) patients. The results of our study also co relates with other study.14”

CONCLUSION

It was concluded that the incidence of scabies was highest in the rural area and in the lower class at age of 5-15 years and highest in hot weather and lowest in cold weather.

Author’s Contribution:
Concept & Design of Study: M Naeeem, Abdul Rehman
Drafting: Shafiq ur Rehman Jamil
Data Analysis: Anwar Khan
Revisiting Critically: Shafiq ur Rehman Jamil, Kamran Hamid
Final Approval of version: M Naeeem

Conflict of Interest: The study has no conflict of interest to declare by any author.

REFERENCES

Diagnostic Accuracy of Ultrasound in Differentiating Benign and Malignant Breast Masses Taking Histopathology as Gold Standard

Zafar Tanveer Ahmed¹, Saima Ameer³, Madeeha Tanveer³ and Fareeha Tanveer³

ABSTRACT

Objective: To determine the diagnostic accuracy of ultrasound in differentiating benign and malignant breast masses taking histopathology as gold standard. Study Design: Cross-sectional validation study Place and Duration of Study: This study was conducted at the Department of Radiology, Lahore General Hospital, Lahore from February 2019 to August 2019. Materials and Methods: Patients between the ages of 20 to 70 years referred to Radiology department from surgical OPD with history of breast lump. Ultrasound was done in radiology department with high frequency linear probe 7.5 MHz of Toshiba Xario 200. Findings were noted. FNAC was done and samples were sent for histopathology. The data was analyzed in SPSS v. 21. Results: The mean age of females was 47.88±11.29 years. There were 121 (66.4%) females belonged to low socioeconomic status, 55 (30.2%) females belonged to middle class while 6 (3.3%) females belonged to high class. In total sample, 147 (80.8%) females were married while 35 (19.2%) were unmarried. There were 79 (43.4%) were nulliparous while 103 (56.6%) had 1 or more children. The mean duration of diagnosis was 12.94±2.36 months. The mean lump size was 37.84±15.87 mm. In this study, the Sensitivity of ultrasound was 94.1%, specificity was 89.3%, PPV was 77.4%, NPV was 97.5% and diagnostic accuracy was 90.7%. Conclusion: Thus the ultrasound is accurate enough that it can be applied as first line diagnostic tool for differentiation of malignant breast lesions from benign lesions. Key Words: Breast Malignancy, Ultrasound, Mammography, Fine Needle Aspiration Cytology, Histopathology

INTRODUCTION

Breast cancer is the most common cancer of females. It is one of the leading cause of morbidity and mortality among females worldwide. According to one study conducted in Iran, 1,671,149 new cases of breast cancer were identified worldwide and it resulted in 521,907 deaths in 2012.¹ One study conducted at Washington showed that breast cancer was responsible for 13.1 million cases of Disability Adjusted Life Years.²

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One study from China showed 1.6 million patients are diagnosed with breast cancer each year and about 1.2 million patients die from breast cancer in China.³,⁴ Breast cancer is also very prevalent in Pakistan. According to Pink ribbon Campaign Pakistan, it was found that 90,000 new cases were diagnosed each year and it caused about 40,000 deaths each year in Pakistan.⁵ According to Karachi cancer registry, breast cancer incidence was found to be 34.6% in 2009.⁶ As breast tumor is very prevalent, so it is very important to diagnose it well in-time for its prompt treatment. There are various modalities available for diagnosis of breast tumor. Physical examination, X-ray mammography, ultrasonography, MRI and FNAC are commonly used diagnostic modalities for breast tumor.⁷,⁸ Although X-ray mammography is widely used screening tool for breast tumor in developed countries but its usage is limited in developing countries like Pakistan because lack of its availability and trained medical staff. Furthermore, X-ray mammography is less effective in detection of breast cancer in younger age groups as compared to older. Some studies also showed that ultrasonography has ability to detect very small, mammographically occult breast tumors.⁹
Ultrasonography is an indispensable tool in breast imaging and is complementary to both X-ray mammography and magnetic resonance imaging of the breast. Advances in ultrasound technology allow confident characterization of not only benign cysts but also benign and malignant solid masses. Knowledge and understanding of current and emerging ultrasound technology, along with the application of meticulous scanning technique, is imperative for image optimization and diagnosis.

Rationale for this study is that breast cancer is the most common cancer and leading cause of morbidity and mortality. So early detection of this disease is very important for prompt treatment to decrease the burden of disease. Furthermore, results for diagnostic accuracy of ultrasonography for diagnosing breast mass has conflicting result. So a study is needed to determine the sensitivity and specificity of ultrasound for diagnosis benign vs malignant breast mass. It will enable the surgeons to diagnose the disease early and start treatment according to the condition. In addition, this study is being carried out at a large tertiary care hospital to get large sample size and statistically significant results.

**MATERIALS AND METHODS**

This study was conducted at the Department of Radiology, Lahore General Hospital, Lahore from February 2019 to August 2019. **Sample Size:** Sample size was calculated through WHO calculator. Sample size will be 182 is calculated at 95% confidence interval, taking prevalence of breast mass as 34.6%, sensitivity as 77% (13% margin of error) and specificity as 96.2% (4% margin of error). **Sampling Technique:** Non-probability consecutive sampling.

**Inclusion Criteria:** Patients between the ages of 20 to 70 years referred to Radiology department of Lahore General Hospital from surgical OPD with history of breast lump. **Exclusion Criteria:** The cases with infection over the skin or signs of abscess making FNAC difficult. Documented cases of previous breast surgery. Patients with lung tumor, transitional cell carcinoma or other neoplasia, able to shorten life expectancy, unstable cardiopulmonary, neurological, or psychiatric disease, cases suffering from end organ disease like chronic kidney, heart or liver disease.

**Data Collection Procedure:** After the acceptance of synopsis from ethical review committee of the hospital 182 cases fulfilled the inclusion and exclusion criteria were included in this study. An informed written consent was taken from all the participants. Particulars of patients like age, duration of illness were taken. Detailed history and examination were performed. Ultrasound was done in Radiology department with high frequency linear probe 7.5 MHz of Toshiba Xario 200. Findings were noted. The cases were assessed for the grey scale findings regarding the shape, size, orientation, margins, echo-pattern, posterior acoustic shadowing and consistency of the lesions to label it as benign, moderate or borderline lesions. Mass was labeled as benign on ultrasonography if mass was homogeneously hypoechoic, well-circumscribed, wider, with smooth lobules and surrounded by echogenic pseudocapsule and was labeled as malignant on ultrasonography if mass was hyphoechoic, deep, contains angular or irregular borders, microlobulations, calcifications and speculations.

The patient’s course of management was methodically followed till the lesion was biopsied and samples were sent to the laboratory. Histopathology was then verified with the report of ultrasound breast. The results were recorded and all the data was collected on the performa.

Patient were labelled to have benign breast mass on histology if there was simple epithelial hyperplasia, non-proliferative fibrocystic changes, early fibroadenosis or calcification present in benign looking duct and were labelled as to have malignant breast carcinoma if there was ductal or lobular hyperplasia with atypia, with cells arranged in clusters or islands, fat necrosis, calcification within the lumen of duct or malignant cells in glandular pattern.

**Data Analysis:** The data was analyzed in SPSS v. 21. A 2x2 table was constructed to measure the sensitivity, specificity, PPV,NPV, accuracy taking FNAC as gold standard.

**RESULTS**

The mean age of females was 47.88±11.29 years. There were 121 (66.4%) females belonged to low socioeconomic status, 55 (30.2%) females belonged to middle class while 6 (3.3%) females belonged to high class.

**Table No.1: Demographics of females**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>47.88±11.29</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socioeconomic status</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>121 (66.4%)</td>
</tr>
<tr>
<td>Middle</td>
<td>55 (30.2%)</td>
</tr>
<tr>
<td>High</td>
<td>6 (3.3%)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>147 (80.8%)</td>
</tr>
<tr>
<td>Unmarried</td>
<td>35 (19.2%)</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>79 (43.4%)</td>
</tr>
<tr>
<td>Multiparous</td>
<td>103 (56.6%)</td>
</tr>
<tr>
<td>H/O Breast feeding</td>
<td>88 (85.4%, out of 103 parous females)</td>
</tr>
<tr>
<td>Duration of mass (months)</td>
<td>12.94±2.36</td>
</tr>
<tr>
<td>Lump size( mm)</td>
<td>37.84±15.87</td>
</tr>
</tbody>
</table>
In total sample, 147 (80.8%) females were married while 35 (19.2%) were unmarried. There were 79 (43.4%) were nulliparous while 103 (56.6%) had 1 or more children and among them history of breast feeding was positive in 88 (85.4%) females. The mean duration of diagnosis was 12.94±2.36 months. The mean lump size was 37.84±15.87mm. Table 1

In this study, the Sensitivity of ultrasound was 94.1%, specificity was 89.3%, PPV was 77.4%, NPV was 97.5% and diagnostic accuracy was 90.7%. Table 2

Table No.2: Accuracy of ultrasound taking FNAC as gold standard

<table>
<thead>
<tr>
<th>Ultrasound</th>
<th>Malignant</th>
<th>Benign</th>
<th>Total on ultrasound</th>
</tr>
</thead>
<tbody>
<tr>
<td>FNAC / histopathology</td>
<td>48</td>
<td>14</td>
<td>62</td>
</tr>
<tr>
<td>Malignant</td>
<td>3</td>
<td>117</td>
<td>120</td>
</tr>
<tr>
<td>Benign</td>
<td>51</td>
<td>131</td>
<td>182</td>
</tr>
</tbody>
</table>

Sensitivity: 94.1%, specificity: 89.3%, PPV:77.4%, NPV: 97.5%, diagnostic accuracy: 90.7%

**DISCUSSION**

To date, mammographic breast density has been classified according to the Breast Imaging-Reporting and Data System (BI-RADS) categories from visual assessment, but this is known to be very subjective. Despite many research reports, the authors believe there has been a lack of physical-led and evidence-based arguments about what breast density actually is, how it should be measured, and how it should be used. Histopathologic patterns and breast cancer biomarkers determine differences in US imaging that can guide radiologists in better understanding the development of breast cancer and its prognosis.

Investigators have studied many breast diagnostic approaches, including X-ray mammography, magnetic resonance imaging, ultrasound, computerized tomography, positron emission tomography and biopsy. However, these techniques have some limitations such as being expensive, time consuming and not suitable for young women.

Breast density-inform legislation is increasing the need for data on outcomes of tailored screening. Dense parenchyma can mask cancers, and denser tissue is also more likely to develop breast cancer than fatty tissue. Digital mammography is standard for women with dense breasts. Supplemental screening magnetic resonance imaging should be offered to women who meet high-risk criteria. Supplemental screening ultrasononographic imaging may be appropriate in the much larger group of women with dense breasts. Both physician- and technologist-performed screening ultrasound imaging increases detection of nodenegative invasive breast cancer.

In our study, the ultrasound showed sensitivity: 94.1%, specificity: 89.3%, PPV: 77.4%, NPV: 97.5% and diagnostic accuracy: 90.7%. Diagnostic accuracy of ultrasonography have been investigated in various studies. According to one study conducted by Gonzaga, sensitivity and specificity of ultrasonography was 57.1% and 62.8% in detection of breast cancer. On the other hand, a study conducted by Iruhe at Nigeria concluded that sensitivity and specificity of ultrasound was 100% and 96.6% for breast lesion taking FNAC as gold standard. In a study conducted at Lahore, it was found that sensitivity and specificity of ultrasonography for breast mass was 77% and 96.2%. On the other, a study conducted at Gujranwala, ultrasonography was found to be 100% sensitive and 67% specific in detecting breast diseases.

**CONCLUSION**

Thus the ultrasound is accurate enough that it can be applied as first line diagnostic tool for differentiation of malignant breast lesions from benign lesions. Now in future, we can apply ultrasound for differentiation of malignant and benign breast lesions.

**Author’s Contribution:**
Concept & Design of Study: Zafar Tanveer Ahmed
Drafting: Saima Ameer, Madeeha Tanveer
Data Analysis: Fareeha Tanveer
Revisiting Critically: Zafar Tanveer Ahmed, Saima Ameer
Final Approval of version: Zafar Tanveer Ahmed

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

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Topical and Intravenous Lignocaine Comparison on Laryngeal Mask Airway Insertion Conditions Quality

Muhammad Shazad¹ and Syed Muhammad Nadeem²

ABSTRACT

Objective: To compare the insertion conditions of laryngeal mask airway using topical and intravenous lignocaine as premedication to propofol induction.

Study Design: Randomised control trial study.

Place and Duration of Study: This study was conducted at the Department of Anaesthesiology, ICU and Pain Medicine Liaquat National Hospital, Karachi during July 2009 and August 2010.

Materials and Methods: This study included one hundred and fourteen ASA I and II, elective day care surgical patients in our hospital between July 2009 and August 2010. Patients were randomized into group I (intravenous lignocaine) and group T (topical lignocaine). Laryngeal mask airway was inserted after inducing general anaesthesia with propofol. After one minute consultant anaesthetist inserted appropriate size deflated LMA. Conditions for LMA insertion i.e. gagging, coughing or laryngospasm was recorded. Acceptable conditions if no gagging, coughing or laryngospasm resulting in successful first pass placement and ventilation recorded.

Results: Fifty seven patients were randomly assigned to two groups, group I (intravenous lignocaine) and group T (topical lignocaine). The mean age in group I was 30+/-9 years and in group T it was 31+/-10 years. There were 12 males in group I and 16 males in group T while 45 females in group I and 41 females in group T. Gagging was noted in 9 patients (16%) in I group while only 2 patients (3.5%) in T group was statistically significant (P<0.026). Coughing and laryngospasm was more in group I in comparison to group T. In group I, acceptable insertion conditions was 89% while in group T 98%. Unacceptable insertion conditions were 11% in group I while only 1.8% in group T (p = 0.05)

Conclusion: Topical lignocaine application to the posterior pharynx for laryngeal mask airway insertion improves the acceptable insertion conditions in comparison to intravenous lignocaine without using any intravenous muscle relaxation agent.

Key Words: LMA, gagging, coughing, laryngospasm

INTRODUCTION

The laryngeal mask airway (LMA) was described by A.I. Brain in 1983. LMA insertion conditions became prime interest for the investigators since its inception. Different types of LMA and insertion techniques were developed.¹ Range of medications used to improve the insertion conditions of LMA² Airway morbidity remained a vital concern in general anaesthesia.³

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Lignocaine was studied with thiopentone using both intravenous and topical modes of administration.⁹ Topical lignocaine provided better LMA insertion conditions (86%) than intravenous lignocaine (63%) when used with thiopentone.¹⁰ Intravenous lignocaine can be effective for decreasing airway sensitivity (55%) to instrumentation by depressing airway reflexes and decreasing calcium flux in airway smooth muscles.¹¹,¹² Intravenous and topical lignocaine has been used with variable success (40%) to blunt hemodynamic responses to tracheal intubation and extubation.¹³,¹⁴ Use
of intravenous lignocaine with propofol showed coughing (20%), gagging (56%) and laryngeal spasm(13%) during LMA insertion. The purpose of this study is to ascertain a better LMA insertion technique preventing adverse effects related with airway and smooth ventilation without using any muscle relaxant. Therefore, we hypothesized that topical lignocaine with propofol induction provides acceptable LMA insertion conditions than intravenous lignocaine with propofol in patients undergoing elective surgery under general anaesthesia.

MATERIALS AND METHODS

The study was conducted at the department of Anesthesia, Critical Care & Pain Management, Liaquat National Hospital, Karachi after approval from hospital Ethics Review Committee between July 2009 and August 2010. Informed written consent was taken from all study participants. Patients were randomly allocated into two groups of equal size. Randomization was done using simple sealed envelope technique prior to study initiation and opened prior to anaesthesia by the investigator who will give topical or intravenous lignocaine. One hundred and fourteen consecutive patients undergoing general surgery meeting the inclusion criteria ASA I & II (no or mild systemic disease over 18 years) were divided into two groups, group I (intravenous lignocaine group) and group T (topical lignocaine group) each with 57 patients. All patients for emergency cases, risk of gastric content aspiration, pregnant females, co-existing renal or liver disease, limited mouth opening, known allergy to study drugs, refusal to give consent were excluded.

All patients had a running intravenous cannula and standard monitors (non invasive blood pressure, pulse oximeter and ECG ) before starting. A baseline heart rate and blood pressure were recorded. Group I received intravenous lignocaine 1.5 mg/kg followed by pre-oxygenation for three minutes. Group T received 5 ml of 4% lignocaine spray to the posterior pharynx in sitting position after depressing the tongue with a tongue depressor. The patients were turned supine immediately followed by pre-oxygenation for 3 minutes. After 3 minutes pre-oxygenation in both groups, intravenous nalbuphine 150 mcg/kg followed by 2mg/kg propofol over 15 seconds were injected. LMA was inserted 60 seconds after completion of propofol injection after loss of consciousness and eye lash reflex. In case , eye lash reflex was still intact further boluses of 0.5mg/kg propofol iv were used. Classic LMA size 4 were used for males and size 3 for females. All LMA insertions were done using method described by Dr. Archie Brain. Water based jelly will be applied on the posterior surface of the LMA and pressed along the hard plate using the index finger . It is finally pushed further down till resistance is felt. Cuff will be inflated with prescribed air in according to LMA size. Proper LMA placement will be confirmed with bilateral equally audible breath sounds, chest movements and capnography. The LMA insertion conditions shall be graded as acceptable provided no gagging, coughing or laryngospasm on first attempt of LMA insertion and unacceptable if there is gagging, coughing or laryngospasm that prevents ventilation on LMA insertion. LMA removed either by patient self or on full awakening of patient. Oxygen will be continued using facemask until full recovery and then the patient will be moved to PACU.

Data were fed and analyzed by using statistical software SPSS-version 10. Frequency and percentages were computed for the categorical variables like age groups, gender, ASA grades and condition of LMA insertion. Mean, standard deviation, 95% confidence interval, median with IQR were computed for quantitative variables like age and weight. Chi-Square test and fisher exact test was applied to observed rate of LMA insertion conditions between groups. Independent t-test and Mann Whitney test were used to compare mean difference between groups for age and weight and which is presented on box and whisker plots. \( P<0.05 \) was considered significant.

RESULTS

Fifty seven patients were randomly assigned to two groups, group I (intravenous lignocaine) and group T (topical lignocaine). The mean age in group I was 30 +/- 9 years and in group T it was 31 +/- 10 years. (fig. 1 and 2). The mean weight in group I was 57 +/- 7 kgs. and in group T it was 58 +/- 6 kgs. (fig. 3) There were 12 males in group I and 16 males in group T while 45 females in group I and 41 females in group T. (fig. 4) ASA I patients were 47 in group I while 41 in group T. ASA II patients were 10 in group I while 16 in group T. (table 1) Gagging was noted in 9 patients (16%) in I group while only 2 patients (3.5%) in T group was found to be statistically significant (\( P <0.026 \)).

![Figure No.1: Age distribution of the patients N=114](image)

Coughing and laryngospasm was more in group I in comparison to group T.(table 2) Average propofol and nalbuphine requirement were comparable in the two groups (table 3).
In group I, acceptable insertion conditions was 89% while in group T 98%. Unacceptable insertion conditions were 11% in group I while only 1.8% in group T. (p = 0.05). (table 4).

Table No. 1: Comparison of asa grade between groups

<table>
<thead>
<tr>
<th>ASA</th>
<th>Group I n=57</th>
<th>Group T n=57</th>
<th>Total n=114</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>47(82.5%)</td>
<td>41(71.9%)</td>
<td>88(77.2%)</td>
</tr>
<tr>
<td>II</td>
<td>10(17.5%)</td>
<td>16(28.1%)</td>
<td>26(22.8%)</td>
</tr>
</tbody>
</table>

Chi-Square = 1.79; p=0.18

Table No. 2: Problems at LMA insertion

<table>
<thead>
<tr>
<th></th>
<th>Group I n=57</th>
<th>Group T n=57</th>
<th>Total n=114</th>
<th>P-Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gagging</td>
<td>9(15.78%)</td>
<td>2(3.5%)</td>
<td>11(9.65%)</td>
<td>0.026</td>
</tr>
<tr>
<td>Coughing</td>
<td>6(10.52%)</td>
<td>1(1.8%)</td>
<td>7(6.14%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>2(3.5%)</td>
<td>0(0%)</td>
<td>2(1.75%)</td>
<td>0.49</td>
</tr>
</tbody>
</table>

Table No. 3: Propofol and nalbuphine requirement

<table>
<thead>
<tr>
<th></th>
<th>Group I n=57</th>
<th>Group T n=57</th>
<th>Total n=114</th>
<th>P-Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Propofol</td>
<td>115.37±14.53</td>
<td>117.09±13.86</td>
<td>0.51</td>
<td></td>
</tr>
<tr>
<td>Dose (mg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Nalbuphine</td>
<td>8.65±1.09</td>
<td>8.77±1.04</td>
<td>0.52</td>
<td></td>
</tr>
<tr>
<td>Dose (mg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table No. 4: LMA insertion conditions

<table>
<thead>
<tr>
<th></th>
<th>Group I n=57</th>
<th>Group T n=57</th>
<th>Total n=114</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptable</td>
<td>51(89.4%)</td>
<td>56(98.2%)</td>
<td>107(93.9%)</td>
</tr>
<tr>
<td>Unacceptable</td>
<td>6(10.5%)</td>
<td>1(1.8%)</td>
<td>7(6.1%)</td>
</tr>
</tbody>
</table>

Chi-Square = 3.805; p=0.05

DISCUSSION

In developing countries, day care surgeries are of utmost importance to reduce costs.16 Classic laryngeal mask airway is a first generation, reusable supraglottic airway device commonly used in developing countries because of cost constraints. Lesser complications and airway morbidity noted with use of laryngeal mask airway making early discharges and shorter hospital stays.7 The successful insertion of LMA requires adequate suppression of upper airway reflexes. Our study showed that LMA insertion conditions can be achieved with minimal complications by using topical lignocaine spray to posterior pharynx with propofol as an intravenous induction agent.

Kanazawa studied the effect of increasing doses of propofol on LMA insertion conditions in sixty patients and found that even high dose propofol (3mg/kg) cannot protect against laryngospasm.8 Moreover, higher propofol dose can lead to greater haemodynamic changes mostly hypotension and bradycardia. In our study, laryngospasm in observed in two patients, both
in intravenous lignocaine group while no patient developed laryngospasm when topical lignocaine was used. Cook et al studied ninety patients and compared two different intravenous lignocaine doses (0.5mg/kg and 1.5mg/kg) vs topical lignocaine bolus 10% but using thiopeptone as an intravenous induction agent. They obtained acceptable LMA insertion conditions in 86% (topical lignocaine group) and 63% (iv lignocaine group) which are both lower than our success rate (98.2% and 89.4%). This may be attributable to better airway reflex obfustnation and deeper plane of anaesthesia by propofol as compared to thiopentone.

Our data comparatively reported a lower incidence of gagging, coughing and laryngospasm than that reported by Stoneham and colleagues using propofol infusion for induction and iv lignocaine bolus for airway reflexes suppression. This may be attributable to the use of propofol as a bolus in our study that can achieve transient higher plasma propofol concentrations thus leading to a better suppression of airway reflexes. Propofol and nalbuphine synergistically induced a deeper plane of anaesthesia which allowed better conditions for placement of laryngeal mask airway. Seavell et al compared propofol 2.5mg/kg with thiopeptone plus topical lignocaine in ninety patients. They reported comparable LMA insertion conditions between the two groups (88.6% vs 91%). Changchien and colleagues studied ninety patients divided into three groups. Group one received topical lignocaine 40 mg followed by propofol 2mg/kg. Other two groups received topical sprays of normal saline followed either by propofol 2mg/kg or 3mg/kg. Adverse responses like body movements, gagging and laryngospasm in topical lignocaine group were less as compared to propofol 3mg/kg group with topical normal saline spray. They reported optimal insertion conditions in 67%, 37% and 73% respectively. Jain and colleagues studied 60 patients using intravenous and topical lignocaine with propofol. They used Vecuronium in dose of 0.1mg/kg. We have not used any muscle relaxation in our study. The higher success rate that we obtained may have been due to several reasons. We used nalbuphine at induction and this may have improved the LMA insertion conditions by synergistically acting with propofol providing a deeper plane of anaesthesia and attenuation of upper airway reflexes. In this study, we use dose of topical lignocaine 200 mg vs 40 mgs mostly reported in previous studies to effectively block upper airway reflexes. We used topical lignocaine close to 4mg/kg much lower than guidelines of British thoracic society of 8.2mg/kg and Williams and colleagues safely used it upto 9mg/kg.22 In our study , three minutes after each lidocaine spray to provide adequate penetration of local anesthetic into the airway mucosa for maximal effect.

This helped us achieving ideal conditions for LMA insertion with minimal airway complications.

CONCLUSION

This study shows that the use of topical lignocaine spray over posterior pharynx provides acceptable LMA insertion conditions as compared to intravenous lignocaine when using propofol induction in patients undergoing elective surgery during general anaesthesia without any use of muscle relaxants.

Author’s Contribution:

Concept & Design of Study: Muhammad Shazad
Drafting: Syed Muhammad Nadeem
Data Analysis: Syed Muhammad Nadeem
Revisiting Critically: Muhammad Shazad, Syed Muhammad Nadeem
Final Approval of version: Muhammad Shazad

Conflict of Interest: The study has no conflict of interest to declare by any author.

REFERENCES

Objective: Study aimed to compare the feto-maternal outcomes in pregnancy with gestational diabetes to pregnant women with preexisting diabetes.

Study Design: Descriptive observational clinical study

Place and Duration of Study: This study was conducted at the Doctors Trust Teaching Hospital affiliated with Rai Medical college Sargodha for one year from January 2019 to January 2020.

Materials and Methods: A population of pregnant women (n= 240) with singleton pregnancies were enrolled and divided into two groups based on pre-existing (group A, n=120) and gestational (group B, n=120) diabetes diagnosed by 2-hr-75g-OGTT. Descriptive analysis of categorical data was presented as frequencies and percentages. Pearson chi square test of independence was applied for qualitative variables. Statistically, p-value <0.05 was considered significant.

Results: The most recurrent maternal complication was vaginal candidiasis (46.67% & 43.3%) as seen in both groups A and B respectively. In the groups, 30 % of the pre-gestational diabetic mothers suffered from preterm labor in comparison to the 23.3% of gestational diabetic mothers. Equal incidence of urinary tract infection (23.3%) and pregnancy induced hypertension (30%), polyhydramnias (16.6%), preterm rupture of membranes (10%), and intra uterine growth retardation (6.67%) were observed in both groups. Though gestational diabetic mothers developed 13.3% and 6.67% hypertension and postpartum hemorrhage respectively as compared to the pre gestational mothers in which only hypertension was observed (13.3%). Fetal complications in “group A” included NICU admission, low birth weight, still births, shoulder dystocia and congenital anomalies whereas group B neonates had higher frequency of macrosomia, and hypoglycemia.

Conclusion: Both GDM and preexisting diabetes have adverse feto-maternal outcomes; however some complications are seen more in pre-gestational as compared to gestational diabetes.

Key Words: Diabetes Mellitus, Gestational Diabetes, Feto-maternal Outcomes


INTRODUCTION

It is estimated that more than 360 million people will have diabetes by the year 2030 and women of childbearing age are at increased risk of developing diabetes during pregnancy. The increased prevalence is attributed to the sedentary life style, urbanization and obesity. Pregnancy affects both the maternal and fetal metabolism and even in non-diabetic women exerts a diabetogenic effect.

The overall prevalence of gestational diabetes mellitus is increasing worldwide, with an overall score of 2.8% to 5% globally and is estimated to rise by the year 2030. Incidence of gestational diabetes in Pakistan is about 8%4. Pre-existing diabetes in women can lead to infertility, and during pregnancy it predisposes the fetus to many developmental alterations, and diabetes related complications to the mother. Normal pregnancy leads to insulin resistance and pancreatic β-cells reserve is stressed aiming to maintain glycemic level within normal ranges. If this reserve fails to maintain glycemic control then the result is development of gestational diabetes. A higher risk of obstetrical complications including miscarriage, pre-eclampsia and preterm labor is observed in women. Fetal exposure to maternal diabetes is associated with birth defects, congenital malformations, macrosomia, birth injury, perinatal mortality and postnatal adaptation problems such as hypoglycemia. On the other hand children exposed in utero to maternal diabetes are at higher risk of obesity and diabetes suggesting the effect not exclusively
Despite major advances in clinical management, a higher incidence of malformations and perinatal morbidity is observed. Therefore this study aimed to compare the feto-maternal outcomes in pregnancy with gestational diabetes to those pregnant women with preexisting diabetes in Pakistani population.

**MATERIALS AND METHODS**

An observational study recruiting a total of two hundred and forty singleton pregnant females was conducted during a period of 1 year. Females with pre-pregnancy diabetes or diagnosed as having diabetes before the 24th week of gestation were classified as pre-diabetics (Group A; n=120); whereas a 2 hour-75gm oral glucose tolerance test was administered at 28th week of gestation for screening and recruiting females with gestational diabetes. The pregnant females were classified as GDM if any of the following plasma glucose value was exceeded; Fasting: ≥92 mg/dL (5.1 mmol/L), 2 h: ≥153 mg/dL (8.5 mmol/L)\(^9\). These females were recruited as GDM (Group B; n=120). Females with impaired glucose tolerance, normal glucose tolerance, hypertension, thyroid disorders, and twin pregnancies or with any other life threatening complications for both mother and fetus were excluded from this study.

The maternal outcomes noted were vaginal candidiasis, urinary tract infection (UTI), preterm labor, polyhydramnios, preterm rupture of membranes (PROM) hypertension, intra uterine growth retardation (IUGR) and pregnancy induced hypertension (PIH). The fetal complications observed were weight over 4 kg or below 2.5 kg, hypoglycemia, shoulder dystocia, congenital abnormalities, still birth and neonatal intensive care unit (NICU) admission.

A statistical analysis of data was performed using SPSS (version 16; SPSS Inc., Chicago, IL, USA). Descriptive analysis of categorical data was presented in terms of frequencies and percentages. Pearson chi square test of independence was applied for qualitative variables. In all statistical analysis only p-value <0.05 was to be considered significant.

**RESULTS**

The detailed results are shown in tables 1 to 4. Briefly, mean age of preexisting DM group was 32.80 ± 5.49 while mean age of GDM was 28.70 ± 3.92. GDM was commonly seen in young women (p=0.002) with multiple pregnancies, while pre gestational DM was associated with a higher rate of caesarian section, and increased maternal mortality [Table 1]. The most frequent maternal complication observed in both groups was vaginal candidiasis (46.67% & 43.3%), while the frequency of preterm labor was more prominent in the pre-gestational diabetic group (30%) as compared to the gestational diabetic mothers (23.3%). Equal incidence of urinary tract infection and pregnancy induced hypertension (23.3% & 30%); polyhydromnias (16.6%), preterm rupture of membranes (10%), and intra uterine growth retardation (6.67%) were observed in both groups. [Table 2] Gestational diabetic mothers had a higher predisposition to develop hypertension and postpartum hemorrhage (13.3% and 6.67% respectively) as compared to the pre gestational mothers. Fetal born to mothers with preexisting diabetes had more NICU admission, low birth weight, still births, shoulder dystocia and congenital anomalies whereas neonates of gestational diabetic mothers had higher frequency of macrosomia, and hypoglycemia. [Table 3]. Most females with pre-existing diabetes and GDM were managed by insulin (85% and 65%) respectively, while few were put on dietary restrictions (15% and 35%) respectively. (Table4).

<table>
<thead>
<tr>
<th>Table No.1: Age Distribution, Gravidity and Mode of Delivery: A Comparison in Pre-Gestational DM &amp; GDM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GROUP – A (Pre Gestational DM) (n=120)</strong></td>
</tr>
<tr>
<td>Age (in years)</td>
</tr>
<tr>
<td>21 – 30</td>
</tr>
<tr>
<td>31 – 40</td>
</tr>
<tr>
<td>&gt; 40</td>
</tr>
<tr>
<td>Gravidity</td>
</tr>
<tr>
<td>Primigravida</td>
</tr>
<tr>
<td>2-4</td>
</tr>
<tr>
<td>&gt;4</td>
</tr>
<tr>
<td>Mode of delivery</td>
</tr>
<tr>
<td>SVD</td>
</tr>
<tr>
<td>LSCS</td>
</tr>
</tbody>
</table>
Table No.2. Common Maternal Complications: A Comparison in Pre-Gestational DM & GDM

<table>
<thead>
<tr>
<th>Complications</th>
<th>GROUP –A (Pre gestational DM) (n=120)</th>
<th>GROUP – B (GDM) (n=120)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of patients(Percentage)</td>
<td>No. of patients(Percentage)</td>
<td></td>
</tr>
<tr>
<td>Vaginal Candidiasis</td>
<td>56(46.67)</td>
<td>52(43.33)</td>
<td>0.795</td>
</tr>
<tr>
<td>UTI</td>
<td>28(23.33)</td>
<td>36(30)</td>
<td>0.559</td>
</tr>
<tr>
<td>PIH</td>
<td>28(23.33)</td>
<td>36(30)</td>
<td>0.559</td>
</tr>
<tr>
<td>Preterm Labor</td>
<td>36(30)</td>
<td>28(23.33)</td>
<td>0.623</td>
</tr>
<tr>
<td>Poly-hydromnias</td>
<td>20(16.67)</td>
<td>20(16.67)</td>
<td>1.000</td>
</tr>
<tr>
<td>PROM</td>
<td>12(10)</td>
<td>20(10)</td>
<td>1.000</td>
</tr>
<tr>
<td>PPH</td>
<td>00(00)</td>
<td>08(6.67)</td>
<td>-</td>
</tr>
<tr>
<td>IUGR</td>
<td>08(6.67)</td>
<td>08(6.67)</td>
<td>1.000</td>
</tr>
<tr>
<td>Hypertension</td>
<td>04(3.33)</td>
<td>16(13.33)</td>
<td>0.161</td>
</tr>
</tbody>
</table>

Table No.3. Common Fetal Complications: A Comparison in Pre-Gestational DM & GDM

<table>
<thead>
<tr>
<th>Complications</th>
<th>GROUP –A (Pre gestational DM) (n=120)</th>
<th>GROUP – B (GDM) (n=120)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of patients(Percentage)</td>
<td>No. of patients(Percentage)</td>
<td></td>
</tr>
<tr>
<td>Weight &gt; 4kg</td>
<td>20(16.67)</td>
<td>24(20)</td>
<td>0.644</td>
</tr>
<tr>
<td>NICU admission</td>
<td>64(53.33)</td>
<td>28(23.33)</td>
<td>0.824</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>12(10)</td>
<td>24(20)</td>
<td>0.375</td>
</tr>
<tr>
<td>Weight &lt;2.5kg</td>
<td>08(6.67)</td>
<td>04(3.33)</td>
<td>0.554</td>
</tr>
<tr>
<td>Shoulder dystocia</td>
<td>08(6.67)</td>
<td>04(3.33)</td>
<td>0.225</td>
</tr>
<tr>
<td>Congenital abnormalities</td>
<td>16(13.33)</td>
<td>04(3.33)</td>
<td>0.375</td>
</tr>
<tr>
<td>Stillbirth</td>
<td>04(3.33)</td>
<td>16(13.33)</td>
<td>0.375</td>
</tr>
</tbody>
</table>

Table No.4. Treatment options: A Comparison in Pre-Gestational DM & GDM

<table>
<thead>
<tr>
<th>Complications</th>
<th>GROUP –A (Pre gestational DM) (n=120)</th>
<th>GROUP – B (GDM) (n=120)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of patients(Percentage)</td>
<td>No. of patients(Percentage)</td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td>18 (15)</td>
<td>42 (35.5)</td>
<td>0.04</td>
</tr>
<tr>
<td>Insulin</td>
<td>102 (85)</td>
<td>78 (65)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

DISCUSSION

Diabetes is the most common disorder complicating 3-5% of all pregnancies; our results are consistent with the previous studies. Incidence in young primi gravida was found to be <1%10. Another study by Akhter et al.11 showed an overall 3.3% prevalence of GDM among Pakistani women. It is plausible by these reports that multiple pregnancies predispose to hyperglycemic states and lead to the development of GDM. However, risk of hypertension and preeclampsia has been proven to increase with increasing age and BMI, independently of maternal glycemia. Contrary to our results no differences were observed in terms of frequency of complications in patients with and without gestational diabetes by Bodmer-Roy. Perhaps this was due to the difference in population, and screening criteria. (Table 1)

Moreover among the study groups, the rate of preterm delivery was higher in pre-existing diabetic mothers which is consistent with the results of previous studies12, especially relating with Indian women where the frequency of preterm deliveries reported was about 8.2%13. The finding of this study indicated that 20% of neonates born to GDM pregnant females were large sized (macrosomia) and suffered from post-delivery hypoglycemia (Table 3). These findings are in accordance with the studies done by Wahabi and group14 where almost 11% of the new born delivered to the diabetic mothers was macrosomic. Poorly controlled maternal diabetes has undesirable influences on fetal weight and growth, which results in macrosomia and intrauterine growth restriction15. This effect may be due to high availability of insulin, amino-acids, and glucose and lipid levels in the blood. All these factors play a role in organogenesis16. Other factors also influences fetal macrosomia including maternal age over 30 years, prolonged pregnancy, multiparity and maternal obesity17. Overall 60% patients were delivered by caesarean section. Similar results were also observed in a study conducted by Reem Zeki et.al which showed total cesarean section rate of 53.6% for women with pre gestational diabetes and 36.8% for women with gestational diabetes18. One of the likely explanations of this is history of previous cesarean section in multigravidas. Another likely explanation for this finding is macrosomia which in turn is associated with significant maternal and
perinatal complications including increased rate of C/S, birth asphyxia and perinatal mortality. The perinatal mortality was high in established diabetics as compared to GDM, in our study population. Similar outcomes were observed by other investigators. The fetal complications including shoulder dystocia, small for gestational age, congenital malformations and NICU admissions were higher in diabetic group when compared with GDM group in our study. These findings are in line with the studies done by Vangen et al, who observed increased risks for low birth weight, macrosomia, preterm birth, preeclampsia, and cesarean sections in women with predominantly type 2 diabetes.

When the overall outcomes where compared to different study populations (like Caucasians, Moroccan, African American, Hispanic, and Indian) we found somewhat similar results with exception of preterm labor, polyhydramnios, pregnancy induced hypertension, macrosomia, shoulder dystocia and still births being more common in our study population. The importance of these findings is that it investigated a key public health problem and that it gives preliminary indicators about the impact on pregnancy outcome in the Pakistani population. Such information is imperative for practice and research considering the paucity of data and health care for managing the complications related to diabetic pregnancy in our population. Very few patients in our under resourced country get pre pregnancy care. It should however be emphasized that pre pregnancy care markers, especially HbA1c prior to discontinuation of contraception is associated with lower rates of adverse pregnancy outcome. Diabetic pregnancy is an important cause of perinatal morbidity and mortality, as more than half of perinatal deaths worldwide are contributed by South East Asia.

CONCLUSION
This study concluded that both gestational and pre-diabetes have adverse feto-maternal outcome. But there are no significant differences or increased association between the two groups. However some complications such as LSCS, NICU admission, shoulder dystocia, congenital malformation are slightly more but statistically non-significantly associated with pre-gestational DM.

Author’s Contribution:
Concept & Design of Study: Asifa Alia
Drafting: Riaz Ahmad
Data Analysis: Maria Husain
Revisiting Critically: Asifa Alia, Riaz Ahmad
Final Approval of version: Asifa Alia

Conflict of Interest: The study has no conflict of interest to declare by any author.

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20. Verheigen EC, Critchley JA, Whitelaw DC, Tuffnell DJ. Outcome of pregnancies in women with pre-existing type 1 or type 2 diabetes, in an ethnically mixed population. BJOG 2005;112: 1500-3.


Prevalence of Hyperprolactinemia in Infertile Females
Riaz Ahmad, Asifa Alia and Maria Hussain

ABSTRACT

Objective: To evaluate the prevalence of Hyperprolactinemia in infertile females.

Study Design: Observational Descriptive Study

Place and Duration of Study: This study was conducted at the Doctor’s Trust Teaching Hospital affiliated with Rai Medical College Sargodha and FertiMed Fertility Centre from February 2019 to February 2020.

Materials and Methods: Female patients who presented with primary and secondary infertility among patients who were married and in the reproductive age group (15-49). Total number of the patients in this study was 120. The cut off level of hyperprolactinemia was >25 ng/ml. The study was not funded. The duration of infertility was not considered.

Results: In this study mean age of the patients was 27.86+ with a variation of 6.17. Mean prolactin level was found to be 22.96 with a variation of 9.27 ng/ml. The frequency of Hyperprolactinemia was recorded in 54% (n=65). The majority of the patients were mild to moderate hyperprolactinemic.

Conclusion: The results of this study advocated the evaluation of infertile female patients with serum prolactin levels, as increased prolactin levels may indicate alteration of hypothalamic pituitary ovarian axis causing reproductive dysfunction.

Key Words: Infertility, Hyperprolactinemia.


INTRODUCTION

Subfertility is quite common in the reproductive age group. The rate of female infertility is about 37% of all the infertile couples and more than half of these have ovulatory disorders. Globally in 2010, 1.9% of all the reproductive age group females wanting to have a child could not have a live birth and 10.5% having a previous live birth had an additional one. Infertility evaluation usually starts after one year of regular unprotected intercourse in women before 35 years of age and after six months aging more than 35. It may be initiated earlier if any associated pathology is suspected. Worldwide, endocrine disorders are affecting up to 14% of couples. Increased prolactin level is a common cause of infertility in women. The incidence of this disorder ranges 9 to 17% in reproductive health disorders of females. The diagnostic value of hyperprolactinemia is increased serum prolactin levels >25 ng/ml on two different occasions.

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Intra ovarian hormonal milieu and follicular function may be influenced due to hyperprolactinemia. A strong association is reported between serum and follicular development at the time of oophorectomy. Females with elevated serum prolactin level may also have significantly increased levels of prolactin in their antral follicular fluid. It may be associated with a significant reduction in FSH levels. Hyperprolactinemia may be physiological, pathological or pharmalogical. Physiological increase in prolactin level is seen in lactating mothers. This should be kept in mind during evaluation. Elevated prolactin level are recorded in 30% of renal failure cases and 80% of those on haemodialysis. Mild elevated prolactin levels are observed in 40% of primary hypothyroidism cases and these respond to thyroxin treatment. There are drugs that cause hyperprolactinemia. Antidepressants and antipsychotic drugs, although some of the newer atypical antipsychotics do not do so. Other medications causing hyperprolactinemia include drugs for increased bowel motility.

Hormone influence on prolactin targeted tissue, e.g. breast tissue and reproductive system is responsible for clinical presentation of hyperprolactinemia. Women may present with decreased libido, infertility, oligomenorrhea, amenorrhea and galactorrhoea. Quantitative serum prolactin evaluation and combination of these clinical symptoms helps in diagnosing clinical hyperprolactinemia.

Paucity in literature review creates ambiguity for gynecologists while managing infertile women. The results of this study emphasize the importance
of evaluation and treatment of this condition which is frequently encountered in our population.

MATERIALS AND METHODS

This study is a descriptive observational type which was February 2019 to February 2020 and patients from Fertimed fertility Centre. Total no of the patients was 120. The inclusion criteria was the married females with a history of inability to conceive after twelve months of unprotected regular sexual intercourse. A detailed examination was done, those being treated for hyperprolactinemia, an organic lesion in the pelvis, urogenital tract abnormalities, female tubal factors for subfertility and thyroid disease were excluded from the study.

All females with regular menstrual cycle were advised to visit the hospital on second or third day of follicular phase with 8-12 hours overnight fasting. Those who presented with a cyclical menstrual cycle or amenorrhea after excluding the pregnancy were advised for a random blood sample after an overnight fast.

For collection of 3ml of whole blood specimen a 5ml disposable syringe was used. The collected sample was sent to the hospital and center’s lab for quantification of serum prolactin level by using Elisa technique. The normal reference range in this study was 8-22ng/ml. Those who had 23-100 ng/ml were categorized as mild, 101-200ng/ml as moderate, 201-1000ng/ml as high and >1000 ng/ml as very high. For data analysis SPSS 21 was used.

RESULTS

In this study total number of women fulfilling the inclusion criteria was 120, out of which 65 (54.1%) had hyperprolactinemia whereas 55 (45.8%) had normal prolactin levels. As p value was < 0.001 it was statistically significant difference with regards to degrees of hyperprolactinemia.

In our study age distribution shows hyperprolactinemia 12.5 % (n=15) between 18-24 years, 54.1 % (n=65) were between 25-34 years and 33 % (n=40) between 35-40 years. Mean age was 27.86±6.17 years.

Table No. 1. Age distribution of 120 patients presenting with subfertility

<table>
<thead>
<tr>
<th>Age in years</th>
<th>No. of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-24</td>
<td>15</td>
<td>12.5</td>
</tr>
<tr>
<td>25-34</td>
<td>65</td>
<td>54.1</td>
</tr>
<tr>
<td>35-40</td>
<td>40</td>
<td>33</td>
</tr>
<tr>
<td>Total</td>
<td>120</td>
<td>100</td>
</tr>
<tr>
<td>Mean+SD</td>
<td>27.86 ± 6.17</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1. Shows percentage of patients with hyperprolactinemia and normal prolactin levels. Serum prolactin levels were categorized into mild, moderate, high and very high.

DISCUSSION

Female infertility is often associated with irregularity of hormones of which Hyperprolactinaemia is most common endocrine disorder of hypothalamic pituitary axis affecting the reproductive function. Hyperprolactinaemia impairs pulsatile secretion of GNRH which then leads to ovulatory disorder.

In this study 54.1% of females presenting with subfertility had hyperprolactinemia. These are comparable to the results by Prianka Sharma et al, who found the incidence as 41% in the infertile group. These results were comparable with a study by Go.
swami et al\textsuperscript{15} by Mohan et al as 42% and Avasthii et al as 46%\textsuperscript{17}. In another study conducted by Madhuprita Agarwal serum prolactin level was raised in 11.5%\textsuperscript{18} which is much lesser as found in this study. Similarly studies conducted by Indu V et al as 18%\textsuperscript{19}, Thirunavakkarasu et al found it as 15%\textsuperscript{20}, and Olooto et al as 28%\textsuperscript{21} where the incidence was again lesser as found in this study. Increased prolactin levels may be because of the stresses found by N Sonino et al\textsuperscript{22}. This difference may be the varying degrees of stress in infertility women in different areas.

The females who participated in this study belonged the reproductive age group ranging from 17-40 years. Of these 54.1% belonged to the mid reproductive age group. The same age group has been identified by E.O. Nwachuku 29-33 years 39.5%\textsuperscript{23}. In a cohort of 150 patients studied by Sanjia Sharma, 68% of primary and 32% with secondary subfertility were in the 26 to 30 years age group\textsuperscript{24}.

Mahuprita Agarwal in her study found that 53% of the cases were in 26-30 years age group as was found by Singh et al\textsuperscript{25} and Ben Mousa Rashid et al\textsuperscript{26}. In a National study conducted in Bahawalpur Hyperprolactinaemia was found to be associated with subfertility, with a mean age 29.32 with a deviation of 6.26\textsuperscript{27}. This is comparable with the findings of this study, 27.86% with a deviation of 6.17. The results of this study were also comparable with a study by Akpan et al\textsuperscript{28}.

Majority of the females found with hyperprolactinemia in this study belonged to the mid reproductive age group which could be because of the late marriages in this society and badly treated patients by quacks.

In this study 45.8% of the patients were having normal prolactin levels and 54.1% had hyperprolactinemia, it was also reported in a study conducted in Nigeria however majority of the patients were having mild hyperprolactinemia with a slight contradiction to this study. In a similar study by Isah et al, it was found that 96.8% had mild hyperprolactinemia and moderate elevation in 3.2%\textsuperscript{29}. In another study by Randal et al where 61.8% of the patients had moderate hyperprolactinemia and 39% had highly elevated levels\textsuperscript{30}. In this study none of the patients had prolactin level of more than 1000 ng/ml. This suggested that micro adenomas and macro adenomas are very rare among the infertile females as suggested by Nadeem\textsuperscript{31}.

**CONCLUSION**

The results of this and many other studies were comparable and it is concluded that all the female patients with subfertility should be evaluated for Hyperprolactinaemia, because it may cause pituitary ovarian axis resulting in menstrual disorders and anovulation. And thus this is suggested that timely management may cure this treatable cause of infertility.

**REFERENCES**

Precipitating Factors of Hepatic Encephalopathy in Patients With Liver Cirrhosis

Tahir Ullah¹, Muhammad Iqbal Qasim², Syed Farasat Ali Shah² and Ihsan Ullah³

ABSTRACT

Objective: The objective of this study was to know the frequency of various precipitating factors in patients with hepatic encephalopathy secondary to hepatic cirrhosis.

Study Design: Descriptive cross sectional study

Place and Duration of Study: This study was conducted at the King Abdullah Teaching Hospital Mansehra for one year from January to December 2019.

Materials and Methods: One hundred and two patients both male and female having age ≥ 16 years with hepatic encephalopathy secondary to liver cirrhosis were included in this study. All the patients with encephalopathy due to causes other than hepatic cirrhosis were excluded from the study. After taking detailed history, physical examination and investigations precipitating factor was identified. All the data was analyzed using SPSS version 19.

Results: One hundred and two patients with hepatic encephalopathy were studied. Mean age of the population was 52.68 ± 17.69 years and the male to female ratio of 1.13:1. In most of the patients cause of cirrhosis was hepatitis C (60.78%) and most of the patients presented with hepatic encephalopathy grade III (39.2%) and IV (33.3%). The most common precipitating factor was infection (24.50%) followed by upper gastrointestinal bleeding (20.58%) and combination of factors (15.68%).

Conclusion: Infection is one of the most common precipitating factors of hepatic encephalopathy and hence need timely identification and treatment.

Key Words: Hepaticencephalopathy, precipitating factors, liver cirrhosis, West haven criteria, ammonia, portosystemic shunting.

INTRODUCTION

Liver diseases are classified as the second most common cause of death among all the digestive diseases and accounts for about 66,000 deaths in the United States of America.¹² If not diagnosed and treated timely, liver disease can lead to cirrhosis which in turn give rise to serious complications like hepatic encephalopathy, ascities and varices.³ Hepatic encephalopathy is described as a combination of neurological and psychiatric symptoms and signs in patients with acute or chronic liver disease or portosystemic shunting after exclusion of other causes of encephalopathy.⁴ Hepatic encephalopathy is a very serious complication of liver disease and very badly affects the quality of life of the patient and the caregivers and also puts heavy burden on health care resources and economy.⁵⁶⁷ The prevalence of overt hepatic encephalopathy varies from 10 to 25 % in patients with cirrhosis and upto 50% in patients with transjugular intrahepatic portosystemic shunts.⁴ The severity of hepatic encephalopathy can be graded according to West Haven classification from grade 0 assigned to normal patients to grade 4 to patients with coma.⁸ Several factors have been studied in the pathophysiology of hepatic encephalopathy but the most important neurotoxin is ammonia. In normal state ammonia generated in intestine is metabolized in the liver to urea and excreted through kidneys. In cirrhosis liver is unable to metabolize ammonia and bypasses to brain through collateral circulation and causes brain dysfunction through various mechanisms eg.increase intracranial pressure, brain edema and altered neurotransmitters level.⁹ Hepatic encephalopathy is almost always induced by one or more precipitating factors. The most common precipitating factors involved in hepatic encephalopathy are gastrointestinal bleeding, constipation and heavy protein intake. This leads to increased production of nitrogenous waste products especially ammonia by the intestinal bacteria. Ammonia crosses the blood brain
barrier and leads to encephalopathy through various mechanisms. The other precipitating factors implicated in hepatic encephalopathy are infections, dehydration, azotemia, sedatives and hypnotics, opioid derivatives and electrolytes imbalance. The identification of precipitating factors is of utmost importance as fixation of these factors usually results in rapid reversal of hepatic encephalopathy. The rationale behind doing these study was to identify the frequency of the most common precipitating factors implicated in hepatic encephalopathy. As the frequency of different precipitating factors vary in different populations, this study will provide us local statistics of the precipitating factors of hepatic encephalopathy.

MATERIALS AND METHODS

This descriptive cross sectional study was conducted at King Abdullah Teaching Hospital, Mansehra from January to December 2019 after approval from hospital research and ethical committee. Informed written consent was taken from the patients or attendants. One hundred and two patients presenting with hepatic encephalopathy were identified through consecutive non probability sampling. All the patients having age 16 years or above diagnosed with hepatencephalopathy secondary to liver cirrhosis (type C) were included. All patients with psychiatric diseases, structural renal diseases with creatinine ≥ 2mg/dl, intracranial infections, head injury and stroke were excluded. Detailed history including present and past medical history, physical examination, biochemical tests and ultrasound was performed in all patients. History included present history of gastrointestinal bleeding, constipation, fever, vomiting, motions, drugs etc and past history of similar episodes. Investigations included blood complete picture, blood culture, albumin, bilirubin, blood sugar, coagulation profile, urea, creatinine, ascetic fluid analysis and culture, viral profile (A, B, C, D, E if not already done), electrolytes, urine routine examination and culture, X ray chest and ultrasound for liver, spleen, ascities and portal vein. The diagnosis of covert hepatic encephalopathy (minimal hepatic encephalopathy + grade I) was based on Psychometric Hepatic Encephalopathy Score. Child Turcotte Pugh score was used for classification of severity of liver cirrhosis while West Haven criteria was used for classification of severity of hepatic encephalopathy. All the patients were managed according to gastroenterology department protocol.

RESULTS

SPSS version 19 was used for data analysis. Mean ± standard deviation were used for quantitative variables like age while frequencies and percentages were used for qualitative variables like gender and precipitating factors. The data was presented in the form of tables.

One hundred and two patients who presented with hepatic encephalopathy due to hepatic cirrhosis were included in this study. There were 55(53.9%) male and 47(46.1%) female with a male to female ratio of 1.13:1. The minimum age of the population was 17 years, maximum 89 years and mean 52.68 ± 17.69 standard deviation. Most of the patients were in the age group ≥ 61 followed by those ranging from 41-60 years.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covert</td>
<td>minimal</td>
</tr>
<tr>
<td></td>
<td>No evidence of mental change but detectable on psychometric or neurophysiological tests</td>
</tr>
<tr>
<td>I</td>
<td>trivial lack of awareness, euphoria or anxiety, shortened attention span, altered sleep pattern</td>
</tr>
<tr>
<td>Overt</td>
<td>II</td>
</tr>
<tr>
<td></td>
<td>Lethargy, disorientation in time, Obvious personality change, dyspraxia, asterixis</td>
</tr>
<tr>
<td>III</td>
<td>somnolence, confusion, gross disorientation</td>
</tr>
<tr>
<td>IV</td>
<td>Coma with or without response to stimuli</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variables</th>
<th>No. of patients</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>47</td>
</tr>
<tr>
<td>Age</td>
<td>16-40</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>41-60</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>&gt; 60</td>
<td>40</td>
</tr>
<tr>
<td>Cause of Cirrhosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hepatitis C</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td>Hepatitis B</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>B+C</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Autoimmune</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>4</td>
</tr>
<tr>
<td>Child’class</td>
<td>A</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grades of Encephalopathy</th>
<th>No. of patients</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covert hepatic encephalopathy</td>
<td>Minimal</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>6</td>
</tr>
<tr>
<td>Overt hepatic encephalopathy</td>
<td>II</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>III</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>34</td>
</tr>
<tr>
<td>Total</td>
<td>102</td>
<td>100</td>
</tr>
</tbody>
</table>

The most common cause of cirrhosis was chronic hepatitis C in 62(60.78%) followed by Chronic Hepatitis B in 31(30.39%) patients. The other less
common causes were co-infection with both hepatitis B and C in 3 (2.94%), Autoimmune Hepatitis in 2 (1.96%) and unknown causes in 4 (3.92%) patients. Most patients presented with Child’s Turcotte Pugh score C in 55 (53.9%) and B in 38 (37.3%). Majority of the patients (40/39.2%) presented in hepatic Encephalopathy grade III while only 8 (7.8%) with covert hepatic encephalopathy.

Table No.4: Frequency of precipitating factors of hepatic encephalopathy

<table>
<thead>
<tr>
<th>Precipitating factors</th>
<th>No. of patients</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>25</td>
<td>24.50</td>
</tr>
<tr>
<td>Gastrointestinal bleeding</td>
<td>21</td>
<td>20.58</td>
</tr>
<tr>
<td>Excess protein intake</td>
<td>15</td>
<td>14.70</td>
</tr>
<tr>
<td>Constipation</td>
<td>10</td>
<td>9.80</td>
</tr>
<tr>
<td>Drugs</td>
<td>8</td>
<td>7.84</td>
</tr>
<tr>
<td>Electrolytes</td>
<td>5</td>
<td>4.90</td>
</tr>
<tr>
<td>Paracentesis</td>
<td>2</td>
<td>1.96</td>
</tr>
<tr>
<td>Combination</td>
<td>16</td>
<td>15.68</td>
</tr>
<tr>
<td>Total</td>
<td>102</td>
<td>100</td>
</tr>
</tbody>
</table>

The most common precipitating factor in this population was infection in 25 (24.50%) followed by Upper gastrointestinal bleeding in 21 (20.58%). 16 (15.8%) patients had Hepatic Encephalopathy due to combination of factors. Among the patients who presented with hepatic encephalopathy secondary to infections, respiratory tract infection was the most common site in 12 (48%). The other sites of infection in decreasing frequency were multiple sites in 7/25(28%), spontaneous bacterial peritonitis in 4/25(16%) and urinary tract infection in 2/25(8%) patients.

DISCUSSION

The development of hepatic encephalopathy in patient with hepatic cirrhosis characterizes decompensation and carries poor prognosis without liver transplantation. In our study chronic hepatitis C was the most common cause of cirrhosis (60.78%) compared to study by Kabir A et al in which hepatitis B was the most common cause (56%) and in western countries where alcoholic cirrhosis is the most common cause.11,16 In our study majority of the patients presented with hepatic encephalopathy grade III (39.2%) while only 8 (7.8%) presented with covert hepatic encephalopathy of which 6 (5.88%) were in grade I and only 2 (1.96%) were in minimal hepatic encephalopathy. The frequency of grade I hepatic encephalopathy varies in different studies. Maqsood et al reported 8% while Sing G reported 24% frequency of grade I encephalopathy.17,18 The reason for this may be that our patients come from far areas and due to lack of awareness and facilities they report very late to proper health care facility. In almost all cases precipitating factors can be identified easily. Early recognition and treatment of precipitating factor is of utmost importance in the management of hepatic encephalopathy. In our study infection (24.50%) was the most common precipitating factor similar to studies conducted by Wang et al and Devrajani BR et al19,16. In a study by kabir A et al, gastrointestinal bleeding was the most common precipitating factor and in a study by Husain W et al, constipation was the most common precipitating factor20. The most common site of infection in our study was respiratory tract (48%), in addition to multiple sites (28%), spontaneous bacterial peritonitis (16%) and Urinary tract infections (8%). Upper gastrointestinal bleed, high protein intake and constipation leads to high protein load in the intestine which is converted to ammonia and carried to brain through portal vein and collateral circulation. Drugs especially diuretics are integral part of treatment of ascities and can lead to precipitation of hepatic encephalopathy either by causing dehydration or electrolytes imbalance.

CONCLUSION

From this study it is concluded that most of the patients presented with hepatic encephalopathy were in grade III and IV. Illiteracy and poor socioeconomic status of the patients are important hurdles in prevention, identification and treatment of precipitating factors before the patients progresses to high grade encephalopathy and thus high rate of morbidity and mortality. Most of the precipitating factors can be easily prevented if we educate and create awareness among the patients and caregivers.

Author’s Contribution:
Concept & Design of Study: Tahir Ullah
Drafting: Muhammad Iqbal Qasim
Data Analysis: Syed Farasat Ali Shah, Ihsan Ullah
Revisiting Critically: Tahir Ullah, Muhammad Iqbal Qasim
Final Approval of version: Tahir Ullah

Conflict of Interest: The study has no conflict of interest to declare by any author.

REFERENCES
3. Flamm SL. Complication of Cirrhosis In Primary Care: Recognition and Management of Hepatic
Evaluation of Serum Lipid Profile in Patients of Coronary Artery Disease
Muhammad Shoaib¹, Rana Tauqir Ullah Khan² and Fouzia Qadir³

ABSTRACT

Objective: The objective of this study to evaluate Serum Lipid Profile in Patients of Coronary Artery Disease in Mirpur, AJK.

Study Design: Cross-sectional study

Place and Duration of Study: This study was conducted at the Department of Biochemistry and Community Medicine, Mohtarma Benazir Bhutto Shaheed Medical College, Mirpur, and AJK from January 2019 to July 2019.

Materials and Methods: In this study we select 70 diabetic patients and 30 controls from AJK and Peshawar. We collected blood samples from both groups test and control. We analyzed blood sample for Glucose, High density lipoprotein, low density lipoprotein IDL, Triglyceride and Total cholesterol. We analyzed the sample of both groups’ diabetic patients and control by Micro lab 300. We use Merck kit for analysis the sample.

Results: We observed in our study that glucose level in serum is high in Coronary Artery Disease patients as compare to Control. We found that fasting glucose mg/dl level is (96.8 ± 4.2) in Coronary Artery Disease patients while in Control fasting glucose level mg/dl is (98.4 ± 4.9). Lipid profile is also high in Coronary Artery Disease patients as compare to Control. Total cholesterol level in Coronary Artery Disease patients is higher compare to Control. Total cholesterol in Coronary Artery Disease patients is (255.5 ± 12.8) mg/dl and in Control is (193.6 ± 30.5) mg/dl. LDL value Coronary Artery Disease patients is (129.8 ± 22.5) mg/dl and in Control is (116.5 ± 18.5) mg/dl. HDL value in Coronary Artery Disease patients is (56.7 ± 8.5) mg/dl and in Control is () mg/dl. Total glyceride value in Coronary Artery Disease patients is (189.2 ± 32.5) mg/dl and in Control is (143.3 ± 31.2) mg/dl

Conclusion: We found and conclude that high lipid profile found in in coronary heart disease patients as compare to control. Reduction of lipid profile is reduction of CHD risk.

Key Words: Coronary Artery Disease, Lipid profile, Control


INTRODUCTION

Morbidity and mortality is caused by Coronary heart disease (CHD) Hyperlipidemia is one of the most important reasons of Coronary heart disease (CHDtransition.¹ There are four primary coronary arteries are present on the surface of the heart².³ CHD is high ratio in man as compare women.⁴⁵ Total cholesterol, triglyceride, HDL, LDL are the factors and reasons of cardiovascular disease.⁶

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Printed: April, 2020

Coronary heart disease strongly and inversely, correlated with TG.HDL increase vasoprotective effects. The progression of heart disease are strongly associated with high levels of cholesterol in blood circulation.⁷⁸ Risk factors of CHD are modifiable and modifiable⁹. Lipids and lipoproteins have, their association with CHD, high level of lipid is mostly occurring factor.¹⁰ The objective of this study to evaluate lipid profile in CHD patient Mirpur AJK.

MATERIALS AND METHODS

In this study we select 70 diabetic patients and 30 controls. The study was conducted in the department of Biochemistry and Community Medicine of Mohtarma Benazir Bhutto Shaheed Medical College Mirpur AJK. We collected blood samples from both groups test and control. We analyzed blood sample for Glucose, High density lipoprotein, low density lipoprotein IDL, Triglyceride and Total cholesterol. We analyzed the sample of both groups’ diabetic patients and control by Micro lab 300. We use Merck kit for analysis the sample.

RESULTS

We observed in our study that glucose level in serum is high in Coronary Artery Disease patients as compare to
Control. We found that fasting glucose mg/dl level is (96.8 ± 4.2) in Coronary Artery Disease patients while in Control fasting glucose level mg/dl is (98.4 ± 4.9). Lipid profile is also high in Coronary Artery Disease patients as compared to Control. Total cholesterol level in Coronary Artery Disease patients is higher compared to Control. Total cholesterol in Coronary Artery Disease patients is (255.5 ± 12.8) mg/dl and in Control is (193.6 ± 30.5) mg/dl. LDL value Coronary Artery Disease patients is (129.8 ± 22.5) mg/dl and in Control is (116.5 ± 18.5) mg/dl. HDL value in Coronary Artery Disease patients (56.7± 8.5) mg/dl and in Control is () mg/dl. Total glyceride value in Coronary Artery Disease patients is (189.2 ± 32.5) mg/dl and in Control is (143.3 ± 31.2) mg/dl.

Table No.1: Participant characteristics

<table>
<thead>
<tr>
<th></th>
<th>(n=70) Coronary Artery Disease Patients</th>
<th>Control (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>50.4 ± 10.2</td>
<td>50.7 ± 10.6</td>
</tr>
<tr>
<td>Male/Female (%)</td>
<td>35/35</td>
<td>15/15</td>
</tr>
<tr>
<td>Body weight (Kg)</td>
<td>68.1 ± 11.4</td>
<td>69.4 ± 11.5</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>24.3 ± 2.6</td>
<td>24.4 ± 2.7</td>
</tr>
</tbody>
</table>

Table No.2: Biochemical profile of pregnant women and non-pregnant women

<table>
<thead>
<tr>
<th></th>
<th>(n=70) Coronary Artery Disease Patients</th>
<th>Control (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Blood Glucose (mg/dl)</td>
<td>96.8 ± 4.2</td>
<td>98.4 ± 4.9</td>
</tr>
<tr>
<td>Total Cholesterol (mg/dl)</td>
<td>255.5 ± 12.8</td>
<td>193.6 ± 30.5</td>
</tr>
<tr>
<td>LDL (mg/dl)</td>
<td>129.8 ± 22.5</td>
<td>116.5 ± 18.5</td>
</tr>
<tr>
<td>HDL (mg/dl)</td>
<td>56.7± 8.5</td>
<td>42.5 ± 9.2</td>
</tr>
<tr>
<td>Triglycerides (mg/dl)</td>
<td>189.2 ± 32.5</td>
<td>143.3 ± 31.2</td>
</tr>
</tbody>
</table>

DISCUSSION

Morbidity and mortality is caused by Coronary heart disease (CHD) Hyperlipidemia is one of the most important reasons of Coronary heart disease (CHD) transition. There are four primary coronary arteries are present on the surface of the heart. In this study we select 70 diabetic patients and 30 controls. The study was conducted in the department of Biochemistry and Community Medicine of Mohtarma Benazir Bhutto Shaheed Medical College Mirpur AJK. We collected blood samples from both groups test and control. We analyzed blood sample for Glucose, High density lipoprotein, low density lipoprotein IDL, Triglyceride and Total cholesterol. We analyzed the sample of both groups’ diabetic patients and control by Micro lab 300. We use Merck kit for analysis the sample. Result showed that high cholesterol caused Coronary heart disease. The Framingham result showed, there is association of high cholesterol with Coronary heart disease. We observed in our study that glucose level in serum is high in Coronary Artery Disease patients as compared to Control. We found that fasting glucose mg/dl level is (96.8 ± 4.2) in Coronary Artery Disease patients while in Control fasting glucose level mg/dl is (98.4 ± 4.9). Lipid profile is also high in Coronary Artery Disease patients as compared to Control. Total cholesterol level in Coronary Artery Disease patients is higher compared to Control. Total cholesterol in Coronary Artery Disease patients is (255.5 ± 12.8) mg/dl and in Control is (193.6 ± 30.5) mg/dl. LDL value Coronary Artery Disease patients is (129.8 ± 22.5) mg/dl and in Control is (116.5 ± 18.5) mg/dl. HDL value in Coronary Artery Disease patients (56.7± 8.5) mg/dl and in Control is () mg/dl. Total glyceride value in Coronary Artery Disease patients is (189.2 ± 32.5) mg/dl and in Control is (143.3 ± 31.2) mg/dl.

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ABSTRACT

Objective: To observe the nephroprotective effects of W. Somnifera root extract against cisplatin induced nephrotoxicity through biochemical parameters in albino Wistar rats.

Study Design: Experimental study

Place and Duration of Study: This study was conducted at the Baqai Medical University, Karachi from November 2018 till February 2019.

Materials and Methods: For this study 80 adult male Albino Wistar rats were divided in to four groups, 20 rats in each group. Group A served as control group, group B received inj. Cisplatin (1mg/kg intraperitoneally) for 7 days, group C received W. Somnifera root extract (500mg/kg) for 15 days before cisplatin treatment and thereafter concurrently with cisplatin for last 7 days. Whereas group D was given only W. Somnifera root extract (500mg/kg) for 22 days. Blood samples of all the groups were collected at the start of the study. Second blood samples of group A, C and D were taken on 23rd day and of group B was taken on day 8th of experiment. Estimation of serum urea and creatinine levels were done by using standard Laboratory kits.

Results: In this study mean (± SD) serum urea level of group A, B, C & D were 31.853± 8.3258 mg/dl, 251.495± 95.4603 mg/dl, 35.57± 22.1801 mg/dl and 30.700± 6.2149mg/dl respectively. While mean (± SD) serum creatinine level of group A, B, C & D were 0.538± 0.0656 mg/dl, 2.109± 0.9247 mg/dl, 0.606± 0.1911 mg/dl and 0.521± 0.0495mg/dl respectively. Significant (p<0.05) mean serum urea and creatinine level differences were observed when WS pretreated and cisplatin treated Group C was compared with cisplatin group B indicative of correction of raised serum urea and creatinine level. While comparison with group A & D showed insignificant changes.

Conclusion: It is concluded from our study that Cisplatin induced renal toxicity in albino Wistar rats may be corrected by W. Somnifera root extract through the renal function analysis (serum urea and creatinine levels).

Key Words: Cisplatin, W. Somnifera, Nephrotoxicity

INTRODUCTION

Renal failure primarily means failure of excretory functions of kidney, which results in retention of nitrogenous waste products of metabolism in blood along with inability to regulate fluid and electrolyte balance and endocrine dysfunction. Some proven medicines which include some antibiotics and chemotherapeutic drugs causes nephrotoxicity. Chemotherapeutic agents are cytotoxic and have severe side effects. Cisplatin is widely used for the treatment of carcinomas and sarcomas. Its common side effects includes bone marrow suppression and nephrotoxicity. Main mechanism for Cisplatin induced acute kidney injury is Oxidative stress. Acute kidney injury (AKI) includes rise in serum creatinine level (decrease in creatinine clearance), rise in blood urea nitrogen (BUN) and low serum Na, K, Mg and Ca. Creatinine is produced by the non-enzymatic conversion of creatine and phosphocreatinine in the muscles. Normal serum creatinine ranges from 0.5-1.0mg/dl. Urea is an organic compound and normal BUN level is 20-40mg/dl.

Withania Somnifera(WS) is known for its nephroprotective effects. Active ingredients in the roots of this herb has proven nephroprotective effects. Keeping in view of the above, the current study was designed to analyze the potential nephroprotective
effect of Withania Somnifera root extract on Cisplatin induced biochemical changes in albino Wistar rats’ renal biomarkers.

MATERIALS AND METHODS

This study was an experimental study conducted in Baqai Medical University, Karachi, from November 2018 till February 2019. For this study 80 healthy adult, male Albino Wistar rats of 14-16 weeks, weighing 180-250gm were purchased. Whereas female and diseased animals were excluded from the study. After 1 week of acclimatization, rats were randomly divided into four groups (A, B, C & D), 20 rats in each group. Cisplatin injections were purchased from local pharmacy and W. somnifera root extract was prepared. Group A was a control group and received normal saline orally for 22 days through gastric gavage and 0.5ml normal saline injection (intraperitoneally) for 7 days. Group B received Inj. Cisplatin only in a dose of 1mg/kg, intraperitoneally for 7 days. Group C received ethanolic extract of W. somnifera roots in a dose of 500mg/kg via gastric gavage for 15 days before cisplatin treatment and thereafter concurrently with cisplatin (1mg/kg intraperitoneally) for 7 days. Group D received ethanolic extract of W. somnifera roots in a dose of 500mg/kg via gastric gavage for 22 days, to evaluate any harmful effect of W. somnifera on rat kidneys. Dosing was done around 9am in morning after overnight fasting. At the start of the study blood samples were collected from all groups through tail venipuncture to assess the kidney functions. Second blood samples of group A, C and D were taken on 23rd day and of group B was taken on day 8th of experiment stored in sterile EDTA tubes for renal function analysis (serum urea and serum creatinine). Blood samples were centrifuged and serum was separated by using standard Auto Analyzer (Architect c8000). Data was statistically analyzed on (SPSS) version 22. Mean comparison of blood parameters of group C with groups A, B & D were analyzed by independent sample T test. P value of less than 0.05 was considered significant (p<0.05).

RESULTS

Mean ± SD of Serum urea level of group A, B, C & D were 31.853± 8.3258 mg/dl, 251.495 ± 95.4603 mg/dl, 35.570± 22.1801 mg/dl and 30.700± 6.2149 mg/dl respectively. Significant mean serum urea level difference was observed when Group C was compared with Group B (P = 0.000) whereas insignificant changes were seen in comparison with group A & D (P values 0.487 & 0.350) respectively as shown in Table I and Figure I.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Mean ± SD (mg/dl)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>C &amp; B</td>
<td>35.570 ± 22.1801</td>
<td></td>
</tr>
<tr>
<td>C &amp; A</td>
<td>35.570 ± 22.1801</td>
<td>0.487</td>
</tr>
<tr>
<td>C &amp; D</td>
<td>31.853 ± 8.3258</td>
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</table>

*(P value ≤ 0.05 is considered statistically significant)*

**Figure No.1: Showing comparison of mean ± SD of serum urea level of group C with groups A, B & D**

Mean ± SD of serum creatinine level of group A, B, C & D were 0.538± 0.0656 mg/dl, 2.109± 0.9247 mg/dl, 0.606± 0.1911 mg/dl and 0.521± 0.0495mg/dl respectively. Significant mean serum creatinine level difference was observed when Group C was compared with Group B (P value 0.035) whereas insignificant changes were seen in comparison with group A & D (P values 0.141 & 0.347) respectively as shown in Table 2 and Figure 2.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Mean ± SD (mg/dl)</th>
<th>P Value</th>
</tr>
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<tbody>
<tr>
<td>C &amp; B</td>
<td>0.606± 0.1911</td>
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<tr>
<td>C &amp; A</td>
<td>0.606± 0.1911</td>
<td>0.141</td>
</tr>
<tr>
<td>C &amp; D</td>
<td>0.521± 0.0495</td>
<td>0.347</td>
</tr>
</tbody>
</table>

*(P value ≤ 0.05 is considered statistically significant)*

**Table I: Comparison of mean serum urea level of group C with groups A, B & D**

**Table No.2: Comparison of mean serum creatinine level group C with groups A, B & D**
DISCUSSION

Serum urea and Creatinine are the hallmark and have been measured to recognize acute kidney injury. Creatinine is generated by muscles from non-enzymatic conversion of creatine and phosphocreatinine and Urea plays an important role in metabolism of nitrogenous compounds. In the current study, biochemical parameters confirmed the nephroprotective effects of W. somnifera root extract against these renal changes.

In our study cisplatin treated group B showed marked elevation of serum and creatinine levels as compared to control groups which is in accordance to the results of (Cheng et al: 2018) who stated that elevation of biochemical parameters might be due to cisplatin induced oxidative stress. In line with our study, results of (Hossenian et al: 2016) also revealed cisplatin induced renal injury which was evident by significant increase in renal biomarkers (BUN & Cr). He reported that elevation of renal biomarkers after cisplatin administration might be due to decrease glomerular filtration rate (GFR) which occurs as a result of production of reactive oxygen species (ROS). ROS increases the production of vasoconstrictors which leads to glomerular vasoconstriction and reduced GFR. Similar changes in renal parameters were reported by (Bambietal: 2017) and (Vasaikaretal: 2018) due to cisplatin induced glomerular and tubular damage. However biochemical parameters were significantly decreased, almost near to normal values, in W. somnifera pretreated and cisplatin treated group C. These findings were in agreement with the previous studies reported by (Govindappa et al: 2019) and (Kushwah et al: 2016), (Jeythanietal: 2014) also mentioned similar renal biomarker changes after pretreatment with W. somnifera along with gentamicin administration. He stated that nephroprotective effect of W. somnifera could be due to anti-oxidant properties of its bio active constituents.

CONCLUSION

It is concluded from our study that Cisplatin induced renal toxicity in albino Wistar rats may be corrected by W. Somnifera root extract through the renal function analysis (serum urea and creatinine levels).

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