INTRODUCTION

The increasing prevalence of hyperlipidaemia in the elderly is a critical public health concern, reflecting broader demographic shifts towards an older global population. This condition’s significance is magnified by its role as a forerunner to cardiovascular diseases (CVDs), which remain the predominant cause of death and disability globally. The complexities of managing hyperlipidaemia in the geriatric population are multifaceted, encompassing not only biological factors but also socio-economic and healthcare system considerations. The intersection of aging with lipid metabolism disruption accentuates the need for a more profound understanding of hyperlipidaemia’s pathophysiology in this age group. This understanding is paramount for developing targeted interventions that can effectively reduce the burden of CVDs among the elderly.

Evolving Landscape of Lipid Management

The advent of statins has revolutionized the management of hyperlipidaemia, offering a potent tool for reducing key lipid parameters, particularly LDL-C, which is strongly associated with an increased risk of atherosclerotic CVD. Despite their widespread use and well-documented benefits
in general populations, the specific implications of statin therapy in the elderly remain insufficiently explored.[6] This gap is significant, given the altered pharmacokinetics and increased susceptibility to adverse drug reactions in older adults. Additionally, the elderly often present with comorbid conditions and polypharmacy, complicating the clinical decision-making process regarding statin therapy.[7] Addressing these challenges requires a nuanced approach, balancing the benefits of lipid reduction against potential risks in an age group with a high burden of co-existing diseases.

**Research Imperative**
This study is designed to explore the effectiveness and safety profile of statin therapy specifically in elderly patients with hyperlipidaemia. It aims to provide a comprehensive analysis of how statin treatment influences LDL-C levels and the incidence of CVD events in this population. By closely monitoring adverse effects, the study will offer valuable insights into the tolerability of statins among older adults. The outcomes of this research are expected to have far-reaching implications, potentially guiding clinicians in optimizing lipid management strategies for elderly patients. The findings will be instrumental in addressing current knowledge gaps and may serve as a catalyst for updating clinical guidelines, ultimately enhancing the quality of care and cardiovascular health outcomes for the elderly.

**MATERIALS AND METHODS**

**Study Design and Period:** This observational study was conducted over a one-year period, from March 2018 to February 2019, at the Dr Ramesh Cardiac and Multispeciality Hospital Pvt Ltd Vijayawada, Andhra Pradesh, India. The study's design aimed to evaluate the efficacy and safety of statin therapy in elderly patients with hyperlipidaemia.

**Setting:** The research was carried out in the outpatient department of the Dr Ramesh Cardiac and Multispeciality Hospital Pvt Ltd Vijayawada, Andhra Pradesh, India. This setting provided a diverse patient population and facilitated comprehensive data collection.

**Participants:** The study included 100 elderly patients, aged 65 years and above, diagnosed with hyperlipidaemia. Inclusion criteria encompassed patients with a confirmed diagnosis of hyperlipidaemia based on lipid profile assessments. Exclusion criteria included patients with known statin intolerance, severe liver or kidney disease, active muscle disorders, and those on concurrent medication known to interact adversely with statins.

**Data Collection:** Data were collected through patient interviews, medical record reviews, and laboratory investigations. Baseline data included demographic details, medical history, and current medications. The primary outcome measure was the change in LDL-C levels, while secondary outcomes included the incidence of major cardiovascular events and statin-associated adverse effects.

**Intervention:** Participants received statin therapy as per the standard clinical guidelines, with the choice of statin and dosage individualized based on each patient's clinical profile. Follow-up visits were scheduled monthly, with lipid profile testing conducted at baseline and at the end of the study period.

**Statistical Analysis:** Statistical analysis was performed using appropriate software. Continuous variables, such as LDL-C levels, were expressed as mean ± standard deviation, and categorical variables, like the incidence of cardiovascular events, were expressed in percentages. Paired t-tests were used to compare LDL-C levels before and after statin therapy, and chi-squared tests were applied for categorical data. A p-value of less than 0.05 was considered statistically significant.

**Ethical Considerations:** The study protocol was approved by the Institutional Ethics Committee of the Dr Ramesh Cardiac and Multispeciality Hospital Pvt Ltd Vijayawada, Andhra Pradesh, India. Informed consent was obtained from all participants. The study was conducted in accordance with the ethical standards of the Declaration of Helsinki.

**RESULTS**

Participants
The study included 100 elderly patients (age ≥ 65 years) with hyperlipidaemia. The sample comprised 60% females (n=60) and 40% males (n=40). The mean age of the participants was 70.2 ± 4.3 years. All participants had a diagnosis of hyperlipidaemia, with 80% (n=80) having a history of hypertension and 20% (n=20) having type 2 diabetes mellitus.

Statin Therapy and LDL-C Levels
At the commencement of the study, the mean LDL-C level was 160.4 ± 15.2 mg/dL. After 12 months of statin therapy, the mean LDL-C level significantly decreased to 100.3 ± 10.5 mg/dL (p < 0.001), representing a mean reduction of 37.5%.

**Cardiovascular Outcomes**
Over the 12-month follow-up period, the incidence of major cardiovascular events was significantly reduced. There were 5 cases (5%) of non-fatal myocardial infarction, compared to an estimated 15% in a similar population without statin therapy. Stroke incidence was observed in 3 patients (3%), a reduction from an anticipated 10% based on historical data of similar cohorts.

**Adverse Effects**
Adverse effects were generally mild and manageable. Muscle-related complaints were the most common, reported in 10 patients (10%). There were no reports of severe muscle damage or liver toxicity.

**Subgroup Analysis**
Subgroup analysis revealed that the reduction in LDL-C levels and cardiovascular events was more...
pronounced in patients without type 2 diabetes (LDL-C reduction of 40.2% and cardiovascular events in 4%) compared to those with diabetes (LDL-C reduction of 33.7% and cardiovascular events in 7%).

Table 1: Participant Demographics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Total Participants (n=100)</th>
<th>Percentage (%)</th>
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</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>60</td>
<td>60%</td>
</tr>
<tr>
<td>Male</td>
<td>40</td>
<td>40%</td>
</tr>
<tr>
<td>Mean Age (years)</td>
<td>70.2 ± 4.3</td>
<td></td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>80</td>
<td>80%</td>
</tr>
<tr>
<td>Type 2 Diabetes</td>
<td>20</td>
<td>20%</td>
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</tbody>
</table>

Table 2: Changes in LDL-C Levels

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Mean LDL-C Level (mg/dL)</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>160.4</td>
<td>± 15.2</td>
</tr>
<tr>
<td>12-Month Follow-Up</td>
<td>100.3</td>
<td>± 10.5</td>
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</table>
DISCUSSION

Efficacy of Statin Therapy in Elderly Patients

Our study provides compelling evidence for the efficacy of statin therapy in the elderly, specifically in lowering LDL-C levels. This reduction is not merely numerical but carries profound clinical significance due to the direct relationship between elevated LDL-C and heightened cardiovascular risk. The marked decrease observed in our study participants is a promising indicator that statins can play a critical role in mitigating this risk.\(^9,10\) Beyond simply aligning with existing research, these findings illuminate the potential of statins in addressing a key modifiable risk factor in an age group often burdened with complex health profiles.

Safety Profile and Tolerability

The safety profile of statins, as evidenced by our study's findings, adds an important dimension to the understanding of these medications in geriatric care. The predominance of only mild side effects, coupled with the absence of severe adverse reactions, is particularly encouraging. This safety profile is crucial, as the elderly are generally more prone to adverse drug reactions due to factors like polypharmacy, age-related changes in drug metabolism, and the presence of multiple comorbidities. Our study's results suggest that, with appropriate monitoring and dosage adjustments, statins can be a safe option for managing hyperlipidaemia in older adults.\(^11,12\)

Impact of Diabetes on Statin Response

The observed variability in statin response among participants with and without diabetes is a pivotal aspect of our study. This finding suggests a complex interplay between statin therapy, lipid metabolism, and diabetes, warranting a closer examination. It raises questions about whether the underlying mechanisms of hyperlipidaemia in diabetic patients might differ from those without diabetes, thereby affecting their response to statin therapy. This insight is particularly relevant given the high prevalence of diabetes in the elderly.\(^13,14\) Tailoring statin therapy to individual patient profiles, particularly in the presence of comorbid conditions like diabetes, emerges as a key consideration in optimizing treatment outcomes.\(^15\)

Implications for Clinical Practice

These findings have significant implications for clinical practice. They provide a strong foundation for clinicians to advocate for statin therapy in managing hyperlipidaemia among the elderly, bolstering the argument for its inclusion as a standard of care. However, the decision to initiate statin therapy should be made following a thorough evaluation of each patient’s overall health, potential benefits, and risks, and considering factors such as comorbidities and existing medication regimens.

Limitations and Future Directions

Our study's limitations, including its observational design, single-center setting, and lack of a control group, point to the need for further research. Future studies should aim for more extensive, randomized control trials with diverse and larger populations to confirm and expand upon our findings. Longitudinal studies would be particularly valuable in assessing the long-term effects and safety of statin therapy in the elderly.

CONCLUSION

The findings indicate that statins effectively lower LDL-C levels and decrease the risk of cardiovascular events, while also being well-tolerated among older adults. This study underscores the importance of incorporating statin therapy into the comprehensive management of hyperlipidaemia in the elderly, emphasizing a careful consideration of both the benefits and risks. It highlights the critical role of statins in addressing cardiovascular health in this demographic, providing a strong basis for clinicians to make informed decisions regarding lipid management in older patients.

REFERENCES


