POST MARKETING SURVEILLANCE OF NIMOTUZUMAB A NOVEL MONOCLONAL ANTIBODY IN INDIAN POPULATION

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INTRODUCTION

Nimotuzumab is approved for head and neck cancer in India and has few incidences of toxicityl. Anti EGFR are known to produce severe toxicities including grade III / IV rashes.

METHODOLOGY

Patients with head and neck cancer or any other tumour who were suitable for nimotuzumab therapy were included. All patients received 200mg nimotuzumab IV infusion weekly for six weeks along with SOC. All Patients who received the treatment were considered for the analysis.

OBJECTIVES

Present study is aimed to evaluate safety and tolerability of nimotuzumab in the real life clinical conditions

RESULTS

75 AE were recorded for (24%) patients. The most common event was mucosal inflammation (44%).The adverse events were mild to moderate and 4 events were life threatening. One patient who died as a result of AE, had diarrhea and leucopenia (both grade 3,) probably had immunosuppression followed by infection due to chemotherapy. Six (8%) events were reported to related to nimotuzumab alone whereas 4 (5.33%) events were reported to be related to nimotuzumab, CT and RT. Among the events reported to be related to nimotuzumab alone, there were 2 events of mild hypotension, one event of pyrexia (grade 3, recovered completely), one event each of pruritis (grade 2, recovered completely), vesicular rash (grade 3, recovered completely) and rash (grade 4). Rash due to nimotuzumab were seen in only 2(1.3%) patients who developed 2 events of rash in them

CONCLUSIONS

Nimotuzumab is found to be safe with no major safety issues and the lower incidences of rash compared to other EGFR Inhibitors