

¹ Luisenkrankenhaus Düsseldorf, ² Internationale Senologie Initiative ISI e.V., ³ Europäisches Brustzentrum Dr. Rezai, Düsseldorf

Introduction:

Chemotherapy-induced peripheral neuropathy (CIPN) is an adverse effect of many commonly used chemotherapeutic agents (cisplatin, oxaliplatin, more rarely carboplatin, vinca alkaloids, especially vincristine, more rarely also vinblastine and vinorelbine, 5-fluoropyrimides (5-FU, capecitabine). CIPN in breast cancer is often caused by taxane-based regimen (Paclitaxel, nab-Paclitaxel, Docetaxel) carboplatin, eribulin and vinorelbine.

CIPN occurs in 30-40% of patients receiving chemotherapy but can be seen to some degree in up to 70% of patients. The peripheral neuropathy (PN) induced by taxanes may persist for several years in about 30% of patients and is negatively associated with quality of life. Often the CIPN results in dose delay, dose reduction or treatment discontinuation.

In our study we found that the prophylactic hand / feet cooling using a new computer - controlled thermotherapy device (Hilotherapy®) prevented the chemotherapy-induced-peripheral neuropathy (CIPN) in breast cancer patients.

Patients and Method:

168 breast cancer patients used a new method of physical thermotherapy, a device equipped with hand and foot cuffs to allow a constant cooling [Fig 1.]. Continuous cooling of hands and feet was performed 30 minutes before to 60 minutes after completing drug infusion with a temperature of 10-12°C.

130 patients used the prophylactic Hilotherapy® for each cytotoxic treatment (Group 1: primary Prophylactic Hilotherapy® - pPHT); [Fig 2.].

38 patients used reactive secondary Hilotherapy®. Hands and feet were cooled after onset of symptoms of CIPN [grade 1-3]; (Group 2: reactive, Secondary Hilotherapy® - rSHT); [Fig 2.].

CIPN symptoms were evaluated after each cytotoxic cycle using common terminology criteria for adverse events (CTCAE). Sustainability of the impact was assessed by long-term data (every 3 months).

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Fig. 1: Patient using prophylactic cooling

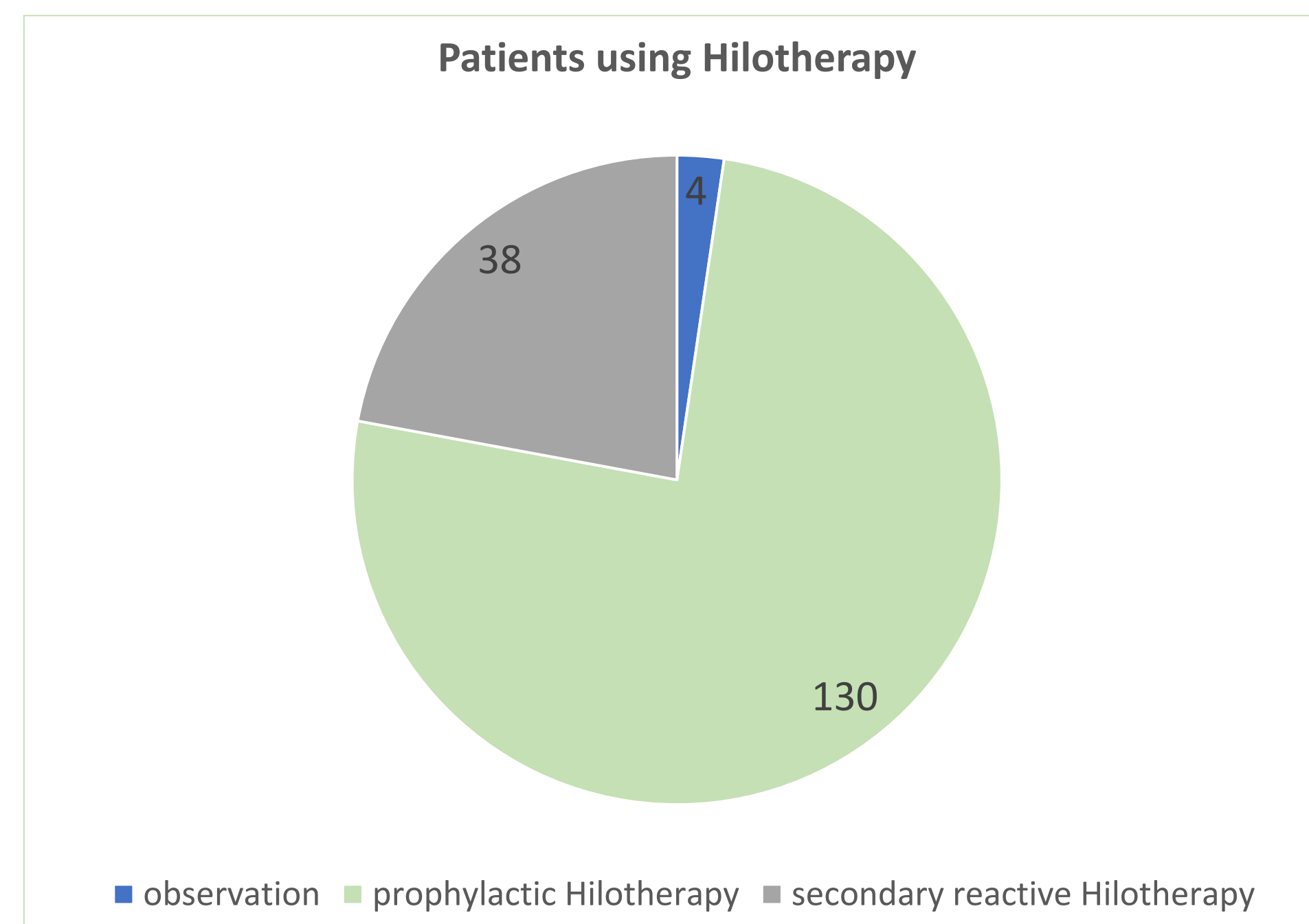


Fig. 2: Patients using Hilotherapy®

Results:

Group pPHT: Out of 130 patients who used pPHT, 121 patients (93%) developed none or mild symptoms of CIPN (grade 0-1), [Fig 3.].

8 patients (6,1%) reported grade 2, 1 patient grade 3 (0,8%) toxicity [Fig 3.].

The symptoms of CIPN were reversible. 4 weeks after last chemotherapy treatment (EOT), 96% of the patients had no CIPN > grade 1, [Fig 4.].

4 months after chemotherapy, 98% of the patients were without symptoms > grade 1. Follow Up data confirmed the sustainability of the results.

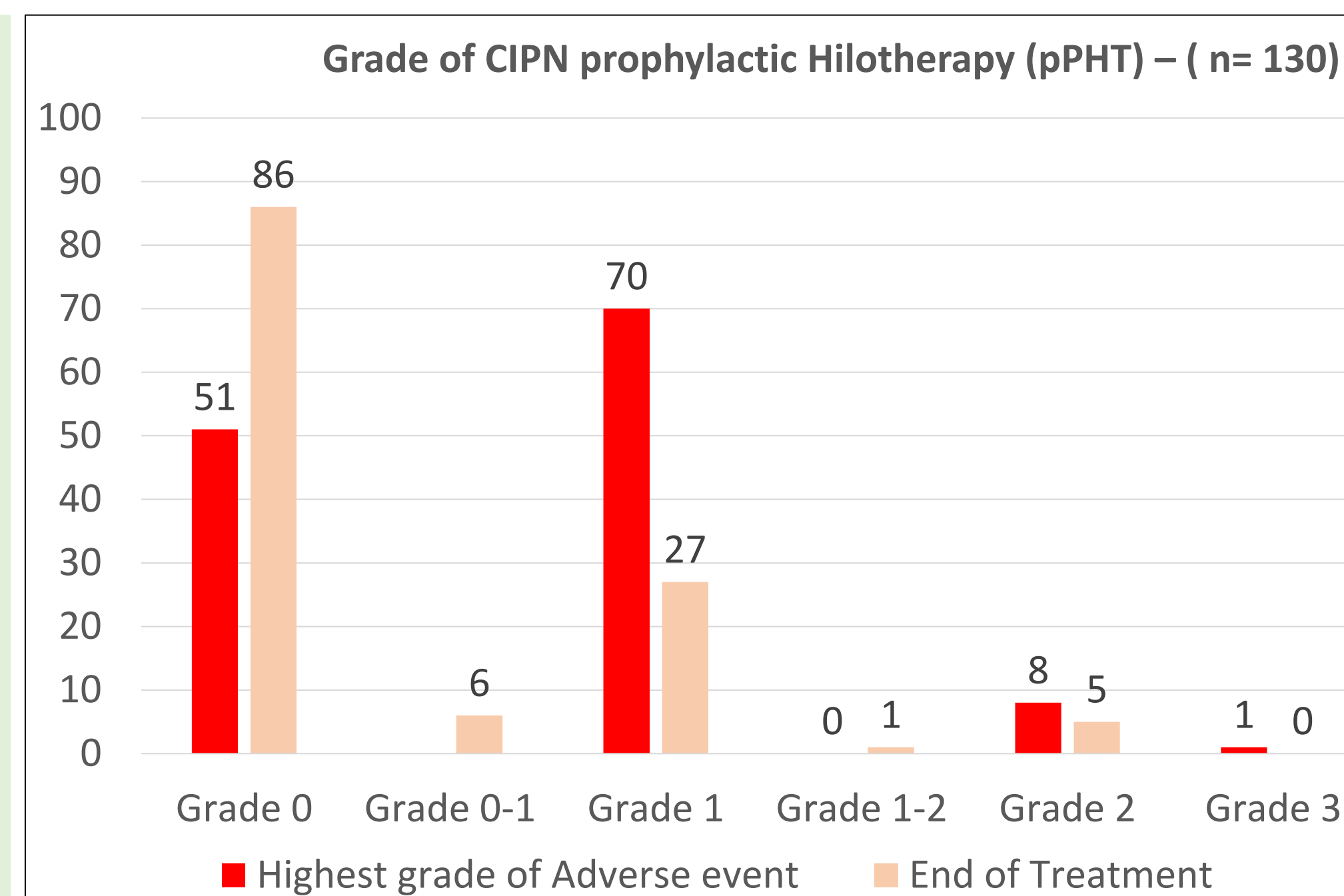


Fig. 3: toxicity grades using primary, prophylactic Hilotherapy®

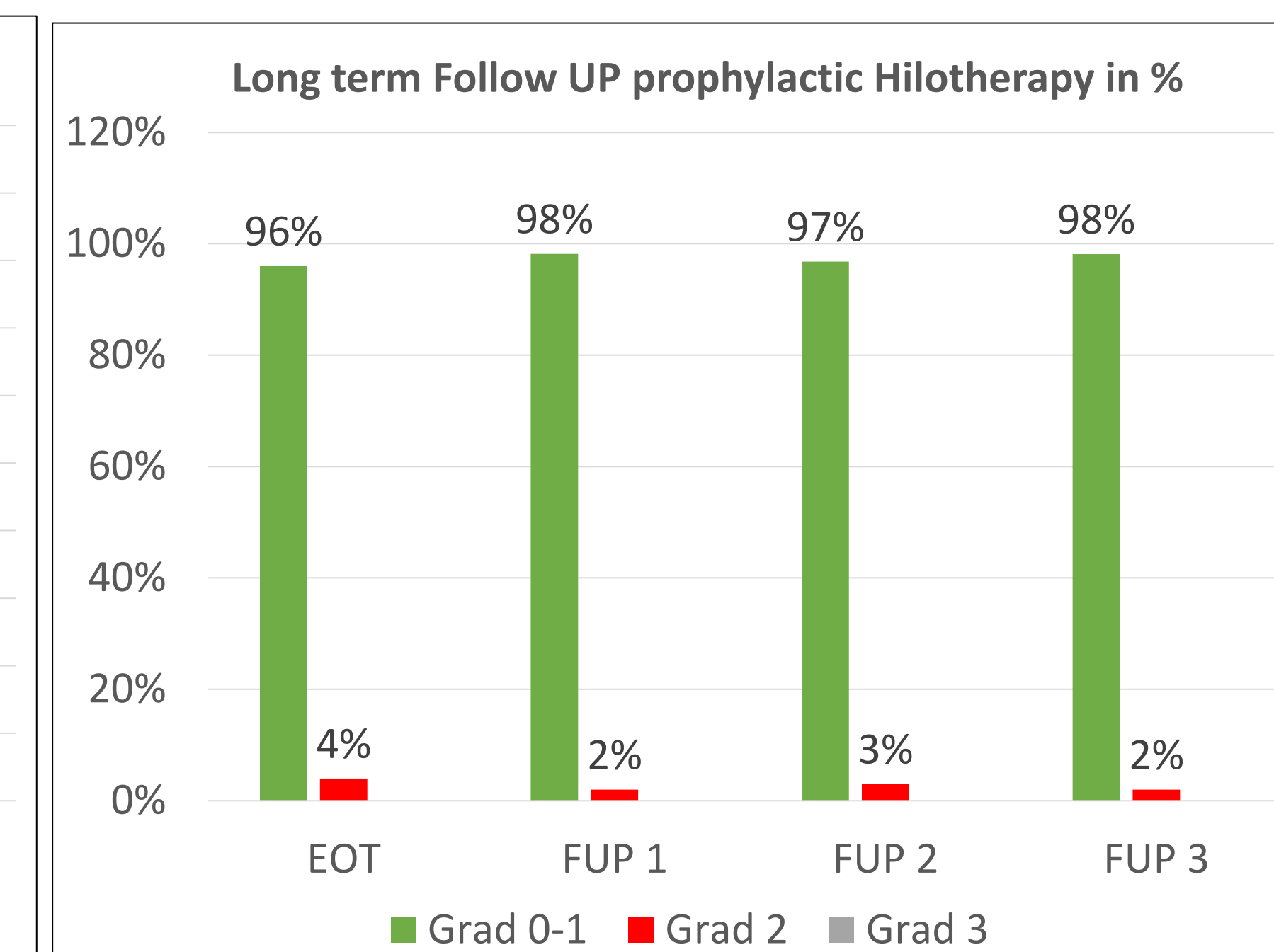


Fig. 4: Long term toxicity grades after pPHT®

EOT: 4 weeks after last chemotherapy treatment (n = 125).
FUP 1: 4 months after last chemotherapy Treatment (n = 113).
FUP 2: 7 months after last chemotherapy Treatment (n = 96).
FUP 3: 10 months after last chemotherapy Treatment (n = 54).

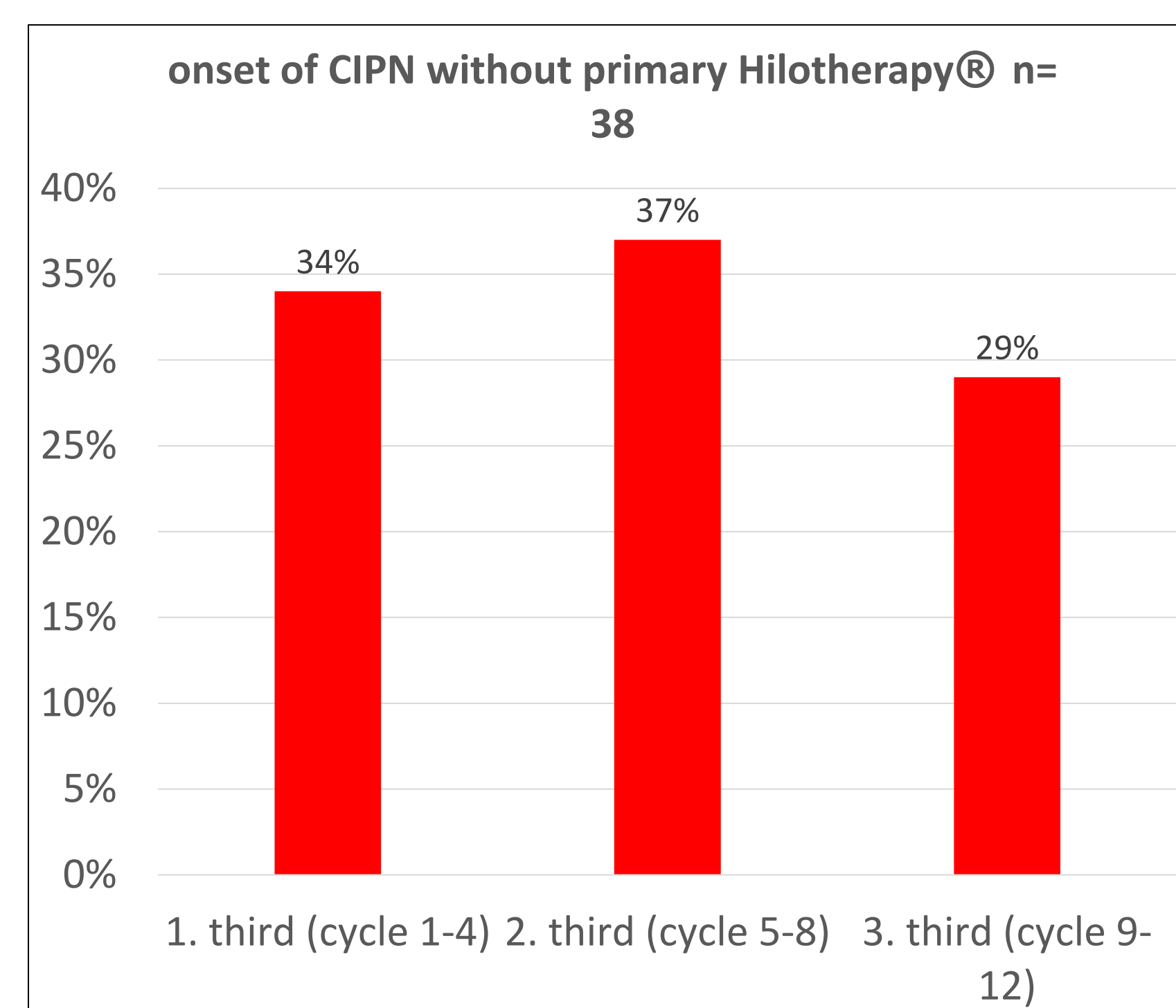


Fig. 5: Onset of CIPN without prophylactic Hilotherapy®

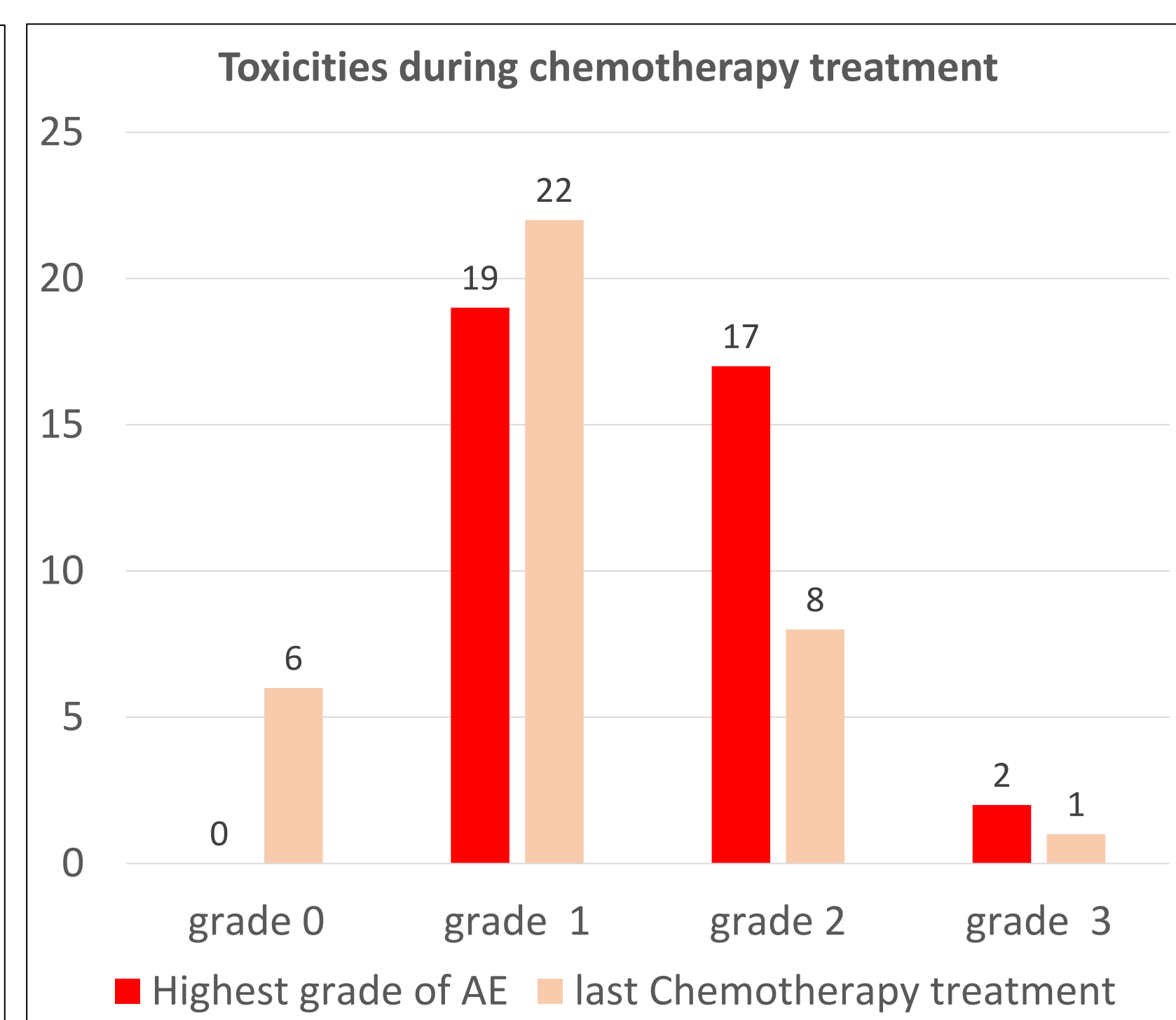


Fig. 6: Grade of toxicity without prophylactic Hilotherapy®

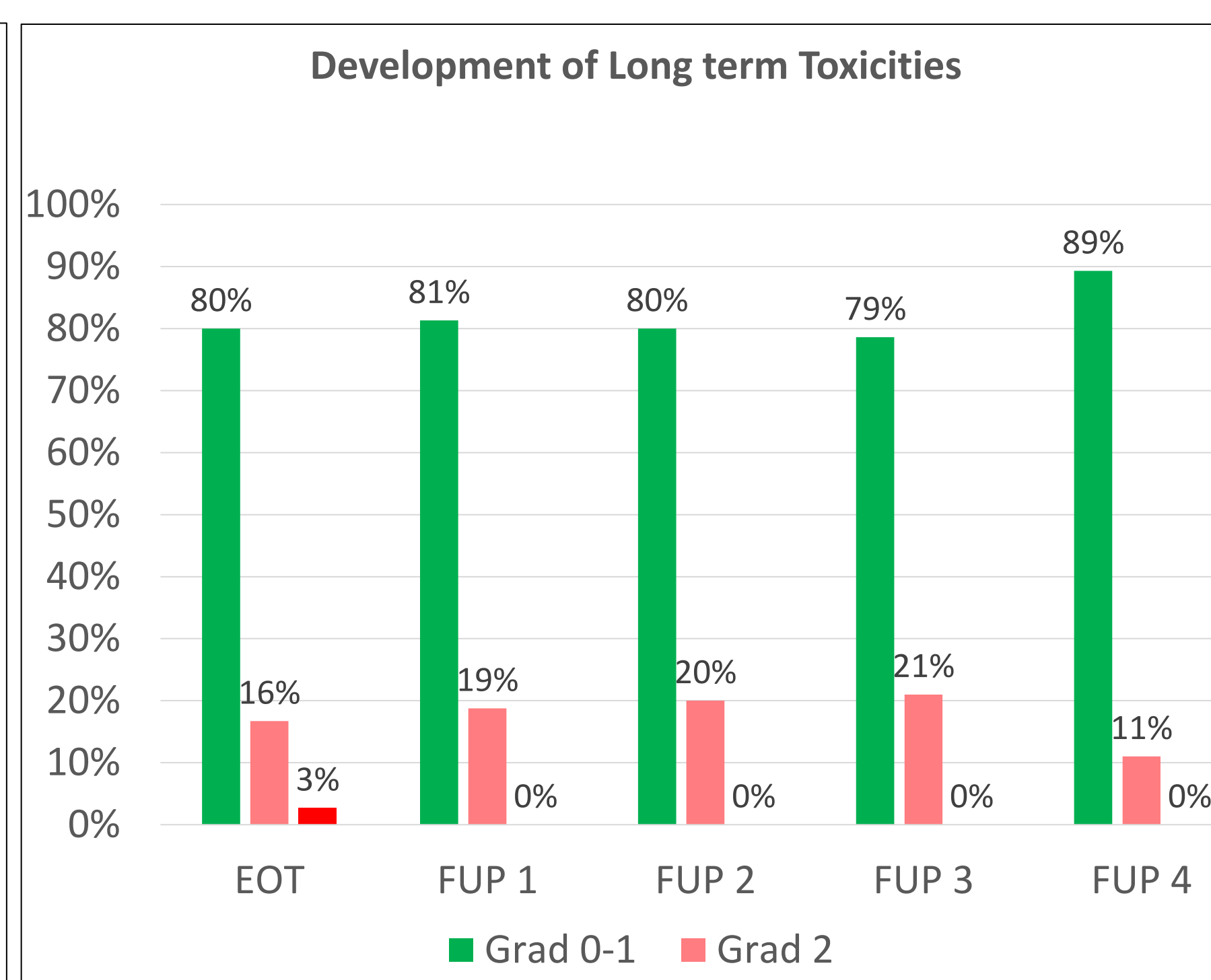


Fig. 7: Long term toxicity grades after rSHT®

Results:

Group rSHT: Without using pPHT 50% of the patients developed grade 3 and 2 CIPN. Using rSHT progression was stopped and reduction of toxicities was reached: at last chemotherapy treatment grade 2 & 3 toxicities were reduced from 50% to 25%.

EOT: 4 weeks after last therapy (n=36)
FUP 1: 4 months after last therapy (n= 32)
FUP 2: 7 months after last therapy (n= 30)
FUP 3: 10 months after last therapy (n=28)
FUP 4: 14 months after last therapy (n=28)

Conclusions:

Prophylactic Hilotherapy prevented symptoms > grade 1 in 93% of patients. 4 months after chemotherapy treatment, 98% of the patients were without limiting symptoms > grade 1. No dose modifications or treatment interruptions had been necessary. Without pPHT, 50 % of the patients developed CIPN grade 2-3. rSHT stopped progression of CIPN and reduced first symptoms of CIPN. CIPN significantly affects the quality of life of patients with cancer and cancer survivors. Due to the modern, targeted and individualized therapeutic options, there is a significant improvement in the long-term prognosis and overall survival for many oncological patients. Therefore maintaining quality of life and avoiding long term complications is becoming more important.