A PROSPECTIVE FOLLOW-UP STUDY OF PALLADONE® SR (HYDROMORPHONE SLOW RELEASE) IN BELGIUM.

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Background and aim

The aim of this observational study was to evaluate patterns of use, safety and efficacy of Palladone® SR (hydromorphone slow release) in daily clinical practice.

Methods

This open, prospective, non-randomized, observational study was designed in accordance with the SAMM guidelines (Waller et al., Br. J. Pharmacol 38(2):-95-97, 1994).

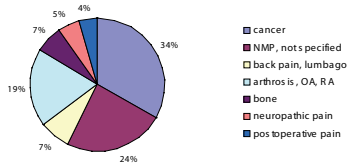
Results

A total of 552 evaluable patients were included in this interim analysis. Forty-one percent (41%) were female with a mean age of 64 years and a pain VAS score of 74 mm at inclusion. Patients were treated for severe cancer pain (34%) or severe non-cancer pain (66%) such as back pain, arthrosis etc (figure 1). Almost half of the patients were pre-treated with step 2 opioids (48%), step 1 analgesics (12%), step 3 opioids (39%) or co-analgesics (1%) (figure 2). One third of the patients was treated with tramadol before Palladone® SR treatment (figure 3). The average daily start dose was 10 mg Palladone® SR. This dose increased during treatment to 14 mg and 17 mg at the second (mean 19 days) and third evaluation (mean 44 days) respectively.
After the last evaluation, the VAS score for pain, effect of pain on work, daily activities and quality of life were reduced with 50% (figure 4). The efficacy of treatment was evaluated as 'satisfied' to 'very good' for 88% of the patients (figure 5). The most frequently reported adverse events (constipation (11%), nausea (10%), sedation (7%), dizziness (7%), dry mouth (2%) and vomiting (2%)) were common opioid-related events (table 1). The severity of the most frequently reported adverse events was mild to moderate (figure 6).

Conclusion:

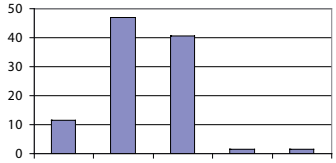
Palladone® SR was effective and safe for the treatment of severe cancer and non-cancer pain in daily clinical practice in Belgium.

Figure 1: Diagnosis.



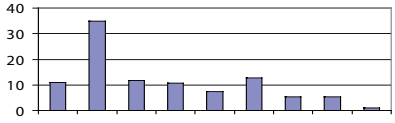
Patients were treated for severe cancer pain (34%) or severe non-cancer pain (66%) such as back pain, arthrosis etc.

Figure 2: Previous analgesic treatment of patients according to WHO ladder.



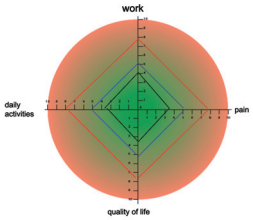
Almost half of the patients were pre-treated with WHO step 2 opioids (48%), step 1 analgesics (12%), step 3 opioids (39%) or co-analgesics (1%).

Figure 3: Previous analgesic treatment of patients.



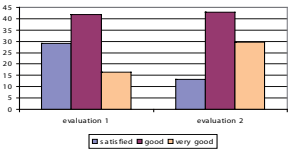
One third of the patients was treated with tramadol before Palladone® SR treatment

Figure 4: Pain Impact score



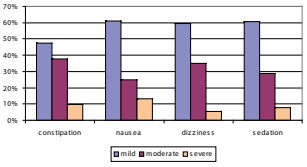
Evaluation of pain and effect of pain on the ability to work, daily activities and quality of life during Palladone® SR treatment (VAS).
The red line indicates the VAS scores before treatment, the blue line indicates the VAS scores after the first evaluation and the black line indicates the VAS scores after the second evaluation.
After the last evaluation the VAS score for pain, effect of pain on work, daily activities and quality of life were reduced with 50%.

Figure 5: Evaluation of Palladone® SR treatment by physician.



The efficacy of treatment was evaluated as 'satisfied' to 'very good' for 88% of the patients.

Figure 6: Severity of most common adverse events



The severity of the most frequently reported adverse events was mild to moderate.

Table 1: Most common opioid related adverse events.

Adverse event	Percentage
constipation	11%
nausea	10%
dizziness	7%
sedation	7%
dry mouth	2%
vomiting	2%