FIGURE 1

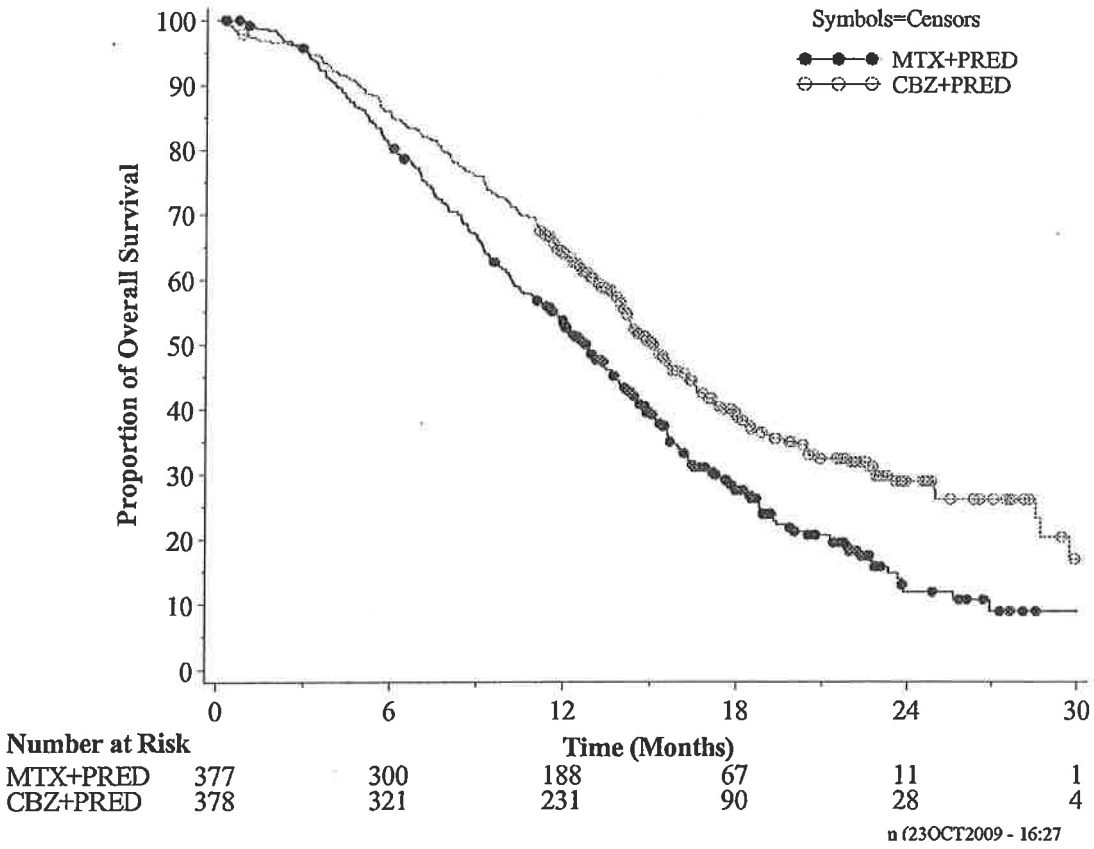

Symbols=Censors
MTX+PRED
CBZ+PRED
Proportion of Overall Survival
100
90
80
70
60
50
40
30
20
10
0
0
6
12
18
24
30
Time (Months)
Number at Risk
MTX+PRED 377 300 188 67 11 1
CBZ+PRED 378 321 231 90 28 4
n (23OCT2009 - 16:27

FIGURE 2

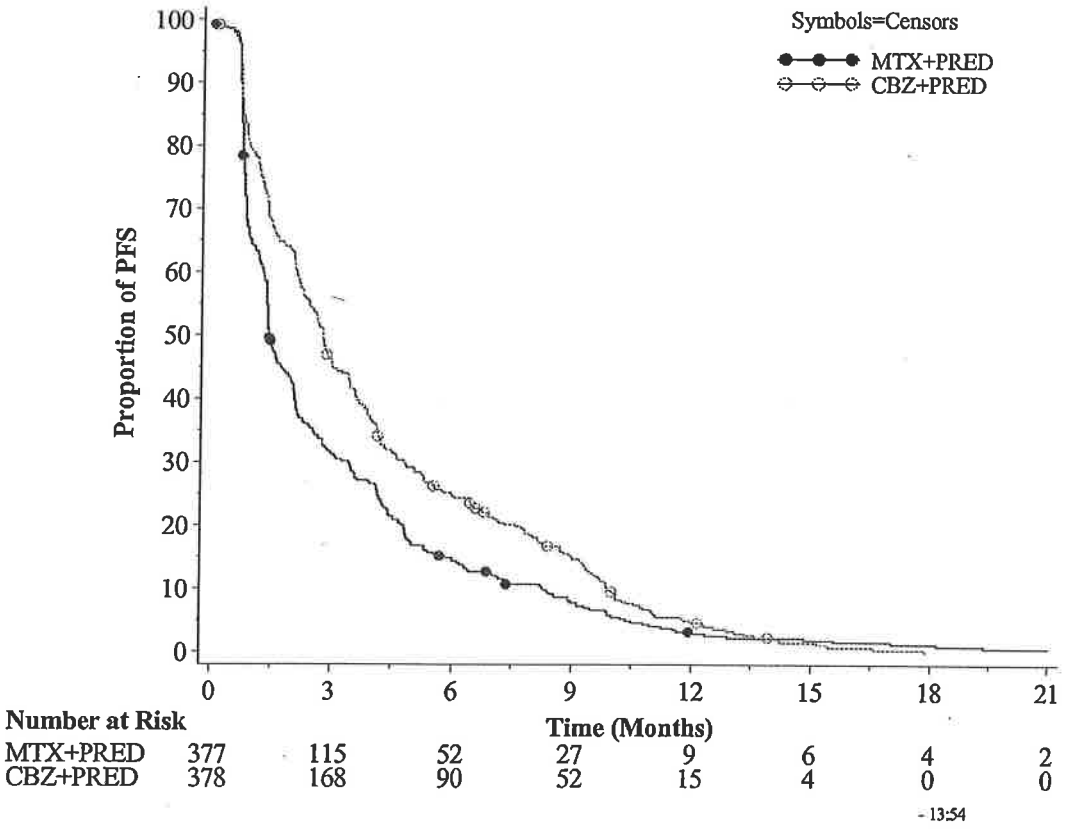

Symbols=Censors
MTX+PRED
CBZ+PRED
Proportion of PFS
100
90
80
70
60
50
40
30
20
10
0
0
3
6
9
12
15
18
21
Time (Months)
Number at Risk
MTX+PRED 377 115 52 27 9 6 4 2
CBZ+PRED 378 168 90 52 15 4 0 0
- 13:54

FIGURE 3

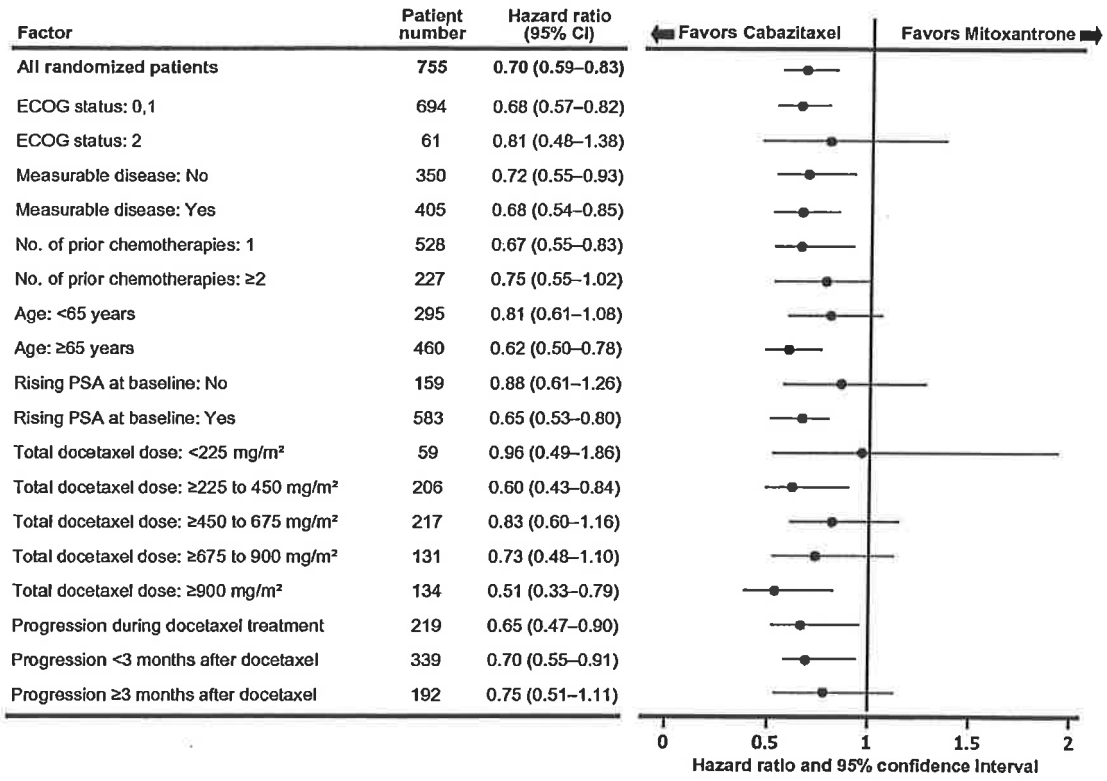

Factor
Patient number
Hazard ratio (95% CI)
Favors Cabazitaxel
Favors Mitoxantrone
All randomized patients 755 0.70 (0.59–0.83)
ECOG status: 0,1 694 0.68 (0.57–0.82)
ECOG status: 2 61 0.81 (0.48–1.38)
Measurable disease: No 350 0.72 (0.55–0.93)
Measurable disease: Yes 405 0.68 (0.54–0.85)
No. of prior chemotherapies: 1 528 0.67 (0.55–0.83)
No. of prior chemotherapies: ≥2 227 0.75 (0.55–1.02)
Age: <65 years 295 0.81 (0.61–1.08)
Age: ≥65 years 460 0.62 (0.50–0.78)
Rising PSA at baseline: No 159 0.88 (0.61–1.26)
Rising PSA at baseline: Yes 583 0.65 (0.53–0.80)
Total docetaxel dose: <225 mg/m² 59 0.96 (0.49–1.86)
Total docetaxel dose: ≥225 to 450 mg/m² 206 0.60 (0.43–0.84)
Total docetaxel dose: ≥450 to 675 mg/m² 217 0.83 (0.60–1.16)
Total docetaxel dose: ≥675 to 900 mg/m² 131 0.73 (0.48–1.10)
Total docetaxel dose: ≥900 mg/m² 134 0.51 (0.33–0.79)
Progression during docetaxel treatment 219 0.65 (0.47–0.90)
Progression <3 months after docetaxel 339 0.70 (0.55–0.91)
Progression ≥3 months after docetaxel 192 0.75 (0.51–1.11)
0
0.5
1
1.5
2
Hazard ratio and 95% confidence interval

FIGURE 4

Proportion of patients with changes in ECOG performance status from baseline during treatment (safety population)

Improved: PS2 at baseline changed to 0 or 1 during treatment

Stable: no change

Worse: PS2 at baseline and changed to ≥3, or 0 or 1 at baseline changed to ≥2 during treatment

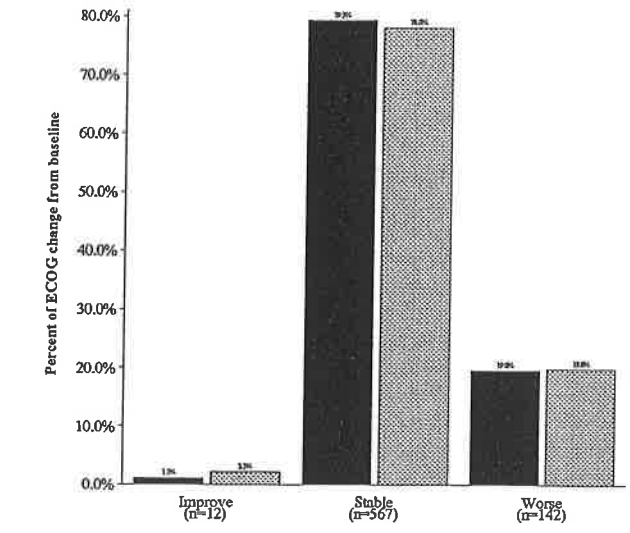


FIGURE 5

Proportion of patients with changes from baseline in the Present Pain Intensity score during treatment (ITT)

Improved: PPI score during treatment was lower vs baseline

Stable: no change

Worse: >1 unit increase in PPI score during treatment vs baseline

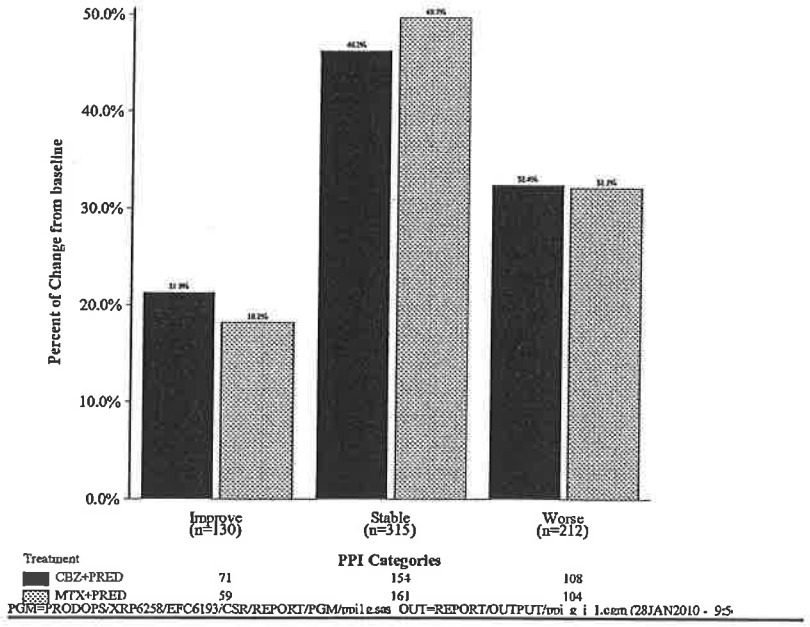
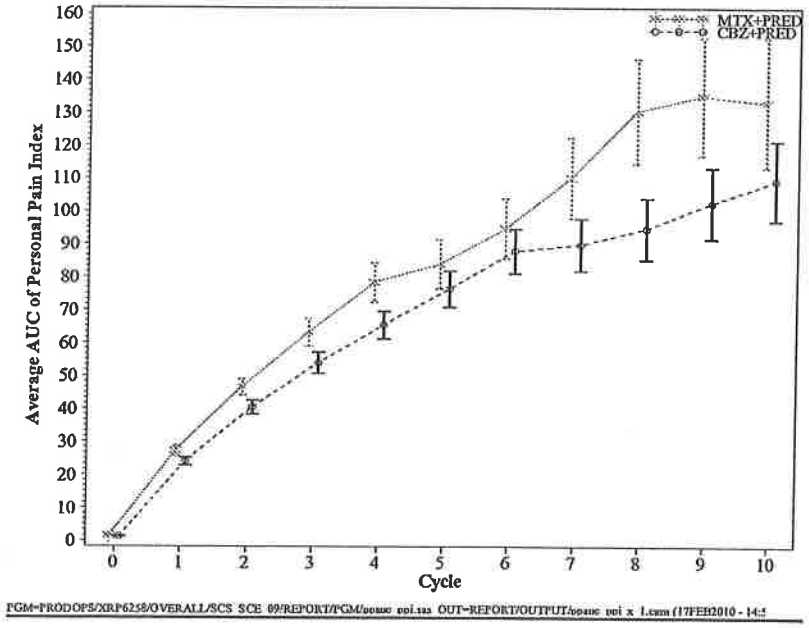


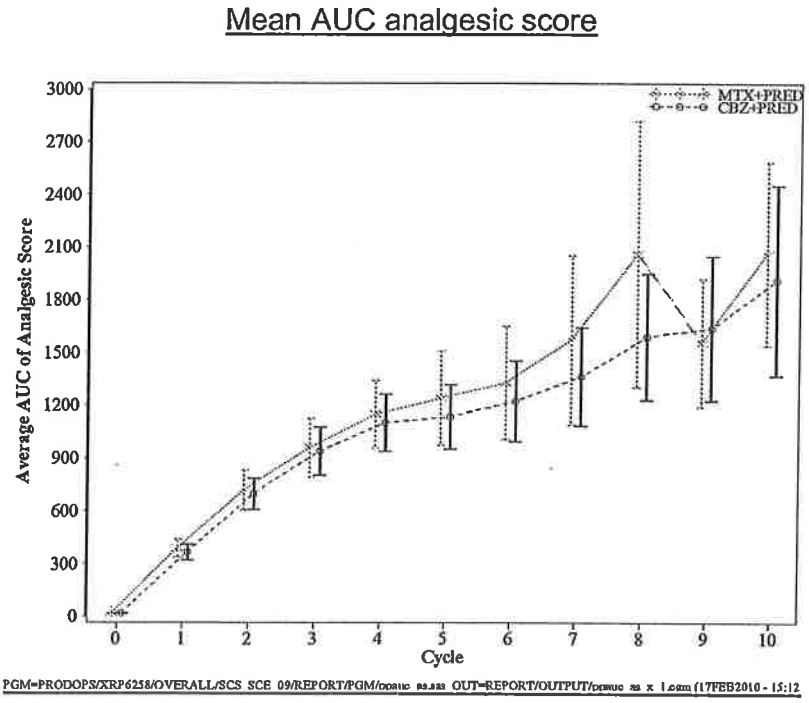
FIGURE 6

Mean area under the curve for PPI and analgesic scores by treatment cycle



PGM=PRODOPS/XRP6258/OVERALL/SCS SCE 09/REPORT/PGM/pmuc poi.sas OUT=REPORT/OUTPUT/pmuc poi x 1.cem (17FEB2010 - 14:

FIGURE 7


Mean AUC analgesic score
MTX+PRED
CBZ+PRED
Average AUC of Analgesic Score
3000
2700
2400
2100
1800
1500
1200
900
600
300
0
0
1
2
3
4
5
6
7
8
9
10
Cycle
PGM=PRODOPS/XRP6258/OVERALL/SCS SCE 09/REPORT/PGM/
OUT=REPORT/OUTPUT/
17FEB2010 - 15:12