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Cetuximab plus capecitabine as first-line treatment for elderly patients (pts) with advanced colorectal cancer (mCRC). Final analysis of activity and survival according to KRAS status – the TTD-06-01 Spanish Cooperative Group trial

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Background: The combination of cetuximab and capecitabine has shown to be feasible at a capecitabine dose of 1000 mg/m²/12 h, and active (overall response rate (RR) 32%) in the preliminary results reported by our group at ASCO 2008. Recent data have clearly established *KRAS* status as a determinant factor for cetuximab efficacy.

Methods: Final results of efficacy from 66 elderly pts with mCRC treated with this combination are presented according to KRAS mutation status. **Results:** RR for the entire population was 33.3% (IC95% 22.2–46.0%). K-RAS status has been determined in 58 of the 66 pts included (88%). RR according to the KRAS status were: 48.3% (IC95% 29.4–67.5%) in KRAS wild-type pts and 24.1% (IC95% 10.3–43.5%) in KRAS mutated. Stable disease (SD) and disease control rate (CD) are listed in table 1. With a median follow-up of 14.7 months, progression-free survival (PFS) and overall survival (OS) for the entire population were 7.2 and 16.5 months, respectively. Median PFS according to K-RAS status was 6.0 months for K-RAS mutated and 8.6 months for K-RAS wild-type, respectively (log-rank p = 0.02); and median OS was 13.4 and 19.0 months, respectively (log-rank p = 0.04).

Table 1

Overall response	KRAS wild-type (N = 29)	KRAS mutated (N = 29)
RR	48.3%	24.1%
SD	44.8%	58.6%
CD (RR+SD)	93.1%	82.8%

Conclusions: This trial confirms that *K-RAS* mutation status distinguishes two groups of pts with mCRC with a different outcome when treated with cetuximab. To our knowledge, this is the first-time this effect is described in elderly pts treated with capecitabine and cetuximab.

1005 ORAI

Trastuzumab-related cardiotoxicity in the elderly: which role for cardiovascular risk factors?

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Background: Elderly breast cancer (BC) patients (pts) are usually excluded from clinical trials. Nevertheless, with the increased use of trastuzumab (T) there is a need to address T-related cardiotoxicity in this population.

Materials and Methods: Records for patients ≥70 years treated with T since 2005 were reviewed. New York Heart Association classification was used to document symptomatic cardiotoxicity. Asymptomatic cardiotoxicity was defined as an absolute drop ≥10% with a final left ventricular ejection fraction (LVEF) <50% or any absolute drop >20%.

Results: Forty-five pts, median age 74.5 years (range 70–92), were identified. WHO performance status was 0–1 in 93% of cases. Basal LVEF was 63.8% (range 46.3–76). Three of 24 early BC pts (12.5%) and 5 of 21 advanced BC pts (23.8%) experienced asymptomatic cardiotoxicity. Four of 45 pts, all with advanced BC, (8.8%) developed symptomatic cardiac heart failure (CHF). Median time to asymptomatic decline of LVEF and to CHF were 34 weeks (range 1–132) and 12 weeks (range 3–72), respectively. All the patients but one recovered in a median time of 4 weeks (range 3–48). Pts with T-related cardiotoxicity presented more often with any cardiovascular risk factor such as history of cardiac disease (16.7% versus 9.1%), diabetes (25% versus 6.1%), BMI > 30 (66.7% versus 33.3%), and hyperlipemia (41% versus 21%) as compared to the rest. Previous or concomitant exposure to anthracyclines was found as a risk factor as well.

Conclusion: This series shows that elderly BC pts treated with T experience reversible cardiotoxicity. Continuous cardiac monitoring is adviced in patients with any cardiovascular risk factor.

Table 1: Cardiovascular Risk Factors in Elderly BC pts treated with Trastuzumab (T)

	all the pts n = 45	pts with T-cardiotoxicity n = 12	pts with no T-cardiotoxicity n = 33
History of cardiac disease	5 (11.1%)	2 (16.7%)	3 (9.1%)
Diabetes	5 (11.1%)	3 (25.0%)	2 (6.1%)
Obesity	19 (42.2%)	8 (66.7%)	11 (33.3%)
Hypertension	25 (55.5%)	7 (58.3%)	18 (54.5%)
Tobacco	1 (3.3%)	0	1 (3.0%)
Hyperlipemia	12 (26.6%)	5 (41.6%)	7 (21.2%)
Exposure to anthracyclines	14 (31.1%)	5 (41.6%)	9 (27.3%)

n: number of pts (%).

Poster presentations (Mon, 21 Sep, 14:00-17:00)

Cancer in the older individuals

DOG POSTER

Descriptive epidemiology of cancer in the elderly population from the Far East – preliminary data Sarawak General hospital, Sarawak, Malaysia

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Background: Risk of Cancer increases with age [1] and it is estimated that a third of septuagenarians will develop a new cancer during the rest of their lives [2]. Information on cancer in elderly patient is globally scanty and far less is known from the developing world. Sarawak has a population of 2.2 million composed of about 1/3 of Natives, 1/3 of Malay and 1/3 of Chinese migrants. About 1500 new cancer cases are seen in the department each year. We present our results on a series of 636 cases (291F; 345M) elderly patients seen between 2005 and 2007 in a single institution.

Material & Methods: The purpose of this study is to evaluate the type of cancers seen in the elderly (65 years and above), the cancer staging at initial presentation, any differences between urban and rural population, type of treatment received and reasons for no treatment. Data were analyzed using SPSS.

Results: The incidence for all cancer (except skin) of all races above 65 is 212/10⁵, with incidence for Chinese at 332.3/10⁵, Malay 186.0/10⁵ and Native at $146.2/10^5$. Common cancers seen were lung (n = 140), colorectal (n = 120), head & neck (n = 58) and breast (n = 44). Seventy-nine percent (n = 483) of the cases presented in advanced stage (stage III & IV), but for breast cancer, 57% (n = 25) presented in early stage (stage I & II) which is keeping with our earlier results on downstaging [3]. Incidence for rural patient is 202.3/10⁵ and that for urban is 222.3/10⁵ and the difference is not significant. More patients from rural areas present in late stage compared to urban areas (n = 282, p < 0.0001). Incidence of Chinese population in urban area is $523/10^5$, which is higher when compared to the Malays and Natives (p < 0.0001). However, there was no difference amongst the three races in the rural areas. Sixty-eight percent (n = 435) of the patients received treatment while radical treatment was received by 51% (n = 326) for surgery, 30% (n = 189) for radiotherapy and 13% (n = 83) for chemotherapy. Twenty percent (n = 121) did not have any treatment other than supportive care due to poor performance status.

Conclusion: Our results are preliminary but reveal interesting feature of elderly patient population in South East Asia. They revealed among other findings that 68% of elderly patient had some form of treatment and that rural patients present more in late stage.