months). One-, two-, three- and five LC rates were 92%, 87%, 84% and 84%, respectively, with a median LC of 18 months. At univariate analysis, the primary histology and previous local ablative therapies were significant (p<0.03 and p< 0.006, respectively). At the time of analysis, 61 patients (30%) are alive. Median OS was 21 months (18-24 IC 95%) and the survival rates were 79%, 27% and 15% at 1, 3 and 5 years after SBRT, respectively. At univariate analysis, sex, primitive disease, intra- and extra- hepatic progression were significant prognostic factors of survival. This analysis confirmed the absence of late toxicity > G3. Acute and late toxicity were detected in 137 (68%) and 5 (2.4%) patients, respectively.

Conclusion

This study confirms the efficacy and safety of SBRT for unresectable liver metastases. Selection of cases with positive prognostic factors may improve survival and local control of these oligometastastic patients. A multidisciplinary evaluation is mandatory to define the best treatment for selected patient, in the optical of tailored therapeutic strategy.

PV-0473 Dosimetry, safety, efficacy and QoL in a study of 5-fraction SBRT for oligometastatic (OM) cancers

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Purpose or Objective

Stereotactic body radiation therapy (SBRT) provides a high level of precision, enabling treatment of oligometastastatic (OM) cancer. The aim of this study was to describe dosimetry, and to evaluate the safety, short-term efficacy, and quality of life in a phase II trial.

Material and Methods

A single institution, prospective, single-arm, phase II trial is currently ongoing for pts with OM cancer with up to 5 sites of extracranial metastases, all planned to receive local ablative therapy, at least one index lesion being suitable for SBRT (5-fraction regimen). The study is designed to provide a unifying approach across disease site groups for pts presenting with potentially OM disease. All cases were peer reviewed to confirm eligibility and treatment plan. We evaluated dosimetry, toxicities (CTCAE G3+), QoL (EORTC QLQ-C30, EQ5D, and ESAS), PFS and OS for an interim analysis.

Results

Between Mar 7 2013 and Dec 31 2016, 197 pts were screened and 116 accrued, including 69 accrued before Dec 31 2015, with 12-month follow-up, who form the basis of this interim analysis. Median follow-up was 20 months (1-48). Median age was 63.5 (36-86). Primary tumor sites were colon (19), lung (9), breast (5) and others (36). Fifty three patients had a single lesion. Index sites were in liver (19), lymph nodes (16), non-axial bone (10), adrenal (9), lung (8), axial bone (4) and other (3). Median prescribed dose was 40Gy (30-50Gy). For solitary non-spine SBRT plans, median PTV $D_{80\ (\%)}$ 102.6% (94.6-113.5), $D_{98\ (\%)}$ 96.7% (73.5-102.8) and conformity index for 95% isodose 1.2 (0.8-1.9). Dose-limiting luminal structures (defined as receiving ≥85% of dose limit) were duodenum (12%), stomach (17%), small bowel (10%), large bowel (9%) and esophagus (4%) receiving a median $D_{0.5cc}$ of 30 (28-31), 29Gy (26-30), 30Gy (29-30), 30Gy (29-32) and 30Gy (29-33) respectively. Liver was a dose-limiting organ in 6 (MLD 14.6Gy; range 13.2-15.3) and kidney in 3 (Dmean 9Gy, 10Gy and 12Gy; limit Dmean<10Gy) pts. G_3 gastric bleeding occurred in 2pts at 5.4 and 9 months after treatment (stomach $D_{0.5cc}$ 29Gy and 30Gy). At 2 years, freedom from local, distant and any progression was 68%, 21% and 19%, while OS was 80%. Fifty seven patients were eligible for 12-month QoL evaluation. In 10 pts without disease progression, EORTC QLQ-C30 Global QoL domain showed significant improvement (+13; p = 0.033), while in 47 pts who progressed, scores declined (-7; p=0.08).

Conclusion

In pts presenting with OM disease, 59% were eligible for trial participation after screening. Luminal structures were dose limiting in 37% of pts precluding delivery of the maximal permissible levels. Pts were treated with highly conformal SBRT plans, which met the dosimetric goals for target coverage and normal tissue tolerances. SBRT as part of an ablative strategy is well tolerated, resulted in improved QoL in pts who were free from disease progression. Majority of pts experience early distant disease progression, although OS remains favourable.

PV-0474 Pelvic re-irradiation with Stereotactic Ablative Radiotherapy (SABR): outcomes and cumulative doses

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Purpose or Objective

To evaluate early clinical outcomes and cumulative organ at risk (OAR) doses in patients re-irradiated for oligometastatic disease in the pelvis using SABR.

Material and Methods

Patient records were reviewed for baseline and outcome data. Former and re-irradiation (reRT) dose distributions were reviewed to assess cumulative OAR doses. The intended reRT D95% was 30Gy in 5 fractions, but could be compromised to respect OAR tolerances. Response was assessed by imaging and/or PSA control in prostate cancer (PCa) patients. To evaluate cumulative doses, reRT PTVs were copied from the reRT plan to the rigidly registered former radiotherapy (RT) plan. To take account of potential anatomical and positional changes between RT courses (particularly for bowel), a 1cm expansion was created around the copied reRT PTV, and OARs within this volume were considered those at greatest risk from reRT. The maximum doses to $0.1cm^3$ ($D_{max0.1cc}$) delivered by the former plan to the OARs within this volume were recorded. These were added to the planned $D_{max0.1cc}$ for the corresponding OARs in the reRT plan to provide a 'worst case' estimate of cumulative dose. All doses were converted to 2Gy fraction equivalent (EQD2, α/β=3Gy) prior to summation. Repair was not considered.

Results

20 patients received SABR reRT for 30 oligometastatic pelvic lesions between 03/16 and 09/17. Table 1 shows baseline characteristics. Androgen deprivation was used concurrently with SABR in 12 PCa patients. Median time from former RT to reRT was 50.1 months (range 14.6-93.8). Median D95% for the reRT PTV was 30.5Gy (range 23-31.6) reflecting de-escalation in some cases due to OARs. Median follow up was 10.7 months. Of 11 imaged re-irradiated lesions, 3 were stable and 5 and 3 showed partial and complete responses, respectively. Local control, based on imaging or PSA control, was 100% at 1 year. 13 of 16 PCa patients had a fall in PSA at 6-12 weeks post-SABR. 6 of 10 imaged patients have developed imaged-defined out of field progression (median time to image-defined progression: 11.8 months) and 5 of 16 PCa patients have developed PSA progression (median time to

PSA progression: 11.3 months). All but one patient remain alive (1 year survival: 88.9%). No grade 3+ acute toxicities were observed and no grade 3+ late toxicities have been reported to date. Vessels were the OAR most often within the reRT PTV, but were not dose limiting. Small bowel, colon and sacral plexus were within the PTV in 7, 5 and 7 cases respectively and were potentially dose limiting. Cumulatively, allowing for potential positional change between RT courses, 'worst case' calculated doses to small bowel, colon and sacral plexus were up to 111, 107 and 123Gy (EDQ2, α/ß=3Gy), respectively (Table 2).

Table 1. Baseline characteristics

Characteristic	Subgroup	n (%)	
Totals			
	Patients	20 (100)	
	Lesions	30 (100)	
Age (median and range)			
	66.5 years	56.0-78.8 years	
Primary cancer			
	Prostate	16 (80)	
	Rectal	4 (20)	
Previous radiotherapy			
	Prostate alone	2 (10)	76Gy in 37 fractions (fr)
	HDR brachytherapy and external beam	3 (15)	15Gy in 1 fr HDR + 37.5Gy in 15 fr (n=2) 17Gy in 2 fr HDR + 35.8Gy in 13 fr (n=1)
	Prostate and pelvis	1 (5)	74Gy in 37 fr
	Prostate bed	10 (50)	52.5-55Gy in 20 fr
	Pelvis (rectal primary)	4 (20)	45Gy in 25 fr (n=1) 45Gy in 25 fr + 6.4Gy in 3 fr boost (n=1) 25Gy in 5 fr (n=1)
Previous pelvic surgery			
	Yes	14 (70)	
	No	6 (30)	
No. re-irradiated lesions			
	1	13 (65)	
	2	4 (20)	
	3	3 (15)	
Site re-irradiated			
	Pelvic node	27 (90)	
	Pelvic bone	3 (10)	
Re-irradiation GTV volume (median and range)			
	1.2 cm^3	0.2-27.0 cm^3	
Re-irradiation dose			
	25Gy in 5 fr	2 (6.7)	
	27Gy in 5 fr	1 (3.3)	
	30Gy in 5 fr	27 (90)	

Table 2. 'Worst case' estimates of cumulative doses

Organ at Risk	Calculated cumulative EQD2 (Gy, α/β=3Gy) Median (range)
Vessels	71.6 (49.8-128.0)
Small Bowel	89.4 (20.1-110.8)
Colon	54.4 (39.5-107.1)
Sacral Plexus	56.6 (44.1-123.4)

Conclusion

SABR reRT appears well tolerated and effective in controlling oligometastatic pelvic disease. Cumulative doses and positional changes in OARs between courses should be considered. SABR reRT requires further evaluation in prospective trials to guide future delivery.

PV-0475 Stereotactic Body Radiation Therapy For Painful Spinal Metastases - Results Of A Phase 2 Study

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Purpose or Objective

Stereotactic body radiation therapy (SBRT) for painful spinal metastases has the potential to improve and extend pain relief, but prospective data on pain response are lacking. This prospective phase II trial addressed the question of overall (complete and partial) pain response after hypo-fractionated SBRT for painful, mechanically stable, previously un-irradiated spinal metastases?

Material and Methods

From 2012 to 2015, 54 patients were treated and analyzed in a prospective, multicenter, non-randomized, single arm phase 2 study (NCT01594892). Inclusion criteria were ≤2 distinct, non-contiguous, painful, mechanically stable, un-irradiated spinal metastases from a solid tumor, Karnofsky performance status ≥60. Patients with long (Mizumoto score ≤4) or intermediate (Mizumoto score 5-9) overall survival expectancy were treated with hypo-fractionated SBRT of 48.5 Gy in 10 fractions or 35 Gy in 5 fractions, respectively. The primary outcome was overall (complete and partial) pain response measured with the International Consensus Guidelines at 3 months after SBRT; the secondary outcome was local control, survival, toxicity and quality-of-life measured with the Euro-quality-of-life Five Dimensions Questionnaire (EQ-5D-5L).

Results

Of 54 patients (30 [56%] male; median [range] age 64 [25-84] years; 60 lesions) 30 (56%) patients were treated with 10-fraction SBRT and 24 (44%) with 5-fraction SBRT. Pain response at 3-months was evaluated in 42 patients (47 lesions). Overall pain response was observed in 41 lesions (87%) and pain response remained stable for at least 12 months. Mean (standard deviation) maximum pain scores on Visual Analogue Score significantly improved from baseline 6.1 (2.5) to 2.0 (2.3) at 3 months post-treatment (P<.001). EQ-5D-5L quality-of-life dimensions (self-reported mobility, usual activities and pain/depression) significantly improved from baseline to 3 months post-treatment. After a median follow-up of 12 months, the 12-month overall survival and local control rates were 61.4% (95% CI, 48-74.8%) and 85.9% (95% CI, 76.7-95 %), respectively. Grade 3 toxicity was limited to acute pain in 1 patient (2%). No patient experienced radiation-induced myelopathy. Six (11%) and 8 (15%) patients developed progressive or new vertebral compression fractures (VCF), respectively, but stabilization (n=1) and decompression (n=1) surgery was only required in two patients.

Conclusion

SBRT for painful vertebral metastases achieved rapid, deep and long-term overall pain response, high local metastasis control and improved quality-of-life and may become a primary treatment in selected patients with longer survival expectancy.

PV-0476 Equivalent cancer-specific survival following surgical resection or SABR for stage I lung cancer

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Purpose or Objective

Surgery is the standard of care for early stage lung cancer. Stereotactic ablative radiotherapy (SABR) is a low