Scheer R. / Becker H. und weitere
Die Mistel in der Tumortherapie 2

Extrait du livre

Die Mistel in der Tumortherapie 2
de Scheer R. / Becker H. und weitere
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Objective of the study

The efficacy and safety of the frequently used mistletoe product Iscador® (ISC), a fermented extract from *Viscum album* L., were evaluated as part of long-term supportive care in hospitals and private practices in patients with surgically treated UICC stage I—III primary non-metastatic colorectal carcinoma, followed by adjuvant chemo- and/or radiotherapy (conventional therapy) or passive aftercare.

Study design and methods

Design

This multicenter, controlled, retrospective, observational cohort study was performed according to Good Epidemiological Practice (GEP) (Bellach, 2000) and similar rules, using anonymized eligible patient data documented chronologically in standardized case report forms. This study design was presented and discussed elsewhere (Schneider, 2001; Bock *et al.,* 2004a; Feinstein, 1984; Benson, 2000), and several controlled epidemiological cohort studies were performed in oncology using this approach (Sakalova *etal,* 2001; Augustin *et ah,* 2005; Bock *et al*$_9$ 2004b).

Outcome endpoints

The efficacy was assessed by evaluation of the following quality of life (QoL) surrogate criteria and of disease-free survival (DFS) in the ISC-treated group, compared to a parallel control group without ISC:

1. Rate of patients with adverse drug reactions (ADR) attributed to the conventional therapy.
2. Persistence of disease- and treatment-associated symptoms.
3. Mean functional capacity (Karnofsky-Index).
4. Mean duration of hospitalization during therapy and follow-up.

In addition, the disease-free survival (DFS) was evaluated.

Adjustment

All endpoint results were adjusted for pre-specified confounder effects by multivariable analysis (age, gender, center group, non-oncologic chronic diseases, tumor localization, tumor stage (UICC) and grade, post-surgical tumor staging (complete response, CR, *vs.* residual tumor), chemotherapy, radiotherapy, duration of chemotherapy and additional supportive therapy with high-dose vitamins).

Results

Inclusion

A total of 804 patients (429 ISC and 375 control) in 26 oncologic hospitals and private practices who were surgically treated between 1990 and 2004 for primary non-metastatic colorectal carcinoma and received oncologic treatment as well as supportive care were included. The baseline demography and prognostic factors are summarized in table 1 and the treatment regimen is presented in table 2.

Tab 1: Baseline characteristics of demographic and prognostic criteria

Colorectal Carcinoma baseline criteria		**Mistletoe group**	**Control group**
	Total sample – valid N	***429***	***375***
Age, years	mean (SD)	57.2 (11.2)	62.8 (11.7)
Body weight, kg	mean (SD)	72.5 (11.1)	74.6 (13.7)
Sex, %	female	49.9	46.7
	male	50.1	53.3
Tumor localization, %	colon	59.8	67.4
	rectum	36.2	30.2
	multiple	4.0	2.4
Tumor stage pT, %	early (1-2, is, x)	43.1	32.3
	advanced (3-4)	56.9	67.7

Colorectal Carcinoma baseline criteria		**Mistletoe group**	**Control group**
	Total sample – valid N	***429***	***375***
Tumor stage pN, %	lymph nodes - (N=0, x)	48.5	68.5
	lymph nodes + (N>0)	51.5	31.5
Tumor grade pG, %	less malignant (1-2, x)	80.2	85.0
	highly malignant (3-4)	19.8	15.0
Tumor stage UICC, %	UICC 0-I	32.4	27.8
	UICC II	16.1	40.8
	UICC III	51.5	31.4
Tumor multiplicity, %	solitary	95.2	90.3
	multiple	4.8	9.7
Tumor status post-op., %	CR	97.9	96.4
	residual tumor	2.1	3.6
Other chronic (non-oncological) diseases, %		59.3	69.8

Tab 2: Therapy and observation

Colorectal Carcinoma baseline criteria	**Mistletoe group**	**Control group**
Total sample – valid N	***429***	***375***
Chemotherapy (mainly 5-FU and combination), %	53.3	53.6
Chemotherapy duration, mean (SD), months	8.1 (11.7)	8.5 (12.3)
Radiotherapy, %	17.8	16.5
Other supportive therapy (overall), %	56.5	34.1
- supportive physical therapy and rehabilitation, %	10.5	22.9
- supportive high-dose vitamins, trace elements, %	32.9	0.8
Mistletoe therapy duration, mean (SD), months	53.4 (29.7)	–
- median (range), months	52.0 (0.25-153.0)	–
Follow-up duration, mean (SD), months	61.0 (31.1)	55.9 (28.3)
- median (range), months	57.8 (1–160)	50.7 (1–144)

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