Background

Patient-centered endpoints - overall survival (OS) and quality of life (QoL) - are considered valid 'direct' endpoints to measure a treatment's efficacy. Extensive and robust QoL assessment data, using EORTC-C30, from patients with advanced hepatocellular carcinoma (HCC) shows consistent improvement in median QoL, experienced a fast and meaningful improvement in quality of life (QoL) status in patients with advanced hepatocellular carcinoma (HCC), using various EORTC-C30 analyses.

Methods

• EMF at amplitude modulation exposure prior to treatment causes autonomic hemodynamic responses which are specific to each patient (Patient Specific Frequencies, or PSF).
• An oral spoon-shaped RF antenna applicator was used to apply EMF exposure. While individuals were kept in a supine position. EORTC-C30 v3.0 was calculated with 17, 15 and 03 parameters between first and second EMF exposures. A change of > 5% in QoL index score was considered relevant.

EORTC-C30 data analysis

1. QoL index (QI) = (mean G+) – (mean G-)
   - Functional status
   - Symptom scale
   - No: symptom scales.
   - Yes: functional status
   - Global health QL
   - Role functioning

2. QoL performance (P) = SS – 2* FS + RF
   - FS: functional status
   - SS: symptom scale
   - RF: role functioning

Results

QoL analysis

188 EMF exposures with 5,640 QoL data points (99.9%). Median time between EMF exposures was 34 days. 30 patients underwent at least two EMF procedures. 7 patients died after first exposure, 5 could not commit with re-exposure.

QoL index (QI) was calculated with 17, 15 and 3 parameters between first and second exposures. 2.5% improvement was observed.

QoL means values for every EMF exposure

Medium QoL parameters by EMF exposure showed continuing improvement supporting long durable benefits.

Change of QoL values during treatment with EMF modulated at PSF

QoL values

<table>
<thead>
<tr>
<th>Mean</th>
<th>Std. Dev</th>
<th>Median</th>
<th>Mean</th>
<th>Std. Dev</th>
<th>Median</th>
<th>Mean</th>
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<td>36.93</td>
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</table>

Toxicity

No treatment related toxicity has been reported in 188 EMF exposure procedures.

Conclusion

Patients with advanced HCC, exposed once a month to EMF at patient specific frequencies (PSF), experienced a fast and meaningful improvement in QoL. The QoL observed in the EMF group exceeded that observed in historical real-hospital data. This new medical device may offer a non-toxic, safe and effective palliative care option, used with advanced HCC with limited treatment options. NCT 01686412.