Clinical Summary

Single-centre randomized trial comparing conventional chemoembolization versus doxorubicin-loaded polyethylene glycol microspheres for early and intermediate stage hepatocellular carcinoma

Aleksandar Gjoreski et al, European Journal of Cancer Prevention 2020, DOI: 10.1097/CEJ.0000000000000623

Background

According to Barcelona Clinic Liver Cancer classification, transarterial chemoembolization (TACE) is preferred treatment for stage B and in certain cases for stage A hepatocellular carcinoma (HCC). Conventional TACE (c-TACE) and drug-eluting microspheres TACE (DEM-TACE) are available intra-arterial therapies.

Objective

The primary aim of this study was to compare the 12- and 24-month survival rates between the two arms. Secondary endpoints were comparison of intensity and duration of post-embolization syndrome (PES) after c-TACE and DEM-TACE and reporting of any serious adverse events after both methods, impact on liver functions, number of treatments and duration of hospital admission.

Methods

- A prospective, single-centre, randomized trial
- A total of 60 patients with unresectable HCC were included during a 36 months period and randomized one-to-one to undergo c-TACE or DEM-TACE
- Chemoembolization sessions were repeated "on demand" every 3-6 weeks until complete response.
- Follow-up of at least 24 months after the treatment or until death.
- 28 patients from the c-TACE group received a mixture of 50– 100 mg of doxorubicin emulsified with 10–15 mL Lipiodol in a ratio 1:2.5, followed by administration of Contour 45–355 μm in diameter or HydroPearl 75–400 μm.
- 32 patients from the DEM-TACE group received LifePearl™ microspheres, 100–400 μm, volume of 2–4 mL preloaded with 50–100 mg of liquid doxorubicin. When needed, additional embolic agents for bland embolization were used, mostly polyethylene glycol particles, 75–200μm, (HydroPearl) at the discretion of the operator.

Results

Aleksandar Gjoreski et al study (n=60) reported:

- Overall Survival was different for the two arms but didn't reached statistical significance. groups, and showed:
  - DEM-TACE: at 12 months 90.2 and at 24 months 76.8%
  - cTACE: at 12 months 85.7 and at 24 months 63.6%
- One session was performed on 7.14% vs 15.63% of patients. This could represent a CR rate after one single intervention that is double for DEM-TACE vs cTACE
- CR/PR/SD rates were not reported

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- **Safety**:
  - No significant difference in terms of adverse events was found.
  - Post Embolization Syndrome (PES) symptoms were slightly more severe after c-TACE, in particular elevated temperature (n. 23 -82.1% vs n. 13 40.6%) (P=0.001)
  - DEM-TACE required shorter in-hospital stay. The mean in-hospital stay was 2.37+1.4 vs 3.07+1.3 days for DEM-TACE vs cTACE. (statistically significant).
- **Limitations**:
  - The bigger limitation is that no hypothesis, neither sample size is described in the study methods, hence the non-significant difference in OS at 12 and 24 months could be due to an underestimate of the number of patients to enrol in order to show a real difference.
  - The authors didn't report the tumour response rates
  - Differences at baseline for nodules diameters: 5.82+2.4 for cTACE vs 6.23+2.6 for DEM-TACE
  - N. of pts with 1 intervention: 7.14% vs 15.63%; that translate in a CR rate after one single intervention that is double for DEM-TACE. This is not captured by the statistical analysis but could be clinically relevant if confirmed on further comparative studies.

CONCLUSION

Aleksandar Gjoreski et al concluded that this study did not demonstrate any statistically significant difference between c-TACE and DEM-TACE techniques in terms of 12-and 24-month survival rates. In real good candidates, both TACE methods are extremely effective and well tolerated with a great proportion of survival after 24 months. The only objective advantage of DEM-TACE over c-TACE is the shorter in-hospital stay after treatment.

Key Takeaways

- According to Gjoreski et al, DEM TACE-and cTACE procedures and effective and well tolerated treatments in selected HCC patients.
- Both procedures have comparable overall survival rates with a trend (NS) for higher rates for DEM-TACE.
- DEM-TACE allows a significant shorter in-hospital stay and a significant difference in one of the PES symptoms (fever)
- Link to the full publication: *https://pubmed.ncbi.nlm.nih.gov/33038087/*

Use/Indications
European Economic Area Indications for use
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