

Balloon-TACE Efficacy

Since the first particle-based tumor embolization in the early 1970's, embolization agents have improved dramatically. Over the same period, development of devices capable of delivering complete tumor fill have been lacking, even though tumor fill is the single most important factor in achieving a CR^{1,2}. Sniper[®] is a superselective delivery device that improves tumor fill and associated complete response at the first procedure. **The efficacy of Balloon-TACE (B-TACE) is remarkable**.

On Average, Balloon-TACE Improves CR on the First Procedure by 1.5X Eight Clinical Studies with 941 Patients are Presented Below

2-Arm Studies, Balloon vs Standard Microcatheter

<u>Golfieri, 2021</u>³ ^C Multi Center, 2-Arm Retrospective 530 patients (p = 0.026) B-cTACE/B- DEB-TACE Improve CR by 40% Retreatment Rate at 6 months: B-TACE 10%, Standard Micro 22% (1.20% Better)

> Irie, 2016⁴ [®] 2-Arm Retrospective 77 patients, p = 0.016 B-cTACE Improves CR by 37% 100% Objective Response 5 Year Survival Improved by 53%

<u>Arai, 2015</u>⁵ [©] 2-Arm Retrospective, 97 patients (p < 0.05) B-cTACE Improves CR by 39% Disease Progression Reduced from 25% to 4%

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2-Arm Retrospective 97 patients (p < 0.05) B-DEB-TACE Improves CR by 39%





1-Arm Studies

Lee, Madoff, 2021 [®] 1-Arm Retrospective, 31 patients 74% CR, 95% OR (p < 0.05) 100% Disease Control

Lucatelli, 2019 1-Arm Retrospective B-DEB-TACE, 22 patients 44% CR (p < 0.05) 100% Objective Response

> Goldman, Fischman, 2018 1-Arm Retrospective, 26 patients 60% CR (p < 0.05) 100% Disease Control

Summary

Eight B-TACE Clinical Studies, including almost 1000 patients from the US, Japan & Italy are consistent in demonstrating a remarkable rate of complete response at the first procedure that is 1.5 times better than a standard microcatheter. This is prognostic for a > 50% improvement in 5-year survival⁸ which was also demonstrated by Irie, 2016⁴.



References

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