

Randomized trials comparing SABR and surgery for early stage NSCLC: Design and endpoints

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Abstract

Objectives: SABR is increasingly used in patients with operable stage I NSCLC who refuse surgery, and outcomes in these patients have been shown to be much better than in medically inoperable patients. Non-matched comparisons of SABR versus surgery generally show a survival benefit of SABR in the first 6-12 months after treatment, due to avoidance of surgical mortality, and a survival benefit of surgery at later time points. The last is due to imbalance in patient characteristics, with less co-morbidity in the surgery groups. Propensity-score matched analyses have shown that outcome of SABR and surgery are more or less comparable. Various attempts have been made to conduct a clinical trial comparing the two treatment options.

Methods: Review of the design and end-points of both closed and ongoing randomized controlled trials comparing surgery and SBAR in early stage NSCLC.

Results: Three studies (STARS, ROSEL, ACOSOG) were closed prematurely due to poor patient accrual. The results of the STARS trial and the Dutch ROSEL study, were recently published (Chang C, Senan S, et al., Lancet Oncol 2015). Although the analysis of 58 randomized patients with a median follow-up of 40 months showed significantly improved 3-year overall survival after SABR compared to lobectomy (95 versus 79 %; $p < 0.05$), it is questionable whether these data will be considered convincing enough. The ACOSOG trial was closed after accruing 10 patients. Two recently opened randomized studies (STABLEMATES trial and SABRtooth), focus on high-risk / borderline operable patients. In this group of patients, it is more likely that outcome will reflect differences in early toxicity and patterns of disease recurrence after both modalities. A study recruiting fitter patients, such as the planned VALOR study is likely to provide more insight on late relapse patterns, late complications and second primary tumors. An important issue is the role of nodal staging. The role of endoscopic nodal staging before SABR in stage IA disease is currently being investigated in a prospective Dutch study to determine whether ultrasound-guided transbronchial needle aspiration is of value in addition to nodal staging based on PET-CT findings only. Finally, other endpoint that should be incorporated into future studies comparing SABR and surgery include patients-reported outcomes, costs of treatment and immunological aspects of SABR and surgery.

Conclusions: Available evidence suggests that SABR and surgery in stage I NSCLC patients have equipoise and both treatments have their specific toxicity profile. However, further randomized

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Abstract

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controlled trials may be necessary to convince the medical community of this. In these trials, special emphasis should be put on patient reported outcomes, economic aspects and effects on the immune system.