

Discussion of:
Intermediate Endpoints in Cancer
Treatment Studies

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Vocabulary

- Intermediate vs Surrogate
- Phase II (Screening) vs Phase III (Comparative)
- What is the RIGHT Primary Endpoint?
 - Smoking Cessation
 - Cancer Prevention
 - Adjuvant Trials

Endpoints

- Survival
- Progression-Free or Disease-Free Survival
- Failure-Free Survival
- Response

Response

- Problems with Definition
 - Confirmations after 4 Weeks
 - 16% vs 26% in Advanced NSCLC
 - Palpable Lesions vs Scans
 - Bidimensional vs Unidimensional
 - Non-Measurable Disease
- How does Response Measure up as a Surrogate?

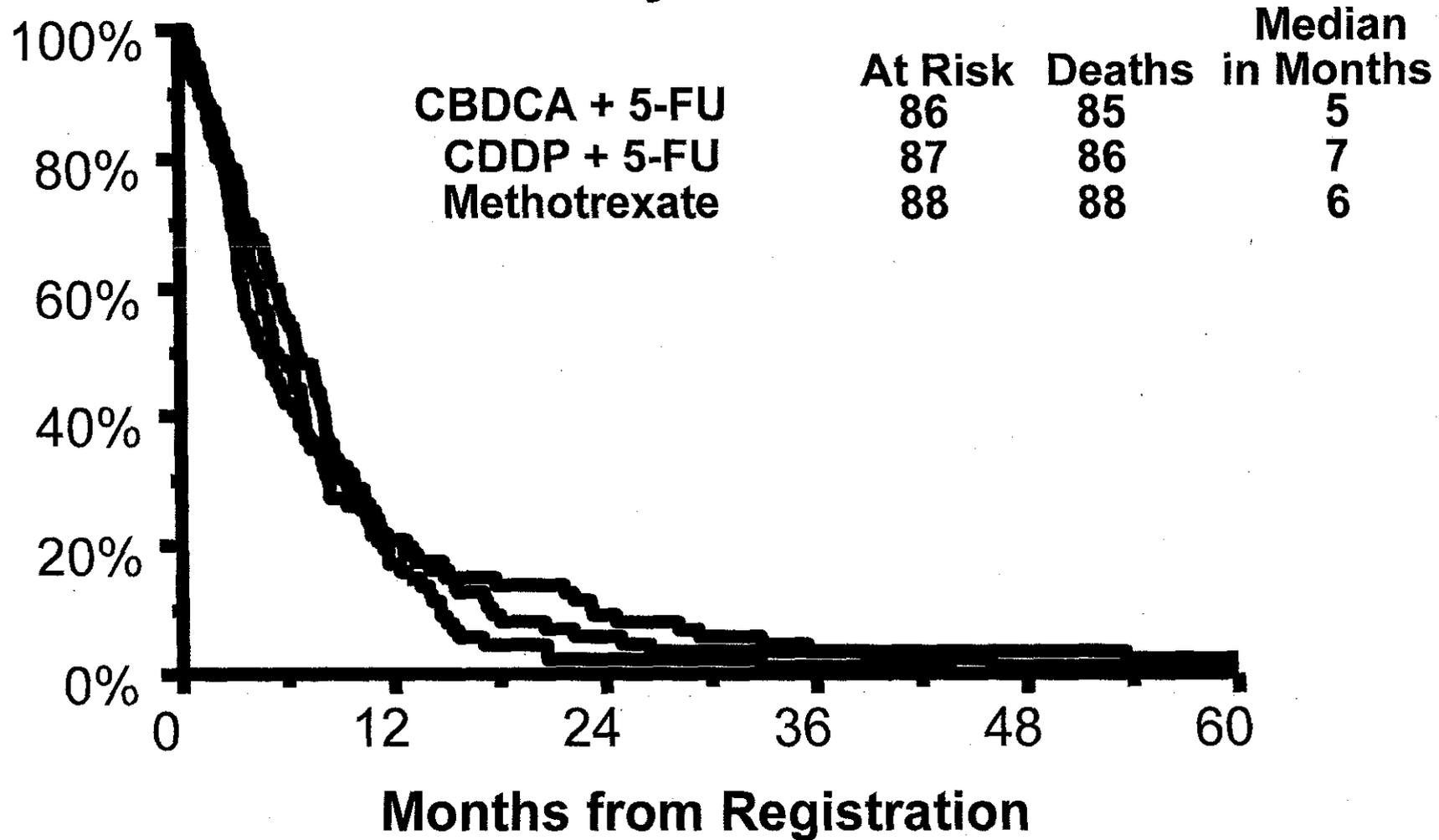
SWOG Advanced HN Trial 8514

Response

- CBDCA + 5-FU • 21%
- CDDP + 5-FU • 34%
- Methotrexate • 10%

SWOG Advanced HN Trial 8514

Survival by Treatment Arm



Vocabulary

- Megavariate
- Plethoratory

Smaller Phase III Trials?

I Don't Think So

The Certainty Principle:
New Cancer Treatments Must be
Tested in Large Randomized
Trials