



Patient Consent Issues

Best practices and “lessons learned”

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EFS Trials

The Reality

- It may be a transcatheter valve trial...
 - But EFS do not mirror Partner 3 CAP nor do they resemble Partner 1
- Patients are not necessarily extreme or high risk
 - Therefore, they have approved choices
- Predicate large datasets with outcomes are nonexistent
- Survival benefit of transcatheter therapy for TV disease is unknown
- Patients need to be screened, recruited and informed differently than your usual valve clinic initial encounter

EFS Trials

The Reality

- While patients may get personal treatment benefit from participating in a clinical trial, they must understand that they:
 - may not benefit from the clinical trial,
 - may be exposed to unknown risks,
 - are entering into a study that may be very different from the standard medical practices that they currently know

EFS Trials The Reality

- It is difficult to be precise about safety or efficacy regarding:
- magnitude and/or likelihood of potential risks associated with the treatment
 - time after procedure for recovery and QOL improvement.
 - extent that the therapy is clinically competitive with existing alternatives.

What are Patient and Family questions in an EFS

- What is your experience with this device and with similar technologies?
- How many patients have been treated in US and OUS?
 - Is it approved OUS?
- What QOL Improvement expectation?
- What and how many adverse events have occurred?
 - What are the alternatives?
 - What are the additional options if the procedure or technology fails?
- What is the number and Frequency of pre-procedure and follow-up visits?

EFS Trials: The Conversation

- When we don't know, we use terms such as “likely” or “unlikely” vs. “great” or low”.
 - These terms can be interpreted by patients in many ways.
- Instead of using general terms, focus on issues such as:
 - What outcomes have been studied in humans in previous trials?
 - What were the results in those studies?
 - Is there something that we wish that we knew, but they don't yet?

EFS Trials: The Conversation

- *Step 1. What are the patient and family goals?*
- *Step 2. What aspects of therapy does the patient consider important for decision-making?*
 - *What is the access route and anesthesia used?*
 - *What is the reversibility of therapy?*
- *Step 3. How proven is the treatment in this trial?*
- *Step 4. What are the alternatives for this patient?*

EFS Trials

Additional Considerations

- Consent for testing
 - Timing of approaching patient for study
 - Who approaches the patient first?
 - MD should be first contact
 - How to initially approach patient by investigator, research team and clinical team
- Consent for Core lab Evaluation of prior testing
 - How to approach out of window screening studies
- Timing of additional testing, screening and review process
- Timing of scheduling the actual procedure

EFS Recruitment Recipe for Success

- Screening of EHR and echo databases
- Assessment of medical conditions and I/E before contacting patient
- Communication with referring MD for contacting patients
- Show a video of the technology
- Explanation of other studies and various requirements to qualify
 - How to approach consent for multiple trials as anatomic qualification is not known on first visit