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Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia

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Objective

To develop a set of suggested objective performance goals (OPG) for evaluating new catheter-based treatments in critical limb ischemia (CLI), based on evidence from historical controls.

Methods

Randomized, controlled trials of surgical, endovascular, and pharmacologic/biologic treatments for CLI were reviewed according to specified criteria regarding study population and data quality. Line-item data were obtained for selected studies from the

sponsor/funding agency. A set of specific outcome measures was defined in accordance with the treatment goals for the CLI population. Risk factors were examined for their influence on key endpoints, and models of stratification based on specific clinical and anatomic variables developed. Sample size estimates were made for single-arm trial designs based on comparison to the suggested OPG.

Results

Bypass with autogenous vein was considered the established standard, and data compiled from three individual randomized, controlled trials (N = 838) was analyzed. The primary efficacy endpoint was defined as perioperative (30-day) death or any major adverse limb event (amputation or major reintervention) occurring within one year. Results of open surgery controls demonstrated freedom from the primary endpoint in 76.9% (95% confidence interval [CI] 74.0%-79.9%) of patients at one year, with amputation-free survival (AFS) of 76.5% (95% CI 73.7%-79.5). An additional 3% non-inferiority margin was suggested in generating OPG for catheter-based therapies. Defined clinical (age > 80 years and tissue loss) and anatomic (infra-popliteal anatomy or lack of good quality saphenous vein) risk subgroups provided significantly different point estimates and OPG threshold values.

Conclusions

For new catheter-based therapies in CLI, OPGs offer a feasible approach for pre-market evaluation using non-randomized trial designs. Such studies should incorporate risk stratification in design and reporting as the CLI population is heterogeneous with respect to baseline variables and expected outcomes. Guidelines for CLI trial design to address consistency in study cohorts, methods of assessment, and endpoint definitions are provided.

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Competition of interest: Patrick Geraghty is a consultant for WL Gore and Cook Medical; Richard Powell is a consultant for AnGes, Inc.

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