A RISK-BASED MODEL FOR PERSONALIZED REHABILITATION IN PATIENTS WITH GASTRIC CANCER: CLINICAL AND MEDICO-SOCIAL EFFECTIVENESS

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Background. Survivors of gastric cancer surgery have heterogeneous rehabilitation needs involving physical function, nutrition, emotional wellbeing and social participation. A uniform postoperative program may under-serve patients with high vulnerability while using resources inefficiently in those with uncomplicated recovery. A transparent, validated risk-based pathway could guide the intensity and composition of multidisciplinary rehabilitation.

Objective. To develop and internally validate a clinical prediction model for unfavorable recovery following gastric cancer surgery and to evaluate the clinical and medico-social effectiveness of a risk-stratified rehabilitation pathway compared with standard postoperative care.

Study Design. A two-stage investigation is proposed. In stage one, a derivation cohort will be used to develop a prognostic model, followed by internal validation using bootstrapping. In stage two, a prospective comparative implementation study will evaluate risk-guided rehabilitation versus usual care. A randomized allocation, ideally at patient or cluster level, is preferred when feasible; otherwise, a carefully designed controlled before–after or matched cohort analysis should address selection bias and temporal changes. The sample size must be calculated from the expected number of primary outcome events and planned model parameters, not selected arbitrarily.

Predictors and Model Development. Candidate baseline predictors will include age, comorbidities, ECOG performance status, nutritional risk, recent weight loss, CT-derived skeletal muscle index, grip strength, frailty, psychological distress, tumor stage and planned surgical extent. A postoperative dynamic update may additionally incorporate complications, oral intake and early mobilization, but this update must be evaluated separately from the preoperative model to avoid information leakage. Predictors will be prespecified based on clinical relevance. Penalized regression or another interpretable modeling approach will be considered, with optimism-corrected discrimination, calibration, Brier score and decision-curve analysis reported. Low-, intermediate- and high-risk thresholds will be determined from predicted probabilities and clinical consequences, not from arbitrary score cutoffs.

Personalized Rehabilitation Pathway. Low-risk patients will receive standardized enhanced recovery education, early mobilization, routine nutritional counseling and scheduled follow-up. Intermediate-risk patients will receive additional dietitian consultations, progressive supervised exercise, symptom management and closer functional monitoring. High-risk patients will be offered coordinated multidisciplinary support including individualized protein-energy targets, physical therapy adapted to postoperative status, psychological assessment, caregiver education, social work input and frequent reassessment. All interventions will be adapted to clinical stability, complications and contraindications. Escalation or de-escalation will follow repeated functional and nutritional assessments.

Clinical and Medico-Social Outcomes. The primary effectiveness endpoint will be the proportion of patients achieving predefined functional recovery at 90 days. Secondary clinical endpoints will include complication-related readmissions, nutritional deterioration, physical performance, symptom burden and health-related quality of life using validated EORTC questionnaires. Medico-social outcomes will include activities of daily living, return to usual roles or employment where relevant, social participation, caregiver burden and direct healthcare resource use. An economic evaluation may report rehabilitation costs, unplanned visits, readmissions and cost per additional patient achieving meaningful functional recovery. Outcomes will be measured at baseline, discharge, 30 days, 90 days and preferably six months.

Analysis of Effectiveness. The implementation study will compare rehabilitation pathways using intention-to-treat analysis if randomized. Effect estimates will include absolute differences, adjusted

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relative measures and 95% confidence intervals. Regression models will account for baseline function, risk category, treatment group and important prognostic variables. Repeated measures will be analyzed with mixed-effects models where appropriate. Prespecified subgroup analyses will examine benefit by risk stratum. Reporting will follow relevant TRIPOD guidance for prediction model development and CONSORT or STROBE guidance according to the evaluation design.

Expected Results and Scientific Significance. The model is expected to improve identification of patients at high risk of prolonged recovery, while the intervention study will test whether targeted rehabilitation improves functional independence and patient-centered outcomes. Potential medico-social benefits include reduced caregiver burden and better return to everyday roles. These are hypotheses rather than observed findings; superiority, cost-effectiveness and model accuracy cannot be claimed before validation.

Conclusion. A risk-based, multidisciplinary rehabilitation strategy has the potential to align supportive care intensity with individual recovery needs after gastric cancer surgery. Rigorous validation and prospective comparative evaluation are necessary before routine clinical implementation.

Keywords. gastric cancer; risk stratification; personalized rehabilitation; prognostic model; quality of life; functional independence; medico-social effectiveness; health economics.

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