# Protocol

梯度压力弹力袜对关节置换患者下肢血流动力学影响的临床研究

Clinical study on the effect of gradient compression stockings on lower limb hemodynamics in patients with joint replacement

1. Annual research contents, objectives, measures and steps:

(1) Research content:

① Before operation, the blood flow velocity of popliteal vein and femoral vein of bilateral lower limbs and the diameter of femoral vein of bilateral lower limbs were collected in 140 patients with joint replacement in the resting supine state.

② Within 24 hours after operation, blood flow velocity of popliteal vein and femoral vein of bilateral lower limbs and diameter of femoral vein of bilateral lower limbs were collected in 140 patients with joint replacement in the resting supine state.

③ The blood flow velocity of popliteal vein and femoral vein of bilateral lower limbs and the diameter of femoral vein of bilateral lower limbs were collected within 24 hours after wearing gradient pressure elastic stockings in the resting supine state of 140 patients undergoing joint replacement.

④ The blood flow velocity of popliteal vein and femoral vein and the diameter of femoral vein of bilateral lower limbs were collected in 140 patients with joint replacement in the supine state after wearing gradient pressure elastic socks and ankle pump exercise within 24 hours after operation.

(2) Research objectives:

① To evaluate the efficacy of gradient compression stockings in patients undergoing joint replacement.

② To evaluate the superiority of B gauge stretch socks compared with A gauge.

(3) Research measures

① Trial design: prospective, single-center, randomized, parallel controlled, superiority trial design.

② Sample size: according to the preliminary test results, the lowest flow velocity of femoral vein was 17.13 ± 5.56 cm/s, and the highest flow velocity was 26.90 ± 13.03 cm/s after wearing the stretch socks of the control group; The lowest flow velocity of the femoral vein was 20.70 ± 9.94 cm/s, and the highest flow velocity was 35.73 ± 15.19 cm/s after wearing the stretch socks of the test group. According to the superiority design, the type I error α=0.05, the power of 1-β=80%, and the loss rate of follow-up 10% were selected. According to the superiority trial design formula, the required sample size was about 70 cases in each group, and a total of 140 cases were obtained.

③ Experimental group: Type B elastic socks, the pressure distribution of ankle, calf, popliteal fossa, middle thigh, and upper thigh was 8, 14, 8, 8, and 6mmHg. In the control group, the pressure distribution of ankle, calf, popliteal fossa, middle thigh, and upper thigh was 8, 13, 10, 8, and 6mmHg.

④ Random method: 140 random numbers were generated by Excel, and then the random grouping table was made. According to the order of enrollment, the subjects were randomly assigned to the experimental group or the control group according to the grouping information in the corresponding serial number random letters. The grouping ratio was 1:1.

⑤ Case selection. Inclusion criteria: age ≥18 years old; Conscious patients undergoing unilateral knee/condylar arthroplasty for the first time; Those who volunteered to participate in this study and signed informed consent. Exclusion criteria: patients with a history of varicose veins of both lower limbs or other history of affecting the microcirculation of lower limbs; Patients with significantly limited preoperative activity; Persons who were deemed by the investigators to be ineligible to participate in the trial for other reasons.

⑥ Research methods:

⑦ Literature search method: by searching PubMed, Embase, CNKI and other databases, the related literature on the effect of gradient pressure stockings combined with ankle pump exercise on lower limb hemodynamics was searched to understand the related research fields, so as to clarify the research direction and content of this subject and provide literature support for this subject.

⑧ Hemodynamic monitoring: the hemodynamics and vessel diameter of both lower limbs were monitored by B-ultrasound.

⑨ Statistical analysis methods: In this study, Excel database was established and SAS 9.4 software was used for statistical analyses between two GCS groups and furtherly, between two lags. The continuous data were expressed as mean (standard deviation) or median (interquartile range) according to normality, and the categorical variables were described by the number of cases (percentage). A two-sided P value of less than 0.05 was considered statistically significant.