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Primary Analysis of a Randomized Controlled Trial of Topical Analgesia Post Haemorrhoidectomy

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Abstract : Background: Post-haemorrhoidectomy pain is concerned by patients/clinicians. Minimizing the postoperation pain is highly interested clinically. Combinations of topical cream targeting three hypothesised post-haemorrhoidectomy pain mechanisms were developed and their effectiveness were evaluated. Specifically, a multi-centred double-blinded randomized clinical trial (RCT) was conducted in adults undergoing excisional haemorrhoidectomy. The primary analysis was conveyed on the data collected to evaluate the effectiveness of the combinations of topical cream targeting three hypothesized pain mechanisms after the operations. Methods: 192 patients were randomly allocated to 4 arms (each arm has 48 patients), and each arm was provided with pain cream 10% metronidazole (M), M and 2% diltiazem (MD), M with 4% lidocaine (ML), or MDL, respectively. Patients were instructed to apply topical treatments three times a day for 7 days, and record outcomes for 14 days after the operations. The primary outcome was VAS pain on day 4. Covariates and models were selected in the blind review stage. Multiple imputations were applied for the missingness. LMER, GLMER models together with natural splines were applied. Sandwich estimators and Wald statistics were used. P-values < 0.05 were considered as significant. Conclusions: The addition of topical lidocaine or diltiazem to metronidazole does not add any benefit. ML had significantly better pain and recovery scores than combination MDL. Multimodal topical analgesia with ML after haemorrhoidectomy could be considered for further evaluation. Further trials considering only 3 arms (M, ML, MD) might be worth exploring.

Keywords : RCT, primary analysis, multiple imputation, pain scores, haemorrhoidectomy, analgesia, lmer
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