FRENCH LARS - FT-LARS (dernière mise à jour : 28/01/2020)

http://archimaid.fr/index.php?action=show&id=896

Informations générales

Titre de l'étude : Validation of the French Version of the Low Anterior Resection Syndrome (LARS) Score for Measuring Bowel Dysfunction After Sphincter-preserving Surgery Among Rectal Cancer Patients

Traitement : Chirurgie

Type d'étude : Qualité de vie / Observationnelle

Phase : NA **Stade** : Localisé à Localement avancé **Ligne(s)** :

Schéma : Oncological rectal cancer outcomes have improved considerably because of optimal surgery by total mesorectal excision in conjunction with multidisciplinary team management by selective multimodal therapy (ie, neo-adjuvant chemo-radiotherapy). The 5-year survival has increased to more than 50% and local recurrence has been reduced to less than 10%. These advancements have resulted in more patient receiving sphincter-preserving surgery (SPS). With an increasing number of rectal cancer survivors, the investigators observe a rising attention to the disordered bowel function after SPS, called "low anterior resection syndrome" (LARS). LARS appear immediately after surgery, becoming most pronounced during the first few months, and improved thereafter, reaching a steady state after around two years. However, up to 60% of patients with SPS suffer from LARS which impaired their quality of life (QoL). The prevalence and severity of LARS is difficult to assess due to heterogeneity of the assessment tools. A group of Danish authors have recently developed and validated a five-item instruments for evaluation of LARS (LARS score). It represents to date the best questionnaire to capture anorectal postoperative function and consists of five items: incontinence for flatus, incontinence for liquid stool, frequency of bowel movements, clustering of stools, and urgency. It allows a categorization of patients into 3 groups: no LARS (0-20 points), minor LARS (21-29 points), and major LARS (30-42 points). Developed in Danish, it is now internationally validated with translations in Chinese, English, German, Spanish and Swedish. To our knowledge, French version of the LARS score is not yet available. The aim of our study will be to adapt the LARS scale questionnaire to the French language (LARS-F), and assess its psychometric properties.

Current primary outcome:
validation of the French version of the LARS score [Time Frame: baseline]
- Cross cultural adaptation
- Reliability :
* Test-retest
* Internal consistency
- Face validity and content validity
- Floor effect - Ceiling effect
- Discriminant validity
* Convergent validity and Divergent validity
* Known-group method and relationship between each item and subscales

The validation study of the French version of the LARS score is based on one hand on the face and content validities and on the other hand on the measurement of its psychometric properties in compliance with the standards published by American Educational Research Association & al.

Outcomes measures
- After translation/back-translation procedures in accordance with the permission from the original authors, the LARS-F score and the whole translation process will be then sent to the original authors for approval. Then, eligible patients will receive a postal invitation to complete the LARS-F score and the l'European Organization for Research and treatment of Cancer (EORTC) QLQ-C30 and QLQ-CR29, respectively. For each item, ceiling and floor effects will be sought.
- The reliability will be assessed by both internal consistency (Cronbach's alpha coefficient).
- To evaluate reproducibility, a test-retest study will be performed in a randomly selected subgroup patients by comparing LARS-F scores obtained between the patient's first and second postal invitation (in an interval of 7-14 days).
- The correlations between the LARS-F score and the EORTC QLQ-C30 and QLQ-CR29 domains will allow to determine convergent validity. For discriminant and divergent validities testing, we will hypothesize that the LARS score will differentiate between the bowel functions of patients with different demographic or clinical features such as sex, age, length of postoperative

period, distance of the tumor from the anal verge, radiation therapy, and prior temporary stoma.
- Sensitivity and specificity for minor and major LARS scores will be assessed.

Spécialités / Localisations

Spécialité n°1 : Organes digestifs

CIM10 - Localisation n°1 : **C20** - Tumeur maligne du rectum

Critères

Critères d'inclusion : - Age between 18 and 80 years
- Rectal cancer patients undergoing curative sphincter-preserving surgery with partial or total mesorectal excision
- Surgery performed between January 2007 to January 2016, with reversal of the defunctioning stoma before January 2016;
- Hence all patients had had bowel continuity restored for at least 24 months - Voluntarily participated in the study

Critères de non-inclusion : - The presence of stoma and/or known disseminated or recurrent disease
- Other diseases of bowel dysfunction (Crohn's disease)
- Cognition and/or language issues

Informations promoteur

Nom du promoteur : CHU de Caen

Type de promoteur : Institutionnel

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials (anglais) : https://clinicaltrials.gov/ct2/show/record/NCT03569488?term=NCT03569488&rank=1