ANORECTAL SYMPTOM MANAGEMENT IN PREGNANCY: DEVELOPMENT OF A SEVERITY SCALE

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ABSTRACT

Background
Anorectal conditions are very common and under-diagnosed in pregnancy, with severe implications on quality of life. Presently no validated scale is available to quantify the severity of symptoms and their response to therapy. The objective of this study was to create and validate a scale for symptoms associated with anal/rectal conditions.

Methods
Patients attending a colorectal clinic were assessed twice, for severity of anorectal symptoms; once by the new questionnaire—ColoRectal Evaluation of Clinical Therapeutics Scale (CORECTS)--followed by a direct examination by a proctologist. Linear regression analysis was performed to correlate the clinician's and CORECTS scores. In parallel, 209 pregnant women with hemorrhoids were assessed using CORECTS before and after treatment with Proctofoam-HC®. We evaluated whether scores' improvement corresponded to changes in quality of life.

Results
There was a significant concordance between each component of the CORECTS scale as well as impact on quality of life, with direct clinical examination of a proctologist. Significant reduction in symptoms, as measured by the scale following use of Proctofoam-HC® highly correlated with changes in quality of life before and after treatment.

Conclusion
CORECTS is a reliable tool in capturing the severity of symptoms associated with colorectal symptoms in pregnancy and is highly sensitive in detecting changes in symptom severity following treatment.

Key Words: *Hemorrhoids in pregnancy; anorectal symptoms evaluation; severity scales*

Anorectal conditions affect a high proportion of pregnant women and can be treated successfully by a primary care physician in an outpatient setting.[1] Many women however, fail to seek treatment due to the embarrassing nature of their condition, or the fear of being diagnosed with cancer.[1]

The most common anorectal conditions are hemorrhoids. They remain a major complaint in developed countries amongst patients with anorectal disease. With an estimated prevalence rate of 4.4% in the US, over one million people in the adult population between the ages of 45-65 are affected annually.[1,2,3,4]

Pregnant women are one of the most vulnerable groups for developing hemorrhoids - with up to a 40% prevalence rate.[5,6] Although the etiology of the disease is unknown, factors that contribute to the higher risk in pregnancy may be: the elevated progesterone; higher iron intake; growing uterus; constipation; and the increased blood flow to the uterus, all of which work in

synchrony to dispose women, especially in their third trimester to developing or aggravating pre-existing hemorrhoids.[5,6,7]

Despite the potentially severe impact of hemorrhoids - they are often frequently dismissed by physicians as a mere part of pregnancy. Treatments are generally conservative, and many women feel they should endure the symptom until delivery, after which most hemorrhoids tend to resolve on their own.

Many patients wrongfully attribute any anorectal symptoms to hemorrhoids. Thus, appropriate diagnosis of hemorrhoids is necessary and it typically involves clonic evaluation by: digital, anoscopic, flexible sigmoidoscopy, colonoscopy, or barium enema.[4] All of these procedures require some form of anorectal examination that commonly causes a great deal of discomfort and shame, thereby explaining the low diagnosis of this very common disease. Less than a third of patients with hemorrhoids are thought to seek help, and then only after significant impact has been made on their quality of life.[1,4]

Currently, no standard tool for assessment of hemorrhoids or any anorectal symptoms, and their response to therapy has been published. The objective of the present study was to establish and validate a clinical scale that addresses the five main symptoms associated with hemorrhoids: pain, itching, swelling, bleeding, discomfort as well as their impact on quality of life.

MATERIALS & METHOD

Establishment of the CORECTS

The COloRectal Evaluation of Clinical Therapeutics Scale (CORECTS) combines the five cardinal symptoms of hemorrhoids: pain, itching, swelling bleeding and discomfort, each rated on a numeric zero to ten scale, where zero indicates no symptoms and 10 indicates worst possible symptoms (Figure 1.) In addition, CORECTS also accounts for quality of life with an "Impact on Well-being (IW)" score, that measures the impact of hemorrhoidal symptoms on well-being; the IW score also ranges from zero (no impact) to ten (worst possible impact). In the post treatment section of the CORECTS there is also an "Overall Improvement" score, which assesses the total improvement in symptoms following treatment; similarly a score of 0 indicates no improvement at all and 10 indicates maximal improvement comparable to the healthy state with treatment.

FIG. 1 CORECTS SCALE

BEFORE TREATMENT
How much pain do you experience? 0 1 2 3 4 5 6 7 8 9 10
How much itching do you experience? 0 1 2 3 4 5 6 7 8 9 10
How much swelling do you experience? 0 1 2 3 4 5 6 7 8 9 10
How much bleeding do you experience? 0 1 2 3 4 5 6 7 8 9 10
How much discomfort do you experience? 0 1 2 3 4 5 6 7 8 9 10
How much impact does your condition have on your well being? 0 1 2 3 4 5 6 7 8 9 10
How do you rate the overall improvement after treatment? 0 1 2 3 4 5 6 7 8 9 10

For the external validation of the study, we administered CORECTS on 29 adult patients visiting the Rudd anorectal clinic between September - December 2008. The reason for their visit included: hemorrhoids, anusitis, fistulas, fissures and anal lesions. All 29 patients were directly examined by a team proctologist who routinely rates the severity of their symptoms from zero (symptom free) to 5 (maximal severity).

After verbal consent, each patient was asked to fill out the CORECTS scale by circling the corresponding number on the scale, with zero indicating no symptom at all and ten indicating symptoms at their worst. The assessment was then repeated by the investigator delivering the questionnaire in order to evaluate the agreement between the scores, and hence the accuracy of the scale.

Concurrently a separate study was being conducted to evaluate the effectiveness and safety of an anti-hemorrhoidal medication Proctofoam-HC® for the treatment of hemorrhoids in pregnancy. 209 pregnant women were recruited from obstetric and gynecology clinics in Montreal and Toronto; all women were consenting adults in the third trimester of their pregnancy and diagnosed by their physician with hemorrohids. Majority of the patients reported great relief after using Proctofoam-HC®. As part of this study, the CORECTS scale was administered to each patient before and after treatment with Proctofoam-HC® to evaluate its effectiveness. The "Prior to Treatment" part of the CORECTS scale was filled out at the time of recruitment to assess the severity of the hemorrhoids, and the post treatment section was completed shortly after delivery; for a subgroup of patient (N=68) the post treatment section was completed within three weeks of using the product and prior to delivering. We used the CORECTS data portion of this study to evaluate its ability to track changes in hemorrhoid symptoms following treatment.

Statistical Analysis

Linear regression and multiple regression analysis were used to correlate between the direct physical examination score and CORECTS, and between different components of the CORECTS scale. Paired student t-test or Wilcoxon signed rank test were performed to quantify the changes in the mean or median scores of each of the components of CORECTS (ie., pain, itching, well-being, etc.) after treatment with Proctofoam-HC®.

RESULTS

Of the 29 patients visiting the Rudd clinic, 10 (34%) had symptomatic hemorrhoids, and the remaining patients' visits were mainly due to fistulae and anusitis. Significant correlation was found between the clinician's score and the pain and bleeding components of CORECTS (Table 1*)*.When we combined the two objective components (bleeding and swelling scores) there was a significant correlation with the clinician's direct examination.

There was also a significant correlation between Impact on Well-being (IW) scores and the pain, swelling and discomfort components of CORECTS, but no correlation with bleeding, and itching. The mean age of the 209 pregnant women receiving Proctofoam-HC® for treatment, at conception was 31.6 (median: 32.2), the median gravidity of 2, parity of 0 and 175 (81%) of these women underwent a vaginal delivery. All women had symptomatic hemorrhoids with pain and swelling as their major complaints. Upon treatment with Proctofoam-HC® there was significant reduction in all parameters of the CORECTS, with a mean "Overall improvement" score of 7.51 and a median of 8 (Table 2). For a subset of the same group (N=68), the CORECTS was administered three times: once prior to treatment with Proctofoam-HC®, then within 2 weeks of using Proctofoam-HC® and finally after delivery. The mean duration of treatment at the first assessment post treatment was 22.2 days, and 64.2 days at the second post treatment assessment. The mean postpartum days at the third assessment was 29.1 days. There was a significant change in pain, itching, swelling and IW components of CORECTS, in the third assessment (long treatment duration) group, in comparison to the second assessment. The scores at both treatment durations, was significantly different than the "prior to treatment" scores (Table 3).

TABLE 1 Correlation between CORECTS components with Proctologist's Score and with Impact on Well-being Scores

CORECTS Component	Proctologist Score P-value [R^2]	IWB Score P-value [R^2]
Pain	0.02 (0.2)§	0.012 (0.2)§
Itching	0.94 (0.0)§	0.24 (0.1)§
Swelling	0.05 (0.2)§	<0.001(0.4)§
Bleeding	0.01 (0.3)§	0.17 (0.1)§
Discomfort	0.09 (0.1)§	<0.001(0.4)§
Swell + Bleed	0.03 (0.3)*	<0.001(0.7)*
Swell + Bleed+ Discomfort	0.05 (0.3)*	0.002 (0.4)*
Impact on WB	0.769 (0.0)	

§ Simple Linear Regression; *Multiple Linear Regression

TABLE 2 Changes in CORECTS scores before and after treatment with Proctofoam-HC®

Symptoms N=209	Prior to Treatment Median (25-75%)	Post Treatment Median (25-75%)
Pain	6.0 (3.0-8.0)	0.0 (0.0-2.0)*
Itching	4.0 (1.8-6.0)	0.0 (0.0-0.1)*
Swelling	6.0 (5.0-8.0)	2.0 (0.0-4.0)*
Bleeding	1.0 (0-4.0)	0.0*
Discomfort	7.0 (4.0-8.3)	0.0 (0.0-3.0)*
Impact WB	7.0 (5.0-8.0)	1.0 (0.0-3.0)*
Overall Improvement		8.0 (7.0-9.0)*

* P-<0.0001[Wilcoxon signed rank test]

TABLE 3 Changes in CORECTS scores following short and long treatment durations with Proctofoam-HC®

Symptoms N=68	Prior-Treatment (Mean±SD)	Post-Treatment 1 Median (25-75%)	Post-Treatment 2 Median (25-75%)	P-value Comparing Post Treatment 2 to 1
Duration (mean±SD) days		22.2 ± 11.7	64.2±33.4	
Pain	5.0 (2.5-6.5)	1.0 (0.0-3.0)	0.0 (0.0-1.0)	0.002
Itching	4.0 (0.0-5.0)	1.0 (0.0)-3.0)	0.0	0.0002
Swelling	5.0 (4.0-7.5)	4.0 (2-5.5)	2.0 (0.0-3.0)	0.0004
Bleeding	0 (0-3.0)	0.0	0.0	0.44
Discomfort	7.0 (4.0-8.0)	2.5 (1.0-5.0)	0.0 (0.0-2.0)	0.01
Impact on WB	7.5 (5.0-8.0)	3.5 (1.0-5.0)	0.0 (0.0-3.0)	0.0001
Overall Improvement		8.0 (5.0-9.0)	8.0 (6.3-9.0)	0.89
Days post partum (days)			2.6(21.0-35.0)	

DISCUSSION

For the validation portion of our tool, we intuitively expected a significant correlation between the objective symptoms of CORECTS (bleeding and swelling) and results of a clinician's direct observation. Indeed significant correlation was found between the physician's score and the pain and bleeding components of the CORECTS, but not with swelling, indicating that the degree of pain experienced by the patient avidly reflects the clinician's score. The lack of correlation between swelling, an objective symptom and the physician's score may be explained by the small sample size, and the fact that the symptom of swelling was not pertinent to every patient's condition. For example, anusitis is accompanied by a burning sensation around the anus, pain, tenderness and bleeding, but no swelling. Furthermore, once we combined the scores for the two objective symptoms, swelling and bleeding, we did observe a significant correlation between patients' and physician's scores; thus with a larger sample size with a wider range of anorectal symptoms, a strong correlation with swelling may be observed.

Using the CORECTS data from the Proctofoam-HC®, showed a significant correlation between pain, swelling and discomfort scores and the impact women reported on their well-being. In contrast, the itching and bleeding scores did not correlate with the IW scores, suggesting that these symptoms of hemorrhoids do not contribute as strongly to quality of life. Proctofoam-HC® is an anti-hemorrhoidal medication that is widely prescribed by physicians for the treatment of hemorrhoids in pregnancy. As shown by our results, CORECTS is sensitive in capturing changes in symptoms following treatment with Proctofoam-HC®. Dramatic decrease in symptom severity was observed following treatment with Proctofoam-HC®, with half the women, scoring zero on pain, itching, swelling and discomfort after treatment with Proctofoam-HC®; about fifty percent of these 209 women, had a mean duration of treatment of two months. This significant reduction in symptom severity is also reflected in the great increase on Impact on Well-being and the high Overall Improvement scores—1 and 8 respectively. It may be argued that the great improvement postpartum, maybe due to the completion of pregnancy itself and not entirely due to the treatment. Although it is known that hemorrhoids tend to reduce following delivery, due to the relief from intra-abdominal pressure and venous congestion during pregnancy. The postpartum assessment was completed within a few weeks after delivery- which was not sufficient for symptoms to resolve fully; most hemorrhoids are still persistence 8 weeks postpartum.[8] Furthermore, in our subgroup of 68 women whom we assessed three times, the first post treatment assessment was completed after a mean of 22 days of treatment (prior to delivery); substantial improvement in all parameters of CORECTS in comparison to the prior to treatment assessment was still observed ($P<0.001$), strongly corroborating the effectiveness of the medication Proctofoam-HC® for hemorrhoids in pregnancy. However, we do acknowledge that the significant difference demonstrated in Table 3, between post treatment two and one, may be confounded by the completion of pregnancy, and may not be entirely due to the effectiveness of longer treatment parse. Nevertheless, the further reduction observed in post treatment 2 scores that is significant for pain, itching and swelling, and an overall less impact on well-being, demonstrate the sensitivity of the CORECTS scale to detect even small differences with the disease progress.

The subjectivity of symptoms such as pain, itching and discomfort, pose a challenge to quantitative assessment of these symptoms, hence questioning the accuracy of CORECTS. However, despite of the individual difference in thresholds for subjective symptoms, changes in severity is still captured with CORECTS, which can be important clinically.

Since hemorrhoids are progressive in nature during the course of pregnancy, many women experience significant impact on their quality of life with symptomatic hemorrhoids, especially in the later stages of their pregnancy. Generally, depending on the type of hemorrhoid (internal or external) symptoms can vary. Many patients initially report to their physician when experiencing bleeding, itching and pain.[4] Enlarged internal hemorrhoids are generally associated with soiling; bleeding; prolapse after defecation and pruritis ani in severe cases. Due to lack of somatic sensory innervation, pain is not a common symptom.[2,6,7] External hemorrhoids on the other

hand are associated with: significant pain; severe discomfort; bleeding; itching; and may be prone to thrombosis and strangulation.[6,7] Left untreated, severe hemorrhoids can lead to secondary complications - incarcerated hemorrhoids may thrombose; become ischemic and eventually gangrenous from vascular insufficiency; iron-deficiency as a result of chronic blood loss; and not to mention the severe pain and discomfort that often accompanies them, tend to severely compromise a woman's daily functioning.[9,10]

The CORECTS is the first tool to encompass all major symptoms associated with hemorrhoids and to include a measure of quality of life. Since the five symptoms associated with hemorrhoids overlap with symptoms from other common anorectal conditions, the use of the scale can be justified in patients with other conditions such as fistulas, fissures, and pruritis ani. As shown by our results it is sensitive to changes in severity of symptoms following treatment.

The concordance of CORECTS with direct assessment by a proctologist, as well as its sensitivity in capturing small changes in symptom severity following treatment, makes it a valuable tool for clinicians. Although no scale can replace a direct examination by a physician, the availability of a tool like this at the initial assessment, may facilitate diagnosis, especially when a direct examination is not possible due to women's embarrassment. Also, the CORECTS can be used by clinicians and researchers to assess the effectiveness of different treatments for common anorectal conditions. The majority of over-the-counter medications for the treatment of anorectal conditions have not been assessed for effectiveness - thus making the choice of the right medication, a cumbersome and expensive trial and error process for most patients. More studies are required to provide guidelines for effective pharmacotherapy, and the availability of a standardized tool such as CORECTS, can be helpful for such studies.

The specificity of CORECTS to hemorrhoid symptoms while taking into account the impact on quality of life, as well as its visual analogue nature, make it a highly efficient and simple scale to use for the assessment of this condition. Since pregnancy is considered a risk factor, and many pregnant patients suffer relentlessly, the existence of such a scale should allow for the adequate evaluation of the patient's status and the implementation of effective treatments for this commonly ignored condition.

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