

Affect on Quality of Life Following Rubber Band Ligation or Cryosurgery for Hemorrhoids: A Randomized Clinical Trial

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Abstract

Objective: To assess and analyze the quality of life of patients suffering with uncomplicated grade I and II hemorrhoids in an adult general population following treatment by either rubber band ligation or cryosurgery through Short Form-36 quality of life survey questionnaire. **Background:** No study comparing the quality of life following treatment of hemorrhoids by rubber band ligation or cryosurgery has ever been done. **Method:** Sixty comparable patients with symptomatic uncomplicated grade I and II hemorrhoids were recruited in the study. Their quality of life was assessed using sf-36 version 2 questionnaire. The patients were then randomized into two equal groups to undergo either rubber band ligation or cryosurgery. The patients were followed after 2 months and Quality of life was reassessed using the same questionnaire. Change in quality of life in either group was then assessed and analyzed using appropriate statistical methods. **Results:** Mean age of patients was 41.15±14.16 years. There were 45 males and 15 females. Bleeding was the main symptom in all patients followed by pruritus ani in 8 patients. The two groups were comparable regarding age and symptoms. There was significant improvement in quality of life after treatment by rubber band ligation and cryotherapy. However, for the cryotherapy group, the change was much higher in mental component score as compared to physical component score. The inter group difference of change in score from pre operative to post operative level was not statistically significant except for general health. **Conclusion:** Hemorrhoids negatively affect the quality of life of patients. Treatment of hemorrhoids

by either rubber band ligation or cryotherapy is equally effective in improving their quality of life.

Keywords: Hemorrhoids; Rubber Band Ligation; Cryotherapy; Quality of Life.

Introduction

Quality of life (QOL) is widely considered an important component in measuring the outcome of surgical interventions. Though the use of QOL measurement in research as an outcome of surgical interventions is increasing [1], the studies measuring the QOL of patients with hemorrhoids are scarce [2,3]. Hemorrhoids is one of the commonest condition to affect mankind for centuries [4]. Patients suffering from hemorrhoids are usually concerned and troubled with bleeding, prolapse of hemorrhoidal masses, mucus discharge and pruritus ani which affect their QOL to varying degrees. Of the various treatment options available for the treatment of hemorrhoids, rubber band ligation is a popular while cryotherapy is a not a widely practiced modality of treatment. However, both these procedures can be performed in outpatient department as they are simple, easy to perform, minimally invasive, economical and require minimal post operative care. Owing to their effectiveness they are supposed to improve the QOL of the patients with hemorrhoidal disease. No study comparing the outcome of these interventions on the QOL has been done before. We have assessed the change in QOL consequent to the use of these modalities for the treatment of hemorrhoids.

Material & Methods

The study was conducted on 60 patients presenting with uncomplicated symptomatic grade I

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& II hemorrhoids to the Department of Surgery of a tertiary care teaching hospital, over a period of 16 months. The study was approved by Institutional Review Board. Patients with complications of hemorrhoids like thrombosis, strangulation, other concomitant anal diseases, inflammatory bowel disease or haematological disorders, those on anticoagulant therapy and those with conditions causing raised intra abdominal pressure like pregnancy, ascites, pelvic tumor and portal hypertension were not included in the study.

A detailed history was taken and general physical and abdominal examination was performed in all recruited patients. Diagnosis was established by digital rectal examination and proctoscopy. An informed consent was taken for inclusion in the study and treatment by rubber band ligation or cryotherapy. The history and examination findings were recorded in a predesigned case record form. QOL was assessed preoperatively in all patients using sf-36 version 2 questionnaire. The patients were then randomized to receive either rubber band ligation or cryotherapy as treatment by stratified randomized method using computer generated random numbers. Sixty numbers were generated and 30 numbers were allotted to each group.

Patients in both groups were treated on an outpatient basis without anesthesia. No special bowel preparation was done apart from ensuring that the rectum was free from feces. All patients underwent treatment of hemorrhoids by banding or cryotherapy in similar manner using same standard instruments. Post-operatively all patients were prescribed high residue diet, mild laxatives [syp. lactulose 10 grams (15 ml) BD] and analgesic (a single tablet of Diclofenac 50 mg) was advised to be taken when needed and not to be repeated before 8 hours. All patients were followed for first 3 days and at one week following procedure for early postoperative assessment and complications. They were then followed after 2 months and QOL was reassessed using sf-36 version 2 questionnaire. Change in QOL in the rubber band

ligation and cryotherapy groups was then assessed. The data so obtained was analyzed using appropriate statistical tools. The two groups were compared with each other using Multivariate test and Tukey procedure for individual component. A 'p' value of <0.05 was considered significant.

Results

Mean age of patients was 41.15 ± 14.16 years with a range of 18-80 years. The two groups were comparable for age ($p=0.188$, student t test). There were 45 males and 15 females with male to female ratio of 3:1. Mean body mass index was 21.58 ± 2.47 . Six patients were overweight but no patient in our study was obese.

Bleeding was observed as main symptom in all 60 patients followed by pruritus in 8 patients. However the patients in two groups were similar regarding the amount of bleeding ($p=0.1$) and pruritus ($p=0.70$). Pain and discharge were not present in any of the patient of either study group.

Mean duration of disease was 4.07 ± 4.90 years with a range of 6 days- 20 years. However the difference in two groups was not significant ($p=0.477$). The distribution of patients in two treatment groups on the basis of different grades and number of hemorrhoids were similar. The patients in the two groups were also found similar with regards to bowel habits ($p=0.6$), straining at stools ($p=0.25$) and duration of symptoms ($p=0.42$).

Procedure time was less than 30 minutes in all patients of either group. 59 patients out of 60 were treated on outpatient basis and were discharged after treatment. One patient required hospitalization for 14 days prior to treatment for severe anaemia.

QOL was assessed by using sf-36 version 2 questionnaire. All patients were asked 36 questions in questionnaire pre-operatively and 2 months after treatment. QOL parameter scores in two groups are

Table 1: Score of QOL parameters in rubber band ligation group

Parameters	Preoperative Mean(SD)	Post operative Mean(SD)	p Value
Physical functioning (PF)	46.57(8.26)	48.47(8.34)	<0.05
Role- physical (RP)	43.85(6.25)	46.89(2.76)	<0.05
Bodily pain (BP)	49.75(9.17)	52.97(6.03)	<0.05
General health (GH)	28.30(1.49)	38.74(2.63)	<0.05
Vitality (VT)	51.13(5.91)	47.72(5.84)	<0.05
Social functioning (SF)	34.66(2.97)	42.66(2.54)	<0.05
Role- emotional (RE)	30.74(6.86)	41.26(6.19)	<0.05
Mental health (MH)	33.77(2.74)	43.34(2.47)	<0.05
summary scale: Physical component score (PCS)	48.28(7.96)	49.43(6.00)	<0.05
summary scale: Mental component score (MCS)	29.39(2.51)	41.07(2.45)	<0.05

Table 2: Score of QOL parameters in cryotherapy group

Parameters	Preoperative mean(SD)	Post operative mean(SD)	p Value
Physical functioning (PF)	47.63(6.73)	51.06(6.47)	<0.05
Role- physical (RP)	42.73(7.40)	49.18(6.12)	<0.05
Bodily pain (BP)	49.66(10.88)	53.20(6.96)	<0.05
General health (GH)	27.67(3.21)	43.32(4.82)	<0.05
Vitality (VT)	38.45(4.29)	50.63(4.96)	<0.05
Social functioning (SF)	32.12(5.10)	45.94(3.79)	<0.05
Role- emotional (RE)	28.28(6.64)	46.03(7.61)	<0.05
Mental health (MH)	30.95(4.77)	47.85(5.61)	<0.05
summary scale: Physical component score (PCS)	48.94(7.91)	50.80(5.09)	<0.05
summary scale: Mental component score (MCS)	25.61(5.75)	45.93(5.33)	<0.05

Table 3: Comparison of QOL parameters between Rubber band ligation and cryotherapy group

Parameters	Cryotherapy		Rubber band ligation		p value
	Pre operative Mean(SD)	Post operative Mean(SD)	Pre operative Mean(SD)	Post operative Mean(SD)	
Physical functioning(PF)	47.63(6.73)	51.06(6.47)	46.57(8.26)	48.47(8.34)	0.36
Role- physical(RP)	42.73(7.40)	49.18(6.12)	43.85(6.25)	46.89(2.76)	0.75
Bodily pain(BP)	49.66(10.88)	53.20(6.96)	49.75(9.17)	52.97(6.03)	0.99
General health(GH)	27.67(3.21)	43.32(4.82)	28.30(1.49)	38.74(2.63)	0.023
Vitality(VT)	38.45(4.29)	50.63(4.96)	51.13(5.91)	47.72(5.84)	0.85
Social functioning(SF)	32.12(5.10)	45.94(3.79)	34.66(2.97)	42.66(2.54)	0.70
Role- emotional(RE)	28.28(6.64)	46.03(7.61)	30.74(6.86)	41.26(6.19)	0.43
Mental health(MH)	30.95(4.77)	47.85(5.61)	33.77(2.74)	43.34(2.47)	0.47
ysical component score(PCS)	48.94(7.91)	50.80(5.09)	48.28(7.96)	49.43(6.00)	0.55
ental component score(MCS)	25.61(5.75)	45.93(5.33)	29.39(2.51)	41.07(2.45)	0.65

shown in Table 1 and 2. Change in QOL in both rubber band ligation and cryotherapy groups was assessed and the two groups were compared with each other (Table 3).

It was observed that there was significant improvement in QOL after treatment by rubber band ligation and cryotherapy ($p < 0.05$ in all parameters). However, for the cryotherapy group, the change was much higher in mental component score as compared to physical component score.

On applying Multivariate test and Tukey procedure for individual components in two groups it was found that inter group difference of change in score from pre-operative to post-operative level was not statistically significant except for general health (Table 3).

Discussion

QOL is considered as an important measure of outcome of various treatment interventions and its potential in effecting the research in future is increasingly being recognized [5]. Realizing this, in recent years there has been a surge in the number of studies which assessed QOL in various diseases or as an outcome measure of various treatment interventions [3]. QOL is an important non-specific

parameter of a person's subjective sense of well-being. It integrates not only the health status, but also comprises physical, mental and social domains. Reiss et al reported that hemorrhoids by themselves do not affect the QOL negatively [2] but considering the fact that the patients of hemorrhoids are frequently troubled with bleeding, prolapse of masses, mucus discharge and pruritus ani for which they frequently seek treatment, suggests that their QOL is affected. This is supported by the work of Hussain JN et al who reported that hemorrhoids are responsible for considerable patient suffering and disability [6].

Rubber band ligation and cryotherapy are commonly performed OPD procedures for the treatment of symptomatic grade I and II hemorrhoids. Rubber band ligation was introduced by Baron [7] in 1963 and has been popularized since then by various researchers in their studies. It is a well accepted procedure [8], routinely used for treatment of grade I and II hemorrhoids for its simplicity, safety, efficacy and minimal side effects.

Cryotherapy is used for treatment of various pathologies like skin lesions, cervical carcinoma and prostatic carcinoma [9]. Despite its introduction in 1969 by Lewis [9] for treatment of hemorrhoids and some initial enthusiasm, it has not become popular because of certain side effects like anal discharge and pruritus during the healing period. However, when used in a modified way, the incidence of side effects

with cryotherapy is less [10-12]. A study from India also supports the same [13]. Since cryotherapy is a simple, non-invasive procedure, that can be conducted on an OPD basis, is economical and requires minimum care in post operative period, it remains an effective alternative to other conventional treatment modalities for hemorrhoids.

There is scarcity in reported literature of studies comparing QOL following treatment of hemorrhoids by various modalities. Various parameters used in assessment of QOL are purely subjective and are therefore frequently assessed by patient questionnaires. In addition, the tools measuring QOL are also designed to assess the impact of disease related symptoms, therapy induced side effects, and even the financial concern to the sufferer. Like other psychometric assessment tools, questionnaires assessing QOL should qualify certain quality criteria, most importantly with regard to their reliability and validity. Several questionnaires have been developed to suit these needs. The available questionnaires can be generalized into two categories:

1. Generic instruments (e.g. sf-36, Short-Form with 36 questions)
2. Disease or Disorder specific instruments (e.g. the LC-13 Lung Cancer module from the EORTC QOL questionnaire library, or the Hospital Anxiety and Depression Scale).

sf-36 is a validated tool to measure the QOL and has been widely used in the research studies as an effective tool for assessment of QOL [14]. In this questionnaire there are eight health domain scales and two summary scales (physical component score and mental component score). All eight health domains contribute to the scoring of both summary scales. Three scales (physical functioning, bodily pain, and role physical) correlate most highly with the physical component and contribute most to the scoring of the Physical Component Summary (PCS) measure. Rest of 5 health domain scales has less contribution to PCS score. Similarly the mental component correlates most highly with the mental health, role emotional, and social functioning scales which also contribute most to the scoring of the Mental Component Summary scale (MCS).

In our study it was found that in both groups there was significant improvement in all eight quality of life scales as compared to baseline after 2 months of treatment ($p < 0.05$; Table 1 and 2).

Improvement in mental component score was more than physical component score in both groups (Table 1 and 2). This mental relief could be due to alleviation of associated depression or persistent concern due to

visible blood loss at defecation.

There was no significant difference between two groups when QOL was compared at 2 months (except for general health which improved more in cryotherapy group; Table 2) suggesting that both treatment modalities are equally effective for management of hemorrhoids (Table 1 and 2).

Conclusion

Quality of life is affected negatively in the patients suffering from hemorrhoids. Treatment of hemorrhoids by rubber band ligation and cryotherapy is equally effective in improving their QOL.

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