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Research Article

QUALITY OF LIFE FOLLOWING AYURVEDIC PARA SURGICALTREATMENT (KSHARASUTRA) FOR RECURRENT FISTULA-IN-ANO

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ABSTRACT

Background The management of fistula-in-ano remains a major surgical challenge and carries a significant morbidity affecting the quality of life (QOL) due to the disease and repeated operations but Ayurvedic para surgical treatment (*ksharasutra*) is considered as a safe in the side effect of surgery concern and least recurrences. The aim of the study was to assess the QOL before and after successful Ayurvedic para surgical treatment of recurrent fistula-in-ano using the gastrointestinal quality of life index (GIQLI) which is a validated instrument consisting of 36 questions for measuring quality of life in patients with gastrointestinal disorders including fistula-in-ano.

All patients who underwent successful Ayurvedic para surgical treatment for recurrent fistula-in-ano over a period of24 months were prospectively analyzed using the GIQLI preoperatively and after a minimum of 20 months after complete cure following Ayurvedic para surgical treatment. The difference in the QOL scores was analyzed using Wilcoxon rank test. Results in the 100 patients recruited for the study there was a significant ($P<0.01$) difference between the average preoperative (97.02) and postoperative (116.14) GIQLI scores of all the areas assessed by the GIQLI questionnaire, greater statistical significance was seen in areas of emotions ($P<0.01$), social integration ($P<0.01$) and effects of treatment ($P<0.01$).

Recurrent fistula-in-ano significantly affects the patients' QOL, and also, successful Ayurvedic para surgical treatment results in significantly improved long-term QOL. This improvement shows the need for those patients with fistula-in-ano to be subjected to Ayurvedic para surgical treatment is the best intervention instead of surgery it carried significant risk to the analincontinence with recurrences.

INTRODUCTION

The surgical treatment of fistula-in-ano remains a major surgical challenge as it carries a significant risk of recurrence of the fistula or postoperative complications such as anal incontinence (Garcia *et al.*, 1996). Surgical treatment of fistula in ano is associated with significant risk recurrence and high risk of impaired continence. (Garcia Agvilar *et.al.*, 1996) .There is growing evidence that even division of the internal anal sphincter, leaving the puborectalis and external sphincter undisturbed, may cause impaired continence after successful elimination of the fistula (Lunnis *et.al.*, 1994). Nevertheless, unless all the secondary tracks are also attended to, there is a risk of recurrent sepsis and fistsulation (Garcia Agvilar *et.al.*, 1996).

Despite the continuous

Improvement in preoperative imaging (Toyonaga *et al.*, 2008), the reported recurrence rates vary from 8 to as high as 40% (Van de *et al.*, 2006).

Recurrent fistula-in-ano carries a significant morbidity affecting the quality of life (QOL) due to the disease as well as due to repeated operations (Wong *et al.*, 2008). Sometimes, even after the ''surgical cure'' of a fistula, long-term complications of surgery such as anal incontinence can affect the QOL with a significant negative impact (Damon *et al.*, 2006).

Ayurvedic para surgical treatment (*ksharasutra)* is considered as a safe in the side effect of surgery concern and least

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recurrences. No studies so far to assess theclinical outcome followingpara surgical treatment (*ksharasutra*)

Despite these significant rates of complications and controversies regarding its impact on QOL after the surgical intervention but so far no studies conduct the assess the outcome of the *ksharasutra* treatment for the recurrence fistula (due to the surgical intervention).only a few previous studies have tried to objectively assess the impact of fistula surgery on patients' QOL (Garcı´a-Aguilar *et al.*, 2000)

Out of these tools, gastrointestinal quality of life index (GIQLI) developed by Eypasch et al. is a validated and widely accepted tool that has been used successfully to assess QOL in patients with benign ano-rectal conditions including fistula-in-ano (Eypasch *et al.*, 2007). The aim of this study was to objectively assess the QOL in patients with recurrent fistula-in-ano and improvement in QOL after successful Ayurvedic para surgical treatment.

MATERIALS AND METHODS

All patients who underwentAyurvedic para surgicaltreatment.at the Ano rectal clinic, GampahaWickramarachchiAyurveda Teaching Hospital of Sri Lanka for recurrent fistula-in-ano during a period of 24 months and subsequently declared cured were recruited for the study. Recurrent fistula was defined as any previous surgery that was done for fistula-in-ano with the intention of curing the fistula supported with documented evidence. Each patient's QOL was analyzed prospectively using an interviewer administered GIQLI questionnaire. The GIQLI consists of 36 questions. In GIQLI, separately set questions are used to measure gastrointestinal QOL in areas of symptoms, associated physical disease, socialintegration, psychological symptoms and treatment-related problems. QOL was assessed at two points. First pretreatment of *ksharasutra*, after treatment of *ksharasutra* and subsequently in the follow-up, after a minimum period of 20 months after declaring complete cure of fistula following *ksharasutra* treatment. Since the patients had varying periods of healing, 18 months was calculated from the time when complete cure of the fistula was declared. During this period, wound healing assess by using unit cutting time and histo pathological readings.

A biopsy was taken from the fistula track at the time of *ksharasutra* treatment from all patients for histological assessment to exclude a secondary cause. At the time of second assessment all patients underwent a clinical examination and an endo-anal ultrasound examination using a 12-MHz endo-anal probe (Olympus RM- 12U-R1) to confirm absence of a recurrence of the fistula. The GIQLI questionnaire has 36 items that can be scored from 0 (worst) to 4 (best) to measure five dimensions of quality of life. The five dimensions are:

- Symptoms (19 items)
- Associated physical disease (7 items)
- Metal wellbeing (5 items)
- Social integration (4 items)
- Effects of treatment (1 item)

The differences in the pre- and post-operative GIQLI score total and score of each dimension were analyzed
Using Wilcoxon rank test.

RESULTS

The total number of patients recruited for the study was 100. Male to female ratio was 78:22. Mean age of the study group was 37.4 (range, 19–75) years. The median number of surgeries each patient had undergone was 3 (range, 2–8).These included fistulectomy, fistulotomy and insertion of cutting setons. The mean follow-up duration was 24 (range, 1–30) months. None of the patients out of the study population of 100 had clinical or endo-anal ultrasonographic evidence of a re-recurrence during the follow-up period. All fistulas were classified according to Parks classification at the time of surgery (Parks*et al.*, 1976). Sixty (60%) patients had inter-sphincteric fistula, followed by trans-sphincteric fistula in 25 (25%), supra-sphincteric in 10 (10%) and extra-spincteric in 5 (5%) patient.

Three patient had two types of fistulas on left and right sides. The types of surgeries included fistulectomy in 91 (91%) patients, excision of the fistula with primary closure of the internal opening in 3 (3%) and cutting setons in 6 (6%). Five patients with complex fistulas underwent more than one type of surgery.

Table1 Pre- and post-treatment Gastro Intestinal Quality Life Index (GIQLI) scores

Category(Maximum score)	Pre-op GIQLI score Average ± SD (95% CI)			Post-op GIQLI score Average ± SD (95% CI)			P-value
Total GIQLI score (144)	46.0	±39.4	(42.1-50.0)	141.1	±13.4	(139.7-142.5)	<0.01
Symptoms (76)	25.1	±17.9	(23.31-26.9)	74.1	±7.69	(73.3-74.9)	<0.01
Associated physical disease (28)	13.6	±8.4	(12.8-14.5)	27.4	±2.42	(27.1-27.7)	<0.01
Emotions (20)	2.7	±4.18	(2.28-3.12)	19.8	±1.88	(19.6-20.0)	<0.01
Social integration (16)	2.16	±3.64	(1.8-2.5)	15.8	±1.2	(15.6-15.92)	<0.01
Effects of treatment (4)	2.44	±0.76	(2.36-2.52)	3.95	±0.22	(3.93-3.97)	<0.01

All fistulas belonged to cryptoglandular variety as none of the histologies showed any evidence of secondary causes such as Crohn's disease or tuberculosis. The average preoperative (*Ksharasutra*) GIQLI score was 46.0 (SD39.4, 95% CI: 42.1–50.0).The average GIQLI score after complete cure of the fistula by *kshara sutra* treatment was 141.1 (SD 13.4, 95% CI: 139.7–142.5). The difference between average pre- and post-*ksharasutra* scores was statistically significant (P<0.01).

Of all the areas assessed by the GIQLI questionnaire, greater statistical significance was seen in areas of emotions.(P<0.01), social integration (P<0.01) and effects of treatment (P<0.01), and Symptom (P<0.01). (Table-1).

DISCUSSION

This study reiterates the fact that recurrent fistula-in-ano has a significant impact on the affected person's QOL. TheQOL is mainly affected due to the problems patients face psychologically and with social integration rather than due to the severity of their fistula symptoms.. The study also shows that all the five areas of QOL -significant improvements in the patients' underwent *ksharasutra* treatment The *ksharasutra* treatment, the psychology, symptoms, effect of treatment, associate physical diseases, and social integration improved significantly. Also this highlights the importance of discussing

and informing the patients prior to *ksharasutra* treatment bout realistic improvements in their symptoms that could be achieved with *ksharasutra*.

The goal of *Ksharasutra* treatment of fistula in ano by virtue of the properties of its content which has necrolytic action on tissues. During application of *ksharasutra* there is a continuous drainages of fistulous track and ingredients used in the thread help in healing. *Ksharasutra* provides continue drainage of the abscess cavity or fistula track enhancing the drainage because *ksharasutra* act as a foreign body in the fistula track. It has been proved as the antibacterial, antifungal and anti-inflammatory action of the *ksharasutra*. The effects include (a) correction of the unhealthy tissues (b) Enhancement of the healthy granulation tissue formation (c) enhancement of fibrolysis (d) separation of debris through the fistulous track (e) removal of debris and cleansing wound.

The highly significant improvement in the QOL after *ksharasutra* treatment shows the need for those patients with fistulain-ano with repeated surgery due to recurrences should subjected to Ayurvedic prasurgical treatment to avoid the, possible risk of anal incontinence due to repeated surgery.

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