A Prospective Study on the Quality of Life After Palliative Surgery for Patients with Advanced Breast or Gastrointestinal Malignancies

Herbert C. Tagab, M.D., F.P.C.S.; Stephen Sixto Siguan, M.D., F.P.C.S. and Saleshe Tracy Anne G. Baking, M.D.

Surgical Oncology and Breast Center, Department of General Surgery, Vicente Sotto Memorial Medical Center

Objective: To evaluate the quality of life (QoL) after palliative surgery of patients with advanced breast or gastrointestinal malignancies

Methods: Quality of Life (QoL) of 32 patients with advanced breast or gastrointestinal cancer (Stage IIIB up to Stage IV) was evaluated before surgery (baseline), then 7 and 30 days after surgery using the Medical Outcomes Study Short form (SF-36v2™ Questionnaire). Statistical significance of the difference in outcomes was tested using the two-tailed T-test at 95% CI.

Results: Preoperatively, the patients scored poorly (scores below the average mean of 50) in all 8 subscales of the SF-36v2™. Seven days after a palliative surgery, patients showed significant improvement in all subscales except Vitality and Social Functioning. The patients experienced statistically significant changes in quality of life subscale scores on Physical Functioning, Role-Physical, Bodily Pain, General Health, Role Emotional, and Mental Health after surgery. A significant change in all subscales occurred 30 days after surgery compared to the baseline and 7 days post-op.

Conclusions: While patients with advanced malignancy experienced problems with quality of life preoperatively, they improved postoperatively but not to the level of a normal person.

Key words: quality of life, advanced breast cancer, advanced gastrointestinal malignancy

A variety of outcome measures collectively referred to as "quality of life" have been studied and included the patients' subjective evaluation of well-being, physical symptoms, sexual function, work performances and satisfaction, emotional status, cognitive function, social participation, and life satisfaction.[1] Quality of life measures have gained increasing attention as outcome variables in studies of cancer and its treatment.[2]

Surgery is an important palliative strategy for patients with advanced malignant disease.[3] Palliative surgery is performed to alleviate symptoms of tumors or complications that can arise from tumors or their treatment. The ultimate goal of palliative surgery is to improve the quality of life for the patient. Quality of life of patients is usually impaired by a number of associated symptoms in advanced cancer irrespective of site. Palliative care is guided by the management of these symptoms which provide care focused on alleviating suffering and promoting quality of life since a cure, as commonly defined, is not possible. Regarding patient satisfaction after palliative surgery, there is a paucity of outcome data.

The Surgical Oncology service of the Department of General Surgery in Vicente Sotto Memorial Medical Center (VSMMC) takes care of quite a number of breast and gastrointestinal malignancies. Patients who are diagnosed with advanced cancer are offered the option of palliative care which involves palliative surgery. Patients with these malignancies suffer a spectrum of progressive symptoms that reduce their quality of life (QoL). Operative palliative strategies seeking to improve QoL and decrease symptom burden are poorly studied. This study seeks to determine patients' satisfaction in terms of quality of life as a measurement of effectiveness of palliative surgery and specifically to compare changes in quality of life over time in advanced breast or gastrointestinal cancer patients before and after palliative surgery.

Methods

This is a prospective longitudinal study of advanced breast or gastrointestinal cancer patients admitted at VSMMC from June 15, 2010 to November 15, 2010. After receiving the approval from the Research Ethics Committee of VSMMC, eligible patients were informed before surgery to solicit their consent in participating in the study. Information about the study protocol, purpose and length of time to participate and complete the study questionnaire were explained to the patients. During the initial contact, an in-depth interview was conducted. Socio-demographic (age and gender), and clinical profile (stages) of patients were elicited. All diagnosed, admitted cases were asked to answer the SF-36™ Health survey questionnaire[4] which served as the primary measure of health related QoL (Appendix A) pre-operatively (Baseline Assessment Period). Each patient was followed up 7 and 30 days post-operatively and was again instructed to answer the same health survey questionnaire each time, to evaluate the impact of surgery on the quality of life over time.

The questionnaire consists of 8 scales describing health related QoL, with a total of 36 questions. The scales are Physical Functioning (PF), Role Function-Physical (RP), Role Function-Emotional (RE), Mental Health (MH), Bodily Pain (BP), General Health (GH), Vitality (VT), and Social Functioning (SF). The scales are grouped into two summary scales: Physical Component Score (PCS) which combines PF, RP, BP, and GH, and Mental Component Score (MCS) which combines VT, SF, RE, and MH. Each subscale is scored from 0 to 100, with 100 being the most favorable score. The data for these scales are presented as T-scores, with a normal healthy population mean score set at 50, and a score of 40 or 60 representing one standard deviation (SD) below or above the mean, respectively. In this norm-based scoring, each scale was scored to have same average (50) and the same standard deviation (10 points). The health status is below average if the scale score is below 50, and each point is one-tenth of a standard deviation.[4]

Descriptive statistics was used to analyze the demographic and clinical profile of the patients. The SF-36v2™ Health survey questionnaires (3 sets per patient) were individually computed using "SF-36v2™ Health Survey Scoring Demonstration" at *http://www.sf-36.org/demos/SF-36v2.html.*[5] For each category, the transformed score represented the raw score. T-test pairs were used to assess whether the mean scores of each subscale at baseline differ significantly from the mean scores of corresponding subscale 7 days or 30 days after surgery. A P-value <0.05 was considered significant.

Results

A total of 32 patients diagnosed with advanced breast or gastrointestinal cancer were included in the study. The patients' ages ranged from 28 to 77 years (mean, 52.84). Majority of the patients were males at 71.3% (22 out of 32). Table 1 shows the breakdown of patients with their corresponding type of cancer. A total of 10 patients had rectal cancer, 10 had colon cancer, 3 had small bowel cancer, 3 had hepatobiliary cancer, 1 had gastric cancer, and 5 had breast cancer. Disease stages at the assessment period were as follows: stage IIIB – 15 patients (46.9%), stage IIIC – 8 patients (25.0%), and stage IV – 9 patients (28.1%).

Baseline, 7 days post-op, and 30 days post-op mean scores and standard deviations for each scale on the SF-36 measure of quality of life is shown in Table 2. The pre-op (baseline) health QoL subscale scores of 32 patients were significantly below the population mean of 50 in all eight subscales of the SF-35v2™. The subscale with the lowest score of 25.9 is Role-Emotional. Results indicate that the patients reported more problems with work or other daily activities as a result of emotional and physical problems.

Seven days post-operatively, though the health status of all 32 patients were significantly below average (QoL subscale scores significantly lower than the population mean of 50), there were significant improvements in all subscales except Vitality and Social Functioning, but these increases are still below the normal population mean score of 50. Compared to their baseline scores, the patients reported statistically significant differences in the Physical Functioning, Role-Physical, Bodily Pain, General Health, Role-Emotional, and Mental Health

Table 1. Demographic and clinical profile.

Age	Gender		Type of Cancer	Total # of Cases	Stage N (%)			%
	M	F			IIIB	IIIC	IV	
28, 58	0	5	Breast	5	5 (15.6%)	0	0	15.6%
66	1	0	Gastric	1	1 (3.1%)	0	0	3.1%
33, 56	2	1	Small Bowel	3	2 (6.2%)	1 (3.1%)	0	9.4%
57, 61	1	2	Hepatobiliary	3	0	0	3 (9.4%)	9.4%
31, 77	9	1	Colon	10	3 (9.4%)	5 (15.6%)	2 (6.2%)	31.2%
43, 72	10	0	Rectum	10	4 (12.5%)	2 (6.2%)	4 (12.5%)	31.2%
	23	9	Total	32	46.9%	25.0%	28.1%	100%

Table 2. Health scoring of 32 patients pre-op, and 7 and 30 days post-op.

SF-36™ Subscales	Preop	7 days post-op	30 days post-op
PhysicalFunctioning (PF)	31.7 ± 8.7	35.5 ± 10.0*	38.5 ± 8.1*
Role-Physical (RP)	31.9 ± 8.9	34.9 ± 8.3*	39.1 ± 7.6*
Bodily Pain (BP)	35.4 ± 6.4	43.8 ± 7.8*	49.8 ± 6.6*
General Health (G)	39.9 ± 7.9	42.1 ± 7.4*	47.2 ± 7.8*
Vitality (VT)	44.4 ± 9.8	46.1 ± 7.6	51.0 ± 7.8*
Social Functioning (SF)	31.6 ± 11.1	33.7 ± 9.4	37.2 ± 8.6*
Role-Emotional (RE)	25.9 ± 9.5	30.2 ± 9.1*	33.7 ± 8.6*
Mental Health (H)	35.3 ± 12.1	37.9 ± 9.7*	42.0 ± 9.4*
PCS	36.4 ± 6.1	40.5 ± 8.3*	45.5 ± 5.8*
MCS	33.9 ± 10.5	35.5 ± 9.0	39.8 ± 8.9*

*Indicate a significant difference from previous health scoring
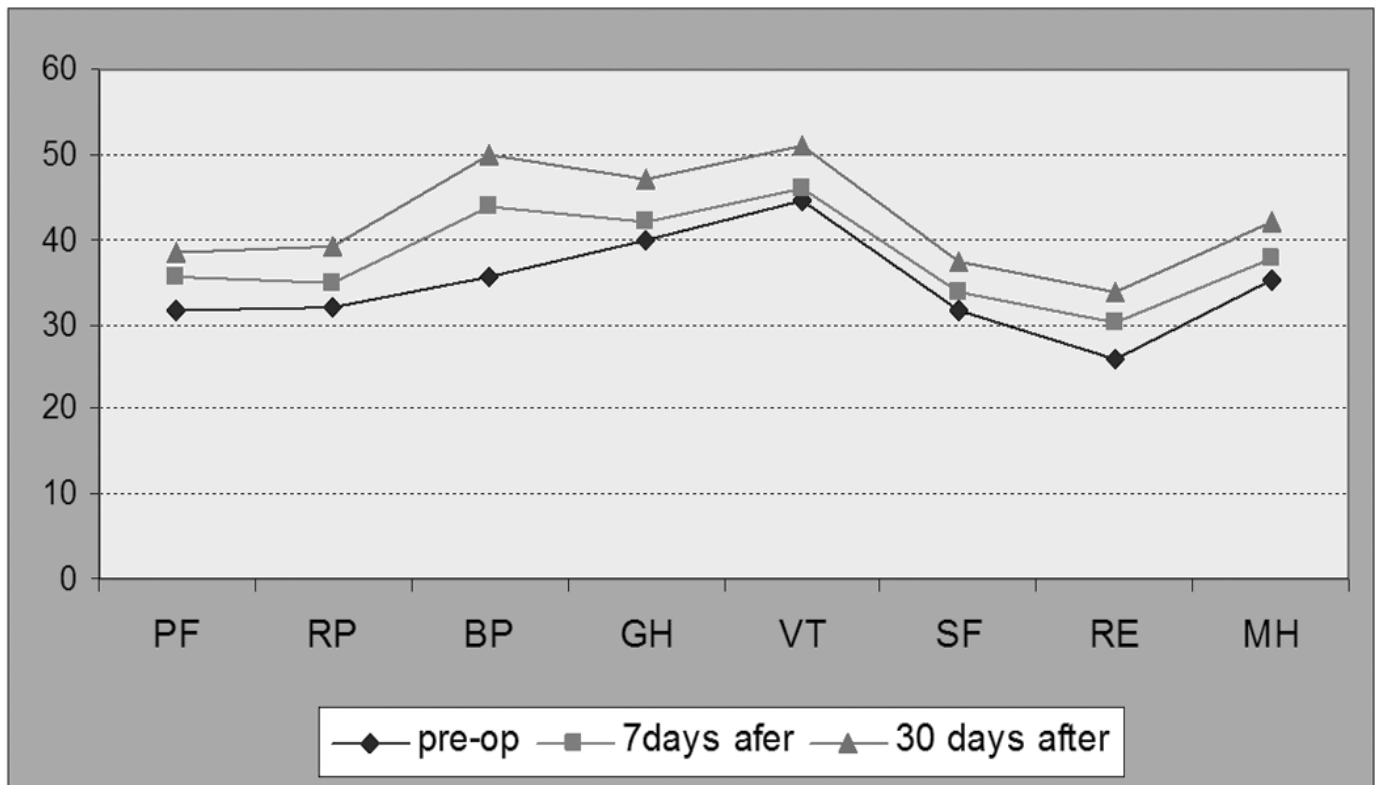
Figure 1. SF-36 QOL subscale scores pre- and post-operatively.

subscales. However, the feeling of being tired and worn-out (Social Functioning) did not change 7 days after surgery. Moreover, the patients reported that their normal social activities were extremely and frequently disrupted due to physical and mental problems. A significant change in all subscales occurred 30 days after surgery compared to the baseline and 7 days post-op. Vitality improved significantly. In general, patients were less worn out and reported some pep and energy 30 days after surgery.

Figure 1 shows a line graph illustrating the SF-36 QOL Subscales Scores while Figure 2 illustrates the Physical and Mental Component Summary Scores pre-op, then 7 and 30 days post-op.

Discussion

The results of the study showed that patients scored poorly (scores below the population mean of 50) in all

eight subscales of the SF-36v2™ preoperatively. Compared to baseline scores, patients reported statistically significant difference in all quality of life dimension scores except in Vitality and Social Functioning subscales seven days after surgery, but these increases are still below the normal population mean score of 50. Similarly, a study by Ngelangel, et al.[2] showed that although there was a trend towards improvement (reduction of nervousness and disturbance in social relationships) of quality of life with control of cancer pain (more so in patients with more severe pain), significant improvement required more than 1 month treatment. In contrast, a study by Sabal, et al.[6] on the Impact of Surgery and Adjuvant Chemotherapy of the Quality of Life of Breast Cancer Patients revealed that health QoL subscale scores were lower after surgery. The successful improvement of quality of life through cancer palliative care goes beyond pain control, and requires control of other symptoms as well as

psychological, social, and spiritual support.[2] Likewise, in a prospective observational study by Amado, et al.[7] on the influence of current treatments on the QoL of patients with metastatic breast cancer, an improvement in QoL was found in the sample evaluated expressed by changes in the overall SF-36 score (P=0.002) and the Beck Depression Inventory (BDI) (P=0.004).

Palliative surgery involves carrying out procedures to reduce the severity of the symptoms of the disease as opposed to finding a cure and to decrease the pain a patient is suffering from and/or to improve their QoL. In this study, bodily pain significantly improved after a palliative procedure. A related study by McCahill, et al.[8] on a prospective evaluation of palliative outcomes for surgery of advanced malignancies illustrates that most symptomatic patients with advanced malignancies undergoing major operations attained good to excellent symptom relief which provides impact to the quality of life.

Conclusion

While patients with advanced malignancy experienced problems with quality of life preoperatively, they improved postoperatively but not to the level of a normal person.

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Neglected Fourth Degree Perineal Laceration with Achievement of Good Continence After Sphincteroplasty, Anoplasty with Skin Advancement Flap - A Case Report

Bryan G. Evangelista, M.D. and Jose Nemesio Granada, M.D., F.P.C.S.

Department of Surgery, St. Paul's Hospital of Iloilo

A case of a 52 year-old female who was admitted due to a neglected 4th degree perineal laceration of 7 years duration due to an obstetrical trauma is reported. The patient presented with severe incontinence preoperatively as graded with the Cleveland Clinic Incontinence Score. Sphincteroplasty and anoplasty with skin advancement flap were done with good continence 2 months postoperatively.

Key words: 4th degree perineal laceration, incontinence, sphincteroplasty, anoplasty

Anal incontinence from sphincter injury at the time of vaginal delivery is more common than had been thought. Numerous case control studies report 6% to 44% of patients after obstetric injury to the anal have some form of anal incontinence despite immediate surgical repair. Sultan and colleagues[1] prospectively studied 202 consecutive pregnant women with multiple modalities and found that although none of the nulliparas entering the study had a sphincter defect before delivery, 35% of primiparous and 44% of multiparous women who delivered vaginally had an internal and/or external sphincter anal defect postpartum. They found that anal incontinence in their study population was significantly associated with the presence of a sphincter defect. Even women without overt injury at the time of vaginal delivery are subject to an increased risk of subsequent impairment of fecal control. Subsequent injuries not only may lead to impaired control for flatus or feces but may also be associated with a fistula between the anus or rectum and the vagina.

The documented injury in our case is a neglected 4th degree perineal laceration of 7 years duration, an unexpected finding in a 52 year old who complained of severe incontinence.

The Case

A 52 year old female consulted at the St. Paul's Hospital of Iloilo and presented with a fourth degree perineal laceration. The condition started 7 years prior to admission when the patient delivered her 4th child at home assisted by a traditional birth attendant. She is a G4P4 (4004) mother, with all deliveries via NSVD. The first three deliveries were at a tertiary hospital with good prenatal consultations.

Her past medical history and family medical history were unremarkable.

The perineal laceration was identified at the time of delivery by the birth attendant but no appropriate management could be performed at that time. The patient was advised but decided not to consult an obstetrician for the problem. Since then, the patient had occasional episodes of incontinence described as occasional soiling of undergarments on liquid stools and gas.

The patient was seen initially by the Obstetrics and Gynecology Service and was subsequently referred to the Surgical Service for further management.

On rectal examination, a grade 4 perineal laceration was noted with the anterior rectal wall having continuity with the posterior vaginal wall. The perineal body was absent. Digital rectal examination revealed a lax sphincteric tone, and no other masses were palpated.

Figure 1 shows a photo of the preoperative findings in the perineum.

Figure 1. Pre-operative findings.

Pre-operatively, incontinence was assessed using the Cleveland Clinic Incontinence Score as shown.

The patient had a score of 16 points and was assessed to have severe incontinence. Pre-operative anoscopy revealed complete separation of the recto-vaginal wall with a 6 centimeter tear from the anal verge to the rectum.

With the patient in prone jack knife position, bilateral full thickness skin advancement flaps were created by creating a cruciate incision across the presumed area of the perineal body for the anoplasty. Figure 2 shows the development of these flaps.

Dissection was carried out to separate the vaginal mucosa from the rectum. The vaginal mucosa was repaired with continuous interlocking suturing with vicryl 3-0, while the redundant mucosa was excised. The plane of the internal and external anal sphincters could not be identified separately. The edges of the sphincters were overlapped and repaired with continuous interlocking suturing with vicryl 3-0. The apices of the flaps were advanced and interdigitated to create a new perineal body separating the vagina to the anorectum. A Penrose drain was left in place for three days. Figures 3 and 4 show the sphincteroplasty done and position of the flaps.
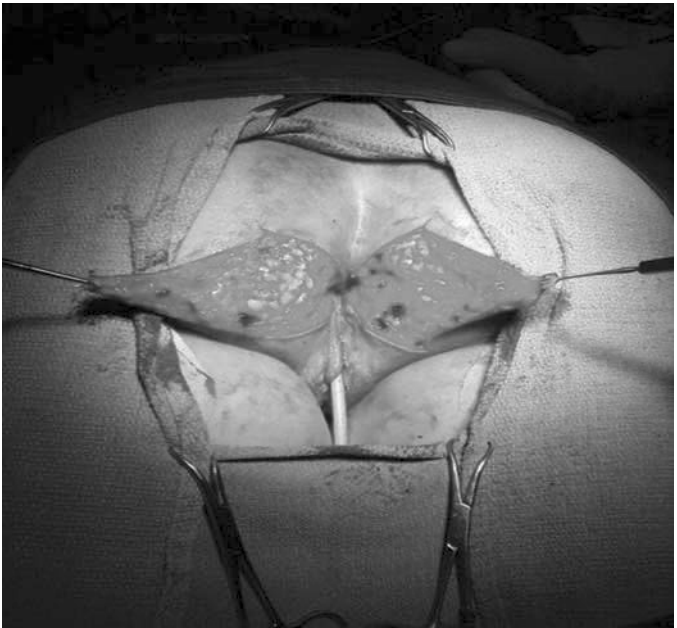

Wexner/ Cleveland Clinic Faecal Incontinence Symptom Severity Scoring System

Name: _____   Score: **/20**

Type of Incontinence		Frequency			
	Never	Rarely < 1/month	Sometimes < 1/week, > or equal 1/month	Usually < 1/day, > or equal to 1/week	Always > or equal to 1/day
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears Pad	0	1	2	3	4
Lifestyle Alteration	0	1	2	3	4

CCIS   0   Perfect continence
CCIS   1-7   Good continence
CCIS   8-14   Moderate incontinence
CCIS   15-20   Severe incontinence
CCIS   21   Completely incontinent

Figure 2. Skin flaps created.

Figure 3. Sphincteroplasty.

Figure 4. Repair completed.

Postoperatively, the patient was started on general liquids on the 2nd postoperative day and maintained on antimotility agents for 6 days. Patient had bowel movement on the 4th postoperative day. Patient was discharged on the 5th postoperative day.

The patient was seen on the first and second month postoperatively. On her last consultation, she had a Cleveland score of 6 and was assessed to have good continence.

Discussion

Anal incontinence may not be a life-threatening disease but is a traumatizing and often disabling condition. Many patients feel so inhibited and are so stigmatized by the affliction that they are reluctant to discuss the problem with a physician. There are limited reports of the incidence of incontinence, which may approximate 1% of individuals older than 65 years of age, but soiling of underclothes, incontinence for flatus, anal discharge, and even loss of fecal control are undoubtedly quite common complaints. Nelson and colleagues attempted to determine the prevalence and characteristics of anal incontinence in the general community.[2] A total of 2,570 households comprising almost 7,000 individuals were surveyed with overall incidence at 2.2%. Thirty percent were older than 65 years, and approximately two thirds were women.

Anal incontinence can result from a disturbance of any one or more of the mechanisms that normally ensures continence: central nervous system damage, spinal cord damage, peripheral nerve injury and disease, loss of afferent sensory component of the rectosphincteric reflex, disease that impair striated muscle and direct muscle damage that occurs with perianal disease or surgical trauma. The causes of fecal incontinence may be a myriad of pathologies including surgical trauma including obstetrical trauma, colorectal disease, congenital anomalies, neurologic disease and many other.

Obstetrical trauma as a cause of anal incontinence is more common as had been thought. Although most injuries to the anal sphincter, so-called third-degree lacerations, are recognized and repaired by the obstetrician, adverse consequences can ensue. Pollack and colleagues prospectively evaluated 349 consecutive

nulliparous patients before pregnancy and at 9 months and 5 years following delivery.[3] Thirty-eight suffered sphincter injury during the delivery (10.8%). In spite of the repair, almost half of the responders reported anal incontinence at 9 months, whereas slightly more than half noted incontinence at 5 years. If these women had a subsequent vaginal delivery, almost two thirds experienced incontinence symptoms. de Leeuw and co-workers found that 12 of their 34 patients (35%) who suffered sphincter injury at the time of delivery experienced bowel control difficulty.[4] Sphincter defects were demonstrated in the majority.

Risk factors for obstetric anal sphincter injury include the following: birth weight over 4kg, persistent occipitoposterior position, nulliparity, induction of labor, epidural analgesia, second stage longer than 1 hour, shoulder dystocia, midline episiotomy, forceps delivery. Of this enumerated risk factors for incontinence, physiologic studies on postpartum women showed multiparity, forceps delivery, increased duration of second stage of labor and high birth weight may lead to pudendal nerve damage and sphincter atrophy even without gross injuries were noted on the sphincters. Chaliha, et al. cited that vaginal delivery is associated with a decrease in anal pressures and increased anal sphincter trauma but has no effect on anal sensation.[5] Furthermore, they noted that postpartum anal endosonographic examination revealed sphincter disruption in 38% of women in their study.

Ideally, complete work up for anal incontinence consists of complete history and physical examination, coupled with a myriad of physiologic studies including: electromyography, nerve conduction studies, anorectal manometry, computerized vector manometry, proctometrography or ampullometrography and defecometry, balloon proctography, defecography and videoproctography, scintigraphic defecography, anal endosonography and MRI. Unfortunately, the lack of these modalities in our locality, evaluation of incontinence largely relies on physical examination and patients complaints.

One of the concerns of interpreting data from numerous reports on anal incontinence has been the lack of a convenient classification system, defining the degree and type of anal incontinence. Currently, the most widely used continence rating scale had been the Cleveland Clinic Incontinence Score proposed by Jorge and Wexner in 1993. This scale is determined by adding points from the table, which takes into account the type and frequency of incontinence and the extent to which it alters patient's life.

The patient had a preoperative score of 16, interpreted as having severe incontinence (solid-1, liquid-3, gas-4, wears pad-4, lifestyle alteration-4).

Treatment of anal incontinence is directed to the cause, thus successful surgical repair requires an understanding of the underlying pathology. Patients who attribute their incontinence to trauma are optimal candidates for repair. The two primary methods of surgical treatment are direct repair of a localized sphincter defect and repair designed to supplement the sphincter mechanism. Direct sphincter repair techniques include the following: apposition of sphincter muscles, overlapping of sphincter muscles, plication (reefing) of sphincter muscles, postanal pelvic floor repair (i.e., Parks' procedure), narrowing of the anal canal and use of perineal muscles other than the anal sphincter as enumerated by Corman.[6] Repairs that supplement the sphincter mechanism includes Gracilis muscle transposition, bilateral Gracilis muscle transposition and Gluteus muscle transposition.

In the acute setting, the initial treatment usually consists of debridement of non-viable tissues, removal of foreign material, open drainage and often proximal colostomy with distal washout. Sorensen, et al. studied delayed primary or early secondary repair after third-degree or fourth-degree anal sphincter rupture.[7] Delayed primary reconstruction was performed more than 72 hours after delivery while early secondary reconstruction was performed within 14 days postpartum all without a covering stoma. The results revealed the safety of performing a delayed primary or early secondary reconstruction with acceptable long term functional outcome. However in the chronic setting, as in this case, direct repair of a localized sphincter defect is difficult as anatomic structures may already be distorted or obliterated by scar. The treatment approach should include excision of skin eschar and definition of the sphincter muscle and preservation of the fibrous ends for securing and suturing.

Three standard operations for repairing the injured sphincters are apposition, overlapping and placation or reefing. The surgeon attempts to repair the external sphincter muscle, puborectalis sling or both. The internal sphincter, as in this case, is usually either unidentifiable or inadequate meaningfully to the result. Intraoperatively, since adequate sphincter muscle remained and the defect after dissection was not excessive, an overlapping technique was used. Corman reported that with this technique, breakdown of the repair is less likely, and the results tend to be better.[6] However, in a recent study by Farrell, evidence showed no difference in symptomatic outcomes between the end-to-end (apposition) or the overlapping repair of external anal sphincters.[8]

It is very difficult to evaluate the relative merits of different operations for the treatment of fecal incontinence because of the rarity of prospective, randomized trials. However for this case, where an overlapping sphincteroplasty and anoplasty was done, results were remarkably good with achievement of good continence (Score of 6: solid-1, liquid-1, gas-2, wears pad-1, lifestyle alteration-4) from a preoperative assessment of severe incontinence (Score of 16: solid-1, liquid-3, gas-4, wears pad-4, lifestyle alteration-4).

In summary, a case of a 59-year old female with a neglected fourth degree perineal laceration with accompanying severe incontinence was presented. Sphincteroplasty, anoplasty with skin advancement flap was done with good continence 2 months post operatively was achieved.

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