METHODS: Eleven patients with FIAF were compared with 11 patients with idiopathic fecal incontinence and with 11 asymptomatic healthy subjects (HS). All of the study participants underwent anorectal manometry and a barostat study (rectal sensitivity, tone, compliance and capacity). The mean time since surgery was 28 ± 26 mo. The postoperative continence score was 14 ± 2.5 (95%CI: 12.4-15.5, St Mark's fecal incontinence grading system).

RESULTS: Compared with the HS, the FIAF patients showed increased rectal tone (42.63 ± 27.69 vs 103.5 ± 51.13, P = 0.002) and less rectal compliance (4.95 ± 3.43 vs 11.77 ± 6.9, P = 0.009). No significant differences were found between the FIAF patients and the HS with respect to the rectal capacity; thresholds for the non-noxious stimuli of first sensation, gas sensation and urge-to-defecate sensation or the noxious stimulus of pain; anal resting pressure or squeeze pressure; or the frequency or percentage of relaxation of the rectoanal inhibitory reflex. No significant differences were found between the FIAF patients and the patients with idiopathic fecal incontinence.

CONCLUSION: In patients with FIAF, normal motor anal sphincter function and rectal sensitivity are preserved, but rectal tone and compliance are impaired. The results suggest that FIAF is not due to alterations in rectal sensitivity and that the rectum is more involved than the anal sphincters in the genesis of FIAF.

Key words: Fecal incontinence; Anorectal surgery; Fistulotomy; Visceral sensitivity; Barostat

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Abstract
AIM: To investigate the anal sphincter and rectal factors that may be involved in fecal incontinence that develops following fistulotomy (FIAF).
been reported that rectal distensibility and thresholds for sensations decrease after hemorrhoidopexy, and that the perception of rectal distension is not always reduced in FI. In our patients with FI after fistulotomy (FIAF), anal sphincter function and rectal sensitivity are preserved, but rectal tone and compliance are impaired. The results suggest that FIAF is not due to alterations in rectal sensitivity and that the rectum is more involved than the anal sphincters in the genesis of FIAF.

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INTRODUCTION

Fecal incontinence (FI) results in poor quality of life[1], FI can appear spontaneously (idiopathic)[2], secondary to systemic diseases or traumatic events, as a result of congenital alteration[3], or after pelvic radiation or anorectal surgery. Fistula in ano is a common proctological disease[4]. Anorectal abscess is very frequent in adults[5]. About 40% of such abscesses result in fistulas[5]. Fistulas are usually treated surgically; postoperative anal incontinence is common, and the recurrence rate is high for complex fistulas. Of the various possible surgical approaches, fistulotomy is the treatment of choice, although all of the surgical treatments are associated with success rates ranging from 30%-80%[6]. The reported incidence of postsurgical incontinence varies according to the procedure performed[7,8]: 20% for fistulotomy, 11.6% for fistulotomy with end-to-end primary sphincteroplasty, 20.3% for fistulotomy treating intersphincteric fistula, 13% for complex fistulae undergoing sphincter division, 12% for the cutting seton fistulotomy, and 6% for the ligation of the intersphincteric fistula tract procedure. It has been reported that FI can present as a late complication of anal fissures[10] or other anorectal procedures[11]. It has also been demonstrated that rectal distensibility and the volume thresholds for sensations decrease after stapled hemorrhoidopexy[12], and the perception of rectal distension is not always reduced in FI[13]. The lack of a universal and effective treatment for FI highlights the need to investigate the underlying mechanisms and develop new therapeutic targets. These mechanisms can be assessed by an electronic barostat, measuring the visceral afferent sensation[14], and by anorectal manometry, measuring motor function in patients with FI after anorectal surgery. This work intended to recognize the rectal and anal sphincter factors that might contribute to the development of fecal incontinence after fistulotomy (FIAF).

MATERIALS AND METHODS

Subjects

The work was conducted at the Experimental Medicine and Motility Unit in the Mexico City General Hospital. The Ethical and Research board approved the protocol, and signed informed consent was obtained from all the subjects. The study was performed in accordance with the Declaration of Helsinki and its subsequent revisions. The epidemiological and clinical data obtained for all of the outpatients presenting with FIAF during a 12-mo period at our motility tertiary unit were saved in a file. The inclusion criteria were being older than 18, having FI for a minimum of 6 mo after anorectal surgery, and giving consent for the study. The exclusion criteria were previous non-anorectal and anorectal surgery, idiopathic or postpartum FI, pelvic radiation, treatments affecting the smooth muscles during the precedent month, a state of pregnancy or nursing, any concomitant disease, and psychiatric alterations. Eleven patients who suffered from anal fistulae (mean age 45 ± 8, range 34-67 years) were enrolled in the study. One patient presented with chronic anal pain. Demographic data and etiology of fistula are shown in Table 1. The laboratory test parameters (chemistry panel, coproparasitoscopic studies, and amoeba assessment) performed on all of the patients was normal. None of the patients had presented with FI before anorectal surgery. The severity of FI after anorectal surgery was graded using the St. Mark's fecal incontinence grading system (minimum score = 0 = perfect continence; maximum score = 24 = totally incontinent)[15].

Controls

The controls were 11 patients with idiopathic FI (mean age 48 ± 17, range 17-71 years) and healthy subjects (HS) who voluntarily agreed to participate in the study as controls. None of the healthy controls was a proctologic patient. Due to ethical restrictions against the performance of manometry and barostat procedures on the same group of volunteers, a different group of subjects was utilized as controls for the manometry (n = 11, mean age 22 ± 2 years, 10 females) and barostat (n = 10, mean age 25 ± 7 years, three females) procedures. However, all patients underwent clinical history, laboratory test, recto-sigmoidoscopic (Welch Allyn 32823 sigmoidoscope, Skaneateles Falls, NY, United States), anorectal manometry (MMS, AN Enschede, The Netherlands) and barostat rectal sensitivity studies (Distender II; G. J. Electronics, Toronto, Canada).

Study and distension protocol

The methodology that we use regularly in our laboratory to evaluate visceral sensation has already
The mean body mass indices of the FIAF patients (29 ± 3 kg/m²), the idiopathic FI patients (27 ± 3 kg/m²) and the HS (26 ± 5 kg/m²) in the barostat group were similar and not significant. The average time for the FIAF patients since surgery was over two years (28 ± 26 mo; 95%CI: 10.8-45.3). All of the patients suffered FI. The mean postoperative continence score was 14 ± 2.5 (95%CI: 12.4-15.5) based on St Mark’s faecal incontinence grading system. The results of laboratory tests and the recto-sigmoidoscopy were normal in all patients.

Rectal tone, compliance and capacity
As shown in Table 2, there was no difference in the IOP between FIAF patients (8.7 ± 1 mmHg; 95%CI: 7.7-9.6), idiopathic FI patients (7.9 ± 10 mmHg; 95%CI: 7.8-8; P = 0.10) and the HS (9.6 ± 2 mmHg; 95%CI: 8.3-10.8; P = 0.28). The rectal bag volume was lower in the FIAF patients compared with the HS (P = 0.002), indicating an increased smooth muscle tone in the rectum of the FIAF patients (Table 2). Rectal bag volume in the FIAF patients compared with the idiopathic FI patients was not different (P = 0.12; Table 2).

The FIAF patients showed less rectal compliance (mL per mmHg; P = 0.009; Table 2) than the HS. There was no significant difference in the rectal capacity (balloon volume at the maximum imposed pressure) of the FIAF patients compared with the HS (P = 0.73; Table 2).

Sensory thresholds to rectal distension
As shown in Table 2, the FIAF patients reported their first sensations and noxious stimulus of pain at levels that were not significantly different from the idiopathic FI patients and HS.

Anorectal manometry
There was no significant difference in the anal resting or squeeze pressures or the frequency or percentage of relaxation of the spontaneous rectoanal inhibitory reflex (RAIR) of the FIAF patients and the idiopathic FI patients and the HS (Table 2).

DISCUSSION
FI is generally considered to be primarily related to the dysfunction of the anal sphincters. Interestingly, the present study demonstrated that in patients with FIAF, the function of the internal anal sphincter is preserved. Normal sphincter function in FI was reported by Siproudhis et al. who found that one-third of their subjects who suffered from FI had anal manometry values within the normal range. This finding was more recently supported by Burgell et al., who reported that only one-third of 160 male patients with FI demonstrated sphincter dysfunction.

In our study, the anal squeeze pressure of the FIAF patients was not significantly different than that of the idiopathic FI patients and the HS. This finding is in contrast with that of Bharucha et al., who reported lower anal squeeze pressures in women with idiopathic FI compared with healthy controls. The etiology of this incontinence may explain this discrepancy. However, the fact that our study included both men and women may be significant because squeeze pressure has been reported to be higher on average in men than women.

Table 1  Demographic data and etiology of fistulotomy

| Case | Age | Gender | Etiology | Type |
|------|-----|--------|----------|------|
| 1    | 38  | Male   | Idiopathic (perianal abscess) | Simple |
| 2    | 34  | Male   | Idiopathic (perianal abscess) | Simple |
| 3    | 67  | Female | Idiopathic (perianal abscess) | Simple |
| 4    | 50  | Male   | Idiopathic (abscess) | Complex |
| 5    | 39  | Male   | Idiopathic (abscess) | Simple |
| 6    | 45  | Female | Idiopathic (abscess) | Simple |
| 7    | 42  | Female | Iatrogenic (miotomy) | Simple |
| 8    | 47  | Female | Iatrogenic (surgery) | Simple |
| 9    | 48  | Male   | Idiopathic (abscess) | Simple |
| 10   | 47  | Male   | Idiopathic (inter-sphincteric abscess) | Complex |
| 11   | 41  | Female | Idiopathic (inter-sphincteric abscess) | Complex |

been published in detail elsewhere. In brief, we have reported that rectal visceral sensitivity is evaluated with an electronic barostat that is a tool that keeps a constant pressure in an air-filled bag through a feedback mechanism. This cylindrical ultra-thin polyethylene bag (Mui Scientific, Ontario, Canada) has infinite compliance and reaches 600 mL. The individual operating pressure (IOP) is defined as the minimum pressure required to overcome passive resistance to bag inflation. To obtain muscle tone, the bag is inflated to the IOP, and the volume recorded over a 15-min period. We and others investigators have also reported that the barostat using the ascending method of limits procedure performs rectal distension for one minute, with increase of 4 mmHg each time and separated by periods of a minute, in which the bag pressure returns to the IOP. The distensions continue until the subject reports pain, press the panic button or reach a pressure of 48 mmHg.

Statistical analysis
The outcome measures were the anorectal manometry and barostat results in patients with FIAF compared with that of the idiopathic FI and HS. A 95%CI was analyzed for all of the variables and used when was appropriate. The results are expressed as means ± SD. P < 0.05 and Student’s two-tailed t tests were utilized. The statistical analyses were performed using 2000 GraphPad Software (San Diego, CA, United States).

RESULTS
Subjects
The mean body mass indices of the FIAF patients (29 ± 3 kg/m²), the idiopathic FI patients (27 ± 3 kg/m²) and the HS (26 ± 5 kg/m²) in the barostat group were similar and not significant. The average time for the FIAF patients since surgery was over two years (28 ± 26 mo; 95%CI: 10.8-45.3). All of the patients suffered FI. The mean postoperative continence score was 14 ± 2.5 (95%CI: 12.4-15.5) based on St Mark’s faecal incontinence grading system.

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In our study, the anal squeeze pressure of the FIAF patients was not significantly different than that of the idiopathic FI patients and the HS. This finding is in contrast with that of Bharucha et al., who reported lower anal squeeze pressures in women with idiopathic FI compared with healthy controls. The etiology of this incontinence may explain this discrepancy. However, the fact that our study included both men and women may be significant because squeeze pressure has been reported to be higher on average in men than women.

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| 11   | 41  | Female | Idiopathic (inter-sphincteric abscess) | Complex |
in women\textsuperscript{[23]}. In addition, our data partially agree with Lindsey \textit{et al}\textsuperscript{[24]} who reported that the maximum squeeze pressure was normal in 52% of 93 patients with FI after anal surgery.

In the current study, there was no difference in the RAIR parameters of the FIAF patients, the idiopathic FI patients and the HS. This finding is inconsistent with a recent study that reported differences in RAIR parameters between incontinent and normal cohorts\textsuperscript{[25]} as well as with another study that reported a reduced frequency of RAIR in patients with idiopathic FI compared with normal controls\textsuperscript{[26]}.

Different methods and etiology of incontinence could explain this disagreement. The presence of RAIR may exclude neuropathy as a factor related to FIAF. It is therefore necessary to identify other potential participants in the continence mechanism, such as the rectum.

In the present study, the FIAF patients and the idiopathic FI patients demonstrated higher rectal tone than the HS. This finding is inconsistent with that of Worsøe \textit{et al}\textsuperscript{[26]}, who reported that in patients with idiopathic FI, the rectal tone during fasting is similar to that of HS. Since we used a barostat technique and Worsøe \textit{et al}\textsuperscript{[26]} used rectal distensibility in 12 patients, differences in the methodology and etiology of incontinence may account for the different results.

Compared with the HS, the FIAF patients demonstrated lower rectal compliance (distensibility). This finding is consistent with that of Corsetti \textit{et al}\textsuperscript{[12]}, who reported that rectal distensibility decreases after a stapled hemorrhoidopexy, and Krol \textit{et al}\textsuperscript{[27]}, who reported that a different form of rectal damage from prostate radiotherapy can also lead to reduced rectal distensibility. Considering that fecal continence requires the relaxation of the rectal wall\textsuperscript{[28]}, post-surgery rectal wall stiffness may explain the observed alteration in the tone and rectal distensibility. Related to this fact is a report that increased rectal wall stiffness after radiotherapy alters the rectal distensibility, most likely by fibrosis\textsuperscript{[27]}.

Furthermore, patients with FI and sphincter defects have been reported to have a reduced rectal capacity\textsuperscript{[29]}. Our results do not agree with this report; our patients with FIAF and idiopathic FI demonstrated rectal capacities similar to those of the HS. Thus, not all FIAF patients present with a reduced rectal capacity after surgery. Our data are consistent with a report that only 25% of women with idiopathic FI have a reduced rectal capacity\textsuperscript{[29]}.

The thresholds for the first, gas and urge-to-defecate sensations as well as the noxious stimulus of pain sensation were similar in FIAF patients, idiopathic FI patients and the HS. Our results differ from those of Burgell \textit{et al}\textsuperscript{[22]}, who reported that one-sixth of incontinent men have rectal hyposensitivity, Bharucha \textit{et al}\textsuperscript{[29]}, who demonstrated rectal hypersensitivity in women with idiopathic FI, and Chan \textit{et al}\textsuperscript{[30]}, who reported that approximately 50 percent of their patients with urge FI demonstrated rectal hypersensitivity. Because we utilized a barostat technique while others typically evaluated sensory threshold volume during balloon distension performed with a hand-held syringe, the etiology of incontinence through differences in methodology may account for these discrepancies. However, it should be noted that in a preliminary report, we have described rectal hyposensitivity in patients with FI after sphincterotomy\textsuperscript{[31]}, and we have also described rectal hyposensitivity in subjects with complete spinal cord injury with neurogenic bowel dysfunction\textsuperscript{[14]}. Interestingly, irradiation for prostate cancer that reduced rectal distensibility did not affect the thresholds of rectal sensation\textsuperscript{[27]}. Therefore, based on these findings, we can infer that FI appearing after fistulotomy is not due to alterations in rectal sensitivity.

We recognize that the small number of subjects

| Table 2  Physiological data | Fecal incontinence after Fistulotomy ($n = 11$) | Idiopathic fecal incontinence ($n = 11$) | Healthy subjects ($n = 11$) | $P$ value |
|-----------------------------|-----------------------------------------------|------------------------------------------|-----------------------------|-----------|
| Barostat                     |                                               |                                          |                             |           |
| IOP (mmHg)                  | 8.7 ± 1.6                                     | 7.9 ± 0.1\textsuperscript{*}             | 9.6 ± 2.1                   | 0.106     |
| Tone (bag volume, mL)        | 42.6 ± 27.7\textsuperscript{*}                | 63.6 ± 34.1\textsuperscript{*}           | 103.5 ± 51.1                | 0.129     |
| Compliance ($v/p$)           | 5 ± 3.4\textsuperscript{*}                    | 8.1 ± 4.3                                | 11.8 ± 6.9                  | 0.075     |
| Rectal capacity (mL)         | 314.7 ± 76.1                                  | 332.6 ± 97.1                             | 302.9 ± 82.3                | 0.636     |
| First sensation (mmHg)       | 15.8 ± 31                                     | 16.6 ± 4.2                               | 14.1 ± 4.5                  | 0.627     |
| Gas sensation (mmHg)         | 22.4 ± 3.3                                    | 20.5 ± 3.6                               | 18.4 ± 6.9                  | 0.381     |
| Urge defecate (mmHg)         | 28.1 ± 6.6                                    | 30.5 ± 10.9                              | 22.5 ± 7.2                  | 0.600     |
| Pain sensation (mmHg)        | 36.8 ± 7.2                                    | 34.1 ± 8.4                               | 35.9 ± 8.8                  | 0.480     |
| Anal resting pressure (mmHg) | 41.7 ± 24.3                                   | 44.2 ± 18.2                              | 34.9 ± 22.9                 | 0.791     |
| Anal squeeze pressure (mmHg) | 94.1 ± 88.8                                   | 109.9 ± 88.9\textsuperscript{*}          | 43.2 ± 24.9                 | 0.680     |
| Spontaneous RAIR frequency (#)| 1.9 ± 2.8                                     | 1.5 ± 1.5                                | 1.4 ± 1.6                   | 0.641     |
| Induced RAIR relaxation (%)  | 66.3 ± 20.5                                   | 63.4 ± 16.7                              | 74.4 ± 31.6                 | 0.721     |
| Induced RAIR duration (s)    | 18.4 ± 6.7                                    | 22.3 ± 6.5                               | 19.8 ± 5.9                  | 0.168     |

\textsuperscript{*}P < 0.05 vs healthy subjects. All data represent the mean ± SD. FIAF: Fecal incontinence after Fistulotomy; IFI: Idiopathic fecal incontinence; HS: Healthy subjects; RAIR: Rectoan inhibitory reflex; IOP: Individual operating pressure.
limits the power of this work and that a small study is at risk to a type-II error. Nevertheless, it is reported that in such cases, power is properly indicated by CI\textsuperscript{(22)}, which we used in this work. Another limitation could be that we did not perform rectal sensitivity studies before surgery. However, due to the large number of colorectal surgical procedures performed\textsuperscript{(23)}, it is not reasonable to perform barostat procedures on all of these patients before surgery. Because only a small percentage of patients develop incontinence after surgery\textsuperscript{(8)}, a comparison of data from FIAF patients with idiopathic FI patients and with HS constitutes a more reliable assessment of physiological and structural changes.

In summary, the finding that internal anal sphincter function is preserved in FIAF patients but rectal tone and compliance is impaired compared with HS suggests that the rectum is more involved than the internal anal sphincter in the genesis of FIAF. Furthermore, based on these results, we can infer that FI that appears after fistulotomy is not due to alterations in rectal sensitivity. Therefore, surgeons should be careful to preserve the rectal anatomy and neural networks as much as possible when performing anorectal surgery.

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