A Randomized Clinical Trial to Compare Two Different Approaches in Women With Chronic Pelvic Pain

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One hundred six patients with chronic pelvic pain were randomly allocated to one of two treatment groups. In the standard-approach group, organic causes of pelvic pain were excluded first and diagnostic laparoscopy was routinely performed. If no somatic cause could be found, attention was given to other causes such as psychological disturbances. In the second group an integrated approach was chosen. From the beginning equal attention was devoted to somatic, psychological, dietary, environmental, and physiotherapeutic factors. In this group, laparoscopy was not routinely performed. Both groups were similar with respect to clinical characteristics of the patients and the severity of their pain as assessed by various pain parameters. Postcoital pain was reported by 27% of the patients. Twenty percent of the patients had had negative sexual experiences such as childhood sexual abuse or rape. Evaluation of the pain 1 year after the institution of treatment revealed that the integrated approach improved pelvic pain significantly more often than the standard approach for three out of four pain parameters ($P < .01$). Laparoscopy played no important role in the treatment of pelvic pain. It is concluded that equal attention to both organic and other causative factors from the beginning of therapy is more likely to result in a reduction of pelvic pain than is a standard approach. (*Obstet Gynecol 77:740, 1991*)

The number of studies on chronic or recurrent pelvic pain in women bears no relation to the frequency of this complaint or to the clinical and scientific problems that still need to be solved in this area. Chronic pelvic pain is often labeled "the disease with twenty different names." Unfortunately, it tends to be managed using even more different treatment methods, often with little improvement.[1] Traditional medical treatment for these problems includes hormonal manipulation and nonsteroidal anti-inflammatories, yet these are often not appropriate.

Because unresolved continuing pain is unacceptable to both the patient and her doctor, it is not surprising that eventually a decision to operate is frequently made. Numerous types of operations have been advocated for chronic pelvic pain, such as antefixation of the retroverted uterus, hysterectomy with or without unilateral or bilateral salpingo-oophorectomy, presacral neurectomy, and adhesiolysis. Follow-up studies with adequate assessment of the results of the surgical procedure are, however, lacking.[2] Somatic fixation is a real problem with such a unilateral somatic approach. On the other hand, addressing only the psychosocial or psychiatric aspects of chronic pelvic pain carries similar risks.

Chronic pelvic pain does not constitute a single, well-defined category of symptoms and findings on physical examination, nor is a single well-defined course of action the most appropriate way to deal with this complaint. During the past decade, the standard treatment approach to chronic pelvic pain at the Leiden University Medical Center was to exclude all organic causes convincingly before devoting any attention to other potential causative mechanisms. This approach included routine laparoscopy in every case. Retrospective analysis revealed little or no beneficial effect of laparoscopy.[3] Furthermore, access to psychosocial care was notoriously unsatisfactory, possibly because of excessive somatization. Apparently, referral for such care was interpreted by these patients as an indication that their complaints were not considered serious enough. Recently some studies have been published in which an alternative approach was adopted for chronic nonmalignant pain. A multidisci-

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Table 1. Admission Criteria of Patients Suffering From Chronic Pelvic Pain

Criteria
Presence of chronic pelvic pain for at least 3 months
No suspicion of malignancy or disease which needed prompt intervention at gynecologic examination
No history of psychiatric or psychotherapeutic treatment for abdominal pain in a period of 2 years preceding the first visit to the outpatient clinic
No elaborate medical analysis in connection with abdominal pain in the 2 years preceding the first visit to the outpatient clinic
No ongoing medical treatment for pelvic pain elsewhere
No problem with the Dutch language
No mental retardation

plinary approach in both inpatient and outpatient pain management programs produced improvements in illness-related behavior and psychological distress as compared with a control group.[4] Kames et al[5] showed that a multidisciplinary approach was effective for chronic pelvic-pain patients for whom standard gynecologic procedures were inappropriate or unsuccessful. The interdisciplinary program included somatic and behavioral therapies. The results of multidisciplinary pain management are often long-lasting.[6]

These findings led us to design and conduct a prospective study to compare this treatment policy with the standard treatment approach as described above. This paper presents the results of this study.

Materials and Methods

A prospective randomized clinical trial was conducted in which women with chronic pelvic pain were assigned to an integrated approach or to the standard form of care described above. Pelvic pain patients were recruited from the outpatient clinic of the Department of Gynecology of the Leiden University Medical Center between January 1, 1983 and January 1, 1987. Secondary- and tertiary-care patients are referred to this clinic. Patients were entered in the study after fulfilling the entry criteria and after providing verbal and written informed consent. Table 1 details the intake criteria of the study.

All patients were seen by a gynecologist at their first visit to the clinic. If pelvic examination revealed any abnormality, additional tests were performed. The second visit of all patients was to a psychologist who took a detailed history of the extent and nature of the pain. After these two visits, randomization was done by means of a closed-envelope procedure.

The first arm consisted of the standard treatment, in which comprehensive exclusion of organic causes of chronic pelvic pain was performed before attention was devoted to other causes such as psychological disturbances. In this group, laparoscopy was routinely performed. In the other treatment arm, an integrated approach was chosen from the beginning. Guidelines for this approach followed the pain model as described for example by Loeser.[7] The model comprises four components: nociception, pain sensation, pain suffering, and pain behavior. In this arm, equal attention was devoted to possible organic, psychological, dietary, and environmental causes of the pain. A consultation with a physiotherapist was also routinely included. The physiotherapist examined physical ability with attention to the abdominal and pelvic-floor muscles. Provocation tests were performed. In this group, laparoscopy was not routinely performed.

In each group, a diagnosis was made within 1 month and an appropriate therapy was instituted after 3 months. This therapy usually took 6 months. One year later, a second detailed assessment of the various pain parameters was performed. This was done by an investigator unaware of the treatment arm to which the patient was allocated.

The following methods were used in both groups for measuring pain at the beginning and at the evaluation 1 year after finishing the treatment: 1) an extensive pain history with attention to the interference of the pain in the daily activities of the patients; 2) the presence of associated symptoms such as backache, nausea, fatigue, headache, vertigo, and insomnia as described by Duncan and Taylor[8]; 3) a pain calendar with attention to fluctuations of the pain during the day, with the menstrual cycle, or with provocations; and 4) a pain questionnaire according to the card sort method of McGill.[8] This questionnaire would be suitable for investigating the multidimensional character of chronic pelvic pain and takes into consideration the sensory, emotional, affective, and temporal aspects of pain.[9] It results in a score of 10 (minimal pain) to 40 (maximal pain).

The results of both groups were analyzed statistically by means of χ^2 test or 2×2 table.

A total of 112 patients were entered into the study. One hundred six of these patients were evaluable: 49 patients in the standard-treatment arm and 57 in the integral-approach group. The six patients who were not evaluable had all been allocated to the standard-treatment group. The reasons for not completing the study were all associated with contraindications to laparoscopy under general anesthesia, which could not have been anticipated at the start of the study. Contraindications included pregnancy, ileus or subileus, or exacerbation of a chronic pulmonary condition. These six patients did not differ from the evaluable group of 106 patients with respect to clinical characteristics or pain parameters.

Table 2. Clinical Characteristics of 106 Evaluable Patients Suffering From Chronic Pelvic Pain

	Standard treatment (*N* = 49)	Integral approach (*N* = 57)
Duration of pain (mo)		
Median	36	48
Range	5–240	3–350
Age (y)		
Mean	35.7	35.5
Range	16–56	21–58
Height (cm)		
Mean	165.4	166.0
Range	154–178	155–185
Weight (kg)		
Mean	65.2	63.6
Range	46–94	46–105

Results

Table 2 presents characteristics of the two groups of patients. Almost all patients were in the reproductive phase of their life. In most, the pain had existed for more than 1 year. The various pain parameters were not statistically different between the two groups (Table 3). In the standard-treatment and integrated-approach groups, the mean McGill pain score was 24.9 and 26.4, respectively.

Disturbances of the menstrual cycle were frequent in the pelvic-pain patients. The same was true of symptoms related to the digestive and urologic tracts. Negative sexual experience such as childhood sexual abuse and rape was experienced by 20% of the patients. Sexual problems were very common: dyspareunia in 71%, anorgasmy in 42%, and postcoital pain in 27%. Almost all patients had undergone previous surgery because of their pain. Ninety percent of the patients had had one or more laparotomies for the pelvic pain: 61% appendectomy, 13% hysterectomy, 15% adhesiolysis, and 9% an antefixation operation for retroverted uterus. Eleven patients had undergone a correction of vaginal "stenosis." Most patients suffered from localized pain: 5% suprapubic, 35% right inguinal, and 38% left inguinal. Table 4 shows the other findings during physical and gynecologic examinations.

Table 3. Characteristics of Pain Parameters in the Different Groups

	Standard treatment (*N* = 49)	Integral approach (*N* = 57)
McGill score		
Mean	24.9	26.4
Minimum/maximum	14/40	15/36
Disturbance of daily activities	33 (67%)	55 (96%)
Associated symptoms		
Backache	39 (79%)	54 (94%)
Nausea	17 (34%)	42 (73%)
Malaise	35 (71%)	52 (91%)
Diarrhea	6 (12%)	10 (17%)
Headache	26 (53%)	40 (70%)
Irritation	33 (67%)	54 (94%)
Vertigo (*N* = 47)	14 (29%)	28 (49%)
Insomnia (*N* = 48)	14 (29%)	32 (56%)

Table 4. Findings at Physical and Pelvic Examination in 106 Evaluable Patients With Chronic Pelvic Pain

	Standard treatment (*N* = 49)	Integral approach (*N* = 57)
Physical examination		
Abdominal tenderness	26 (53%)	42 (74%)
Abdominal-wall tenderness	25 (50%)	23 (40%)
Positive pain trigger points	12 (24%)	14 (24%)
Gynecologic examination		
Enlarged adnexa	1 (2%)	3 (5%)
Enlarged uterus, tenderness	6 (12%)	6 (10%)
Motion tenderness	23 (47%)	28 (49%)
Pain punctum ovaricum	13 (27%)	15 (26%)

Ultrasound was performed in 70 patients, but never added any new information to the pelvic examinations. In the standard-treatment group, all 49 patients underwent diagnostic laparoscopy. No abnormalities were found in 32 patients (65%), whereas endometriosis was diagnosed in four (two American Fertility Society[10] revised stage I, one stage II, and one stage III). The diagnosis of endometriosis was suspected before based on the typical history and additional pelvic examination. This was also true for the two patients with a small ovarian cyst and the one patient with uterine fibroids. The most frequently detected pathology was adhesions: six grade 2, one grade 3, and two grade 4.[11] All of these patients had had previous laparotomies for their pain. The adhesions were more likely a consequence of these procedures than a cause for the pain. Their presence never changed the proposed treatment. Varicosis pelvi was found in one patient.

In the integrated-approach group, various treatments were instituted based on the findings of the gynecologist, psychologist, physiotherapist, and nutritionist (Table 5). Table 6 presents the results of treatment in both groups at the 1-year evaluation. The integrated approach showed significantly more improvement of the pain in all pain parameters (Table 6); this difference was statistically significant for three out of four parameters. At entry into the study, there was an unexplained difference in duration of pain, disturbance of daily activities, and some associated symp-

Table 5. Proposed Treatments in the Integrated-Approach Group of 57 Patients

Treatment	N
Gynecologic	21 (37%)
Surgery	5
Drug treatment	16
Diet/nutritional	22 (39%)
1× advice	18
Treatment for a longer period	4
Physiotherapy	28 (49%)
1× advice	2
Treatment	26
Psychosocial	43 (75%)

toms. The fact that the integrated-approach patients had pain for a longer period made the difference even more impressive. If we look at the difference in the number of associated symptoms before and after the treatment, the average difference in group 1 was −0.8 and in group 2, +1.7. The change is significant between the groups in favor of the integrated approach ($P < .001$, t test).

Discussion

The data of this study indicate that an integrated approach is more likely to result in a reduction of pelvic pain than is the standard form of care. Laparoscopy was shown to provide too little benefit to warrant its routine use in the management of chronic pelvic pain. Although abnormalities were found in 35% of the patients, the clinical consequences of these findings were negligible. No therapeutic intervention was considered necessary in the four patients with either uterine fibroids, small ovarian cyst, or pelvic varices. The probable diagnosis of endometriosis in four patients was already suspected by history and pelvic examination. Nine of the 49 patients (18%) had intraperitoneal adhesions. This figure, however, is similar to the 14% adhesion rate found in asymptomatic women at the time of sterilization.[12] Therefore, laparoscopic findings did not justify the institution of medical or surgical treatment in our study.

Table 6. Results of Treatment of Chronic Pelvic Pain in the Standard- and Integrated-Approach Groups

	Standard approach (N = 49)	Integral approach (N = 57)	Significance (P)
General pain experience			
Improvement	20 (41%)	43 (75%)	<.01
No improvement	29 (59%)	14 (25%)	
Disturbance of daily activities			
Improvement	18 (37%)	39 (68%)	<.01
No improvement	31 (63%)	18 (32%)	
Associated symptoms			
More	26 (53%)	4 (7%)	<.01
Some	10 (20%)	10 (18%)	
Fewer (improvement)	13 (27%)	43 (75%)	
McGill score			
No improvement	24 (47%)	22 (39%)	.38
Improvement	25 (51%)	35 (61%)	

In the individual woman, there is usually more than one factor that can be responsible for the complaint of chronic pelvic pain, although this is not always recognized by those providing care. Surgical approaches have certainly been overemphasized. The tendency among gynecologists to select a surgical approach to the problem appears to be related to the values and specific functions that are attributed to the organs that can be removed. There is a tendency to limit the importance of internal genital organs to their reproductive function and thus to consider them largely superfluous after that function has been fulfilled. This may explain why hysterectomy is the most frequently performed surgical treatment in The Netherlands and why surgical approaches to chronic pelvic pain are applied more frequently by gynecologists than by other medical specialists. Our data also indicate that too little attention is usually given to sexual history in this category of patients. Negative sexual experience, such as incest and rape, was reported by 20% of the women included in the study.

We concluded that integrated care is likely to be more effective than the standard approach, which predominantly seeks to diagnose or exclude somatic causes of chronic pelvic pain. A possible explanation of this finding might be that the risk of somatic fixation is less with an integrated approach. Other factors that seem important are the diminished impairment from the pain and the adventitious distress. The attention to factors other than somatic is also more easily accepted by the patients than after an extensive and fruitless hunt for somatic abnormalities. Of course, organic abnormalities remain important and should not be overlooked, but if a carefully taken history and an expert pelvic examination are negative, it is doubtful whether invasive measures such as laparoscopy have any additional information to offer.

References

1. Renaer M, Vertommer H, Nijs P, Wagemans L, van Hemelrijck T. Psychological aspects of chronic pelvic pain in women. Am J Obstet Gynecol 1979;134:75–80.
2. Lundberg WI, Wall JE, Mathers JE. Laparoscopy in evaluation of pelvic pain. Obstet Gynecol 1973;42:872–6.
3. Kramlinger KG, Swanson DW, Maruta T. Are patients with chronic pain depressed? Am J Psychiatry 1983;140:747–50.

4. Peters JL, Large RG. A randomised control trial evaluating in- and out-patient pain management programs. Pain 1990;41:283–93.
5. Kames LD, Rapkin AJ, Naliboff BD, Afifi S, and Ferrer-Brechner T. Effectiveness of an interdisciplinary pain management program for the treatment of chronic pelvic pain. Pain 1990;41:41–6.
6. Mareta T, Swanson DW, McHardy MJ. Three years follow-up of patients with chronic pain who were treated in a multidisciplinary pain management center. Pain 1990;41:47–51.
7. Loeser JD. A definition of pain. Medicine 1980;7:3–9.
8. Duncan CH, Taylor HD. Psychosomatic study of pelvic congestion. Am J Obstet Gynecol 1952;64:1–6.
9. Reading ME. A card sort method for pain assessment in gynaecology. A multidimensional approach. Acta Obstet Gynecol Scand 1979;58:105–9.
10. Revised American Fertility Society classification of endometriosis: 1985. Fertil Steril 1985;43:351–2.
11. Siegler A. Surgical treatments for tuboperitoneal causes of infertility since 1967. Fertil Steril 1977;28:1019–32.
12. Trimbos JB, Trimbos-Kemper GCG, Peters AAW, vd Does CD, van Hall EV. Findings in 200 consecutive asymptomatic women, having a laparoscopic sterilization. Arch Gynecol Obstet 1990;247:121–4.

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