TREATING FALLOPIAN TUBE OCCLUSION WITH A MANUAL PELVIC PHYSICAL THERAPY

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Objective: To determine the efficacy of a non-invasive, manual soft-tissue physical therapy in opening completely blocked fallopian tubes in infertile women with confirmed bilateral occlusion and a history indicative of abdominopelvic adhesions.
Design: Retrospective analysis.
Setting: Clear Passage Therapies, Inc, clinic, Gainesville, Florida.
Patients: 28 infertile women (mean age=35.2) with diagnosed complete tubal occlusion (proximal, midtubal, distal, or combination). The patients were being treated for various types of abdominopelvic pain and dysfunction (eg, intercourse and/or pelvic pain, menstrual cramps, endometriosis pain).
Intervention: A 20-hour series of manual physical therapy treatments (mean duration=1 week) designed to address pain and restricted soft tissue mobility due to adhesions and micro-adhesions. The therapists accessed some of the deeper structures (such as the fallopian tubes) indirectly by manipulating the peritoneum, uterine and ovarian ligaments, and neighboring structures.
Main outcome measures: (1) Unilateral or bilateral tubal patency confirmed by diagnostic test or natural intrauterine pregnancy; (2) natural intrauterine pregnancy rate achieved by patent patients within the 2-year follow-up period.
Results: Of the 28 patients, 17 (61%, 95% exact CI 41%-78%) demonstrated post-treatment unilateral or bilateral patency, as measured by hysterosalpingography or natural intrauterine pregnancy. The median interval between the last treatment date and patency confirmation was 1 month. Nine of the 17 (53%) patent patients reported a subsequent natural intrauterine pregnancy.
Conclusion: Since truly occluded tubes are not known to reopen spontaneously, the results suggest this non-invasive therapy might be considered as an adjuvant to standard gynecological procedures in treating tubal occlusion. (*Altern Ther Health Med.* 2008;14(1):18-23.)

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It is generally agreed that adhesions within the fallopian tubes are a major cause of infertility.[1] Pelvic adhesions may negatively impact the efficacy of in vitro fertilization (IVF) and other assisted reproductive techniques.[2] Many gynecologists concur that when the occlusion is caused by pathology (vs spasms), the tubes rarely, if ever, spontaneously reopen. Although some contend that diagnostic hysterosalpingograms (HSGs) may themselves enhance fertility, others proclaim this a myth, and the debate continues.[3] Moreover, despite the variety of surgical procedures to correct tubal adhesions, the optimal treatment of infertility due to tubal occlusion has not been established.[4]

Tubal adhesions are most often caused by previous abdominopelvic surgery, endometriosis, infection, polyps, ectopic pregnancy, and chronic inflammation.[5,6] At 1 to 2 months post-injury, collagen fibrils organize into discrete bundles that eventually mature into a fibrous band. Collagen cross-links may evolve from microadhesions to adhesions to scars. Ironically, the adhesions formed as a byproduct of healing after surgical procedures to open blocked fallopian tubes may themselves be a cause of the high tubal reocclusion rates over time.[7]

The ability of manual therapy to effect structural change in adhesions is supported by the basic literature on mechanical tissue

testing, as well as connective tissue physiology and remodeling. In brief, specific sustained physical force applied to a given area has been shown to alter connective tissue length and mobility.[8,9] Theoretically, soft-tissue mobilization creates microfailure of the collagenous cross-links that cause pain and dysfunction and hence can effect restoration of normal mobility and function to previously adhered structures.

The purpose of this retrospective analysis was to determine the efficacy of a manual soft-tissue therapy in increasing tubal mobility and function in women with total bilateral tubal occlusion and a gynecologic history indicating likely pelvic adhesion formation. Since an individual's subfertility may be a function of concurrent factors, the therapy also addressed (by default) probable adhesions affecting neighboring reproductive organs and adjacent structures.[10,11]

METHODS

The soft-tissue techniques used in this study were developed after extensive investigation of current, innovative physical therapy methods, including techniques taught and endorsed by the American Physical Therapy Association (APTA). The encouraging results obtained in prior retrospective and prospective investigations[10] prompted this retrospective analysis of the therapy's efficacy in treating tubal occlusion. All therapists had met the criteria for certification in the use of this therapy.

Patient Selection

A total of 28 infertile women, self-selected from the general population, were evaluated and treated over a 3-year period. Patients presented with a variety of symptoms appropriate to women's health physical therapy (eg, dyspareunia, dysmenorrhea, incontinence, chronic pelvic pain).

The primary criteria for inclusion in this analysis were the following: (1) a history indicative of abdominopelvic adhesions; (2) documented complete bilateral tubal occlusion (ie, no spillage of contrast medium) or unilateral occlusion if the contralateral tube had been surgically removed before treatment; and (3) documented radiologic, surgical, or pregnancy reports after treatment. Pre-treatment diagnoses of tubal occlusion were by laparoscopy or laparotomy with chromotubation or HSG as reported by the patients' physicians, along with a description of the extent and type (proximal, midtubal, distal, combination) of tubal blockage.

In addition to the diagnostic reports of tubal occlusion and histories indicating probable abdominopelvic adhesions, these patients met the US requirement for infertility by failing to achieve a natural intrauterine pregnancy after a minimum of 1 year of unprotected intercourse. None were excluded from this analysis on the basis of such potentially confounding variables as hormonal problems, hydrosalpinx, advanced age, or (possible) male factor.

Follow-up data were obtained via radiologic, surgical, and pregnancy reports. The 28 (primarily Caucasian) patients ranged in age from 26 to 43 years. Mean age was 35.2 (median, 36);

mean duration of infertility was 4.7 years (median=2.0); and the mean body mass index was 24.3.

Including the 3 subjects with only 1 tube (the functional equivalent of bilateral occlusion), the types of tubal occlusion were as follows:

- proximal occlusion in both tubes or equivalent (n=12);
- midtubal occlusion in both tubes (n=5);
- distal occlusion in both tubes or equivalent (n=6); and
- combinations: proximal/distal (n=4), proximal/midtubal (n=1).

Patient histories were obtained from medical records and included physical therapy and biomechanical assessments; gynecological, surgical, and trauma history; and prior infertility tests, diagnoses, and treatments. Among the factors indicating a strong probability of pre-treatment abdominopelvic adhesion formation were abdominopelvic surgery (86%); infection/inflammation, including endometriosis (86%); trauma (78%); miscarriage (21%); and tubal pregnancy (18%).

Statistical Plan

Although no formal sample size calculation was prospectively done, N=28 is typical of pilot studies. This sample size assures, with 95% confidence, estimation of a proportion within 20% of the true value.

Procedures

Because all patients had reported a variety of abdominopelvic problems (eg, pelvic and/or intercourse pain, menstrual cramps, endometriosis pain), their physical therapy treatment protocols were designed to address these conditions as well as tubal occlusion. The manual therapy (a protocol of soft tissue physical therapy) was described in more detail in an earlier study.[10] The treatment team was composed of 5 therapists, all trained in this protocol to treat pelvic adhesions. The 28 subjects were treated by a combination of 2 or more therapists.

After reviewing patient histories and performing extensive manual palpation of the abdominopelvic region, the therapists determined the areas of decreased mobility. They then engaged the soft tissues by using their hands to apply a specific force to restricted structures (visceral, myofascial, and ligamentous) until they perceived a release of the cross-links. The fallopian tubes, which are very difficult to palpate, were accessed via external, internal, and bi-manual manipulation of more palpable neighboring soft tissue structures. Manual internal (vaginal) therapy has been practiced by US physical therapists to treat pelvic pain and incontinence since 1977, when the APTA Section on Obstetrics and Gynecology was created. It is common practice today and is taught and endorsed by the (renamed) APTA Section on Women's Health.

To illustrate for non-specialists how our therapists were able to indirectly access the tubes, the following brief review of pelvic anatomy may be helpful. The fallopian tube is located in the superior aspect of the free margin of the broad ligament, between

the ovary and round ligament. Due to the close anatomical relationship between the peritoneum and the ovary, any surgical, inflammatory, traumatic, or infectious damage to the peritoneum can affect ovarian or tubal function. At the sides of the uterus, 2 layers of peritoneum (from the anterior and posterior aspects of the uterus) join to form the broad ligament that extends to the lateral walls of the pelvis. The mesosalpinx is the part of the broad ligament that goes from the tube to the ovary and comprises the anterior and posterior layers of the peritoneum. The ovaries are attached to the posterior aspect of the broad ligament. The peritoneal mesovarium surrounds the ovaries and connects the superior ovary to the fimbriated end of the tubal infundibulum. Thus, there are sufficient structural elements attaching to the fallopian tubes via adjoining structures to allow indirect manipulations by the therapist.

The therapists palpated these soft tissues and assessed their texture, tension, and relative temperature while feeling for decreased elasticity, distensibility, or increased heat. They used their palpation skills to access restrictions in these parameters in the tissues and organs surrounding the fallopian tubes by manipulating the peritoneum, uterine and ovarian ligaments, and neighboring structures.

In general, release was noted by a marked increase in soft-tissue mobility, extensibility, flexibility, and range of motion at the targeted sites after each therapy session. Further evidence of release included improved alignment and biomechanics, along with an increased range of motion of osseous and ligamentous soft tissue structures. Patients who had recounted pain symptoms at their initial visit often reported pain relief during the course of treatment—presumably due to the decreasing tension and pressure on nerves and pain-sensitive structures and improved mobility of the structures during normal movements.

Data Collection

All 28 patients received manual physical therapy treatments for pelvic pain and/or adhesions, and each signed an informed consent agreeing to the compilation and (confidential) publication of her complete case history, treatment data, and results. Manual physical therapy is considered conservative and non-invasive and is included in *Current Procedural Terminology*, the official American Medical Association list of commonly accepted clinical procedures. Although its potential to facilitate fertility is a relatively new concept, manual physical therapy is commonly used by physical therapists to treat pain or adhesions (as in this case). The collection of existing data when patients cannot be identified is excluded from the requirements of institutional regulatory boards under 45CFR 46.101(b)(4).

In accordance with the standards of the APTA, detailed clinical records were kept of all patient visits, including symptomatic complaints, areas treated, treatment techniques performed, treatment dates, and duration.[12] All but 4 patients completed the recommended 20-hour treatment within 1 month; 23 of 28 did so within 1 week. If a patient reported she was pregnant during the course of therapy, any remaining sessions were cancelled.

The standard therapy session was 1-2 hours, minus 15 minutes for room preparation and paperwork.

Because there is no agreed-upon estimate of how long tubes remain open (thus enabling pregnancy), an arbitrary decision was made to end the follow-up period 2 years after the patients' last treatment dates. (Some studies allow a minimum 1-year follow-up; others continue for 2-5 years[13] or longer.)

None of the 28 patients in this study received any other treatment (medical or integrative) for tubal occlusions while undergoing the manual therapy or in the interval between manual therapy and the post-therapy patency test (including pregnancy).

RESULTS

To evaluate the effectiveness of the therapy in treating tubal occlusion, the primary outcome measures were (1) confirmed tubal patency or natural intrauterine pregnancy and (2) natural intrauterine pregnancy within the 2-year follow-up period. Although the latter is assuredly the "gold standard" for tubal patency, a meta-analysis of HSG showed that its high specificity (0.83) makes it a "useful test for ruling in tubal obstruction."[14(p486)] As mentioned previously, patients were treated by a combination of 2 or more therapists from the 5-person treatment team. Data analysis showed there were no observable differences in success rates among the various therapists.

Patency

Of the 28 participants, 17 (61%, 95% exact CI 41%-78%) demonstrated post-treatment unilateral or bilateral patency as measured by HSG (n=15) or natural intrauterine pregnancy (n=2). The mean interval between last treatment date and patency confirmation was 2 months (median=1 month).

In a preliminary attempt to determine if the treatment had equal efficacy for various types of tubal occlusion (proximal, distal, midtubal), the data were subdivided into 3 groups. Including the 3 women whose contralateral tube had been surgically removed, 23 of 28 subjects had the same type of obstruction in both tubes. Five women had occlusion "combinations," (ie, proximal/distal [n=4] or proximal/midtubal [n=1]) (Table 1).

TABLE 1 Patency by Occlusion Type			
Type Occlusion	n	No. Patent	% Patent
Proximal	12	8	66.7
Distal	6	3	50.0
Midtubal	5	2	40.0
Combination*	5	4	80.0
Total	28	17	60.7

*Proximal/distal (4); proximal/midtubal (1).

The results were as follows: 8 of 12 (66.7%) patients with proximal lesions in both tubes demonstrated post-treatment patency as did 3 of 6 (50%) patients with distal lesions; 2 of 5 (40%)

patients with midtubal lesions; and 4 of 5 (80%) patients with "combination" occlusion achieved patency. Of the 4 patients with a combination of proximal/distal occlusion, 2 achieved patency in both tubes, and 1 achieved patency only in the distally occluded tube. The 1 patient with proximal/midtubal occlusion achieved patency in the tube with midtubal obstruction.

Pregnancy

Of the 17 patent patients, 9 (53%; 95% exact CI 28%-77%) reported a natural or intrauterine insemination–assisted (n=1) intrauterine pregnancy by the end of the 2-year follow-up period. No ectopic pregnancies occurred in any of the patent patients. The mean interval between last treatment date and confirmation of pregnancy was 11 months (median=9 months).

The natural intrauterine pregnancy rate for all treated patients was 32% (9 of 28). Any patient who demonstrated post-treatment total occlusion was automatically considered a failure in terms of (potential) pregnancy. Table 2 shows the relationship between type of tubal occlusion and subsequent patency for the 9 pregnant patients. It is evident that clinical pregnancies were documented in all 3 (proximal, distal, midtubal) types of occlusion.

TABLE 2 Pregnancies* by Occlusion Type and Post-treatment Patency

Patient	Type of Occlusion	Post-treatment Patency
1	proximal/proximal	patency via pregnancy
2	proximal/proximal	patency via pregnancy
3	proximal/proximal	1 tube opened
4	proximal/proximal	1 tube opened
5	proximal/proximal	1 tube opened
6	midtubal/midtubal	2 tubes opened
7	distal/removed	distal tube opened
8	proximal/distal	distal tube opened
9	proximal/distal	2 tubes opened

*Nine of 17 (53%) patent patients had an intrauterine pregnancy.

Effects of Age and Overweight/Obesity

Although no subjects were excluded from this analysis on the basis of advanced age or overweight/obesity, we suspected these variables might affect the outcomes. The statement, "a woman's 35th birthday marks a watershed that irreversibly lowers the probability of reproduction in her life"[1(p10)] apparently holds true even in the various surgical/medical treatments of tubal obstruction.[15] Thus, we looked at the patency and pregnancy data sets both by age group: <35 years vs 35+ and body mass index (BMI).

Age/Patency

As of their last treatment date, the mean age for the <35 group was 30.5 years (range=26-34), and the mean age for the ≥35 group was 39.2 years (range=35-43). Thus, the difference in mean age between the 2 groups was 8.7 years. The results showed that 10 of 13 (77%) patients <35 vs 7 of 15 (47%) patients ≥35 demonstrated post-treatment fallopian tube patency (Table 3).

TABLE 3 Post-treatment Patency by Age Group

Age	n	No. Patent	% Patent
<35*	13	10	76.9
≥35†	15	7	46.7
Total	28	17	60.7

*Mean=30.5 years; †mean=39.2 years.

Age/Pregnancy

As of the patients' last treatment date, the mean age for the patent <35 group was 30.8 years (range=26-34), and the mean age for the patent ≥35 group was 38.6 years (range=35-42). Thus, the difference in mean age between the 2 groups was 7.8 years. The results showed that 7 of 10 (70%) patients <35 vs 2 of 7 (29%) patients ≥35 achieved a post-treatment natural intrauterine pregnancy (Table 4).

TABLE 4 Pregnancies of Patent Patients by Age Group

Age	n	No. Pregnant	% Pregnant
<35*	10	7	70.0
≥35†	7	2	28.6
Total	17	9	52.9

*Mean=30.8 years; †mean=38.6 years.

Although we have no insights on why age affects tubal patency, the results suggest that the efficacy of this therapy was (per usual) considerably greater for the <35 group. Nevertheless, nearly half of the age ≥35 patients had 1 or both tubes opened, and 29% of these patent patients conceived by the end of the follow-up period.

Overweight/Obesity

Our primary concern was that structures as small and delicate as fallopian tubes would be more difficult to manipulate in overweight and obese women. Nine patients had a BMI of 25-29, and 2 had a BMI of >30; thus, 11 of 28 (39%) were overweight or obese. Somewhat to our surprise, 8 of 11 (73%) overweight patients (including both obese women) demonstrated post-therapy patency, suggesting that the therapists were able to indirectly access the tubes via the adjoining structures as described earlier. Because the fallopian tubes presumably would be more difficult to access in obese/overweight women, the effectiveness of the technique with overweight patients suggests that micro-manipulation of the fallopian tubes may be achieved via macro-manipulation (release of tension/adhesions/scar tissue) of the adjoining cardinal and broad ligaments.

Treatment Safety

None of the patients reported any observable complications or adverse side effects as a result of their treatment.

DISCUSSION

The results indicate that manual soft-tissue therapy helped restore patency and function in women with tubal occlusion and a history indicating probable adhesion formation. Abdominopelvic adhesions are particularly relevant to several aspects of reproductive medicine, as outlined below:

(1) Pelvic adhesions that interfere with access of the fallopian tubes to the ovaries are widely recognized as a major cause of infertility.[1] Whereas some types of tubal obstruction can be considered a biomechanical reproductive organ dysfunction associated with an indication of pelvic adhesions, 1 study of falloscopic tuboplasty reported, "a high incidence of multiple adhesions was observed in the entire length of tubal lumen in patients having bilateral occlusion."[16(p71)]

(2) Tubal adhesions are a major factor affecting the success rates of medical/surgical procedures designed to facilitate fertility. For example, although a transvaginal fallopian tube catheterization study achieved a 100% successful catheterization rate for fallopian tube ostia and a 64% successful recanalization rate, the subsequent intrauterine pregnancy rate was only 11%. The authors concluded that "the higher incidence of adhesions in the patients' background caused the low incidence of pregnancy."[17(p49)] A large-scale (n=246) investigation of background factors in relation to pregnancy outcomes after a variety of fertility surgery procedures (adhesiolysis, salpingostomy, tubal anastomoses, implantation, and myomectomy) also found that the extent of tubal damage was the most relevant factor in subsequent fertility, and that "adhesion formation is not negligible."[18(p281)]

(3) The adhesions that form as a byproduct of healing from the various invasive procedures may themselves be a cause of the high reocclusion rates over time. For example, a repeat HSG 6 months after an ambulatory, minimally invasive catheter procedure showed a total reocclusion rate in 35 of 43 (81%) patients.[7]

We believe a major strength of this retrospective analysis was its inclusive population. Patients were not excluded for conditions such as hydrosalpinx, hormonal problems, advanced age, overweight/obesity, duration of occlusion, prior removal of 1 tube, or possible male factor—any of which might have lowered the success rates.

Although the main weakness of this analysis may be the lack of an external control group, we did not consider one as no published study of a standard surgical procedure compared its results to a planned "no treatment" control group. The rationale, presumably, is that occluded tubes do not spontaneously reopen. Thus, other than natural pregnancy, the only way to know if patency was achieved in a control group member must be via yet another diagnostic test. Although some researchers contend that a second diagnostic HSG may itself permit enhanced fertility in proximal occlusion cases, this ongoing debate is complicated by the oil-soluble vs water-soluble contrast agent issue.[3]

In trying to determine the estimated patency rate of a relatively large untreated control group, however, we found a study in which participants enrolled on the basis of diagnosed proximal tubal occlusion (HSG and/or laparoscopy) underwent another HSG to confirm occlusion prior to receiving transcervical balloon tuboplasty (TBT). Eight percent (12 of 147) of the patients did demonstrate patency, thereby forming a default control group for comparing pregnancy rates with the TBT-treated group.[7] To compare: the patency rate in our retrospective analysis (61%; 17 of 28) differed from this (8%) historical control rate, $P < .001$ by chi-square analysis.

The fact that laparoscopy may be the more definitive means of diagnosing tubal obstructions notwithstanding, we could not insist that our "adhesion-ridden" patients undergo yet another potentially adhesion-inducing (and costly) surgery just to reconfirm the absence or presence of post-treatment occlusion.

Although the incidence of proximal tubal occlusion (PTO) represents just 20%-33% of all cases with tubal occlusion,[5,19] considerable progress has been made in its treatment relative to the other types. Published reports, however, still show patency and pregnancy rates to be extremely variable. Direct comparisons of treatments are difficult as not all studies distinguish between intrauterine and ectopic pregnancies, and many surgical cases do report a sizable percentage of ectopic pregnancies after tuboplasty.

We did not originally distinguish between the 3 main types of tubal occlusion, so we are at a disadvantage in comparing our results with standard treatments (eg, microsurgical tubal anastomosis, tubal catheterization and recanalization, balloon tuboplasty), many of which deal only with PTO. Given the relatively small size of our (unplanned) subgroups, we chose to cite our total group results, which also included midtubal, distal, and combination cases.

Nearly every study of PTO shows a discrepancy in the success rates for patency and subsequent pregnancy. For example, although some contend that "pregnancy rate rather than tubal patency should be the measure by which transcervical tubal recanalization procedures are judged,"[20(p1425)] there is no clear explanation of the widely varying pregnancy rates (7% to 61%) that have been reported.

Accordingly, we have arbitrarily limited comparison of our results to the putative largest study of infertile patients (total N=3424) treated with selective salpingography and balloon tuboplasty.[21] A subgroup of 277 women with bilateral PTO but "no other identified cause for their infertility" (including distal disease or hydrosalpinges) were first treated with selective salpingography and, if that failed, with balloon tuboplasty. The median age was 27.8 years, and the combined success rates for patency and (all) subsequent pregnancies were 68% and 36%, respectively.[21] Although the median age of our 28 subjects was 36.0 years (ie, 8 years older), the success rates for patency and subsequent intrauterine pregnancies were similar: 61% and 32%, respectively. Moreover, as mentioned above, no patients in our analysis were excluded on the basis of any "other identifiable causes" of infertility, including the more problematic midtubal and distal occlusion.

The importance of distinguishing between types of tubal occlusion was shown by a large, multicenter transcervical balloon tuboplasty study that found that patients with PTO had significantly higher pregnancy rates than those with midtubal or

distal obstruction.[7] The results of the few relatively recent studies of distal occlusion were most discouraging. Although one 1994 study of several laparoscopic treatments showed variable patency rates (33%-66%), the pregnancy rate was 19 of 81 (23%), of which only 10% were intrauterine pregnancies.[22] Hence, many investigators have concluded that assisted reproductive techniques (eg, IVF) may represent the most effective means of treating patients with poor tubal status, severe adhesions, etc.[4,13,23]

Although the number of subjects with bilateral (or equivalent) distal occlusion in our analysis was too small (n=6) to determine pregnancy rates, 3 of 6 (50%) patients with distal lesions in both tubes demonstrated post-treatment patency in the distally occluded tube, including the 2 patients whose second tube had been surgically removed. Moreover, 3 of the 4 women with combination proximal/distal occlusion also demonstrated patency in the distally occluded tube. (Of these, 2 of 3 showed patency in both tubes.) Thus, 6 of 10 women (60%) with distal occlusion in 1 or both tubes showed post-treatment patency of a distally occluded tube. As shown in Table 2, patients 7 and 8 subsequently conceived via their previously occluded distal tube, and patient 9 (proximal/distal combination) may have done so.

Another noteworthy finding was that 4 of 8 (50%) patients with diagnosed hydrosalpinges showed post-treatment patency; 2 of these 4 patent patients had a subsequent intrauterine pregnancy.[24] Incidentally, 8 of the 9 women shown to have achieved pregnancy had a subsequent live birth, including the 2 women with hydrosalpinx. Clearly, there is a need for a large-scale, randomized, controlled trial of this therapy.

In conclusion, there are various indications for a noninvasive manual soft-tissue physical therapy directed toward breaking down existing adhesions. This therapy already has been shown to decrease abdominopelvic pain and improve sexual function[11] and IVF pregnancy rates[10] and may prove similarly effective in treating tubal occlusion and facilitating subsequent fertility. The therapy may be used alone or in conjunction with other medical/surgical treatments (eg, various recanalization procedures).

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